

ANNUAL INTELLECTUAL PROPERTY REPORT TO CONGRESS

April 2023

"In America, everything is possible. We believe every and anything is possible. It's part of the soul of this country. I mean, it really is.

We can channel all our resources. Most of all, we can channel the full talents of all our people into a greater measure of hope and opportunity for our nation and for the world — to create good jobs, empower workers, grow the economy, not just for the wealthy but grow it for everyone; to change the course of human health and disease; to tackle climate crisis with innovation and jobs; to lead the world — not — this is not hyperbole — lead the world in future industries and protect our national security."

-- President Joe Biden¹

¹ Remarks by President Biden at Signing of H.R. 4346, "The CHIPS and Science Act of 2022," August 9, 2022, at https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/08/09/remarks-by-president-biden-at-signing-of-h-r-4346-the-chips-and-science-act-of-2022/.

IPEC ANNUAL INTELLECTUAL PROPERTY REPORT TO CONGRESS:

This report is submitted pursuant to 15 U.S.C. § 8114.

The Annual Intellectual Property Report to Congress, developed by the Office of the U.S. Intellectual Property Enforcement Coordinator, brings together the combined and coordinated efforts of the White House, the Departments of Agriculture, Commerce, Defense, Health and Human Services, Homeland Security, State, and Treasury, the Office of the U.S. Trade Representative, and the U.S. Copyright Office. What follows is an overview of the intellectual property enforcement strategy and related efforts undertaken by departments and agencies during fiscal year 2022.

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DEPARTMENT OF AGRICULTURE

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Geographical Indications (GIs)

Overview

Article 22(1) of the Agreement on Trade-Related Aspects of Intellectual Property Rights provides that "[g]eographical indications are, for purposes of this Agreement, indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin."

USDA's GI-related Activities during FY 2022

The Foreign Agricultural Service (FAS) of the Department of Agriculture actively works with other Federal agencies, particularly the lead agencies USTR and USPTO, to monitor and directly engage with countries on the issue of GIs. USDA's main goal is to ensure GI protections do not disadvantage U.S. producers by unfairly granting protection to products with common names, which could ultimately result in a loss of market access.

During FY 2022, USDA engaged at the most senior levels with key foreign country counterparts to emphasize concerns and counter harmful GI policies, such as those of the European Union (EU), emphasizing transparency, adherence to internationally recognized standards, seeking an opportunity to comment on any proposed GIs through comment period, and requesting the countries be fair in the evaluations. USDA worked with interagency partners to engage a number of countries, including Chile, the MERCOSUR countries, China, the European Union, and Morocco to raise the importance of procedural fairness and transparency as well as preserving common terms for food products.

Consortium for Common Food Names Activities Supported by USDA

The U.S. Dairy Export Council, on behalf of several U.S. agricultural associations including the U.S. Meat Export Federation and California Wine Institute, established the Consortium for Common Food Names (CCFN) in 2013 to monitor and combat GI-related trade restrictions. These activities are partially supported by USDA's Market Access Program through a Global Broad-based Initiative. Since 2013, CCFN has received \$200,000 in funding annually from USDA for these efforts; beginning in calendar year 2022 CCFN's grant was expanded to \$300,000. Each item listed below helped preserve U.S. exporters' rights to use common food names.

CCFN coordinated responses to various ongoing EU Free Trade Agreement (FTA) negotiations, including:

- Australia EU FTA: In March 2022, CCFN contacted the Department of Foreign Affairs and Trade (DFAT) regarding the ongoing EU-Australia FTA negotiations to emphasize CCFN's interest areas on common names in those trade talks.
- Chile EU FTA: On January 28, 2022, CCFN held a videoconference meeting with the General Manager of the National Federation of Dairy Producers (FEDELECHE) of Chile, to share CCFN's comments and concerns regarding the possible outcome of the GI discussion as part of the modernization of the EU-Chile FTA. In the 2nd and 3rd quarters of 2022, CCFN met with local counsel from Chile to discuss a strategy considering the *impasse* in the conclusion of the EU-Chile FTA and new avenues given the changes in the Chilean government.
- Mexico EU FTA: In June 2022, during a visit by USDEC's President and CEO and CCFN's Executive Director to Mexico City, a meeting was held with the authorities of the Secretariat of Economy, where concerns were shared about the negative impact the Mexico-EU FTA's registration of multiple GIs would impose on common name use in that market and how to best mitigate this.
- Vietnam EU FTA: CCFN submitted a letter to Vietnam's National Office of Intellectual Property and Ministry of Industry and Trade and the Ministry of Science and Technology to urge further clarity and action on how Vietnam is implementing certain provisions of the EU-Vietnam FTA, focusing on how generic name users are grandfathered under the agreement. In January 2022, CCFN sent a follow up letter, urging the authorities to share their response as soon as possible. During the first and third quarters of 2022, CCFN has repeatedly contacted Vietnamese authorities to receive an answer to the request.

CCFN continued to build a strong relationship with the new Director General of the World Intellectual Property Organization (WIPO) and his incoming leadership team:

- In January 2022, following a December 2021 in-person visit to WIPO's office in Geneva, CCFN sent a letter to the WIPO's Deputy Director-General, Brands and Designs Sector, to reiterate its requests that all WIPO staff be tasked with the shared responsibility of ensuring that common name-related concerns, including appropriate due process procedures and generic usage safeguards, are incorporated into all relevant areas of interest (for example: capacity building, events and guidelines related to GIs and other WIPO workstreams touching on IP and common name issues).
- Over the course of the following months, CCFN had several interactions with WIPO officials to reinforce these policies and programs. For example, in March 2022, CCFN's local legal counsel met with WIPO's Director General during a visit to Mexico City. The meeting was an opportunity to reinforce CCFN's message about the need for greater consideration to be given to the "common names" element in the preparation of WIPO

events and training sessions on GIs. CCFN also met with a WIPO official during the INTA Annual Meeting in Washington, D.C. in May 2022. CCFN has been developing proposals for WIPO based on feedback from WIPO and interactions with USPTO over this period.

CCFN has also served as an Observer to the WIPO <u>Standing Committee on the Law of Trademarks</u>, <u>Industrial Designs and Geographical Indications</u> and participated in the <u>Information Session on Geographical Indications</u>. CCFN was also an Observer for the Working Group on the Development of the Lisbon System in June 2022. CCFN monitors the countries and names registered in the Lisbon and Geneva systems to identify any issues of concern.

CCFN continued working with the International Trademark Association (INTA):

- CCFN obtained two seats on INTA's GI Committee for the 2022-2023 period on the Governance and Expansion & Monitoring Subcommittees to promote and defend CCFN's interests and objectives, by working on several proposals (webinars, papers, interviews, podcasts) within INTA's framework. CCFN participated in the January 2022 kick-off meeting of the GI Committee the April Governance Subcommittee meeting, and the 2022 1st quarter Expansion & Monitoring Subcommittee meetings. Within the latter, CCFN has contributed to the review of an INTA document including GI provisions under FTAs negotiated around the globe. CCFN identified and reviewed the FTAs in force that include IP and GI provisions and is coordinating with the chair of the Subcommittee to continue this process. CCFN representatives participated in-person at INTA's May 2022 Annual Meeting. CCFN also monitored the June 2022 WIPO Working Group on the Development of the Lisbon System for INTA.
- CCFN continued media outreach concerning common names, placing media pieces in the food press, including in multiple international publications regarding the benefits of preserving common names and the authenticity of U.S. food products.

CCFN submitted comments to government officials in key markets regarding how to best preserve the rights of common name users:

- El Salvador: In March 2022, as part of CCFN's membership in INTA's GI Committee, CCFN submitted comments on El Salvador's Industrial Property Bill. Comments and proposals were developed based on INTA's Model Trademark Law Guidelines and its 2019 Board Resolution on GIs. They focused on the need for a transparent local registration and opposition process for GIs and to ensure the free use of common names.
- **European Union:** In August 2022, CCFN submitted comments on the European Commission's recent GI regulations proposal regarding the inclusion of sustainability factors in EU quality schemes, in addition to other changes to EU GI regulations.
- **Japan:** In August 2022, CCFN submitted comments on the Ministerial Ordinance amending parts of the *Regulation for Enforcement of the Act on Protection of the Names*

- of Specific Agricultural, Forestry and Fishery Products and Foodstuffs urging appropriate balancing of stakeholders' interests as Japan makes modifications to its GI regulations.
- Malaysia: In December 2021, the Geographical Indications Bill 2021 was approved by the Parliament. The corresponding Act, Guidelines and Regulations became effective on March 18, 2022. CCFN reviewed and prepared an assessment of those March 2022 provisions to determine the risks for continued free use of common names.
- Mexico: In January and February 2022, CCFN engaged with the Mexican Association of the Protection of Intellectual Property (AMPPI) by developing comments and recommendations on the draft implementing regulations of the IP law of 2020. During Q2 and Q3 2022, CCFN continued monitoring developments and sharing comments and suggestions to ensure the effective implementation of the USMCA side letters between the United States and Mexico on cheeses and prior users.
- Philippines: On May 8, 2022, CCFN submitted comments on the country's Draft Rules and Regulations on GIs and attended virtually the Philippine's Public Consultation on GIs on May 11. At the consultation, CCFN shared with the Intellectual Property Office of the Philippines (IPOPHIL) and other stakeholders its comments and proposals on the regulations. As part of the exchange, CCFN referred to the importance of avoiding "TRIPS-Plus" provisions that constitute unilateral concessions from the Philippines. CCFN also mentioned its proposal for a list with common terms, and the need of having the prior trademarks exemption applying to agricultural products and foodstuffs.
- Vietnam: CCFN contacted the National Office of Intellectual Property in June 2021 requesting the issuance of clear guidelines regarding the GIs and trademarks issues regulated by the FTA and the relationship between the agreement and Vietnam's domestic IP law. On January 13, 2022, CCFN sent a follow up letter, urging the authorities to share their response as soon as possible. During the first quarter of 2022, CCFN contacted again the Vietnamese authorities to receive an answer to the previous request.

Monitoring of GI applications in foreign markets to take appropriate action:

- CCFN developed logos that include, but do not claim exclusive rights in, words that are
 commonly used to describe certain food products, such as bologna or feta. CCFN has filed
 trademark applications to register its logos in jurisdictions around the world and has
 obtained registrations in several countries. CCFN plans to allow producers of such
 products to use its trademarks in order to help preserve those producers' ability to use
 common terms on their products and defend against others' attempts to monopolize such
 terms through GI protection.
- Australia Opposition filing against "Le Gruyere Switzerland" trademark application: In August 2022, as part of the task of monitoring trademark applications comprising common names, CCFN identified the LE GRUYERE SWITZERLAND

trademark application. CCFN worked with Dairy Australia to confirm that based on industry data, 'gruyere' cheese has been manufactured in Australia for the best part of forty years and there are at least five companies currently producing and marketing gruyere in Australia. CCFN decided to file a notice of intention to oppose to this trademark application.

- Canada Opposition filing against "Grana Padano" trademark applications: In July 2022, a CCFN member flagged two trademark applications applying for services rather than the usual dairy products. After examining the applications, it was determined they were blockage trademarks to expand the scope of protection of the GI. CCFN is preparing oppositions against these applications to ensure the good faith use of traders and producers in Canada to describe their products and services in advertisement.
- Chile Opposition filing against "Gorgonzola" GI application: In 2022, the process for the registration of "gorgonzola" by the Italian Consorzio as an AO in Chile resumed after its suspension due to the COVID pandemic. CCFN had previously challenged this registration and in April 26, submitted the written submission of the evidence. A decision from the Chilean authorities on this issue has not been made and Chile does not have a timeframe for when it intends to reach a decision on this or any registration request.

Plant Variety Protection

USDA plant variety protection certificates are recognized worldwide and expedite foreign plant variety protection application filing. The USDA Agricultural Marketing Service (AMS)'s Plant Variety Protection Office (PVPO) works actively with members of the International Union for the Protection of New Varieties of Plants (UPOV) to promote cooperation on the standards for variety examination. Once plant variety protection is granted, the certificate owners have exclusive legal rights to market and to exclude others from selling their varieties. This legal protection for breeders and inventors promotes the development of new varieties that can increase yield and crop productivity, increase farmer income, and expand trade opportunities. Other benefits of plant variety protection include provisional protection upon application receipt, priority when filing in another country, user-friendly filing without the need for an attorney, no annual maintenance fees, and applicant-conducted field trials. FAS encourages free trade agreement partners to become UPOV members to protect U.S. plant breeders' rights across the globe. For example, at a TIFA meeting in February 2022, FAS raised Uruguay's possible accession to the 1991 UPOV Convention and emphasized the benefits of the Convention for Uruguay's plant breeders.

USDA Plant Variety Protection Activities in FY 2022

PVPO received 646 applications for sexually reproduced, tuber propagated, and asexually reproduced varieties during the fiscal year. Among these were more than 45 applications for asexually reproduced varieties including varieties of almond, blackberry, calibrachoa, camellia, canna, celosia, sweet cherry, fuchsia, grapevine, hemp, hydrangea, kiwifruit, magnolia,

mandarin, nightshade, orange, pear, phalaenopsis, phlox, pistachio, pomegranate, and raspberry. PVPO issued 465 certificates of protection and examined 484 applications. It achieved mutual standard recognition with Canada for asexually reproduced plants so that the two countries will accept each other's examination results, which eliminates duplicative work, saving money and time for plant breeders.

PVPO staff provided presentations on the program, the electronic Plant Variety Protection System, and examination procedures – to participants from Jamaica, Pakistan, Japan, and Ecuador. The presentations reviewed the benefits of the electronic plant variety protection system, an overview of PVPO examination procedures, and how the addition of asexually reproduced varieties has been implemented. PVPO continues to actively work with the American Seed Trade Association (ASTA), the International Community of Breeders of Asexually Reproduced Horticultural Plant Varieties (CIOPORA), the U.S. Patent and Trademark Office, and other seed and vegetative industry stakeholders regularly.

The current Plant Variety Protection (PVP) Board was appointed by the Secretary on September 24, 2022. The Board consists of 14 members representing farmers, the seed industry, trade and professional associations, and public and private institutions involved with developing new plant varieties. Members of the PVP Board provide oversight and guidance to the program on plant variety protection issues. The last PVP Board meeting was held on December 14, 2021, by videoconference. The meeting included updates from PVPO on 2021 program accomplishments, 2022 program initiatives, international outreach, status of incoming asexually reproduced variety applications, and acceptance of examination reports from other countries. Presentations on the soybean molecular marker method was provided by PVPO and the ASTA molecular marker working group.

AMS provides intellectual property rights protection through PVPO, which protects breeders of varieties of seed and tuber propagated plants, and asexually reproduced plants that are new, distinct, uniform, and stable. Authorized by the Plant Variety Protection Act, PVPO examines new variety characteristics to grant certificates that protect varieties for 20 years (25 years for vines and trees).

Agricultural Research Service's Protection of USDA's Own Intellectual Property

USDA's Agricultural Research Service (ARS) has a comprehensive program to protect U.S. Government-owned intellectual property. In addition to IP protection, ARS delivers a comprehensive training program on IP. The program has four components: (1) training scientists on Dual Use Research of Concern, Technology Transfer (TT), and insider threats; (2) training TT Staff on U.S. Department of Commerce regulations; (3) Export Control Reviews; and (4) entrance and exit procedures for agency employees to minimize insider threats.

DEPARTMENT OF COMMERCE

DEPARTMENT OF COMMERCE

"There is no fair access to the innovation ecosystem when someone can compete with you illegally using your own brand — especially when they can do so more cheaply and with inferior products."²

"Whether it is car or video game components, make-up or prescription drugs, or purses and shoes, this pervasive criminal activity must be stopped. Secretary of Commerce Gina Raimondo and I are committed to cracking down on counterfeit goods for the benefit of every American and entrepreneur."

 Kathi Vidal, Under Secretary of Commerce for Intellectual Property and Director of the USPTO

Department of Commerce Appendix for FY 2022 Annual Report

This appendix discusses the FY 2022 activities of the Commerce Department, through the Commercial Law Development Program (CLDP), the International Trade Administration (ITA), the National Telecommunications and Information Administration (NTIA), and the U.S. Patent and Trademark Office (USPTO). The Commerce Department continues to engage in training and capacity building programs to strengthen intellectual property awareness and enforcement internationally. Additionally, the USPTO provides many different patent, trademark, copyright, and trade secret capacity building programs as fully described in our TRIPS Article 67 report each year, and the following highlights some enforcement activities during FY 2022.

COMMERCIAL LAW DEVELOPMENT PROGRAM

The Commerce Department's Commercial Law Development Program (CLDP) creates a level playing field for U.S. firms overseas, in particular by building the capacity of foreign countries to improve the protection and enforcement of intellectual property rights (IPR).

As the Office of General Counsel's technical assistance arm, CLDP upholds the Department of Commerce's mission, as stated in its 2018-2022 strategic plan to "Accelerate American Leadership." Strategic Objective 1.3 is "Strengthen Intellectual Property Protection," and one of the plan's strategies is to "strengthen the protection of intellectual property" abroad.

CLDP helps enforce IPR overseas through two types of technical assistance programs: programs that help countries develop an effective IPR enforcement environment, and programs that help countries create their own intellectual property, which gives them a vested interest in enforcing IPR.

² Remarks at the International Trademark Association Annual Convention (May 3, 2022) at https://www.uspto.gov/about-us/news-updates/remarks-uspto-director-kathi-vidal-inta-convention.

³ National Crime Prevention Council, press release on "McGruff the Crime Dog® and NASCAR's Joey Gase want you to buy smart" (August 24, 2022) at https://www.prnewswire.com/news-releases/mcgruff-the-crime-dog-and-nascars-joey-gase-want-you-to-buy-smart-301611605.html.

Conducted in close cooperation with the USPTO, other Commerce bureaus, USTR, and other Federal agencies, CLDP's activities typically include consultations, seminars, workshops, and meetings.

Starting in March 2020, in light of the public health situation (COVID-19) and of the resulting impossibility to travel overseas, CLDP suspended its traditional activities, most of which took place overseas and conducted, instead, online video-conferences and webinars. At the suggestion of the Director of the USPTO's Global Intellectual Property Academy (GIPA), GIPA and CLDP created an "IP eLearning Community of Practice" that has been effective in sharing lessons learned by both institutions as they conducted virtual programs.

In FY 2022, CLDP IP activities were conducted for the following countries and regions: Algeria, Azerbaijan, Bahrain, Bosnia and Herzegovina, Central Asia, Egypt, Pakistan, Sri Lanka, and Ukraine.

As outlined below, CLDP's FY 2022 activities mainly fell into four categories: Judicial Capacity Building in IPR Enforcement; Capacity Building for Institutions that Grant IPR; Capacity Building for Institutions that Enforce IPR; and Development of Innovation Ecosystems, in particular through Technology Transfer.

OVERVIEW OF CLDP's FY 2022 IP PROGRAMS

1. Judicial Capacity Building in IPR Enforcement

Azerbaijan

CLDP Holds Judicial Webinar on Intellectual Property Rights

On April 27, 2022, CLDP, in coordination with U.S. Embassy Baku, the Azerbaijani Justice Academy, and USPTO, held a webinar on the basic tenets of intellectual property (IP) rights for judges in Azerbaijan. The webinar was a refresher on the basics of IP in preparation for an extensive workshop that took place in May (discussed directly below) and is part of a series of workshops and consultations to strengthen IP in Azerbaijan and focus on rule of law technical assistance.

CLDP Leads Workshop on Intellectual Property Adjudication

On May 17-18, 2022, CLDP, in coordination with U.S. Embassy Baku, the Azerbaijan Justice Academy, and the Azerbaijan Intellectual Property Agency, led a workshop focused on intellectual property rights enforcement on issues related to technology and software licensing for judges in Azerbaijan. Following a virtual program on the basic tenets of IPR, the workshop focused on case studies and hypothetical scenarios that addressed challenging and nuanced licensing and technology disputes.

Balkans Regional

CLDP Hosts Workshop on Counterfeit Goods and IPR Protection

On September 6-9, 2022, CLDP, in coordination with U.S. Embassy Podgorica and interagency and judicial experts, hosted a workshop on customs, prosecutorial, and judicial elements of counterfeit goods when seized at the border. The goal of the workshop, attended by customs officials, judges and prosecutors, was to provide a platform for participants to align customs processes and facilitate regional cooperation and exchange of information on laws and best practices on intellectual property rights (IPR) enforcement and protection. The next steps will focus on targeted issues within both customs processes and IPR.

Bosnia and Herzegovina

CLDP Organizes Intellectual Property Bench Book Update

On June 20-21, 2022, CLDP supported a workshop for a working group consisting of judges, private sector representatives, academics, and an IP institute representative, to update an existing intellectual property (IP) bench book. This workshop, a follow-up to monthly virtual idea exchanges and drafting exercises, is designed to facilitate collaboration among Republika Srpska and Federation entities, as well as to encourage private sector, institutional, and judiciary collaboration. The bench book update will be used as a reference point and an educational tool to boost IP adjudication capacity in the country.

Georgia

CLDP Hosts Workshop on Adjudication of Civil Intellectual Property Infringement Cases On July 30-31, 2022, CLDP held a Workshop on Adjudication of Civil Intellectual Property Infringement Cases for Georgian judges in Batumi, Georgia. CLDP brought two U.S. Federal District Court judges and a European Union intellectual property (IP) expert to the workshop to train judges from the Georgian local, appellate, and Supreme Court levels on the legal principles governing the adjudication of civil intellectual property cases in the U.S. and European systems. The workshop allowed the Georgian judges, through case studies taken from both the U.S. and Georgian courts, to practically apply and cement the principles learned throughout the workshop. Through this workshop, CLDP continued its ongoing efforts to strengthen the capacity of the judiciary and rule of law in Georgia.

2. Capacity Building for Institutions that Grant IPR

Egypt

CLDP Initiates an Interagency Review of the Trademark Registration Manual

In November 2021, CLDP, in close cooperation with USPTO, initiated an interagency review of the existing guidelines for trademark examination and registration (the Guidelines) by the Egyptian Trademarks and Industrial Designs Office (ETMO). Prior to initiation of the

interagency review, CLDP arranged for the translation of the Guidelines and related documents to facilitate the timely completion of the review.

CLDP Discusses with Embassy Officers the Potential for Expanding Intellectual Property Technical Assistance

During CLDP's December 2021 meetings at the U.S. Embassy in Cairo, the Economic Office highlighted CLDP's work in intellectual property and asked if it might be possible to expand work in this area to include technical assistance for the National Committee, the patent office, and further assistance for the judiciary. CLDP will carry on this conversation with USAID and USPTO, and make suggestions in terms of further intellectual property rights technical assistance that CLDP could offer.

Pakistan

Distinctiveness, Acquired Distinctiveness and Disclaimers in Trademark Examination

On December 15, 2021, CLDP, in close cooperation with USPTO, conducted the second 2-hour session for the Intellectual Property Organization (IPO) of Pakistan Trademark Directorate (IPO-TM) in a series of webinars focusing on the critical elements of trademark examination, classification, registration and appeal. Session 2 focused on USPTO practices concerning the element of distinctiveness, including acquired distinctiveness and the use of disclaimers. USPTO experts employed a lecture format interspersed with examples and a question-and-answer period, followed by open discussion to deliver effective understanding of the subject matter.

Non-Traditional Trademarks and Madrid Protocol Obligations

On January 27, 2022, CLDP, in close cooperation with USPTO, conducted the third 2-hour virtual session for the IPO-TM. Session 3 focused on non-traditional trademarks, with an emphasis on the U.S. legal tests of functionality and distinctiveness, including examples and discussion of the types of non-traditional marks registrable in the U.S. Additionally, USPTO experts discussed the handling of out-going trademark applications under the Madrid Protocol.

Trademark Opposition, Appeal and Cancellation, and Operational Procedure

On February 23, 2022, CLDP, in close cooperation with USPTO, conducted the fourth 2-hour virtual session for IPO-TM officials. Session 4 focused on trademark opposition, appeal and cancellation, and operational procedure followed by USPTO's Trademark Trial and Appeal Board (TTAB). The session began with an overview of the TTAB, including its make-up and mission. USPTO experts then discussed TTAB opposition and cancellation proceedings in general, before covering the specifics of ex parte appeals and inter-partes oppositions practice, both of which occur before trademark registration. Actions after trademark registration, such as inter-partes cancellations practice, were discussed in detail and included a question-and-answer period.

Georgia

CLDP Presents Recommendations on Collective Copyright Management

On November 10, 2021, CLDP led a workshop with the National Intellectual Property Center of Georgia and members of the Georgian Parliament's Culture Committee Working Group on Intellectual Property, to review CLDP recommendations on strengthening the legal and institutional framework for collective copyright management in Georgia. The recommendations were produced after a March 2021 CLDP webinar on the collective management system and a gap analysis of Georgia's Law on Collective Management of Copyright and Related Rights. Georgia has been a model for collective management in the Caucasus and Central Asia region, but due to recent developments in the collective management field, rightsholders and users have expressed confusion about the system and concerns about royalty collection and distribution.

3. Capacity Building for Institutions that Enforce IPR

Central Asia

CLDP Holds Roundtable Discussions on Intellectual Property Rights

On March 14-15 and March 17-18, 2022, CLDP partnered with the U.S. Department of Justice to conduct roundtable meetings with government officials and intellectual property (IP) private-sector stakeholders in Nur-Sultan, Kazakhstan and Bishkek, Kyrgyz Republic to discuss the protection and enforcement of IP rights. These meetings, which focused on counterfeit goods and digital piracy issues and helped develop regional case studies, were part of CLDP's support of the Central Asia IP Working Group, established under the U.S.-Central Asia Trade and Investment Framework Agreement. CLDP's technical assistance to the Central Asia IP Working Group seeks to strengthen and improve IP protections in order to increase foreign direct investment and trade in the region.

CLDP Holds Consultations on IP Rights in Kazakhstan and Kyrgyz Republic

On April 14 and April 20, 2022, CLDP held virtual meetings with the delegates of the Central Asia Expert Level Working Group on Intellectual Property Rights from Kazakhstan and Kyrgyz Republic, respectively. These consultations were the latest in a series of engagements with government officials that culminated in an in-person meeting of the Central Asia Expert Level Working Group on Intellectual Property Rights in July. CLDP's work furthers the objectives of the U.S.-Central Asia Trade and Investment Framework Agreement to facilitate trade and economic connectivity in, among, and between the countries of Central Asia and other regions of the world.

CLDP Holds Roundtable Discussions on IP Rights in Uzbekistan

On April 18-19, 2022, CLDP hosted roundtable discussions with the Uzbekistan delegates to the Central Asia Expert Level Working Group on Intellectual Property Rights. The discussion focused on the roles of government agencies responsible for identification and interdiction of counterfeit goods and planning for the July meeting of the Working Group. CLDP's support of the Expert Level Working Group on Intellectual Property Rights, established in conjunction with

the U.S.-Central Asia Trade and Investment Framework Agreement, focuses on addressing the deficiencies in protection of intellectual property rights in Central Asia.

CLDP Conducts Consultations on Intellectual Property Rights in Tajikistan and Turkmenistan

On April 21-26, 2022, CLDP conducted consultations with the governments of Turkmenistan and Tajikistan to help guide planning for the next meeting of the Central Asia Expert Level Intellectual Property Rights Working Group. CLDP and government officials discussed the responsibilities and challenges of combatting the trade of counterfeit goods, which will ultimately strengthen and improve intellectual property protection and increase foreign direct investment and trade in the region.

CLDP Holds Bilateral Meetings of Central Asia Expert Level Intellectual Property Working Group

On June 2-3, 2022, CLDP held virtual bilateral meetings with members of the Central Asia Expert Level Intellectual Property Working Group (IP Working Group). The meetings gathered officials responsible for the protection and enforcement of intellectual property rights in preparation for the next meeting of the IP Working Group, which will focus on best practices in the identification and interdiction of counterfeit goods. Aligning protection and enforcement of IP rights in Central Asia with international best practices promotes innovation and economic diversification leading to increased trade and investment in the region.

CLDP Holds Fourth Meeting of the Central Asia Expert Level Working Group on Intellectual Property Rights

On July 20-22, 2022, CLDP, in collaboration with USTR, CBP and USPTO, and with the support from U.S. Embassies Bishkek and Ashgabat, led the fourth meeting of the Central Asia Expert Level Working Group on Intellectual Property Rights (IP Working Group) in Tbilisi, Georgia. The meeting gathered expert-level government officials from Kazakhstan, Kyrgyz Republic, Tajikistan, Turkmenistan, and Uzbekistan, and focused on identification and interdiction of counterfeit goods at border crossings. A set of recommendation was developed and sent for each country's consideration for adoption.

CLDP Conducts Workshop on Brand Protection in Kazakhstan

On September 8, 2022, CLDP, in partnership with anti-counterfeiting network REACT, conducted a workshop on identification and protection of brands in Almaty, Kazakhstan. The audience was composed of government officials from customs, law enforcement and IP agencies. This workshop was designed to enhance customs officials' skills for more effective detection of IPR infringing goods, thereby attracting foreign investment and increasing international trade.

CLDP Conducts Workshop on Brand Protection and Consultations with Kyrgyz Patent On September 12-13, 2022, CLDP, in partnership with Kyrgyz Patent and anti-counterfeiting network REACT, conducted a workshop on identification of brands in Bishkek, Kyrgyz Republic for government officials from judiciary, customs, police and IP agencies. This workshop is part of CLDP's efforts to build capacity for effective protection IP rights in the Kyrgyz Republic. Following the workshop, CLDP held consultations with the leadership of

Kyrgyz Patent, focused on priorities and challenges for protection and enforcement of IP. The meeting furthered CLDP's continued efforts in Central Asia to strengthen protection and enforcement of intellectual property rights in the region, thereby supporting regional trade and investment.

Georgia

CLDP Hosts "Georgia Against Counterfeiting and Piracy" Conference

On July 25-26, 2022, CLDP partnered with the National Intellectual Property Center of Georgia "Sakpatenti" to host the 6th Annual International Conference "Georgia Against Counterfeiting and Piracy" in Batumi, Georgia. CLDP and Sakpatenti brought together intellectual property government officials from Estonia to Kyrgyzstan; experts from the USPTO, WIPO, the World Customs Organization, the European Union Intellectual Property Organization, and Europol; and private sector representatives from the textile, technology, and pharmaceutical industries for the two-day conference. The conference addressed current trends and challenges in the protection and enforcement of intellectual property rights (IPR); private sector representatives explored the impact of counterfeit and pirated goods across the region; and government officials shared best practices and common challenges faced by their respective countries. The participants gained a deeper understanding of the challenges, solutions, and best practices in cross-sector and cross-border IPR issues across the region.

Pakistan

CLDP and USPTO Lead Interagency Planning to Conduct Capstone Sessions in the Multi-Series Program on Intellectual Property Rights Enforcement at the Border, Focusing on Best Practices in Combating Counterfeit Medical Products

On October 7, 2021, CLDP, in close cooperation with USPTO, the U.S. Food and Drug Administration (FDA), U.S. Customs and Border Protection (CBP), and the Pakistan Customs Service (PCS) began planning for Module 4 of the multi-series program on stopping counterfeit goods transiting through ports of entry in Pakistan. Modules 1-3 were conducted virtually, whereas Module 4 is being structured as in-person training consisting of delegations traveling to the U.S. and Pakistan to observe on-the-ground activities combating counterfeit goods transiting through ports of entry. The program continues to focus on the enforcement of intellectual property rights as a primary tool in the identification, interdiction, and seizure of contraband (e.g., counterfeit medical products) transiting through air, land, and seaports of entry. U.S. and U.K. capabilities and practices, concentrating on air freight and air mail facilities, serve as aspirational goals for improving Pakistan's anti-counterfeiting activities.

South Caucasus

CLDP Establishes Working Group on Intellectual Property Rights

On July 27, 2022, CLDP chaired the inaugural meeting of the Eastern Europe Expert Level Working Group on Intellectual Property Rights. CLDP invited the participation of intellectual property (IP) government officials from Armenia, Azerbaijan, Moldova, Georgia, and Ukraine for the Working Group and succeeded in the participation of officials from all but Azerbaijan and Ukraine. The Working Group seeks to promote greater harmonization, cooperation, and

information sharing in the protection and enforcement of IP within the region, as well as increasing the commercialization and utilization of IP in line with internationally accepted standards and best practices. The assembled delegations agreed upon several baseline procedures to guide future meetings of the Working Group and engaged in an open discussion of salient IP topics and issues to be addressed by the Working Group going forward. CLDP will continue stewarding the Working Group through its early stages with the goal of developing it into an integral, self-sustaining piece of multilateral IP landscape in Eastern Europe and the South Caucasus.

South Caucasus and Central Asia

CLDP Convenes Intellectual Property Forum

On July 28, 2022, CLDP brought together delegations of intellectual property (IP) government officials from Eastern Europe and Central Asia (Armenia, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, Uzbekistan) for the Trans-Caspian Intellectual Property Forum. Following the meetings of the Eastern Europe and Central Asian Expert Level Working Groups, the Forum allowed the assembled delegations to engage in direct dialogue with their counterparts from across the Trans-Caspian region on best practices in the enforcement and protection of IP rights. The Forum divided the delegations into three groups to discuss different aspects of IP protection and enforcement – internal markets, customs and transshipment, and digital and online piracy – with each group reporting on the most pressing regional issues, best practices, and proposed solutions. By the end of the Forum, participants had not only broadened their perspective of IP issues affecting other countries throughout the region, but also gained valuable insight into how to best address these issues in their home countries.

4. Development of Innovation Ecosystems/Technology Transfer

Algeria

CLDP Co-Organizes, and Presents at Workshop on The Viability of Advanced Technology Start-ups

The development of advanced technology start-ups (ATS) is a priority for the Algerian government, as it will be a key condition of the country's transition from a resource-based economy to a knowledge-based economy. The U.S. Embassy in Algeria supports this priority because it will contribute to better enforcement of intellectual property rights. In light of the embassy's position, CLDP proposed to join forces with the Algerian Information Technology Association (AITA) to organize a workshop focused on ways to ensure the viability of ATS. The embassy agreed and the Algerian government, at the highest level, embraced this initiative.

On October 5-6, 2021, a workshop focused on *The Viability of Algerian Advanced Technology Start-ups* took place in Algiers. This workshop – co-organized by CLDP, AITA, and Algerian government institutions – had more than 100 participants, including government officials, managers of technology incubators, and members of start-ups. A delegation from the U.S. embassy attended the workshop, with CLDP joining virtually. CLDP gave a presentation on the

methodology it has created to assess the viability of ATS; the Algerian government coorganizers, in a written message, praised this presentation.

Bahrain

CLDP Conducts Technology Transfer Online Consultations

On January 20, 2022, in collaboration with the University of Maryland technology transfer office, and on January 24, with the George Mason University Office of Technology Transfer, CLDP conducted online consultations for representatives from the Bahrain Innovation and Technology Transfer Center (BITTC) to meet with directors of the aforementioned U.S.-based centers to learn the structure and management of technology transfer offices. Collaboration between BITTC and U.S. universities will provide opportunities to commercialize innovations developed in Bahrain and increase access to the Gulf Cooperation Council market for innovations developed in U.S. universities.

Bosnia and Herzegovina

CLDP Leads Workshop on Challenges of Intellectual Property Protection in the Information Technology Age

On October 18, 2021, CLDP held a roundtable with ICT companies in Bosnia and Herzegovina (BiH) to address some of the key challenges for the private sector in protecting IP rights. The workshop was a comparative approach to protection of software, database, and trademark law among the U.S., Bosnia and Herzegovina, and Serbia, which served as a regional example. Importantly, experts and participants discussed gaps in IP protections with respect to the current BiH law during a panel discussion with the Institute for Intellectual Property and the experts and identify next steps. Strengthening intellectual property rights will help BiH to develop as a knowledge-based economy, improving employment opportunities and economic stability, and will protect the IP of both Bosnian and U.S. companies.

Sri Lanka

CLDP Participates in a Conference of University Business Linkages Offices

On January 25, 2022, CLDP virtually participated in the eleventh meeting of the University Business Linkage (UBL) Cell Standing committee of the University Grants Commission. The meeting gathered UBL Cell managers from over 40 private and public universities in Sri Lanka, and featured progress updates on research and commercialization. CLDP confirmed its commitment to support strengthening the activities of the UBL Cells through continuation of the Technology Transfer Workshops series. Technology transfer and commercialization of intellectual property promote innovation and economic development and create opportunities for future research and development partnerships with American institutions.

CLDP Conducts Series of Technology Transfer Workshops

On March 31, 2022, CLDP, in cooperation with the Sri Lankan Ministry of Higher Education (MoHE), conducted the third workshop in a series for the managers of university technology transfer offices (TTOs). The workshop consisted of recorded presentations and live discussions focused on concepts and issues related to software licensing agreements and negotiations. This

workshop series builds on previous programs conducted by CLDP with MoHE, USPTO, and others to establish and enhance TTOs in public and private universities across Sri Lanka. TTOs play a key role in creating and maintaining an ecosystem of innovation and contribute to the strengthening of Sri Lanka's IP rights enforcement regime.

CLDP Continues Series of Technology Transfer Workshops

On April 15 and April 25, 2022, CLDP, in cooperation with the former director of Cornell University's technology transfer office, conducted two workshops on pre-negotiation valuation of licensing agreements. The workshops, which combined recorded presentations with live virtual discussion sessions, were the fourth and fifth in a series for the managers of university TTOs.

CLDP Continues Series of Technology Transfer Workshops

From September 26 to 28, 2022, in Kathmandu, Nepal, CLDP, in cooperation with USPTO and the Sri Lanka Ministry of Higher Education, conducted a technology licensing workshop for the managers of university TTOs. This was the sixth workshop in a multi-series program designed to strengthen the capabilities of the country's TTOs to commercialize patented inventions through technology licensing. Ensuring effective enforcement of intellectual property rights overseas is an important objective of the U.S. Department of Commerce and CLDP helps develop innovation ecosystems where IP rights are enforced, benefiting U.S. firms that operate overseas.

Ukraine

Intellectual Property Moot/Licensing Webinar

On December 15-17, 2021, CLDP and a group of stakeholders conducted a series of interactive lectures and trainings for Ukrainian law students. This builds on a September 2021 in-person training for students that introduced them to high-level concepts in IP law. The December program focused more specifically on domestic and international legal concepts surrounding licensing agreements. In addition to substantive topics, students heard from practicing IP attorneys about various careers in the field. The webinar is part of CLDP's Ukraine IP moot initiative aimed at increasing interest and appreciation for IP law and protection among Ukrainian law students.

INTERNATIONAL TRADE ADMINISTRATION (ITA)

Office of Standards & Intellectual Property (OSIP)

STOPfakes.gov

The International Trade Administration's Office of Standards and Intellectual Property (OSIP) helps lead the STOPfakes.gov program including resources provided on the STOPfakes website.

STOPfakes.gov hosts digital materials which seek to educate and assist businesses, consumers, government officials, and the general public.

Industry Specific IP Toolkits

These industry sector toolkits focus on IP and provide guidance to U.S. companies seeking to acquire, use and protect copyrights, patents, trademarks, and trade secrets in overseas markets. Our newest IP Toolkit focuses on Clean Technology including providing links to resources supporting that industry sector. Additional industries covered include Sporting Goods, Marine Technology, Pleasure Boats, Medical Devices, Auto Parts, Building Products, and Smart Mobility.

IP Snapshots

IP Snapshots are one-page documents that provide IP information about a foreign country. The following information is included on each IP Snapshot: Contact information for local IP Offices, country membership in important IP treaties, the USTR Special 301 Report rankings for the prior three years, and contact information for the IP attaché in the region. Seventy-nine (79) IP Snapshots are currently available on STOPfakes.gov.

USG Commerce Training Module

OSIP created a unique IP training module made available to International Trade Administration (ITA) employees through the Commerce Learning Center. The ESkillz training module provides ITA employees with an overview of intellectual property terminology, directs their clients to the correct USG IP experts, and helps to guide them on how to respond to intellectual property questions.

Country IP Toolkits

Country Toolkits seek to assist U.S. entrepreneurs with thorough country specific insight focused on IP protections in foreign markets. Available toolkits include China (updated), Singapore, Korea, Malaysia, Vietnam, Thailand, Brunei, Brazil, Colombia, Egypt, European Union, Italy, and Peru.

IP Highlights

These digital resources raise awareness on a range of IP related issues. The inaugural *IP Highlight* was on <u>Suspicious Solicitations</u>, and it noted how bad actors negatively impact rightsholders by impersonating government agencies. Additionally, the *IP Highlights* provide information on an array of U.S. Government IP Resources, including the IP Attaché Program, the Interior Department's Indian Arts and Crafts Board, Enforcement on Counterfeit Car Seats, and the USPTO's Patent Pro Bono Program.

STOP fakes at 2022 Consumer Electronics Show

The STOPfakes team provided IP education and direct outreach to over 600 businesses of all sizes over 3 days in person at the 2022 Consumer Electronics Show in Las Vegas, Nevada.

STOPfakes Roadshows

The <u>STOPfakes Roadshows</u> deliver critically important information about intellectual property to the audiences that need it most – start-ups, entrepreneurs, small and medium-sized businesses, independent creators, and inventors. The information is presented by experts from multiple government agencies focused on advancing stakeholders' intellectual property interests:

- The U.S. Patent and Trademark Office provides information about how to protect patents and trademarks;
- The U.S. Copyright Office discusses the importance of copyright protection to creators and businesses;
- U.S. Customs and Border Protection (CBP) explains how a registered trademark or copyright can be recorded with CBP to facilitate the seizure of infringing goods at our borders;
- The Federal Bureau of Investigation (FBI) or a U.S. Attorney's Office discusses how to protect trade secrets and identify internal and external threats;
- The U.S. Department of State highlights the role diplomacy and our diplomatic missions play in advocating for U.S. businesses overseas;
- The International Trade Administration identifies mechanisms for obtaining intellectual property rights protections in export markets; and
- The Small Business Administration advises on the potential use of grants and loans to help with the costs of obtaining IP protection before exporting.

Participating agencies also identify additional resources they make available to assist U.S. businesses with acquiring and protecting their intellectual property rights.

Due to COVID-19, in-person Roadshows were not held during FY 2022, and have recently restarted. Instead, as discussed below, STOPfakes webinars were held during FY 2022.

STOPfakes Webinars

For FY 2022, OSIP continued its virtual STOPfakes webinars with several webinars to various audiences. These webinars were co-hosted by STOPfakes and feature some of the same topics and speakers from the roadshow agendas as well as some content from new partners. (The

STOPfakes roadshows resumed in-person roadshows in late Fall 2022 with a successful program in Orlando, Florida.)

An example of topics covered in the FY 2022 STOPfakes engagement included:

- Promoting World IP Day's theme "IP and Youth: Innovating for a Better Future" focusing on our youngest inventors, entrepreneurs and innovators with blog posts, social media outreach and virtual events.
- Delaware ExporTechTM is a national export assistance program helping companies enter or expand in global markets. IP topics included: specific countries where IP protection and enforcement is more risky; best practices to ensure IP protection on new innovations; and broad overview of IPR resources.
- Participating in a US and UK Small and Medium Enterprises Dialogue
- "IPR Border Enforcement: Recording Trademarks and Copyrights" with CBP
- "Trademark Basics: What Every Small Business Should Know Now, Not Later" with USPTO
- Patent Basics and USPTO Resources: What Every Small Business Should Know When Developing their Business Plan and Moving Forward
- Registering Your Trademark Internationally
- Participating in the Discover Global Markets: Blue Economy Event including specialized business consultations

IP Consultations for Businesses and Associations

OSIP provided IP business guidance and insight for entities as they sought to expand their opportunities for exporting. Additionally, OSIP participated as a panelist on webinars for associations seeking to provide IP information for their association members.

Combatting Trafficking in Counterfeit and Pirated Goods

OSIP undertook a critical role in the interagency process to develop and implement the January 2020 Report by the Department of Homeland Security on *Combating Trafficking in Counterfeit and Pirated Goods*

(https://www.dhs.gov/sites/default/files/publications/20_0124_plcy_counterfeit-pirated-goods-report_01.pdf). In FY 2022, OSIP continued to meet regularly with industry leaders and provide industry's unique perspective as part of OSIP's support for the ongoing USG activities to combat trafficking in counterfeit and pirated goods.

NATIONAL TELECOMMUNICATIONS AND INFORMATION ADMINISTRATION (NTIA)

Protect Intellectual Property at ICANN

The National Telecommunications and Information Administration (NTIA), USPTO, and other Federal agencies, including the Federal Trade Commission and the Department of Justice, continue to engage within the Internet Corporation for Assigned Names and Numbers (ICANN) and the Governmental Advisory Committee (GAC), highlighting the importance of timely access to domain name registration information (known as WHOIS) for IP rightsholders, to combat infringement online. In response to the European Data Protection Regulation (GDPR), which went into effect during 2018, crucial domain name registration information details are no longer publicly provided. The U.S. Government continues playing an active role in the ongoing discussions to establish a sustainable access and accreditation model as soon as possible, so that IP rightsholders and other legitimate interests can access non-public WHOIS information for enforcement and security purposes.

In addition, the USG also will be closely following the upcoming review of the Uniform Domain Name Dispute-Resolution Policy (UDRP). Since its introduction in 1999, the UDRP has been a successful tool in assisting trademark rightsholders to combat cybersquatting.

As ICANN takes further steps for implementing a second round of new gTLDs, the U.S. Government will continue to work through the GAC to ensure that intellectual property rights are respected in the various ICANN policy development processes.

The Section 1201 Rulemaking

In an extensive consultation letter, transmitted October 1, 2021, NTIA formally shared its views with the Copyright Office on the rulemaking proceeding under 17 U.S.C. § 1201(a)(1)(C). The rulemaking process allows the Librarian of Congress to determine whether the Librarian should grant any temporary exemptions to the prohibition on circumvention in 17 U.S.C. § 1201(a)(1). NTIA worked to fulfill its statutory role to engage in consultation with the U.S. Copyright Office during the rulemaking proceedings. NTIA reviewed the proposals and additional comments received in the process.

NTIA appreciates the positive process changes that the Copyright Office has continued to implement in the rulemakings, several of which track closely with recommendations NTIA has made both in its previous consultations and in less formal discussions. For example, although necessitated by the ongoing COVID-19 pandemic, NTIA found remote participation at the public hearings to be a success, as it allowed for more inclusive public participation in the process.

UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)

The Under Secretary of Commerce for Intellectual Property and Director of the USPTO has the responsibility of, among other things, advising "the President, through the Secretary of Commerce, on national and certain international intellectual property policy issues" and advising "Federal departments and agencies on matters of intellectual property policy in the United States and intellectual property protection in other countries." 35 U.S.C. § 2(b)(8)-(13). Consistent with this responsibility, the USPTO provides expert legal and policy advice to the Administration on issues related to the protection and enforcement of patents, industrial designs, trademarks and geographical indications, copyrights, plant varieties, and trade secrets, including regulatory test data.

The USPTO represents the United States at the World Intellectual Property Organization (WIPO) and in other international intergovernmental organizations that discuss IP-related matters. In addition, during FY 2022, the Department of Commerce – including the USPTO – provided advice to the Office of the United States Trade Representative (USTR) through extensive input into: the annual Special 301 review of global IP regimes, the Notorious Markets Review, the National Trade Estimate Report, as well as the Section 301 investigations when intellectual property issues are involved. Additionally, the USPTO participates in the Asia-Pacific Economic Cooperation (APEC) Intellectual Property Experts Group (IPEG) meetings and advises USTR on IP enforcement-related issues in the context of APEC initiatives. The USPTO provides advice on initiatives, reports, proposed programs, and developments related to IP enforcement made or produced by other APEC economies. The USPTO also organizes and conducts IP enforcement-related programs/seminars for APEC economies.

Strengthen Intellectual Property Enforcement through International Organizations

The USPTO continues to lead the U.S. delegation to the WIPO Advisory Committee on Enforcement (ACE). ACE provides a multilateral forum for exchanging information and best practices on combatting trademark counterfeiting and copyright piracy. USPTO is also a bureau member of the OECD's Countering Illicit Trade Task Force (TF-CIT).

Promote Enforcement of U.S. Intellectual Property Rights through Trade Policy Tools

Throughout FY 2022, the USPTO provided policy advice and technical expertise on domestic and international IP matters to multiple other federal agencies. These included USTR, the U.S. Department of State, the IPEC, and other bureaus of the Commerce Department. The USPTO also advised USTR on the intellectual property aspects of its trade discussions, such as a country's Trade Policy Forum (TPF) or Trade & Investment Framework Agreement (TIFA); reviews under U.S. trade preference programs such as the Generalized System of Preferences and the African Growth and Opportunity Act (AGOA); Science and Technology Agreements involving the 2015 Model IP Annex, Trade Policy Reviews undertaken at the World Trade Organization (WTO); participation in the U.S.-E.U. Trade and Technology Council (TTC); amendments to the South Africa copyright and performers laws; a draft Nigerian copyright bill; support for Ukraine in the 2022 Special 301 Review and our actions to reduce our bilateral IP relationship with Russia due to the War in Ukraine, Ukrainian copyright law reform and software

legalization; ongoing legislative reform in India and several ASEAN/APEC members; the U.S.-Kenya Trade Dialogue and the African Continental Free Trade Area (AfCFTA); Mexico's implementation of its USMCA obligations; and accessions underway at the WTO. In addition, the USPTO assisted USTR in the preparation of its annual review of global developments on trade and IP and the Special 301 Report. The Special 301 Report identifies U.S. trading partners in which IP protection and enforcement has deteriorated or remained at inadequate levels and where U.S. persons who rely on IP protection have difficulty with fair and equitable market access. The USPTO assisted in its preparation by providing extensive information on the state of IP protection and enforcement in 80 countries under review. The USPTO likewise provided USTR with information in connection with its evaluation and compilation of the annual Notorious Markets List, which highlights prominent online and physical marketplaces that reportedly engage in and facilitate substantial copyright piracy and trademark counterfeiting.

Support U.S. Small and Medium-Size Enterprises (SMEs) In Foreign Markets

The USPTO offers basic- and advanced-topic programming for U.S. Small and Medium Sized Enterprises (SMEs) doing business abroad through its Global Intellectual Property Academy (GIPA), a component of the Office of Policy and International Affairs (OPIA). These in-depth programs – organized and conducted by OPIA attorneys – cover best practices in domestic and international IP protection and enforcement and are typically delivered through face-to-face and distance learning modes, both from the USPTO's headquarters in Alexandria, VA, and around the country in cooperation with the USPTO's regional offices and other business units. OPIA collaborates with the USPTO's IP Attachés, Regional Offices, other USG agencies, and the Federal Judiciary. In FY 2022, GIPA provided IP awareness and education programming to over 6,526 U.S. SMEs, U.S. government officials, and other U.S. stakeholders. About 22% of GIPA's 175 programs in FY 2022 targeted this domestic audience of IP rights owners, users, and policymakers. During FY 2022, GIPA continued its successful 2020 pivot to all-remote outreach and education delivery, thanks to prior investments in technology platforms and e-learning strategies. However, a slow transition has begun to in-person outreach and education programs as well.

The USPTO through OPIA/GIPA continued certain domestic training and outreach initiatives, converting previously in-person programming to the virtual environment for several audiences, including IP education programming for universities in cooperation with the ITA on DOC Resources to Assist U.S. Higher Education Institutions, and Webinars for U.S. SMEs, as well as a virtual pilot program on IP for U.S. SMEs doing business in Southeast Asia.

USPTO continued a successful multi-year webinar initiative to provide comprehensive IP education to grantees of the Small Business Administration's (SBA) SBIR-STTR programs participating in the SBA Office of Trade webinar on IP basics and USPTO resources for SBIR/STTR applicants and support organizations; supported small business advisors by providing information about USPTO resources, international IP protection and enforcement, and customs recordation sessions in the international trade track and plenary at the annual America's Small Business Development Center (ASBDC) conference; and offered a program on copyright basics and considerations for entrepreneurs for several Small Business Development Centers (SBDCs) in cooperation with the USPTO Eastern Regional Outreach Office.

In conjunction with the Commercial Service under the International Trade Administration, the USPTO has participated in programs with representatives of the Minority Business Development Agency, specifically addressing the interests of minority business owners concerning domestic and foreign IP registration and protection protocols.

As part of the EU Trade and Technology Council (TTC) working group, the USPTO helped produce a webinar titled, "Intellectual Property and SMEs in the Digital Economy" on the importance of intellectual property for SMEs seeking to do business abroad. Slides from the webinar are publicly available online and include free government resources to support SMEs. More information is available at: https://futurium.ec.europa.eu/en/EU-US-TTC/wg9/events/trade-and-technology-council-working-group-9-webinar-intellectual-property-and-smes-digital-economy

The USPTO supported DOC and whole-of-government efforts to support Women's Economic Empowerment (WEE) through providing IP subject matter expertise to WEE programming. USPTO participated in USAID and ITA WEE programming, including the January 2022 virtual event on APEC Supporting Women Entrepreneurs in E-Commerce in Vietnam, which was marketed to policymakers who can provide support to women-owned businesses.

In the interest of further ensuring efficiency and coordination, GIPA also presented programs for U.S. officials and policymakers, providing updates on domestic and IP law and policy. The USPTO's OPIA once again collaborated with the Department of State's Foreign Service Institute (FSI) and Economic Bureau to provide (virtual) IP training for outbound Foreign Service Officers, and to provide subject matter expertise in developing an update to FSI's IP distance learning products. GIPA continued to engage in interagency training coordination meetings with other USG IP training donors such as DOJ, CBP, and DOC's CLDP program, on a whole-of-government basis as well as in smaller, more focused groups. These meetings facilitate discussions around avoiding duplication of efforts to allow agencies with aligned goals to leverage each other's resources to streamline the planning, execution and wrap-up of IP capacity building programs.

Raise Public Awareness of International Intellectual Property Protection and Enforcement

The USPTO engages in many outreach activities to raise public awareness of IP. Knowledge is shared through libraries and resource centers, universities, regional offices, face-to-face and distance learning educational programs, and through presence at trade shows. Additionally, content covering all areas of IP is available on the <u>USPTO's website</u> and promoted through the USPTO's social media platforms.

In FY 2022, GIPA continued its decade-long commitment to produce on-demand content through distance-learning modules on the USPTO website. These modules are available in five languages and cover six different areas of IP protection. In addition, self-study materials — including recordings of events, training slides, and IP toolkits — were updated for asynchronous learning. According to USPTO, the most recent videos covering Patents and Trade Secrets have received a combined 88,031 views as of September 30, 2022.

On November 30, 2021, the USPTO released the "You're Smart. Buy Smart" video public service announcement (PSA). The PSA, directed by Oscar®-nominated producer Trevor White, was released and rolled out to more than 2,100 broadcast outlets, including YouTube, social media channels, electronic billboards, online gaming sites, radio and music services, and other platforms that directly reach tweens and teens as part of the OPIA enforcement team's Go For Real anti-counterfeiting campaign. On August 11, 2022, the Go For Real campaign released a second PSA "The Real McGruff" in English and Spanish. The newest PSA, also directed by Oscar®-nominated producer Trevor White, features a 3D animated McGruff the Crime Dog and his nephew Scruff. According to USPTO, at the close for FY22, the two campaigns had a combined 78,435 airings on tv stations, over 570 million impressions and an estimated ad value of over \$20 million.

On February 22, 2022, the USPTO's OPIA enforcement team and trademarks teams, together with U.S. Customs and Border Protection, co-hosted the virtual workshop on *IPR Protection Beyond US Borders: Preventing Infringing Exports from China* as part of U.S. Customs and Border Protection's Year of the SME outreach program.

In celebration of the annual World Intellectual Property Day (April 26, 2022), USPTO headquarters and IP Attachés in cooperation with WIPO, other U.S. government agencies, and national IP offices hosted a number of events overseas in FY 2022 to commemorate and raise awareness of the 2022 global theme: *IP Youth: Innovating for a Better Future*. Events included USPTO's World IP Day celebration, a virtual program encouraging the world to leverage the innovative power of youth to solve problems and create opportunities. The virtual event included an intimate fireside chat discussion with the leadership of the USPTO, WIPO, and the U.S. Copyright Office about promoting IP adoption among young innovators. In addition to the USPTO, organizations participating in this event included WIPO, the American Intellectual Property Law Association, the International Trademark Association, the American Bar Association's Section of Intellectual Property Law, the Intellectual Property Owners Association, the U.S. Copyright Office, the Licensing Executives Society International, the U.S. IP Alliance, and the U.S. Chamber of Commerce's Global Innovation Policy Center.

In April 24-30, 2022, the Public Affairs section of the Rio Consulate and the Rio IP Attaché Office partnered to produce and publicize an awareness video on the importance of IP, presented by the popular Brazilian singer Anitta. The video has been posted at least on the Rio Consulate's Instagram and Facebook accounts, the Embassy's Facebook, Instagram, and Twitter accounts, and the São Paulo Consulate's Instagram account. According to USPTO, on the Instagram accounts of the Rio and São Paulo consulates alone, the video quickly reached a combined 40,000+ views, and the video likely has at least that many views on the Embassy's Instagram account. Across all three Instagram accounts, the video generated over 1000 comments. Notably, the video sparked increased awareness of and excitement about IP and attracted widespread attention to the topic. At least five online articles have been published regarding the famous singer's video. One article, posted on the website POPline, mentioned the U.S. Mission to Brazil, the USPTO, and World IP Day. The article also quoted the video regarding the importance of protecting intellectual property and described the U.S. Mission's IP-related work in Brazil. Another article, on the website Noticias do Mundo, quoted the video and the U.S. Mission's website, explaining that "intellectual property rights are the universal currency of

today's innovation economy." A third article used the video and a brief discussion of World IP Day as a jumping off point to discuss the Special 301 report and Brazil's place on the Special 301 Watch List. While the overall impact of the video cannot be quantified, the video achieved the desired result: it has brought attention to the issue of IP, to a younger audience (Anitta fans), in a country where IP awareness is lacking, and during a time when popular support of IP rights is more important than ever (given ongoing discussions of IP treaties and laws in Brazil's executive and legislature).

On June 9, 2022, the USPTO's Enforcement Policy Team participated in the Hispanic National Bar Association (HNBA)-Microsoft IP Law Institute (IPLI), an annual IP program for law school students that provides an in-depth look into various career opportunities in the field of IP protection and enforcement.

Capacity-Building and Training

The USPTO's Global Intellectual Property Academy (GIPA)

In FY 2022, the USPTO's GIPA continued to develop and provide capacity-building programs, organized and conducted by OPIA attorneys, to help improve IP systems in key countries and regions to the benefit of U.S. stakeholders. Although traditional, face-to-face training programs did not start taking place until mid-FY 2022, the USPTO continued to meet training obligations during this unprecedented time through increasing its leverage of various technologies to provide live online IP training. GIPA's established capacity for e-learning supported a successful pivot to all-remote delivery of its programs in mid-FY 2020 and continued this delivery into FY 2022. Through these well-attended and well-received distance learning initiatives, the USPTO provided tailored content to developed and developing countries and Least Developed Countries (LDCs).

The programs addressed a full range of IP protection and enforcement matters, including enforcement of IP rights at national borders, Internet piracy, trade secrets, copyright policy, and patent and trademark examination. Participants included officials with IP-related responsibilities, such as judges, prosecutors, patent and trademark examiners, and IP office and Collective Management Organization (CMO) administrators. In FY 2022, GIPA conducted 222 IP programs covering all areas of IP. About 78% of these programs targeted foreign officials with IP portfolios, engaging over 10,679 officials from 161 countries and intergovernmental organizations. A complete list of all countries represented at GIPA trainings in FY 2022 is available online at the USPTO Data Visualization Center (https://www.uspto.gov/dashboards/externalaffairs/main.dashxml). Generally, programs are delivered from GIPA's headquarters in Alexandria, VA, and around the world, through face-to-face and distance learning modules.

In the interest of further ensuring efficiency and coordination, GIPA also presented programs for U.S. officials and policymakers, providing updates on domestic and IP law and policy. The USPTO's OPIA, which includes the Office of Chief Economist (OCE), once again collaborated with the Department of State's Foreign Service Institute (FSI) and Economic Bureau to provide (virtual) IP training for outbound Foreign Service Officers, and to provide subject matter

expertise in developing an update to FSI's IP distance learning products. GIPA continued to engage in interagency training coordination meetings with other USG IP training donors such as DOJ, CBP, and DOC's CLDP program, on a whole-of-government basis as well as in smaller, more focused groups. These meetings facilitate discussions around avoiding duplication of efforts to allow agencies with aligned goals to leverage each other's resources to streamline the planning, execution and wrap-up of IP capacity building programs.

Other USPTO Activities Related to IP Protection and Enforcement

In April 2022, pursuant to a Joint Project Agreement (JPA), USPTO and the National Association of Attorneys General (NAAG) Consumer Protection Training and Research Institute, co-organized an in-person workshop on Intellectual Property and Consumer Protection in Denver, Colorado, for State Attorney General (AG) Officers, attended by more than 30 State AG officers from the Midwest and Rocky Mountain region.

In May 2022, USPTO hosted its fourth trade secret symposium. Open to the public, the event featured six panels, with an overall focus on cross-border issues in trade secret protection. The World Intellectual Property Organization's (WIPO) Advisory Committee on Enforcement (ACE) met for the first time since the pandemic began in March 2020, allowing individuals and teams working in the enforcement field to share their experiences on IP and enforcement. The ACE, established by the WIPO General Assembly in 2002, is mandated to carry out technical assistance and coordination in the field of enforcement. Norm-setting is explicitly excluded from the mandate. The 14th session of ACE met from August 31 to September 2.

<u>Africa</u>

On December 7, 2021, the USPTO OPIA's Enforcement Team co-hosted a program with the Organisation Africaine de la Propriété Intellectuelle, *Best Practices for the Disposal and Destruction of IP-Infringing Goods*.

USPTO OPIA's Africa Team provided the following trainings for African Intellectual Property Organization (OAPI) member countries: 1) The U.S. Registration System on February 23, 2022; 2) Rights Implicated in Digital Business Models on March 30, 2022; 3) Collective Management of Copyright and Neighboring Rights on April 20, 2022; and 4) Learn about the Mechanical Licensing Collective (The MLC) which is the nonprofit mechanical licensing collective management organization designated by the U.S. Copyright Office (pursuant to the Music Modernization Act of 2018) on July 12, 2022.

On May 25, 2022, the USPTO OPIA's Enforcement Team spoke on a panel for the U.S. Embassy in South Africa's World IP Day event.

On June 29, 2022, the USPTO OPIA's Enforcement Team co-hosted a program with the American Business Council (Nigeria), *Blockchain for IP Enforcement: More than Crypto and NFTs*.

On September 12-16, 2022, the USPTO OPIA's Enforcement Team, in collaboration with the U.S. Department of Homeland Security, U.S. Department of Justice, and U.S. Customs and Border Protection, conducted a training program at the Kenya School of Government in Nairobi, Kenya, for Kenyan government officials on IP enforcement efforts and to share global best practices in both the United States and Kenya.

USPTO OPIA's Africa Team provided training to the U.S. Foreign Commercial Service and State Department economic officers in Africa on IP issues, including enforcement. USPTO's OPIA also evaluated proposed copyright laws and copyright law changes in Comoros and Kenya, and discussed proposed copyright law changes with the governments of Nigeria, Namibia and Gambia.

USPTO's OPIA's Africa Team provided support for the U.S. Embassy in Botswana's World IP Day event held April 26, 2022 in Francistown, co-sponsored by Botswana's Companies and Intellectual Property Authority.

Eurasia

In November 2022, the IP Attaché for Eurasia, in coordination with AmCham Ukraine and DOJ's International Computer Hacking & IP Attorney for Eastern Europe, organized and conducted an online industry roundtable on counterfeit medicines in Ukraine. During the program, participants discussed criminal liability for counterfeit medicines in Ukraine and existing gaps in counteracting medical counterfeits, IP enforcement mechanisms to mitigate the risks posed by counterfeits, and cooperation with the Office of the Prosecutor General on effective anti-counterfeiting activities.

In April 2022, USPTO OPIA's Enforcement Team, with support from CBP, presented a virtual program for Uzbekistan Customs and other government officials: *Workshop on the Destruction and Disposal of Counterfeit Goods*.

On April 27, 2022, the IP Attaché for Eurasia participated in the Ambassador's Roundtable to commemorate World IP Day, which was organized by the US Embassy Tashkent, Uzbekistan. The event included a discussion with local lawyers and industry representatives on the current status and challenges of IP enforcement in the country.

On April 29, 2022, the IP Attaché for Eurasia spoke during the annual conference of the International Anti-Counterfeiting Coalition (IACC) on a panel titled "What's So Special About 301? – Working with Government to Set Global IP Priorities."

In May 2022, the IP Attaché for Eurasia worked with the U.S. Department of Commerce's Commercial Law Development Program (CLDP) and Georgian IP Office on the 6th International Conference "Georgia Against Counterfeiting and Piracy," which was held on July 25 – 26, 2022 in Batumi, Georgia. USPTO's enforcement team also supported the conference by, among other things, providing training on the impact of infrastructure investments on the trade in counterfeits.

In September 2022, USPTO's enforcement team presented anti-counterfeiting strategies to customs, prosecutors, and judicial officials from various Balkan and Eurasian countries at a CLDP-hosted Western Balkans Regional IP Training Workshop in Tivat, Montenegro.

Latin America and Caribbean

On October 5, 2021, the U.S. IP Attaché for the Mercosur Region delivered remarks at Brazil-U.S. Cybercrimes Dialogue – IP Day which was organized by the Department of Justice – International Computer Hacking and Intellectual Property (ICHIP).

On October 27-28, 2021, the Peru IP Attaché's Office co-sponsored with CBP and HSI the training program "Combatting the Distribution and Sale of Counterfeit Medicines," which was targeted at the Multisectoral Technical Group on Preventing and Combating Smuggling, Illegal Trade and Counterfeiting of Pharmaceutical and Related Products (CONTRAFALME), the General Bureau for Medicines, Drugs, and Supplies (DIGEMID), National Police, Customs, and the National Institute for the Defense of Competition and Intellectual Property (INDECOPI) officials. The program provided an opportunity to share US best practices and experiences in regard to the fight against counterfeit medicines. There were 210 attendees at this event.

On November 4, 2021, the USPTO IP Counselor in Mexico City worked with AmCham Guatemala and with other AmChams around the region to put on a webinar on *IP Enforcement Actions and Best Practices in Central America*. The Counselor led a discussion with IP Attorneys from Costa Rica, Guatemala, El Salvador, Honduras, Nicaragua, and Panama on enforcement matters.

On November 9, 2021 the USPTO IP Counselor in Mexico City, the OPIA Copyright Team and the Copyright Office organized a webinar on *Copyright in the Digital World: Notice and Takedown* for 94 government officials from Mexico's Specialized Intellectual Property Chamber, the Mexican Institute of Industrial Property and the National Copyright Institute.

On November 17, 2021 the USPTO IP Counselor in Mexico City, U.S. Customs and Border Protection (CBP), and the Mexican Association for the Protection of Intellectual Property (AMPPI) organized a webinar on IP Enforcement for Mexican customs officials and local prosecutors.

On December 3, 2021, the U.S. IP Attaché spoke during a webinar entitled "NFTs Role in Combatting Piracy" which was part of a National Combatting Piracy Day that was sponsored by the Rio de Janeiro chapter of the Brazilian Bar Association.

On December 4, 2021, the U.S. IP Attaché participated in Brazil's National Counsel to Combat Piracy (CNCP) 2021 6th Ordinary Meeting. This meeting was the first hybrid activity by CNCP since the beginning of the pandemic, and it focused on (1) the launching of the National Plan to Combat Piracy; and (2) an award ceremony for the National Award on Piracy Combat – Highlights of the Year.

On December 8, 2021 the USPTO IP Counselor in Mexico City worked with the U.S. Copyright Office and IMPI on a webinar on the *U.S. Experience on Alternative Methods of Dispute Resolution*.

On February 9, 2022, the USPTO OPIA Enforcement Team in conjunction with the Brazil USPTO IP Attaché Office co-hosted a workshop on the *U.S. Protecting Lawful Streaming Act* for a Brazilian audience which included the Ministry of Justice, Copyright Office, Brazil's CNCP, Motion Picture Association and other private stakeholders.

On February 22-25, 2022 the USPTO IP Counselor in Mexico City participated in a *Workshop on Investigation of Crimes Against Intellectual Property*, that was organized by the International Computer Hacking and Intellectual Property (ICHIP) Advisor for Latin America and the Caribbean for law enforcement and prosecutors in Panama.

On March 22, 2022 the USPTO IP Counselor in Mexico City co-organized with the International Anti-Counterfeiting Coalition (IACC) and AmCham Guatemala a webinar for U.S. industry representatives on *Intellectual Property Enforcement in Guatemala*.

On March 23, 2022 the USPTO IP Counselor in Mexico City co-organized with IACC a webinar for U.S. industry representatives on *Intellectual Property Enforcement in Mexico*. Representatives from the Mexican Institute of Industrial Property (IMPI), and Mexico's National Customs Agency spoke about practices and gave tips to members of IACC on how to enforce their IP Rights in Mexico.

On March 29, 2022, OPIA's Copyright and Enforcement Teams, the U.S. Copyright Office, and the USPTO IP Counselor in Mexico City participated in a webinar on *Current Developments in U.S. Copyright Law* for approximately sixty Central American government officials and entrepreneurs. Topics addressed included recent copyright case law developments in the United States, the Protecting Lawful Streaming Act, the Music Modernization Act, and the new Copyright Claims Board within the U.S. Copyright Office.

On April 27, 2022 the USPTO IP Counselor in Mexico City worked with Aprodica – a non-profit association that fights against cable piracy in Central America, especially in Guatemala – to put on a webinar about Digital TV and Internet Protocol TV (IPTV) piracy. On May 18, 2022 the USPTO IP Counselor in Mexico City co-organized with USPTO's Rocky Mountain Regional Office, Silicon Valley Office, and Texas Regional office the fourth webinar on enforcement of the Mexico IP Series: *Diversifying your Market or Supply Chain*. Three Mexican IP Attorneys gave presentations on Mexico's process for enforcing IP Rights (civil and administrative enforcement), IMPI's role on border measures, and briefly discussed differences between the Mexican and U.S. enforcement system.

In May 2022, USPTO OPIA's Enforcement Team and the Peru IP Attaché Office participated in a *Workshop On Combating IP Crime* for approximately 60 Ecuadorian authorities from SENADI, the Attorney General's Office and National Police, Ecuador's National Agency for Sanitary Regulation, Control and Surveillance (ARCSA), Customs and others, and presented on current legislative initiatives in the US to combat online counterfeiting and piracy.

On June 8, 2022, the Brazil IP Attaché Office in conjunction with the U.S. Embassy Buenos Aires hosted a webinar regarding streaming piracy. The event featured remarks from representatives of USPTO, State – IPE, DOJ/ICHIP, and State ECON, as well as speakers from MPA and La Alianza, and was presented to an Argentinean and Paraguayan audience.

On June 2, 2022, Federal Police, supported by the Brazilian Ministry of Justice (Cyber Operations Laboratory) and the U.S. and U.K. Embassies, launched the fourth phase of "Operação 404" against digital piracy. The purpose of this phase was to seize electronic equipment used for the illegal transmission of television channels in the State of Mato Grosso. "Operação 404" is considered by many (including U.S. stakeholders) an excellent example of international cooperation in the fight against digital piracy.

On June 21, 2022, as a continuation of "Operação 404" against digital piracy, the Civil Police, supported by the Brazilian Ministry of Justice (Cyber Operations Laboratory) and the U.S. and U.K. Missions, conducted the fourth phase, which included, for the first time, seizures in the metaverse. Beyond the audiovisual piracy target, this phase focused on channels that illegally streamed music. Four channels that carried out illegal content transmissions were disabled, and 90 videos were taken off the air. In 11 states across Brazil, Civil Police removed 266 sites and deleted 15 profiles on social networks for luring consumers to illegal content. According to authorities, the main focus of the operation is to combat copyright infringement, which generates an annual loss of R\$15 billion for Brazil.

Throughout the year, the USPTO IP Attaché office in Lima, Peru presented at 13 in-person and virtual training programs run by the Government of Peru and a law firm representing major brands. These programs trained more than 975 officials all around Peru on the importance of combatting counterfeiting and provided practical advice from major stakeholders about how to identify counterfeits.

On July 20-22, 2022, the USPTO and INTERPOL conducted a *Practical Workshop on Investigating Intellectual Property Crime* for approximately 30 police, prosecutors and investigators from Antigua & Barbuda, Bahamas, Barbados, Belize, the Dominican Republic, Grenada, Guyana, Haiti, Jamaica, St Lucia, St. Vincent & Grenadines, Suriname and Trinidad and Tobago. The workshop focused on best practices for conducting online investigations, current IP challenges in the U.S., recent legislation to combat digital piracy, resources available at INTERPOL, and INTERPOL's IP Crime College.

On August 3-5, 2022, the Rio IP Attaché Office, along with DOJ and the Lima IP Attaché Office, hosted a *Workshop on Measures Against Trade in Illicit and Counterfeit Agricultural Chemicals*. The event was held in Asunción, Paraguay and included attendees from Argentina, Brazil, Paraguay, Peru, and Uruguay.

On August 8-10, 2022, the Rio IP Attaché, along with DOJ and the IPR Center, hosted a *Regional Workshop on Combatting Digital Piracy*. The event was held in Asunción, Paraguay and included attendees from Argentina, Brazil, Paraguay, and Uruguay.

On August 9, 2022, the Brazil IP Attaché Post Advisor Maria Beatriz Dellore hosted a luncheon on the topic of strengthening gender diversity to women attending the Regional Workshop on Combatting Digital Piracy.

On August 25, September 1, and September 8, 2022, the USPTO IP Counselor in Mexico City co-hosted a series of three webinars on the Illicit Trade of Medicines in Mexico. This webinar was co-organized by the IP Counselor with the Mexican Association for the Protection of Intellectual Property (AMPPI), the Pharmaceutical Security Institute, Moderna and Homeland Security Investigations. A total of 200 Mexican government officials attended the webinar in each of the three sessions. The series featured remarks from over 15 pharmaceutical companies about the challenges they face in the Mexican market.

On August 29, 2022, the Peru IP Attaché Office, the Ministry of Production and Barlaw IP law firm co-sponsored the IP enforcement training program titled "Strengthening the Enforcement of Intellectual Property Rights" in Puno, in southeastern Peru. 97 police Officers, prosecutors, and Customs officials attended this face-to-face event.

On September 14, 2022, the Brazil IP Attaché Post Advisor, Maria Beatriz Dellore, represented USPTO at the CNCP 2022's 4th Ordinary Meeting and provided a report on the DOJ-USPTO Workshop on Combating Digital Piracy, hosted in August in Asunción, Paraguay.

On September 14, 2022, the Brazil IP Attaché participated in the IACC/USPTO/DOJ Webinar on *Brand Protection in LatAm Region*. The Brazil IP Attaché coordinated with USG colleagues and IACC to organize this event, where each of the IP Attachés in Latin America as well as DOJ's ICHIP Advisor spoke to IACC members regarding counterfeiting concerns in their respective regions of responsibility.

South East Asia

On September 1-30, 2021, USPTO's OPIA organized and participated in a series of 12 webinar sessions on *Intellectual Property and the Digital Economy*, held in conjunction with the Intellectual Property Office of Singapore and jointly sponsored by the Singapore Cooperation Program and the U.S. Department of State under the Singapore-United States Third Country Training Programme (TCTP). The program explored the intersection of intellectual property and the digital economy, including enforcement approaches and strategies online and in the digital environment including sessions focused on enforcement-related issues faced by civil litigators, law enforcement authorities, criminal prosecutors, and the courts.

In October 2021, the Senior IP Specialist participated in a virtual American Chamber of Commerce (AMCHAM) Annual General Meeting and Meet the Embassy Program, along with approximately 20 representatives of U.S. government agencies in Thailand. The Senior IP Specialist introduced the role of the IP Attaché Program in supporting U.S. stakeholders on global IPR protection, and the duties/responsibilities of the IP Attaché for Southeast Asia Office. Approximately 150 AMCHAM members in Thailand participated virtually in the meeting.

In December 2021, the IP Attaché for Southeast Asia Office and the U.S. Embassy Jakarta jointly organized a virtual meeting between the representatives of USTR, USPTO's OPIA Enforcement Team, IP Enforcement Coordinator, U.S. Copyright Office, U.S. Customs and Border Protection, and the representatives of the Government of Indonesia (GOI)'s IPR Taskforce to discuss the U.S.- Indonesia IPR workplan and the next steps, including the U.S. stakeholders' ongoing concerns over the Copyright Law, Patent Law, Trademark and Geographical Indications Law, IPR enforcement, and Customs regulations. The Indonesian IPR Taskforce included representatives of the Directorate General of Intellectual Property (DGIP), National Agency for Drug and Food Control (BPOM), Indonesian National Police, Directorate General of Customs and Excise, and the Ministry of Communication and Information Technology.

In December 2021, the IP Attaché for Southeast Asia Office and the U.S. Embassy Hanoi, in cooperation with the Ministry of Science and Technology of Vietnam, co-organized a hybrid enforcement coordination training program entitled "Enforcement Coordination and Approaches Against Online and e-Commerce Counterfeiting and Content Piracy" for members of the Committee 168 and authorities responsible for IPR enforcement in Vietnam. The program was led by Peter Fowler, OPIA Senior Counsel for Enforcement. Participants include 28 Vietnamese officials from the Ministry of Science and Technology, Ministry of Culture, Sport and Tourism, Ministry of Agriculture and Rural Development, Ministry of Finance, Ministry of Information and Communication, Ministry of Investment and Trade, People's Supreme Court, People's Supreme Procuracy, Ministry of Public Security, and Ministry of Science and Technology – Inspectorate Department.

In February and March 2022, the Senior IP Specialists, along with the Economic Officer and U.S. Customs and Border Protection at the U.S. Embassy Bangkok, provided comments on the new customs regulation and discussed the ongoing development of the new customs recordation database, enforcement protocol/coordination, possible training programs, and customs-related issues with the Thai Customs Department.

In March 2022, USPTO's OPIA organized and conducted a nine-part webinar roundtable series on *Intellectual Property and Case Management* for judges from the Southeast Asia and South Pacific regions. The event was attended by nearly 100 foreign judges and 12 U.S. judges.

In March 2022, the IP Attaché for Southeast Asia Office, and the U.S. Embassy Jakarta, in cooperation with AmCham Indonesia, co-organized a virtual meeting with AmCham members, representatives from U.S. Government Agencies (USG), and the Indonesian IP Task Force to discuss the Indonesian government's approaches in tackling IPR infringements and the U.S. stakeholder's concerns. Approximately 100 U.S. IP stakeholders participated in the meeting.

On May 10-26, 2022, the USPTO and the IP Attaché for Southeast Asia Office co-organized the "ASEAN Workshop on Development in Copyright Law and Enforcement" to provide an overview and discussion of recent developments in copyright protection and enforcement in the region and the United States, including legislative revisions, administrative and judicial case decisions, treaty implementation, public awareness campaigns, ADR/mediation services, and litigation practices for IP officials and copyright enforcement authorities. The workshop

included 9 online sessions. Approximately 144 participants in the ASEAN region, including Timor Leste participated in the program.

In May 2022, the Senior IP Specialist participated as a guest speaker at the 2nd International Conference on Technologies and Business Incubation Among Educational Institutions (ICTBIEI2022) hosted by Silliman University of the Philippines. The Specialist introduced the USPTO IP Attaché program and gave an overview of IP, especially patents, trademarks, copyright, and trade secret to approximately 124 attendees, including students, technology transfer officers, R&D staff, lecturers/professors, and local SMEs.

On June 28-30, 2022, USPTO's OPIA co-organized with the ASEAN Intellectual Property Academy, an Indo-Pacific Regional Workshop on *Enforcement Against Trade in Counterfeit Goods*, in Bangkok, Thailand. The in-person event drew more than 115 governmental officials and speakers from across the Indo-Pacific region, including from Interpol, various U.S. Government agencies, and the International Trademark Association.

On July 18, 2022, the USPTO's OPIA organized a webinar on *Protecting and Enforcing IPRs in Southeast Asia: What Small Businesses Need to Know* (or *SE Asia IP Roadshow*), in cooperation with the US-ASEAN Business Council, the U.S. Department of Commerce's International Trade Administration, and the U.S. Commercial Service. The webinar provided IP information, including experiences and practical challenges in doing business in Southeast Asia. The IP Attaché spoke on the USPTO IP Attaché program and the services provided by the IP Attaché Southeast Asia Office. Over 140 business entrepreneurs, legal practitioners, and officials in the U.S. and the Southeast Asia region attended the program.

On September 26-30, 2022, the USPTO, in collaboration with the Ministry of Science and Technology Inspectorate Division, the U.S. Embassy Hanoi, the Consulate General Ho Chi Minh City, the Vietnam Intellectual Property Association (VIPA), the Ho Chi Minh City Intellectual Property Association (HCMCIPA), the Vietnam Anti-counterfeiting and Intellectual Property Protection Association (VACIP), and Ho Chi Minh City University of Law Faculty of Civil, organized a *Vietnam IP Enforcement Week*, featuring an Ambassador's Roundtable on Intellectual Property and Enforcement in Hanoi; a Consul General's Roundtable on Intellectual Property Enforcement in Ho Chi Minh City; brand protection and product identification workshops in Hanoi and in Ho Chi Minh City; a Roundtable Dialogue on Current IP Issues and Enforcement with the HCMC Intellectual Property Association and the Vietnam Intellectual Property Association, in Ho Chi Minh City; and a Seminar on Copyright Protection and Enforcement hosted by the Ho Chi Minh City University of Law Faculty of Civil Law, in Ho Chi Minh City.

In September 2022, the IP Attaché for Southeast Asia Office and the USPTO's OPIA Enforcement Team, in cooperation with the U.S. Mission Vietnam and the Vietnamese Ministry of Science and Technology, jointly organized a series of roundtable discussions on IPR enforcement and workshops on brand protection and product identification in Hanoi and Ho Chi Minh City. Approximately 200 Vietnamese officials and enforcement authorities participated in the programs.

South Asia

On September 28, 2021, the USPTO South Asia IP Counselor's office in collaboration with CLDP hosted a 3-hour virtual program for university technology transfer offices (TTOs) on the University-Industry relationship, consisting of a 90-minutes prerecorded lecture. The prerecorded lecture was provided in advance to encourage the participants to study the materials, discuss within their university teams, and submit questions for the live/interactive session. The session focused on the various subject critical to the successful commercialization of IP, such as key provisions in licensing agreements, establishing start-ups, and other forms of technology transfer and its enforcement.

On September 29, 2021, the IP Counselor delivered a special address on "Safeguarding Trade Secrets in Emerging Digital Era: Way Forward" organized by Confederation of Indian Industry (CII) Southern Region with the support of USPTO. His address stressed the need for an overarching legal framework on trade secrets highlighting their importance. The IP Specialist spoke at the last panel discussion focused on "Trends in Trade Secret Protection in the Wake of Emerging Digital Environment and Emerging Technologies – U.S. and EU Perspectives" and shared U.S. perspectives on the topic.

On February 9, 2022, the USPTO – in partnership with CLDP, USAID, FDA, CBP, and other U.S. agencies – launched a multi-part series to exchange best practices on combating counterfeit medicines and medical devices with enforcement officials from the Government of Pakistan. The objective of the series was to curb the flow of counterfeit pharmaceuticals into and out of Pakistan by enhancing the capacity of Pakistan customs officials to help protect the country's drug supply from the threat of counterfeits. The series covered three modules. Module 1 was executed between February 16 to March 30, 2021.

On February 16, 2022, the IP Counselor delivered a special address at the inaugural session at the virtual "National Conference on Trademarks" organized by Associated Chambers of Commerce and Industry of India (ASSOCHAM) with the support of USPTO. The Conference deliberated on identifying key issues, emerging trends, development, and implementation of strategies for the successful prosecution of trademark application, cross-border and domestic enforcement of trademarks, combating online counterfeiting, and the need for administrative and legislative reform in India for enforcement of trademarks. The IP Counselor's address stressed the need for adequate protection and enforcement of trademarks, highlighting their importance for businesses.

On February 18, 2022, the IP Counselor delivered a special address at the inaugural session at virtual Roundtable on "*Trade Secret Protection in India: Road Map for a Legislation*" organized by the Centre for Intellectual Property Research and Advocacy (CIPRA) at National Law School of India University (NLSIU), Bangalore. The Roundtable highlighted the key issues pertaining to challenges of trade secrets protection and aimed for a separate legislation roadmap in India. IP Counselor's address stressed the need for an overarching legal framework on trade secrets highlighting their importance for the economy.

On April 6 and April 16, 2022, the USPTO's OPIA— in partnership with CLDP, USAID, FDA, CBP, and other U.S. agencies – hosted Module 2 to exchange best practices on combating

counterfeit medicines and medical devices, which consisted of two 2-hours of virtual sessions, with one session per week focused on concerns, experiences, perspectives, and best practices of the pharmaceutical and medical device industry in Pakistan and across the globe. The program was for Pakistan officials involved in the protection of Pakistan's drug supply from the threat of counterfeits transiting through air freight and air mail facilities in Pakistan.

During the week of April 18, 2022, the USPTO South Asia office participated at a country session organized by the U.S. State Department in collaboration with Indian Chamber of Commerce (ICC) as part of the Bengal Global Business Summit (BGBS) 2022. On April 20, Consul General, Consulate General, Kolkata, delivered opening remarks to kick off the country session. IP Counselor Cabeca spoke on importance of IP for entrepreneurs. The IP Counselor also delivered special addresses at the USPTO's two interactive sessions - first on customs enforcement of IP rights, and second on importance of IP for students, hosted in collaboration with local partners CII, and West Bengal National University of Juridical Sciences (WBNUJS) respectively. The customs enforcement program hosted on April 19 at National Academy of Customs, Indirect Taxes, and Narcotics (NACIN), Kolkata, aimed to promote IP awareness and effective customs enforcement best practices for the Customs officials in the State with the hopes of enhancing their capacity in combating counterfeits and infringing products. The IP Counselor briefly spoke on the importance of customs enforcement of IP highlighting the U.S. position on the subject. U.S. CBP Attaché provided an overview of U.S. position on the subject and highlighted some of the best practices in customs to tackle the menace of counterfeiting. Other speakers who spoke at the panel were officials/representatives from NACIN, industry, and law firm. The USPTO South Asia office supported/joined all these sessions to promote IP awareness and help cultivate a culture of respect for IP, as part of its celebrations of World IP Day 2022.

On April 30, 2022, the U.S. IP Counselor and team attended TiECON CHANDIGARH 2022 organized by TiE Chandigarh with the support of USPTO. This was the biggest entrepreneurial event in the Northern Region focusing on opportunities and challenges faced by the young and emerging entrepreneurs. The IP Counselor delivered a keynote at a session on "Global Panel: Flight to Global Expansion" at the event. The IP Counselor's keynote highlighted several aspects including the intersection of trade and IP, the role of IP in economic growth as well as the impact IP has on all businesses, and states' role in evolving a strong IPR protection and enforcement regime that has certain, predictable, and reliable results. The other speakers at the session were the British Deputy High Commissioner and the Consul General of Canada in Chandigarh.

On May 2, 2022, the U.S. IP Counselor participated virtually at the IP Attaché Roundtable at the 2022 Annual Meeting of the INTA. He spoke on recent trademark trends in the broader South Asia region highlighting some longstanding trademark related issues faced in India including oppositions backlog, unclear procedure for determination of well-known trademarks, problematic levels of trademarks counterfeiting, and cumbersome procedure for search and seizure under Indian Trade Marks law. In addition, he highlighted various programs conducted through the mission over the past year to help improve IP ecosystems throughout the region. The program drew 117 participants.

On May 12, 2022, the U.S. IP Counselor participated virtually at the U.S. overseas insight panel of the USPTO Trade Secrets Symposium 2022. He spoke on the trade secrets regime in India

and recent developments highlighting best practices for protection of trade secrets. He stressed the need for a standalone legislation on trade secrets in India. The program drew 98 participants.

On June 28-30, 2022, the U.S. IP Counselor co-hosted a three-day USPTO-DOJ Regional Workshop on Enforcement Against Trade in Counterfeit Goods in Bangkok. Around 115 participants from 24 countries across the Indo-Pacific region were in attendance, including over a dozen enforcement, judicial and intellectual property office representatives from India, Bhutan, Pakistan, Bangladesh, Nepal, Sri Lanka, and the Maldives. The *Indo-Pacific IPR Enforcement Workshop* focused on IPR priorities for public enforcement and aimed to support the participating countries' efforts to develop and implement criminal enforcement strategies to help combat counterfeiting crimes involving health and safety. In addition to USPTO and DOJ, the IP Counselor was joined by other USG interagency experts from HSI, FDA, CBP in delivering presentations on the various aspects of IP enforcement. Industry experts also shared their enforcement experiences in the Indo-Pacific Region.

On June 30, 2022, the IP Specialist delivered training to Indian customs officers which included IP enforcement related to counterfeit and pirated goods as part of the five-day Bureau of International Narcotics & Law Enforcement Affairs Airport Interdiction Training hosted by DHS-HSI at NACIN, Bengaluru, from June 27-July 1, 2022. During the training program, IP Specialist interacted with NACIN officials, as well as the participants joining an expert USG interagency team from HSI and CBP. Around 25 participants from across the country were in attendance.

On September 16, 2022, the USPTO South Asia office, Maharashtra IP Crime Unit (MIPCU), and International Trademark Association (INTA) co-organized a closed-door policy roundtable on piracy and counterfeiting. The roundtable deliberated on how law enforcement agencies can help in protecting IP Rights in the digital world. The stakeholders from diverse industries, including fast-moving consumer goods (FMCG), pharmaceuticals, automobile, e-commerce, and media & entertainment gathered at the Hindustan Unilever campus in Mumbai to discuss existing challenges faced by creators and brand owners in fighting online piracy and counterfeiting. The speakers who delivered the keynote at the roundtable were U.S. IP Counselor, and Special Inspector General of Police (IGP) from Maharashtra Cyber. At the discussion, IGP announced MIPCU's expansion to address online counterfeiting in addition to online piracy. He stressed the critical importance of transversal collaborations through enforcement agencies to strongly thwart the pervasive menaces of piracy and counterfeiting.

On September 17, 2022, the IP Specialist delivered a keynote virtually on "Intellectual Property, Youth, and Anti-Counterfeiting" at a diplomacy simulation on "Global Counterfeit Trade: The High Cost of Cheap Goods" organized at the American Center by the Public Affairs Office at the New Delhi Post as part of the larger Youth Democracy Summit campaign. Public Diplomacy Officer Darryl Woolfolk delivered the opening remarks and English Language Fellow Shannon Smith led the session.

Middle East/North Africa

On December 14, 2021, USPTO OPIA's Enforcement Team organized a virtual discussion for Kuwait and Bahrain on IPR Border Enforcement. The program leveraged support from U.S.

Customs Border Protection's IPR Branch and National Threat Analysis Center. The program hosted 25-30 participants.

On June 14, 2022, USPTO OPIA's Enforcement Team organized and hosted a three-day workshop held in Rabat, Morocco on IPR Border Enforcement. The program hosted 15 customs officials from Jordan, 14 customs officials from Tunisia and 25 customs officials from Morocco. The program provided advanced training in IPR Border Enforcement measures and leveraged support from the U.S. interagency, including U.S Department of Justice, Homeland Security Investigations and U.S. Customs and Border Protection. The program featured substantive exchange of best practices.

On June 20, 2022, USPTO OPIA's Enforcement Team organized and hosted a three-day workshop held in Algiers, Algeria on IPR Border Enforcement. The program hosted 25 Customs officials, 7 Ministry of Commerce officials and 10 Ministry of Justice officials. The program provided advanced training in IPR Border Enforcement measures and leveraged support from across the U.S. interagency, including U.S. Department of Justice, Homeland Security Investigations, and U.S. Customs and Border Protection. The program featured several panel discussions and included opportunities of substantive exchange.

East Asia

The USPTO's OPIA China Team engaged regularly during FY 2022 with counterparts in the PRC, both directly, and through USTR, regarding draft amendments to IP enforcement related amendments to PRC laws, regulations, and judicial guidance. These engagements resulted in important amendments to draft provisions to protect the interests of U.S. rights holders. For example, following China's accession to the Hague Convention on Design, USPTO met virtually with CNIPA officials in July 2022 to discuss the latest legal development on designs and answer Chinese officials' questions on implementation of the Hague provisions, while raising concerns of U.S. IP stakeholders.

The USPTO's OPIA China Team conducted regular outreach to U.S. rights holders over the course of FY 2022. In December 2021, March 2022, and July 2022, the China Team hosted webinar updates on recent IP developments in China. The updates provide U.S. businesses, inventors, and IP rightsholders the opportunity to hear from senior USPTO attorneys about the recent developments, and obtain the knowledge needed to navigate China's rapidly changing IP landscape. Each of the quarterly webinars reached hundreds of attendees.

In addition to the quarterly updates on Chinese IP legal developments, the USPTO's OPIA China Team organized and presented several virtual programs on various topics related to China IP enforcement. These webinars included a two-part series on E-Commerce in China for small and medium sized enterprises facing the online sale of counterfeits sourced in China. The first program, in October 2021, focused on the use of online enforcement mechanisms. The second program, in December 2021, focused on moving those investigations from online enforcement efforts to offline enforcement, in administrative, civil, and criminal proceedings in China as well as in the United States. The team also hosted a webinar in February 2022 on bio-pharma patents in China, providing detailed discussion of recent litigation, licensing, and patent linkage

developments. In June 2022, the OPIA China team organized a webinar on commercializing IP in China through licensing, and provided a September 2022 joint webinar with the China National Intellectual Property Administration on developments in trademark law.

In addition to public facing webinars, the China Team regularly meets with stakeholder organizations, both in-person and virtually, to receive the viewpoints and concerns of members who help identify issues, as well as provide briefings on recent developments in IP issues relevant to rights holders. These organizations include, but are not limited to, the U.S.-China Business Council, the U.S. Chamber of Commerce, the International Anti-Counterfeiting Coalition, and International Trademark Association.

In FY 2022, the Shanghai IP Attaché's office provided commercial assistance on numerous IP matters involving patents, trademarks, copyrights, and trade secrets, related to a range of products, including advanced capacity batteries, information and communications technology, pharmaceuticals, medical devices, chemicals, food, beverage, nutrition, infant care, and design.

The Shanghai Attaché addressed protection and enforcement of trademarks and other IP at three industry events organized by the Department of Commerce's Export Assistance Centers and the Commercial Section of the U.S. Consulate General in Shanghai. The Shanghai office hosted and supported the Beijing IP Counselor's visit to Shanghai in October and November 2021 to engage with high-level SAMR officials at the China International Import Expo's (CIIE) IP forum and to gather feedback from affected rights holders in conjunction with the China Attachés' reporting for USTR's annual Notorious Market List (out-of-cycle) review.

In April 2022, to commemorate World IP Day, the Beijing IP Counselor and Guangzhou IP Officer each promoted the importance of IP protection and enforcement. The Beijing IP Counselor prepared op-ed pieces for our Ambassador to China that was disseminated through various media outlets. The Guangzhou IP Officer and local USPTO Guangzhou staff hosted public discussions, highlighting the contributions of women and individuals who invented new and innovative products and methodologies that provided solutions to vexing problems. They also focused on young Chinese artists and entrepreneurs seeking to safeguard their intellectual creations.

Since arriving at post in quarter 4 of this fiscal year, the Shanghai Attaché has engaged in local outreach on IP issues throughout her consular district.

In early September, the Beijing IP Counselor gave keynote remarks at an event organized by the International Publishers Coalition in China (IPCC), which focused on recent developments related to copyright enforcement of scientific publications in the PRC online environment, as well as areas for possible engagement with the PRC government (including PRC judges) on copyright enforcement issues. Following that event, the Beijing IP Counselor spoke with individual attendees regarding several ongoing enforcement matters, and how the U.S. Embassy could play a supporting role.

In mid-September, the Beijing IP Counselor hosted the first Ambassador IPR Roundtable with U.S. Ambassador to China, Nicholas Burns. Ambassador Burns and the IP Counselor engaged

with a wide range of U.S. industries, including fashion, software, telecommunications, publishing, pharmaceuticals, films, sports, chemicals, and fast-moving consumer goods on pressing IPR enforcement-related challenges in China, and how the Embassy could better engage with PRC officials to seek positive reforms and improve the overall effectiveness of PRC IPR enforcement.

During Q4 of FY 2022, the Guangzhou IP Attaché and Senior IP Specialist virtually conferred with at least fifteen U.S.-based rights holders seeking remedies for trademark infringement in South China. With other members of the USPTO Guangzhou team, they also met with Chinabased rights holders in their offices and at Consulate Guangzhou, concerning IP challenges occurring in South China. They offered constructive input on effecting solutions. USPTO Guangzhou also counseled rights holders with issues concerning patent infringement, trade secret theft, and enforcement challenges.

As part of USTR's Notorious Market List research, USPTO Guangzhou enlisted the assistance of the new State Department Consular Officers' assistance in visiting different markets in Guangdong Province, including Guangzhou, Shenzhen, and Shantou, and Putian in Fujian Province. The added benefit was wider geographic investigation of problematic markets, known for offering a broad range of counterfeit products, including apparel, footwear, toys, watches, mobile and other electronic devices, hardware, and software, and pharmaceuticals.

With rights holders continuing complaints about Chinese e-commerce venues and social-commerce platforms offering counterfeit goods for sale, USPTO Guangzhou engaged with other U.S. Government agencies at post and in Washington to pursue solutions, including the State Department, ICE/HSI, and the Commercial Service. It also worked with U.S.-based e-commerce platforms to help rights holders take down spurious listings.

Importantly, during this period, the Senior IP Specialist has maintained USPTO and Consulate Guangzhou's contacts. The Senior IP Specialist has represented USPTO and the Consulate, either in person or virtually, at several different IP conferences in Sanya, Shenzhen, and Guangzhou. The IP topics ranged from protection of seed and agricultural IP to region-wide IP commercialization and enforcement initiatives in the Greater Bay Area, consisting of Hong Kong, Macao, and Guangdong Province. The central government is promoting the Greater Bay Area as a regional hub of research, development, and innovation, with IP playing a central role in its evolution.

European Union

Building on the efforts in FY 2021, during FY 2022, USPTO Brussels continued to engage with counterparts in the EU institutions and key EU Member States to facilitate the sharing of best practices on IP enforcement; explore areas of transatlantic cooperation, such as best practices to enhance enforcement efforts; and plan public-awareness and capacity-building programs and campaigns. With respect to China's detrimental influence in IP matters relevant to U.S. stakeholders and EU economies (especially the sustained surge of China-origin counterfeit and substandard COVID-19 related products), USPTO Brussels continued to emphasize the

importance of establishing a strong risk-based, national-security-focused customs screening system that identifies and removes counterfeit goods from the stream of commerce.

USPTO Brussels continued its work in raising public awareness on the importance of IP protection and enforcement, especially as it relates to consumer health and safety, including the situation around the COVID-19 crisis and ensuing economic recovery efforts. To that end, the IP Attaché for Europe spoke at several events on trade in counterfeit products, its negative impact on IP and the economy, and the risks for public health.

In November 2021, USPTO OPIA's Enforcement Team, with support from CBP, presented two virtual workshops to Romanian customs officers and other relevant Romanian officials. The first program was an *Overview of Intellectual Property Enforcement at the Border*. The second program was a follow-up on Risk Targeting.

In December 2021, USPTO OPIA's Enforcement Team, in conjunction with DOJ, presented a virtual program for Romanian law enforcement entitled *Workshop on Investigation and Prosecution of Digital Piracy Crimes*.

In January 2022, USPTO OPIA's Enforcement Team, in conjunction with DOJ, presented a virtual program for Bulgarian law enforcement: *Workshop on Investigation and Prosecution of Digital Piracy Crimes*.

In January 2022, the IP Attaché for Europe participated in a regional program for enforcement officials and a workshop on the investigation and prosecution of digital piracy crimes for officers from Eastern Europe. Moreover, the Attaché spoke at the annual AmCham EU IP Committee roundtable. At AmCham EU in Brussels, the Attaché highlighted the importance of strong IP protection for U.S. businesses to be competitive in Europe.

In April 2022, USPTO Brussels organized the World IP Day together with AmCham EU. On this occasion, the IP Attaché for Europe discussed innovation policies for young generations with an Expert from the Cabinet of the European Commissioner for Innovation, Research, Culture, Education, and Youth, before U.S. stakeholders. Moreover, a panel consisting of a member of the European Parliament and young entrepreneurs focused on the importance of IP rights and their enforcement for businesses to access and remain competitive in technology markets.

In May 2022, the IP Attaché for Europe took part in *Operation Lascar*, an operation launched by U.S. FDA in 2017 concerning trade in illicit products traveling to the U.S. from the U.K. In addition, the Attaché spoke at the *Virtual Dialogue on Digital Marketplaces and IP Counter-infringement* organized by the U.K. Intellectual Property Office. The event gathered government officials from the G7 countries and focused on countering IP crime and infringement, with specific a focus on online marketplaces and initiatives to tackle counterfeits and enforce IP rights on these platforms. The Attaché spoke also at the first of three events of the program on "Whole of Governments Approach to Protect Consumers Against Illicit Health and Safety Regulated Products" jointly organized by FDA and the Organization for Economic Co-operation and Development (OECD) Task Force on Countering Illicit Trade (TF-CIT). The event gathered officials from several countries and intergovernmental organizations and focused on the need for

a whole of governments approach to tackle effectively trade in illicit medicines. The Attaché stressed the importance of IP protection and discussed how the U.S. government agencies cooperate to address the complex international problem of trade in counterfeit medicines.

In June 2022, USPTO OPIA's Enforcement Team, with the support of other USG agencies and international organizations, presented a three-day in-person program for government representatives from Bulgaria and Romania entitled *Workshop on the Investigation and Handling of Counterfeit Medicine Cases*.

Oceania

In November 2021, the USPTO organized an "IPR Dialogue" event with the Oceania Customs Organization (as part of a larger IP legislative technical assistance project with OCO focused on trademark and copyright laws).

DEPARTMENT OF DEFENSE

Department of Defense Appendix for FY 2022 Annual Report

This appendix discusses the FY 2022 activities of the Department of Defense (DoD).

<u>Defense Acquisition University</u>: The Defense Acquisition University (DAU) continued to engage in training and educational initiatives during FY 2022 that reflect the following themes:

- (1) Intellectual property as a critical component of DoD acquisitions in maintaining U.S. military technological superiority;
- (2) DoD's desire to collaborate with U.S. Government agencies to identify and build partnerships to address areas of economic, technological, and informational vulnerabilities; and
- (3) the need to respect and protect technology development investments by the private sector and U.S. Government in the acquisition of military systems.

<u>DAU's Great Power Competition Initiative</u>: DAU established the Great Power Competition (GPC) Initiative (https://www.dau.edu/greatpowercompetition) focused on educating the acquisition community as they strive to address the impact of peer and near-peer adversaries, per the National Defense Strategy.

The GPC Initiative provides domain expertise by connecting with experts, consulting, curating resources, and educating on a spectrum of challenges that global adversaries present, such as global supply chain risk management, intellectual property (IP) issues in the acquisition of military technology, industrial base challenges, international acquisition, innovation and speed, and how peers and near-peers conduct acquisition. A primary goal of the GPC is to educate the acquisition workforce on these challenges and assisting them in developing and implementing strategies to meet them.

In connection with the GPC Initiative, DAU began a monthly webinar series, "Competing to Win," where the workforce engages with experts in the field as they share their insights and advice on GPC issues (https://www.dau.edu/greatpowercompetition/pages/events-and-webcasts.aspx).

Other Key FY2022 DAU Intellectual Property Educational Initiatives:

- Developing 2 additional on-demand topical videos (e.g., Negotiating IP and SBIR and STTR).
- Engaging in a two-year project to update DAU's online suite of IP courses addressing the fundamentals of IP and Data Rights in DoD acquisitions; the suite is core to DAU's Foundational IP Credential for the acquisition workforce.
- Incorporated IP into Executive Level Courses and Workshops (PMT 4010, 4020, Defense Acquisition Executive Overview Workshops DAEOWS).

- Participated in numerous webinars and in-person events on IP (e.g. Aerospace Industries Association (AIA) and National Defense Industrial Association (NDIA) 2022 Technical Data Rights Forum and DAU's Hacking Program Management webinar series on IP, Part 2).
- DAU has conducted IP Strategy Workshops with several Program Offices across all of the services to assist these offices in the development of program specific IP strategies.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

"The FDA's Cybercrime Investigation Unit has been working for a number of years to disrupt and dismantle the growing number of dark web marketplaces, vendors, and networks that are manufacturing and selling counterfeit, misbranded, and unapproved drugs.

"In one investigation in Massachusetts, for example, a man who called himself 'KillWill' distributed counterfeit oxycodone pills that bore markings similar to the Mallinckrodt Pharmaceutical company's oxycodone tablets. Instead of containing oxycodone hydrochloride, the tablets were made up of heroin and fentanyl.

"We're also continuing to collaborate with the DEA to crack down on activities that contribute to potential abuse, misuse, and overdoses. Just last week, FDA and DEA issued joint warning letters to operators of two websites illegally selling amphetamine drug products marketed as Adderall. Administrator Milgram and I are focused on this, and will do everything we can to bring to justice those involved in this kind of illegal and dangerous activity."

- Robert M. Califf, FDA Commissioner

Food and Drug Administration (FDA) Appendix for FY 2022 Annual Report

Drug counterfeiting is a serious threat to public health. Counterfeit drugs or other illegally marketed medical products can raise significant public health concerns because their safety or effectiveness may be unknown. In the United States, a relatively comprehensive system of laws, regulations, and enforcement by Federal and state authorities have helped reduce drug counterfeiting incidents, and FDA works to ensure that Americans can have a high degree of confidence in the drugs that they obtain through legal channels. FDA has made it a priority to investigate reports of concerns associated with counterfeit and other unapproved new drugs and works with U.S. drug supply chain stakeholders to improve our ability to prevent, detect, and respond to threats associated with such drugs. FDA also educates consumers and the health care community about the risks of, and minimizing exposure to, counterfeit drugs, unapproved new drugs, and substandard drug products through oversight of voluntary recalls, public awareness campaigns, and other steps. Additionally, FDA works with our foreign counterparts to identify global supply chain vulnerabilities as well as identify and implement realistic solutions, nationally and internationally.

Improving the Security of the Pharmaceutical Supply Chain

Drug Traceability

FDA continues to implement provisions of the Drug Supply Chain Security Act (DSCSA) (Title II of the Drug Quality and Security Act), which was enacted on November 27, 2013. The DSCSA helps to improve the integrity and security of the pharmaceutical distribution supply chain for most prescription drugs by establishing product tracing, product identifier, authorized

⁴ Remarks by FDA Commissioner Robert Califf to the 2022 Rx and Illicit Drug Summit (April 20, 2022) at https://www.fda.gov/news-events/speeches-fda-officials/remarks-fda-commissioner-robert-califf-2022-rx-and-illicit-drug-summit-04202022.

trading partner, and verification requirements for manufacturers, repackagers, wholesale distributors, and dispensers. The DSCSA also requires critical steps to achieve electronic, interoperable tracing of certain prescription drugs at the package level by November 27, 2023. These requirements will help to identify and trace such prescription drugs that are distributed in the United States, in addition to establishing national standards for licensure of wholesale distributors and third-party logistics providers. The DSCSA enhances FDA's ability to help protect U.S. consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful by improving detection and removal of potentially dangerous drugs from the supply chain.

In FY 2022, amongst other continued stakeholder engagement, FDA held a virtual public meeting in November 2021 for discussion around enhanced drug distribution security. In February 2022, FDA issued the proposed national standards for the licensure of wholesale drug distributors and third-party logistics providers (3PL) along with several key guidance documents for industry. The proposed rule would establish standards for all State and Federal wholesale distributor or 3PL licenses. The comment period for the proposed rule closed on September 6, 2022, and FDA is now in the process of reviewing comments submitted to the public docket. Additionally, FDA proposed to remove certain requirements related to the Prescription Drug Marketing Act (PDMA). This action was taken because the PDMA requirements are duplicative of the proposed rule.

In 2022, FDA issued a series of guidance documents laying out FDA recommendations for how to comply with applicable DSCSA requirements, including those for product tracing, verification systems under the DSCSA, identifying trading partners, and standards for the interoperable exchange of information. The guidance documents are summarized below:

- The final guidance on *Drug Product Tracing: The Effect of Section 585 of the Federal Food, Drug, and Cosmetic Act, Questions and Answers* was issued to assist industry and State and local governments in understanding the effects of section 585 (Uniform National Policy) on drug product tracing as required by the DSCSA, which establishes a Federal system for tracing prescription drug products through the pharmaceutical distribution supply chain and requires trading partners to pass, receive, and maintain certain product and distribution information. Section 585 requires there be a uniform national policy, preempting States from establishing or continuing in effect certain standards and requirements.
- The revised draft guidance *Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs* covered the verification system requirements that include the quarantine and investigation of a suspect product and the quarantine and disposition of a product determined to be illegitimate. It also addresses the requirement for notification to FDA of a product that has been cleared by a trading partner after a suspect product investigation because it is determined that the product is not an illegitimate product. Finally, this draft guidance addresses the requirement for responding to requests for verification and processing saleable returns.

- The revised draft guidance DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry identifies the standards necessary to facilitate the DSCSA-mandated adoption of secure, interoperable, electronic data exchange among the pharmaceutical distribution supply chain, and clarifies the trading partners, products, and transactions subject to such standards. The revisions update the policy articulated in the November 2014 draft guidance to reflect the enhanced drug distribution security requirements that will go into effect on November 27, 2023, including that paper-based methods of product tracing will no longer be permitted and verification of product at the package level will be required, unless a waiver, exception, or exemption applies.
- The revised draft guidance *Identifying Trading Partners Under the Drug Supply Chain Security Act* was issued to assist industry and State and local governments in understanding how to categorize the entities in the drug supply chain in accordance with the DSCSA. The guidance explains how to determine when certain statutory requirements will apply to entities that are considered trading partners in the drug supply chain (e.g., private-label distributors, salvagers, and returns processors and reverse logistics providers), provides clarification on certain scenarios, and addresses the interpretation of section 582(a)(7) of the FD&C Act, which discusses third-party logistics providers licensure status prior to the effective date of the forthcoming regulations establishing licensure standards.
- The final guidance Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act (DSCSA) for the Distribution of FDA-Approved Naloxone Products During the Opioid Public Health Emergency clarifies the scope of the public health emergency exclusion and exemption under the DSCSA as they apply to the distribution of FDA-approved naloxone products indicated for the emergency treatment of opioid overdoses to harm reduction programs during the opioid public health emergency.

FDA is planning for additional stakeholder engagement and discussions on systems and processes needed for enhanced supply chain security requirements that go into effect in 2023. For updates about DSCSA implementation and copies of the guidance documents see http://www.fda.gov/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm.

Engagement with Other Countries on Counterfeit Medical Products and Supply Chain Security

Asia Pacific Economic Cooperation (APEC) Global Medical Product Quality and Supply Chain Security Efforts

FDA continues to support and advance the APEC Supply Chain Security Toolkit, which is a comprehensive resource that addresses prevention, detection, and response with regards to vulnerabilities in the medical product supply chain. The toolkit is the culmination of a collaborative project that was commissioned by APEC with the oversight of the Regulatory

Harmonization Steering Committee (RHSC) and is updated as the medical product supply chain evolves. Efforts are currently underway to update both the post-marketing surveillance (PMS) and internet sales sections of the APEC Toolkit, with United States Pharmacopeia (USP) and Alliance for Safe Online Pharmacies (ASOP Global), respectively, taking the leads. Updates to the APEC Toolkit are being made with guidance from the pharmaceutical industry, member states regulators, and the World Health Organization (WHO).

WHO Member State Mechanism

FDA is highly involved in the technical, policy, and strategic implementation of the World Health Organization Member State Mechanism on Substandard and Falsified Medical Products (WHO MECH) and serves as a vice-chair for the America's region on its Steering Committee. FDA supports the WHO MECH in its global efforts to prevent, detect, and respond to substandard and falsified (SF) medical products, including the development of reports, guidance, tools, and other products. The WHO MECH, composed of public health and national medicines regulatory authorities, focuses on the public health aspects of SF medical products, and does not address intellectual property rights issues.

Global Surveillance and Monitoring System

FDA has supported the WHO to establish the Global Surveillance and Monitoring System (GSMS) for Substandard and Falsified Medical Products which was launched in 2013. The GSMS provides national medicines regulatory authorities (NMRAs) with an information portal to report counterfeit medical products, and the ability to check if similar products have been found around the globe. If similar products have been found, the WHO works with NMRAs to investigate suspected counterfeit cases and issue alerts as necessary. The GSMS portal is available in English, French, Spanish, and Portuguese. The online portal, search facility, and access to the photo library have also enhanced participation by Member States. Manufacturers can also submit information on counterfeit products to the GSMS. The WHO has reported that the quality and number of reports to GSMS has been steadily increasing in the last few years.

FDA and the Organization for Economic Co-Operation and Development Bilateral Initiative

In May 2022, FDA and the Organization for Economic Co-Operation and Development launched a three-part program entitled "Whole of Governments Approach against Illicit Health Products." With increasingly sophisticated criminal networks, the threat posed by the illicit pharmaceutical trade has become too complex to be adequately addressed by a singular stakeholder. Through this program, participants from multiple countries collaborate and use their respective authorities to safeguard consumers from harm, hold bad actors accountable, and identify threats as they emerge.

Addressing Illegal Controlled Substances, Other Illegally Marketed Drugs, and Consumer and Health Care Provider Education

Illegal Stimulants Online and Warning Letters Issued

Schedule II stimulants have an acknowledged high potential for abuse, and it is important to address the public health impact of their diversion and nonmedical use. Diversion is the primary source of prescription stimulants for nonmedical use, and nonmedical use is most frequent among young adults and college students. Polysubstance use is common among those who use prescription stimulants nonmedically, with individuals frequently co-using illicit drugs and/or prescription opioids. These concerns come against a backdrop of rising mortality from psychostimulant-involved overdoses, which involve illicit stimulants the vast majority of the time, but sometimes involve prescription stimulants.

In FY 2022, FDA and DEA issued joint warning letters to operators of two websites illegally selling Schedule II stimulants, including amphetamine drug products marketed as Adderall, that are misbranded in violation of the Federal Food, Drug, and Cosmetic Act. The website operators also violate the Ryan Haight Online Pharmacy Act (RHA) by failing to register their online pharmacies with the DEA despite knowingly or intentionally advertising the sale of controlled substances. See https://www.fda.gov/news-events/press-announcements/fda-and-dea-warn-online-pharmacies-illegally-selling-adderall-consumers.

Illegal Opioids Online and Warning Letters Issued

organizations-and-illicit-drugs/.

Opioid addiction is an immense public health crisis and addressing it is one of FDA's highest priorities. Tragically, more than 100,000 Americans died from drug overdoses in the 12 months leading up to April 2021, representing a 28% increase over the same period during the prior year. The illegal online marketing of unapproved opioids is particularly concerning in light of the nation's opioid addiction and overdose crisis. In addition, opioids bought online may be counterfeit and could contain other dangerous substances.

In addition to opioids, benzodiazepines are drug products with an acknowledged potential for abuse, and it is important to address the public health impact of their nonmedical use. Benzodiazepine nonmedical use is widespread, and individuals frequently co-use benzodiazepines with alcohol, prescription opioids, and illicit drugs. Associated harms of benzodiazepine nonmedical use are substantial, but occur primarily when people use benzodiazepines in combination with other drugs. Further, in cases where benzodiazepines were co-used with other substances, medical outcomes are typically more severe than in cases involving benzodiazepines alone. Polysubstance overdose deaths account for the vast majority of overdose deaths documenting involvement of benzodiazepines.

⁵ FACT SHEET: The Biden Administration Launches New Efforts to Counter Transnational Criminal Organizations and Illicit Drugs, December 15, 2021, at <a href="https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/15/fact-sheet-the-biden-administration-launches-new-efforts-to-counter-transnational-criminal-releases/2021/12/15/fact-sheet-the-biden-administration-launches-new-efforts-to-counter-transnational-criminal-releases/2021/12/15/fact-sheet-the-biden-administration-launches-new-efforts-to-counter-transnational-criminal-releases/2021/12/15/fact-sheet-the-biden-administration-launches-new-efforts-to-counter-transnational-criminal-releases/2021/12/15/fact-sheet-the-biden-administration-launches-new-efforts-to-counter-transnational-criminal-releases/2021/12/15/fact-sheet-the-biden-administration-launches-new-efforts-to-counter-transnational-criminal-releases/2021/12/15/fact-sheet-the-biden-administration-launches-new-efforts-to-counter-transnational-criminal-releases/2021/12/15/fact-sheet-the-biden-administration-launches-new-efforts-to-counter-transnational-criminal-releases/2021/12/15/fact-sheet-the-biden-administration-launches-new-efforts-to-counter-transnational-criminal-releases/2021/12/15/fact-sheet-the-biden-administration-launches-new-efforts-to-counter-transnational-criminal-releases/2021/12/15/fact-sheet-the-biden-administration-launches-new-efforts-to-counter-transnational-criminal-releases/2021/12/15/fact-sheet-the-biden-administration-launches-new-efforts-to-counter-transnational-criminal-releases/2021/12/15/fact-sheet-the-biden-administration-releases/2021/12/15/fact-sheet-the-biden-administration-releases/2021/12/15/fact-sheet-the-biden-administration-releases/2021/12/15/fact-sheet-the-biden-administration-releases/2021/12/15/fact-sheet-the-biden-administration-releases/2021/12/15/fact-sheet-the-biden-administration-releases/2021/12/15/fact-sheet-the-biden-administration-releases/2021/12/15/fact-sheet-the-biden-administration-releases/2021/12/15/fact-sheet-the-biden-administratio

In FY 2022, FDA issued a warning letter to the operator of a network of 25 websites illegally offering for sale unapproved and misbranded opioids and benzodiazepines to U.S. consumers in violation of the Federal Food, Drug, and Cosmetic Act.

Unproven products that claim to treat, cure, or prevent COVID-19 and other conditions

As part of its response to the public health emergency, FDA has also addressed the increase in unproven products sold with fraudulent claims to prevent, diagnose, treat, mitigate, or cure COVID-19 and has issued more than 219 warning letters to companies. See https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products for more information. In addition, since the start of the COVID-19 pandemic, FDA has issued 22 warning letters to owners and/or operators of internet pharmacy websites that illegally offer for sale unapproved and misbranded drugs purported to treat, cure, or prevent COVID-19 to U.S. consumers. See https://www.fda.gov/drugs/drug-supply-chain-integrity/internet-pharmacy-warning-letters.

The FDA's *Operation Quack Hack* leveraged agency expertise and advanced analytics to protect consumers from fraudulent medical products during the COVID-19 pandemic. Building upon our previous experience with illegal online pharmacies, a team of consumer safety officers, special agents, and intelligence analysts triage incoming complaints about fraudulent and unproven medical products. Where appropriate, complaints are sent to other agencies or to FDA centers for additional review and possible follow-up action. In some cases, following a preliminary investigation, the *Operation Quack Hack* team sends an abuse complaint to the domain name registrars or a report to online marketplaces. As of September 30, 2022, FDA issued more than 660 abuse complaints and reports, which are intended to notify companies that may not have been aware that their platforms were being used to sell an unapproved, unauthorized, or uncleared medical product during the COVID-19 pandemic. Through *Operation Quack Hack*, online marketplaces and registrars have been notified by the FDA of more than 2,200 fraudulent COVID-19 related product listings and websites. Please see <u>FDA's website</u> for more information regarding *Operation Quack Hack*.

On December 27, 2021, the U.S. District Court for the District of New Jersey entered a consent decree of permanent injunction that prohibits a New Jersey-based company from receiving or distributing any drugs until the company complies with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and other requirements. The complaint, filed by the Department of Justice on behalf of the FDA, alleged that Natural Solutions Foundation, an organization, and its two principals, Rima Laibow and Ralph Fucetola, violated the FD&C Act by selling unapproved and misbranded drugs intended to cure, mitigate, treat or prevent COVID-19. The defendants had received a jointly issued warning letter from FDA and FTC on May 19, 2020.

FDA Warns 12 Companies Selling Unapproved Skin Lightening Products

On April 19, 2022, FDA addressed the sale of unapproved over-the-counter (OTC) skin lightening drug products containing hydroquinone that do not meet the requirements to be legally sold as OTC drugs in the U.S. marketplace. The agency had received reports of serious side effects, including skin rashes, facial swelling, and ochronosis (discoloration of skin), from the

use of skin lightening products containing hydroquinone. Due to the potential harm they may cause, consumers were advised not to use these products. As a part of its response, FDA issued 12 warning letters to manufacturers and distributors of OTC skin lightening drug products and 19 notification letters to manufacturers who listed these products with FDA but did not actively distribute them, notifying them that these products are unapproved new drugs and are misbranded. The letters explained that OTC skin lightening drug products containing the active drug ingredient hydroquinone are unapproved drugs and are not generally recognized as safe and effective. FDA also added certain skin lightening drug product manufacturers to an import alert to help stop their products from entering the U.S.

FDA Warns Consumers Not to Purchase or Use Artri and Ortiga products

In April 2022, FDA <u>warned</u> consumers not to purchase or use products marketed with variations of the names "Artri" and "Ortiga" due to potentially dangerous hidden active drug ingredients not listed on the product label. FDA purchased and tested various Artri and Ortiga products from online sources and found that products purchased from Amazon, eBay, and Walmart and the website <u>www.latinfoodsmarket.com</u> contained hidden drug ingredients. The FDA's laboratory testing found the products contained various undeclared active ingredients, including diclofenac, dexamethasone, and methocarbamol. FDA urged consumers taking these products to immediately talk to their health care professional (e.g., doctor) to safely discontinue use of the product because suddenly stopping these drugs may be dangerous. Walmart and Latin Foods Market voluntarily recalled the products sold on their platforms.

FDA Warns Website Operator Illegally Selling Domperidone Products

In May 2022, FDA issued a warning letter to the operator of a website offering unapproved domperidone drug products for sale to U.S. consumers in violation of the Federal Food, Drug, and Cosmetic Act. Domperidone is not currently a legally marketed human drug and it is not approved for sale in the U.S. There are serious risks associated with domperidone including cardiac arrhythmias, cardiac arrest, and sudden death. These risks are related to the blood level of domperidone, and higher levels in the blood are associated with higher risks of these events. Concurrent use of certain commonly used drugs, such as erythromycin, could raise blood levels of domperidone and further increase the risk of serious adverse cardiac outcomes. The easy availability of domperidone via the Internet poses significant risks to U.S. consumers.

Enforcement Actions

The FDA Office of Criminal Investigation's Cybercrime Investigations Unit (CcIU) continues to target darknet marketplaces and vendors that manufacture and sell counterfeit opioids, by identifying those responsible, arresting perpetrators, and seizing manufacturing equipment, counterfeit drugs, and assets.

Since the start of the program in November 2017 until September 30, 2022, CcIU's *Operation CyberPharma* has led to 60 arrests, 26 convictions, and aided in the takedown of a major darknet marketplace as well as the seizure of drug counterfeiting tools, counterfeit drugs, and over \$8.4 million in virtual currencies and other assets. CcIU agents also monitor the surface web to identify sellers of counterfeit FDA-regulated products. Cybercrime agents can swiftly make test

purchases from online merchants selling consumer goods suspected to be counterfeit or substandard.

In response to the COVID-19 pandemic, CcIU agents have participated in *Operation Quack Hack*, an FDA-wide initiative targeting counterfeit or substandard COVID-19 related products. Cybercrime agents have used this operation in support of a number of COVID-related criminal cases, including the identification of counterfeit masks and the closure of a website claiming to sell the Moderna COVID-19 vaccine.

In March 2022, OCI successfully partnered with the U.S. Customs and Border Protection, U.S. Patent and Trademark Office, U.S. Embassy London, and the United Kingdom's Revenue and Customs, Border Force, and Intellectual Property Office to execute *Operation Lascar V*. *Operation Lascar* was first launched in 2017 in response to illicit FDA regulated products being shipped to the U.S. from and through the United Kingdom (U.K.). Since then, *Operation Lascar* has included five unprecedented joint enforcement operations, bilateral training opportunities, and senior-level engagement. Further, through these enhanced relationships, with a range of U.K. counterpart agencies and the posting of an FDA special agent at U.S. Embassy London, we have successfully participated and supported several criminal investigations, including those related to fraudulent COVID-19 and counterfeit products. *Operation Lascar V*, which was conducted in the U.K. from March 21-25, 2022, examined more than 300 shipments of violative medicines intended for the U.S., identified new types of products being transshipped through the U.K. (including an increase in the shipment of veterinary products), and obtained updated intelligence regarding how these products are being distributed.

Pilot Process to Reduce the Availability of Opioids Online Launched

In June 2020, FDA and the National Telecommunications and Information Administration (NTIA) partnered to announce the launch of a 120-day pilot to help reduce the availability of unapproved opioids illegally offered for sale online. Under the pilot, the FDA notified participating internet registries – Registry Services (formerly Neustar), Verisign, and Public Interest Registry – when the agency sent a warning letter to a website operator and the website operator did not respond adequately within the required timeframe. The internet registries reviewed the FDA's notifications and assessed whether to take further voluntary action, including possible domain name suspensions or blocks. As a result of the pilot, nearly 30 websites illegally offering opioids for sale became inaccessible to the public.⁶

In FY 2022, FDA continued this collaboration to help prevent illegal online opioid sales, in addition to other controlled substances, including benzodiazepines.

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⁶ FDA In Brief: FDA Continues Efforts to Curb Illegal Availability of Unapproved Opioids Online, February 1, 2021, at https://www.fda.gov/news-events/fda-brief/fda-brief-fda-continues-efforts-curb-illegal-availability-unapproved-opioids-online. Please note the pilot was directed to websites offering misbranded and/or unapproved opioids for sale to U.S. consumers and did not specifically address counterfeits.

Outreach to Health Care Providers

FDA provides various online courses to inform healthcare professionals and provide them continuing education opportunities. One of these courses, *Tainted Products Marketed as Dietary Supplements*, is available for access through the FDA website. The course focuses on the prevalence of adulterated and misbranded products masquerading as dietary supplements sold in convenience stores, retail establishments, and online. These products continue to be the source of adverse event reports submitted to the agency. The webinar outlines how healthcare professionals can help protect consumers and patients from these products, how adverse events can be reported to FDA, and what measures FDA is taking to protect consumers and patients.

Using Advanced Technology to Identify Suspect Products: CDx (handheld Counterfeit Detection tool)

FDA scientists developed a handheld Counterfeit Detection (CDx) tool intended to be used to rapidly screen suspect products and packaging, by visualizing differences between suspect and authentic products and providing preliminary findings in the field. The current CDx technology is used at the U.S. International Mail Facilities (IMFs) and other ports of entry to screen suspect incoming packages to assess finished dosage form pharmaceuticals that are offered for entry.

The goal is to put affordable tools for identifying counterfeit FDA-regulated products, including pharmaceuticals, in the hands of global regulatory law enforcement, and public health officials.

An updated prototype, CD5, is currently being evaluated for field-screening of suspected counterfeit pharmaceuticals, and sampling of products for further examination and confirmation/analysis. Nine consumer safety officers from the Office of Import Operations received training on the CD5 in 2022. Information gathered during a pilot study is being used to finalize the CD5 production units and to refine the training program and materials to support their use.

In FY 2022, a total of 29 products, consisting of 3,811 tablets/capsules/pieces, were examined by import investigators using the CDx. The identified products were examined using the CD5, which has a library that includes over 170 pharmaceutical product profiles. Of the 29 unique products examined, 18 of them were sent to the Forensic Chemistry Center (FCC) for confirmation and/or analysis. Since June 2022, the CD5s have been out of the field and at the manufacturer receiving hardware updates based on field staff suggestions to make the instrument more user friendly. These updates will allow closer viewing/display of tablets and simplified matching to the library. Once updates are complete the instruments will be returned to field staff and expanded training will be provided.

Scientific presence and field deployable tools for rapid field detection of illegal, unapproved, and counterfeit pharmaceuticals and tainted supplements

In October 2020, FDA, with DHS/CBP and DHS/ICE Commissioners formalized a partnership at International Mail Facilities (IMF) in a Memorandum of Understanding. This agreement increases collaboration to maximize inspection and detection capabilities in order to prevent

illegal and harmful products entering the U.S. through the nation's IMFs. This partnership includes an increase in scientific resources at selected IMFs and sharing of space, technologies, and information, which will facilitate mission responsibilities by improving efficiency and reducing duplication of efforts. Additionally, FDA and CBP partnered in 2022 to conduct joint operations targeting opioids and other unapproved drugs. Phase 1 of this operation included data sharing across FDA and CBP to inform location and product targeting for Phase 2. During phase 2, FDA and CBP partnered at eight IMFs and five Express Courier Hubs (ECH) to identify products of interest. Under *Operation Opioids and Other Drugs* (OOOD), over 3,500 parcels containing opioids, controlled substances, and unapproved drugs were examined by FDA and CBP which resulted in refusals, including some violative drug products subject to destruction, and referrals to CBP. Through these examinations, approximately 395,000 tablets/capsules/pieces consisting of unapproved drugs and controlled substances were refused, destroyed, or referred to CBP for regulatory action. Operational findings from work completed in FY 2022 OOOD operations will drive future targeting efforts in FY2023.

FDA's Office of Regulatory Affairs (ORA) Forensic Chemistry Center (FCC) identified specially trained field-based scientists who use an established set of tools designed to be the most scientifically reliable and efficient approach for the rapid identification of illicit FDA-regulated products (such as falsified and counterfeit drugs, including opioids, and adulterated "supplements"). ORA expanded collaborative efforts with Federal partners in the fight against illegal/unapproved drugs by establishing the first of several planned satellite laboratories at the Chicago O'Hare IMF in partnership with CBP's Laboratories and Scientific Services (LSS). The FCC continues its work on field detection of pharmaceutical based agents. While COVID interrupted IMF lab operations in 2020, full satellite lab operations resumed in June 2021 and FDA's FCC trained eight additional chemists in 2022 to support additional satellite laboratories.

Collaboration with CBP at international mail facilities (IMFs)

As part of FDA's Import Operation Strategy, FDA import operations personnel work daily with U.S. Customs and Border Protection (CBP) personnel at IMFs. FDA regulatory investigators determine admissibility of FDA-regulated products. All parcels reviewed that contain pharmaceuticals, are documented and processed by FDA. FDA generates data at eight IMFs regarding the number of mail parcels examined, detention of unapproved drugs, suspected counterfeit pharmaceuticals, products marketed as foods and/or dietary supplements containing undeclared active pharmaceutical ingredients, and other non-compliant FDA-regulated products. This data is routinely shared within FDA and CBP.

FDA also shares technology with CBP. For example, FDA and CBP personnel collaborate to utilize FDA's handheld CDx (discussed above) to identify counterfeit pharmaceuticals. FDA's OIO, in cooperation with ORS, is looking at extending the CDx in conjunction with other handheld technologies to identify additional potential counterfeit pharmaceuticals and FDA-regulated products containing undeclared APIs. Beginning in May 2022, ORS held four training sessions for OIO field staff and nine OCI Special Agents on a handheld Raman device, with a potential for further advanced training in FY 2023. The handheld Raman is also used by IMF satellite lab chemists to complement the CDx for identification of falsified/counterfeit pharmaceuticals. This tool can screen for potentially misbranded and adulterated drug products,

assist investigators in making sampling decisions, and add a margin of safety for investigators by permitting some identifications to be accomplished on intact containers.

International Capacity Building and Training: FDA Capacity Building and Training

Below are examples of FDA's Office of Criminal Investigations (OCI) capacity building and training activities with foreign countries.

In October 2021, OCI participated in the 30th Meeting of the Head of Medicines Agencies (HMA) Working Group of Enforcement Officers, which was sponsored this year by the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia.

In November 2021, OCI provided results to Europol regarding *Operation Shield II. Operation Shield* is an initiative funded by the European Union Intellectual Property Office (EUIPO) and coordinated by Europol. This year's operation was led by France, Italy, Finland, and Greece and was focused on illicit COVID-19 related products, Benzodiazepines (such as Clonazepam), hormonal substances, food supplements and medicines for erectile dysfunction.

In November 2021, OCI participated in the Europol Intellectual Property (IP) Crime Conference. This annual meeting is an overview of general activities being undertaken in the European Union to combat IP violations.

In February 2022, OCI met with the London representative of India's Directorate of Revenue Intelligence (DRI) regarding general investigative trends and issues with DRI and the United Kingdom.

In March 2022, OCI participated in the 10th plenary session of the Organization for Economic Development' Task Force on Countering Illicit Trade (OECD-TFCIT).

In March 2022, OCI met with the West Midland Police Department to participate in a brief of the West Midlands Regional Cyber Crimes Unit and their work with OCI. OCI discussed general investigative trends and issues with counterfeit pharmaceuticals.

In March 2022, OCI participated in the Universal Postal Union's (UPU) Postal Security Group Meeting. This hybrid meeting was held physically at UPU headquarters in Berne, Switzerland. OCI delivered a brief presentation entitled "Challenges and approaches in the arena of pharmaceutical and medical devices."

In March 2022, OCI provided an OCI 101 presentation to the Metropolitan Police Intelligence Unit, and representative to the UK Government Agencies Intelligence Network (GAIN). The GAIN Unit provided a brief regarding to the investigative jurisdiction of the unit and their work to share criminal intelligence among the UK law enforcement community.

In March 2022, OCI partnered with the U.S. Customs and Border Protection, U.S. Patent and Trademark Office, U.S. Embassy London, and the United Kingdom's Revenue and Customs, Border Force, and Intellectual Property Office to execute *Operation Lascar V*. Initially

launched in 2017, *Operation Lascar* addresses illicit FDA regulated products being shipped to the U.S. through the United Kingdom (U.K.).

In May 2022, OCI hosted representatives from the U.K. Food Crimes Unit at the U.S. Embassy in London and provided a presentation to unit members on OCI mission and work. OCI also discussed how the two agencies could cooperate further in the future, to include possible participation in the next *Lascar* operation.

In June 2022, OCI participated in the biannual meeting of the Heads of Medicines Agencies' Working Group of Enforcement Officers (WGEO). The Heads of Medicines Agencies is a network of the leaders of the National Competent Authorities who are responsible for the regulation of medicinal products for human and veterinary use in the European Economic Area. The WGEO was established in 2007 to contribute to the protection of human and animal health.

In June 2022, OCI participated in a joint training program with the USPTO for the countries of Romania and Bulgaria. This initiative provided training to law enforcement officials from both countries training regarding the investigation and handling of counterfeit medicines.

In June 2022, OCI participated in an anti-counterfeiting panel for the Pharmaceutical Manufacturing and Packaging Conference held in Berlin, Germany.

In June 2022, OCI participated in a workshop (Indo-Pacific Regional Workshop on Enforcement Against Trade in Counterfeit Goods) and a series of USG interagency meetings (International Law Enforcement Academy (ILEA), State Department, USAID-OIG, CDC) in Bangkok, Thailand.

In June 2022, OCI participated in meetings with the Scotland Food Crime Unit regarding the types of investigations OCI conducted between the two organizations.

In July 2022, OCI, FDA Europe Office, and the Organization for Economic Co-Operation and Development (OECD) participated in part two of a three-part program calling for a "whole of governments" approach, utilizing coordinated efforts by multiple countries and their arsenal of authorities that crosscut multiple sectors of government, to safeguard consumers from harm, hold bad actors accountable, and identify threats as they emerge.

Laboratory/Analytical Capacity Building through International Collaboration

The International Laboratory Forum on Counterfeit Medicines (ILFCM) is comprised of scientific experts from National Regulatory Control Laboratories. It began in 1999 with a bilateral arrangement between FDA and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA), and it developed into a partnership with global regulatory counterparts from Europe, North America, Asia, and Australia to maximize the benefits of a scientific network and exchange information on emerging issues related to counterfeit and illegal medicines. The ILFCM also focuses on issues related to falsified/substandard medicines, adulterated dietary supplements, and other important public health topics. The ILFCM is closely

aligned with the Permanent Forum on International Pharmaceutical Crime (PFIPC) and provides scientific guidance and laboratory support.

Enforcement Activities

OCI's Cybercrime Investigation Unit (CcIU)

OCI's internet-related criminal investigations are led by its Cybercrime Investigations Unit (CcIU), which strategically targets online transnational criminal networks that threaten the public health of Americans. In FY 2022, CcIU focused resources to counter public health threats, such as the COVID-19 pandemic and the opioid crisis, through enforcement operations such as *Operation Quack Hack* and *Operation Cyber Pharma* (described above). CcIU also participates with the FBI's Joint Criminal Opioid and Darknet Enforcement (JCODE) group, the Permanent Forum on International Pharmaceutical Crime (PFIPC), the Public Safety Working Group of the Internet Corporation for Assigned Names and Numbers (ICANN) Governmental Advisory Committee (GAC), and several cybercrime-related international law enforcement working groups.

OCI's International Operations Program

OCI's International Operations Program (IOP) assists in detecting violative shipments of FDA-regulated products entering our domestic ports and facilities. It is led by three senior operations managers, two of which are posted internationally, and consists of 15 full-time and one part-time IOP special agents and is supported by two intelligence research specialists. Recently, OCI established a new operations officer position to serve as a focal point within OCI to engage with U.S. and international stakeholder agencies regarding the importation of violative FDA-regulated products. IOP's priorities include engaging with foreign counterpart agencies and international organizations, responding to U.S. Postal Service International Mail Facilities (IMFs), express consignment carrier facilities (including integrators such as DHL, UPS, and FedEx), air cargo facilities, and sea and land ports. IOP special agents routinely conduct joint enforcement activities, including internationally, and play a critical role as part of the FDA's support to the U.S. government-wide effort to combat cross-border crime.

IOP frequently provides training to its foreign law enforcement counterparts. Continuing from FY 2021, IOP successfully completed a six-month virtual bilateral training workshop and joint exercise for the Pakistan Customs Service, together with the Commerce Department's Commercial Law Development Program (CLDP) and the U.S. Patent and Trademark Office (USPTO). The focus of this workshop was to help identify, interdict, and seize contraband transiting through air freight and air mail facilities in Pakistan that poses a significant health and safety risk to the public in the United States, Pakistan, and elsewhere. IOP also provides training to federal partner agencies, State and local law enforcement personnel, and regulated industry.

OCI Enforcement Actions

OCI plays a leading role in combating counterfeit pharmaceuticals and medical devices. Below are notable examples of OCI's enforcement activities. Additional FDA enforcement cases are discussed further below.

Review of Certain Imported Drugs

FDA has implemented the enforcement tool provided by section 708 of the Food and Drug Administration Safety and Innovation Act (FDASIA) to combat illegal drug importation. Section 708 amended section 801(a) of the FD&C Act to give FDA the authority to administratively destroy refused drugs that are valued at \$2500 or less. This authority was implemented nationwide in FY 2017.

In addition, in the SUPPORT Act (Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act), which became law on October 24, 2018, Congress granted FDA additional import authority to help the Agency advance efforts to stop illegal and unsafe drugs from being imported into the United States. For instance, section 3022(d) of the SUPPORT Act added section 801(u) to the FD&C Act; the provision authorizes FDA to treat certain imported articles as "drugs" for purposes of determining admissibility, including if the article is an ingredient "that presents significant public health concern" and it is, or contains, the same active pharmaceutical ingredient of an FDA approved drug. This provision enhances FDA's ability under its importation authorities in section 801 of the Act to detain, refuse and potentially destroy illicit articles imported in the IMFs.

FDA developed procedures for the section 801(u) authority and began using this new authority on March 4, 2019. In FY 2020, FDA destroyed over 34,000 violative drug products that were not in compliance with U.S. requirements. More than 22,000 (65%) of those violative drug products were destroyed based on the new authority under section 801(u). In FY 2021, FDA destroyed over 59,000 violative drug products with more than 43,000 (74%) utilizing this authority. In FY 2022, FDA destroyed over 56,000 violative drug products with more than 33,000 (58%) utilizing this authority.

The Safeguarding Therapeutics Act

In the Safeguarding Therapeutics Act (Pub. L. 116-304), signed into law on January 5, 2021, Congress amended section 801(a) of the FD&C Act to grant FDA the authority to administratively destroy medical devices valued at \$2500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that have been refused admission into the United States. FDA is in the process of revising the associated regulation(s) necessary for implementing this new destruction authority.

Operation Opson

FDA continues to participate in the annual *Operation Opson*, which is a joint operation lead by Europol and INTERPOL that targets counterfeit and substandard food and beverages. *Operation Opson* began in 2010 and has grown to include over 60 participating countries.

Operation Pangea

FDA continues to participate in the annual *Operation Pangea*, which is coordinated by INTERPOL. *Operation Pangea* is a well-established international effort to disrupt the online sale of counterfeit and illicit health products. Since its launch in 2008 until now, *Operation Pangea* has removed more than 105 million units (pills, ampoules, sachets, bottles and so on) from circulation and made more than 3,000 arrests.

Other FDA Enforcement Actions

In addition to the operations discussed above, FDA-led enforcement cases during FY 2022 include the following prosecutions:

Woman sentenced for importing counterfeit products to the U.S. On March 18, 2022, Dina Al-Sbeihi of Merrillville, Indiana, pleaded guilty to a consumer fraud charge and was sentenced in the U.S. District Court, Northern District of Indiana, to 2 years of probation and 6 months of home detention, and ordered to pay a judgment of \$260,739.49. The investigation was initiated upon the detention by U.S. Customs and Border Protection of multiple packages addressed to Al-Sbeihi. The packages were found to contain counterfeit units of Restylane and Juvederm. The investigation revealed that Al-Sbeihi was selling the products through "The Beauty Pharmacy" located in Merrillville, Indiana and thebeautypharmacy.com. Through a series of undercover online purchases, additional evidence was obtained from Al-Sbeihi. Laboratory analysis conducted by the Forensic Chemistry Center determined that the products were not consistent with the authentic product provided by the manufacturer. Al-Sbeihi was indicted in June 2020 and later pleaded guilty to selling the counterfeit products from July 2015 through August 2019.

https://www.justice.gov/usao-ndin/pr/merrillville-woman-indicted-mail-fraud

https://property-reporter.com/merrillville-woman-gets-home-detention-for-selling-wrinkle-remover-knockoffs-crime-and-courts/

Texas man sentenced for selling counterfeit prescription drugs. Albert Boozer was sentenced to 4 months of imprisonment and a fine of \$2,000 for introducing misbranded drugs into interstate commerce. Investigation revealed that Boozer offered for sale counterfeit versions of Ambien, Cialis, clonazepam, hydrocodone, Soma, Tramadol, Valium, Xanax, and zopiclone, among others through the internet domain www.cheapmedstore.com.

https://casetext.com/case/united-states-v-boozer-4

DEPARTMENT OF HOMELAND SECURITY

Department of Homeland Security

"Customs and Border Protection remains committed to intercepting counterfeit and potentially dangerous consumer goods, and we strongly encourage consumers to protect themselves and their families by purchasing goods only from reputable vendors."

 Mark Laria, CBP Area Port Director, Area Port of Norfolk-Newport News

"A vehicle's airbag is an essential car safety feature and counterfeit airbags pose an invisible threat to a vehicle's occupants. Protecting the health and safety of the American consumer is a top priority for Customs and Border Protection, and CBP officers will continue to work closely with our law enforcement and consumer safety partners to intercept counterfeit and potentially dangerous consumer products."

 Joseph Martella, CBP Area Port Director, Area Port of Philadelphia

"Counterfeit airbags pose real dangers to unsuspecting members of the public. The risks of counterfeit and substandard auto parts are known by those who work in the automotive industry. . . . This investigation is yet another reminder of the risks posed by counterfeit goods." 9

 William S. Walker, Acting Special Agent in Charge, HSI Philadelphia

Department of Homeland Security Appendix for FY 2022 Annual Report

This appendix discusses the FY 2022 activities of the Department of Homeland Security (DHS). As outlined below, DHS's activities including protecting public and private acquisition supply chains from counterfeits; conducting law enforcement operations; engaging with stakeholders; educating the public; cooperating with foreign law enforcement; enhancing IP enforcement through international organizations; and providing capacity building and training to support IP enforcement in other countries. At the Department level, the DHS Office of Strategy, Policy, and Plans continues to maintain responsibility for coordinating the development and implementation of strategies and policies for the Department, including those related to trade, specifically, illicit trade, intellectual property rights, and counterfeiting and piracy. The DHS Private Sector Office (PSO) continues to coordinate U.S. Government-wide efforts to catalyze and support private sector and non-governmental-based counter-illicit trade activities. On the international stage, PSO seeks to coordinate conferences and workshops in key global locations (e.g., Asia, Eastern Europe, and Western Hemisphere) to collaborate on U.S. and international government efforts to bolster enforcement through the sharing of best practices and approaches for detecting and disrupting illicit trade activities. The U.S. Department of State is key to this

⁷ CBP press release, "Norfolk, VA CBP Officers Seize nearly \$2 Million in Counterfeit Diabetic Socks Destined to Loudoun County, VA" (July 14, 2022), at https://www.cbp.gov/newsroom/local-media-release/norfolk-va-cbp-officers-seize-nearly-2-million-counterfeit-diabetic.

⁸ CBP press release, "Federal Authorities Arrest Philadelphia Man who Allegedly Imported Counterfeit Airbags" (February 2, 2022), at https://www.cbp.gov/newsroom/local-media-release/federal-authorities-arrest-philadelphia-man-who-allegedly-imported.

⁹ DOJ press release, "Philadelphia Man Charged with Trafficking Counterfeit Airbags from China" (February 2, 2022) at https://www.justice.gov/usao-edpa/pr/philadelphia-man-charged-trafficking-counterfeit-airbags-china.

effort as their respective Missions work with host governments to strengthen their enforcement regimes.

The appendix includes two sections – submissions by the Homeland Security Investigations (HSI)-led National Intellectual Property Rights Coordination Center (IPR Center) and those of U.S. Customs and Border Protection (CBP).

National Intellectual Property Rights Coordination Center (IPR Center)

HSI is the principal investigative arm of the U.S. Department of Homeland Security, and is responsible for investigating transnational crime and threats, specifically those criminal organizations that exploit the global infrastructure through which international trade, travel, and finance move. As part of these efforts, HSI maintains a global footprint available to support investigations into IP violations with 86 attaché offices covering 55 countries, territories, and islands; and leads the IPR Center, bringing regulatory, civil, and criminal authorities under one roof—including the tactics, techniques, and procedures of the partner agencies—to fight counterfeiting and piracy, and to provide education to both agencies and the public about the danger and impact of IP theft.

Protecting Public and Private Acquisition Supply Chains from Counterfeits

Counterfeiting is a significant challenge that can impair supply chains for both the public and private sectors. This challenge has increased with the rise of e-commerce, as DHS explained in its January 2020 report on *Combating Trafficking in Counterfeit and Pirated Goods*.

In the context of the U.S. Government, acquiring products or services from sellers with inadequate integrity, security, resilience, and quality assurance controls create significant risks, from a national security and mission assurance perspective, as well as from an economic standpoint (due to the increased costs to American taxpayers). Counterfeiting can have significant consequences for the Department of Defense (DoD) supply chain by negatively affecting missions, the reliability of weapon systems, the safety of the warfighter, and the integrity of sensitive data and secure networks.

The goal is to reduce the risk of counterfeits entering the supply chain; quickly and collectively address those that do enter the supply chain; and strengthen remedies against those who provide counterfeit items.

DHS Training for Acquisition Professionals

Buyers in the public and private sectors need better visibility into and understanding of (1) how the products, services, and solutions they buy are developed, integrated, and deployed, and (2) the processes, procedures, and practices used to ensure the integrity, security, resilience, and quality of those products and services. This requires understanding the threat that counterfeits pose, mitigating their purchase and distribution, and identifying counterfeits and reporting them.

To address the systemic threat from counterfeits, the HSI-led IPR Center provides educational opportunities for public and private acquisition professionals. The IPR Center has coordinated with the ICE Chief Financial Officer to provide this training to all purchase card holders across the agency. Additionally, the IPR Center has posted free training on its website that is designed to provide acquisition professionals with the knowledge and skills they need to combat the counterfeit threat. The training on *Acquisition Professional Training: Counterfeit Awareness, Mitigation, Identification, and Reporting* is at https://www.iprcenter.gov/file-repository/acquisition-professional-training-1.pdf/view.

Law Enforcement Efforts to Secure the USG Supply Chain (Operation Chain Reaction)

In addition to the steps taken to secure the front end of the U.S. Government's supply chain (through Federal procurement regulations, supplier requirements, and acquisition training), the U.S. Government is also committed to protecting its vital interests by taking robust enforcement measures against those who sell counterfeit goods to the U.S. Government.

Operation Chain Reaction

Operation Chain Reaction provides comprehensive, cradle-to-grave supply chain risk management that targets counterfeit items entering the Department of Defense and U.S. Government supply chains. Meaningful results are garnered by focusing on key public and private partnerships, modernizing existing infrastructure and processes, exploiting inter-agency data sources, and identifying, neutralizing, and exploiting supply chain threats. This IPR Center-coordinated effort is led by HSI and consists of 17 Federal law enforcement agencies (including HSI, U.S. Customs and Border Protection (CBP), and DoD's criminal investigative offices).

In FY 2022, under *Operation Chain Reaction*, HSI initiated 16 criminal investigations, conducted 7 criminal arrests, and helped secure 11 indictments and 4 convictions, as well as 27 seizure incidents of counterfeit goods.

Other notable *Operation Chain Reaction* activities during FY 2022 included the following.

- The IPR Center coordinated with Orange County HSI for *Operation Chain Reaction* on a multi-year investigation resulted in an indictment on July 8, 2022. HSI Orange County and CBP, from July 2016 to February 2022, targeted 200 shipments resulting in 176 seizures valued well over \$5 million. In July 2021, HSI Miami and HSI Orange County executed a federal search warrant resulting in the seizure of 1,156 counterfeit network items with an estimated MSRP value of over \$7 million. The July 2022 indictment effectively disrupted an importer of over \$1 billion in counterfeit electronics.
- In March 2022, the IPR Center coordinated with HSI Oklahoma City for *Operation Chain Reaction* on targeting the importation and trafficking of counterfeit network equipment. On July 28, 2022, HSI Oklahoma City executed a federal residential search warrant resulting in the seizure of 1,388 items with an estimated MSRP value (if genuine) of \$3.4 million.

Law Enforcement Operations

Protection and enforcement of IP is a national priority, and U.S. law enforcement stands at the forefront of these efforts.

In addition to *Operation Chain Reaction* (discussed above), the DHS law enforcement efforts during FY 2022 included the following operations:

Operation Apothecary

Operation Apothecary is the IPR Center's public health and safety initiative that addresses, analyzes, and attacks potential vulnerabilities in the entry process that might allow for the smuggling of commercial quantities of counterfeit, unapproved, and/or adulterated drugs through international mail facilities, express courier hubs, and land borders.

In FY 2022, the IPR Center conducted two advanced domestic IP pharmaceutical trainings in New York City, NY and Los Angeles, CA. These trainings provided specialized investigative methodologies to special agents from HSI and the Federal Bureau of Investigations, as well as U.S. CBP officers. This training was geared towards advanced targeting and criminal investigative techniques that focused on the increase in mail and e-commerce shipments of counterfeit pharmaceuticals through illicit online pharmacies.

In September 2022, the IPR Center conducted two State-INL funded international trainings in conjunction with the Department of Justice (DOJ), International Cyber Hacking and Intellectual Property (ICHIP) division. The first training in Nairobi, Kenya provided advanced cyber, IP, and pharmaceutical training to Kenyan officials from various law enforcement agencies, the Pharmaceutical and Pesticide Board, and local prosecutors. Additionally, a second training was conducted in Ulaanbaatar, Mongolia where administrative, civil, and criminal judges were in attendance as well as prosecutors, law enforcement and the Mongolian Intellectual Property Rights Office. This training also focused on cyber, IP and pharmaceutical training and sought to establish key partnerships within the region.

During FY 2022, under *Operation Apothecary*, HSI initiated 63 criminal investigations, 22 arrests, 28 indictments, and 21 convictions, as well as 66 seizure incidents of counterfeit items.

E-Commerce/Operation in Our Sites

The E-Commerce Program is an on-going HSI initiative targeting entities that sell counterfeit products through the internet. This program consists of the well-known operation, *Operation in Our Sites* (IOS), which was initiated in 2010 as a method to disrupt this activity online. The e-Commerce initiative focuses on developing long term investigations that identify targets, assets, and financial schemes used in operating infringing websites devoted to trafficking in infringing materials. It also emphasizes working in partnership with third-party entities, such as online marketplaces, payment processors, and the express consignment industry. Additionally, the IPR Center coordinates with rightsholders, who utilize civil and administrative remedies to shutdown infringing sites.

In recognition of the wide reach of e-commerce into many of its programmatic areas, HSI promulgated a single agency strategy on February 14, 2018. The HSI e-Commerce Strategy emphasizes an agency approach that leverages collaboration between private industry and law enforcement partners in an effort to act as a force-multiplier in a cooperative enforcement approach to identify and dismantle organizations, and to prosecute persons or entities, that traffic in all manners of dangerous and illicit goods utilizing various e-commerce outlets including open-net websites, the dark web, point-to-point sales platforms, social media, and a variety of payment processors and shipping methods.

In FY 2022, in furtherance of the e-Commerce Strategy, IPR Center personnel conducted several meetings with representatives from online platforms, payment processors, and the shipping industry for the purpose of furthering dialogue about how to share information for the purpose of stopping the online sale of counterfeit goods.

In FY 2022, under *e-Commerce/IOS*, HSI initiated 22 criminal investigations, conducted 4 arrests, and helped secure 3 indictments and 1 conviction, and 102 seizures. These investigations are initiated and developed by HSI field offices through IPR Center leads, seizures, informants, complaints, industry leads, and/or other investigative techniques.

Operation Engine Newity

Operation Engine Newity (OEN) is an HSI-led, IPR Center initiative that focuses on securing the supply chains of automotive and other heavy industry from counterfeit components. The proliferation of counterfeit parts – including critical components such as airbags, bearings, brake pads, accelerator arms, and windshields – has grown exponentially over the last several years and now poses a significant health and safety threat to end users and an economic cost to businesses and consumers through lost revenue, downtime, and replacement costs.

OEN personnel work closely with automotive original equipment manufacturers (OEMs), aftermarket parts manufacturers and suppliers, and other automotive parts and equipment companies, including members of the Automotive Anti-Counterfeiting Council (A2C2) and the Automotive Aftermarket Suppliers Association (AASA) Intellectual Property Council. The companies support criminal investigations by providing case support and product authentication.

- In October 2019, *Operation Engine Newity* industry partner notified HSI New York, Seaport Border Enforcement Security Task Force (NYC BEST) regarding counterfeit automotive merchandise. On January 14, 2022, HSI NYC BEST executed a federal search warrant resulting in the seizure of approximately 307 items with an estimated MSRP value (if genuine) of \$331K.
- On April 15, 2022, the IPR Center coordinated with HSI Portland for *Operation Engine Newity* on targeting the importation and trafficking of counterfeit automotive merchandise. On May 4, 2022, HSI Portland executed a search warrant resulting in the seizure of 5,124 items with an estimated MSRP value (if genuine) of \$375K and \$70K in seized currency.

- In March 2022, *Operation Engine Newity* brand partners notified HSI Detroit about counterfeit automotive merchandise. On April 25, 2022, HSI Detroit conducted a knockand-talk resulting in the seizure of approximately 2,400 items with an estimated MSRP value (if genuine) of \$100K.
- On May 2-4, 2022, IPR Center representatives traveled to Portland, OR to meet with HSI Portland and assist with executing a search warrant with Portland Police Bureau, and representatives of A2C2.
- In March 2019, U.S. Customs and Border Protection notified HSI Detroit regarding a detained shipment of suspected counterfeit automotive merchandise. This multi-year investigation became *Operation Slow Your Roll* and culminated on July 5, 2022, when HSI Detroit executed a search warrant resulting in the seizure of approximately 23,397 items with an estimated MSRP value (if genuine) of \$14.4 million.

In FY 2022, under *Operation Engine Newity*, HSI initiated 21 criminal investigations, conducted 3 criminal arrests, and helped secure 3 indictments and 5 convictions, as well as 61 counterfeit goods seizures incidents with an estimated MSRP value (if genuine) of approximately \$14 million.

Operation Surge Protector

Operation Surge Protector (OSP) was initiated by the IPR Center in December 2016 to target the sale and trafficking of counterfeit consumer electronics and technology products, such as batteries, chargers, smartphones, and charging cords. OSP combines the expertise of HSI, CBP and the Consumer Product Safety Commission (CPSC).

From May 24-26, 2022, representatives of OSP worked in conjunction with CBP and HSI on an enforcement operation, *Operation Apple Peel*, at JFK Airport, New York that focused on identifying counterfeit Apple products.

In FY 2022, under *Operation Surge Protector*, HSI initiated 18 criminal cases, conducted 5 arrests, and helped secure 5 indictments and 4 convictions, as well as 57 counterfeit goods seizures incidents with an estimated MSRP value (if genuine) of approximately \$229 million.

Operation Body Armor

Operation Body Armor, which combines the expertise of HSI, CBP, and FDA-OCI, was initiated in January 2015 by the IPR Center in partnership with industry and other entities associated with the healthcare and beauty product community to combat the sale of counterfeit personal healthcare and beauty products.

In FY 2022, under *Operation Body Armor*, HSI initiated 4 criminal cases and seized counterfeit goods with an estimated MSRP (if genuine) of approximately \$11 million.

Operation Intangibles

In December 2019, the IPR Center hosted the inaugural event for *Operation Intangibles* at the first ever HSI digital piracy symposium. This symposium brought law enforcement and CCI experts together to address stakeholders' concerns in copyright protection and enforcement efforts. This symposium further addressed collaborative efforts in countering digital piracy to further protect a vital sector of the U.S. economy.

Through this initiative, the IPR Center collaborates with industry partners to develop effective digital piracy training for law enforcement and creates avenues of access to CCI subject matter and techincal experts for investigative assistance. This initiative merges HSI's foreign and domestic investigative resources with industry partners in a global effort to counter the growth of digital piracy. Through *Operation Intangibles*, HSI investigative and operational programs will be more effective in targeting the entire digital piracy ecosystem for disruption and dismantlement.

- On April 21, 2022, the IPR Center and the Recording Industry Association of America (RIAA) signed a memorandum of understanding. Through the agreement, the IPR Center and RIAA will coordinate public and private sector efforts to disrupt and combat all forms of digital piracy by implementing an aggressive multi-layered strategy to strengthen the digital ecosystem, conducting joint training events, educating consumers on the dangers of illegal streaming, enforcing the nation's intellectual property rights laws, and dismantling large-scale online criminal enterprises. The agreement will also work to develop comprehensive lead referral packages on the most egregious violators for criminal investigation.
- On June 14, 2022, HSI DC executed six seizure warrants for commercial website domain names offering unauthorized copyright-protected content. The enforcement action was part of a Government of Brazil-led international operation targeting digital piracy dubbed "Operation 404." This was an HSI DC led investigation with significant support from HSI Brasilia and the IPR Center; DOJ's EDVA, ICHIP and CCIPS; and Brazil entities.

Operation Team Player

Operation Team Player (OTP) targets the sale and trafficking of counterfeit sports merchandise, apparel and tickets, a multi-million-dollar criminal industry. The culmination of the sports season—playoffs and finals games—are events that stimulate the sale of counterfeit items. HSI special agents and CBP officers worked with sports leagues and law enforcement agencies throughout the nation to identify shipments of counterfeit sports merchandise being imported to the United States or being sold by vendors. In FY 2022, the IPR Center continued coordinating enforcement actions at multiple high-profile sporting events, including the National Football League (NFL) Pro Bowl and Super Bowl, Major League Baseball (MLB) World Series, National Hockey League (NHL) Winter Classic, National Hockey League (NHL) and National Basketball Association (NBA) All-Star games NCAA Championships, and the English Premier League international matches.

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- On December 5-8, 2022, IPR Center representatives traveled to Los Angeles, CA to meet with HSI Los Angeles, law enforcement partners, and the NFL to coordinate planning of IPR enforcement efforts for Super Bowl LVI.
- On February 4-14, 2022, IPR Center representatives traveled to Los Angeles, CA to coordinate *Operation Team Player* enforcement operations targeting the importation and trafficking of counterfeit sports merchandise and media activities related to Super Bowl LVI. As a result of these efforts, task force officers arrested 4 individuals and seized approximately 55,797 items with an estimated MSRP value of \$5,737,763.
- On May 4-6, 2022, a representative of OTP and representatives from HSI New York, traveled to Portland, OR to meet with representatives from Nike and discuss ongoing collaboration and lead development.
- On June 8, 2022, the IPR Center presented at a virtual INTERPOL seminar on *IP Crime and Sports Events*. The IPR Center provided an overview of *Operation Team Player* including operational and investigative planning consideration for law enforcement. The seminar included presentations from law enforcement and rightsholders. Participants included law enforcement representatives from more than 30 countries.
- On July 10-14, 2022, a representative of OTP traveled to Cincinnati, OH to conduct a joint enforcement interdiction operation, Home Plate VIII, with CBP targeting counterfeit sports apparel and merchandise.
- The IPR Center coordinated *Operation Team Player* gameday enforcement operations targeting the trafficking of counterfeit sports merchandise around high-profile sporting events involving the English Premier League in Baltimore, MD and Houston TX. On July 15-16, 2022, IPR Center representative traveled to Baltimore, MD to conduct training and gameday enforcement operation at M&T Bank Stadium for the Charm City Match, involving the English Premier Clubs Everton and Arsenal. On July 18-21, 2022, IPR Center representatives traveled to Houston, TX to conduct training and gameday enforcement anti-counterfeiting operations at NRG Stadium for the Copa Lone Star Match, involving the English Premier League club Manchester City and Liga Mexico Club America. The operations were conducted by teams comprised of HSI Baltimore, HSI Houston, IPR Center, Houston Police Department, and representatives from the English Premier League.
- On August 1-3, 2022, representative of OTP traveled to Phoenix, AZ to meet with HSI Phoenix, CBP, law enforcement partners, and industry representatives from the NFL, NHL, NBA, MLB, and National Collegiate Athletic Association (NCAA). The OTP representative provided training on the IPR Center and OTP at the Super Bowl LVII Law Enforcement Training event hosted by the NFL. In attendance were representatives of federal, state, and local law enforcement, as well as industry representatives from the sports brand industry.

Operation Pangea

Operation Pangea is a coordinated global effort led by INTERPOL as a means of further reducing the advertisement, sale, and supply of counterfeit, unapproved, and substandard medicines and medical devices. Websites providing counterfeit pharmaceuticals are a significant and growing global problem both from a public health and safety standpoint, as well as from an intellectual property protection standpoint. INTERPOL conducted Operation Pangea XV from June 23-30, with IPR Center personnel assigned to the Interpol Command Center. During the FY 2022 iteration of Operation Pangea, 94 INTERPOL member countries undertook more than 7,800 seizures of illicit and falsified medicines, totaling more than 3 million individual units. Additionally, participating countries shut down or removed more than 4,000 web links containing adverts for illicit products. The seizures resulted in over 600 new investigations being opened and 200 warrants being issued.

Operation Stolen Promise

Operation Stolen Promise (OSP) was launched by HSI in April 2020 to protect the Homeland from the increasing and evolving threat posed by COVID-19-related fraud and criminal activity. *Operation Stolen Promise* combines HSI's expertise in global trade, financial fraud, international operations, cyber-crime, and criminal analysis to investigate financial fraud schemes, the importation of prohibited pharmaceuticals and medical supplies, websites defrauding consumers, and any other illicit criminal activities associated with the virus that compromise legitimate trade or financial systems or endanger the public.

Operation Stolen Promise is based on the following pillars:

- Develop Actionable Investigative and Intelligence Leads
- Disrupt and Dismantle Fraud Schemes, Take Down Illicit Websites and other Online Marketplaces, and Seize Counterfeit or Illicit Pharmaceuticals and Medical Devices
- Launch a Robust Public Awareness Campaign

Since the launch of *Operation Stolen Promise*, HSI has made 3,958 COVID-19 related seizures, initiated 1,570 criminal investigations, conducted 540 search warrants, arrested 557 perpetrators, and seized over \$65M in illicit proceeds (as of September 30, 2022). As efforts to combat COVID-19 progress, HSI initiated *Operation Stolen Promise 2.0* in November 2020 to focus on counterfeit vaccines, while continuing to investigate the trafficking of counterfeit personal protective equipment.

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DHS's law enforcement activities during FY 2022 also included the following activities:

• In FY 2022, HSI initiated 829 intellectual property theft investigations and was involved in 258 arrests, 191 indictments, and 94 convictions.

• In FY 2022, the IPR Center vetted 13,222 investigative leads; of these, 61 were referred to law enforcement partners. Finally, the IPR Center de-conflicted 87 investigative targets for partner agencies and industry.

Engaging with Stakeholders

The IPR Center forms the communications hub around which much of the interaction between private sector stakeholders and the law enforcement and regulatory communities takes place.

The January 2020 DHS report on *Combating Trafficking in Counterfeit and Pirated Goods* recommended numerous "Immediate Actions by DHS and Recommendations for the U.S. Government" (https://www.dhs.gov/sites/default/files/publications/20_0124_plcy_counterfeit-pirated-goods-report_01.pdf). Recommendation six acknowledged the work of the IPR Center E-Commerce Working Group (ECWG) and recommended the formation of the Anti-Counterfeiting Consortium to Identify Online Nefarious Actors (ACTION).

On January 13, 2022, the IPR Center hosted an ACTION meeting. During this meeting, 14 ACTION participants engaged in discussions concerning the structure of ACTION and the E-Commerce Working Group moving forward, including standardizing the procedures for joining ACTION and for information sharing between companies and law enforcement.

Operation Joint Venture and Project Trade Watch

Through the IPR Center's Outreach and Training Section, HSI coordinates with the public and private sectors to combat IP infringement through its *Operation Joint Venture* (OJV) initiative. This IPR Center-led outreach initiative is designed to increase information sharing with public and private sectors to combat the illegal importation and distribution of counterfeit, substandard and tainted goods, as well as the evasion of duties. The initiative is aimed at fostering investigations into commercial fraud, including activities that threaten public health and safety and violate IP rights. Through OJV, the IPR Center engages with rightsholders, manufacturers, importers, customs brokers, freight forwarders, bonded facilities, carriers, and others to discuss the IPR Center's priorities of protecting public health and safety, the economy, and the U.S. Government's supply chain. Through outreach and public engagement, the IPR Center raises the public's awareness of the dangers of commercial fraud violations (such as those involving IP) and serves as a public point of contact for investigative leads. The IPR Center's audience includes a broad spectrum of industries and government agencies, including but not limited to the pharmaceutical, entertainment, wearing apparel, sports, electronic, and automobile industries, as well as customs bonded entities, importers, and law enforcement officials.

Project Trade Watch is HSI and CBP's outreach campaign to the importing community to facilitate informed compliance by private industry and to enhance public awareness of law enforcement efforts within the trade community. This campaign exists under the IPR Center's broader OJV initiative. Through **Project Trade Watch**, HSI and CBP field personnel provide information and red-flag indicators of potential import fraud and importer identity theft.

Other Engagements

DHS law enforcement agencies which support IP enforcement had numerous other engagements with stakeholders during FY 2022. Some of these public education and outreach efforts are described below.

The IPR Center has a unique role within the U.S. Government by serving as a one-stop shop for IP enforcement efforts. In this role, the IPR Center has regular contact with the international community, the media, Members of Congress, trade organizations, industry leaders, and the public. In FY 2022, the IPR Center conducted 107 outreach and training events with 5,494 attendees.

In FY 2022, the IPR Center continued the monthly publication of the *IPRC Connections* newsletter to keep stakeholders up to date on the most significant IPR Center enforcement efforts and outreach activities. Additionally, the IPR Center collects, tabulates, and catalogs victim impact accounts of brand holders and consumers with the aim to show more clearly the full effect of IP infringement and trade fraud on the U.S. and global economies, public health and safety, and any related threat to government supply chains.

Throughout FY 2022, HSI – through its leadership at the IPR Center – collaborated with industry and other government agencies to present training and foster communication. Examples of this include:

- Engaged the Automotive Anti-Counterfeiting Council (A2C2) and the Automotive Aftermarket Suppliers Association (AASA) to provide case-study training addressing counterfeit automobile parts.
- Collaborated with DOJ's Computer Crime and Intellectual Property Section (CCIPS) and USPTO to provide virtual training on various IP Enforcement topics and COVID-19-related fraud.
- Liaised with CBP's Office of Trade on numerous virtual training opportunities in combating commercial fraud and intellectual property rights enforcement.
- IPR Center HSI personnel assigned to the National Cyber-Forensics and Training Alliance (NCFTA) leverage the resources and analytical tools of the NCFTA to identify domain names and networks affiliated with infringing activity in support of criminal investigations or potential civil enforcement action. (The NCFTA is a non-profit corporation that conducts real-time information sharing and analysis with subject matter experts in the public and private sectors and academia.)

Educating the Public

In FY 2022, the IPR Center – in coordination with Michigan State University's Center for Anti-Counterfeiting and Product Protection (A-CAPP), hosted a forum with Co-Founder of Detroit - vs- Everybody to discuss brand protection to help creatives protect their business against IP theft

in support of World Intellectual Property Day 2022. With more than 6 million business owners in the U.S. under the age of 35, the April 2022 World IP Day theme focused on young entrepreneurs. Supporting the theme "IP and Youth: Innovating for a Better Future," this outreach effort focused on sharing best practices for future innovators who will, in turn, supply the world with their own world-changing ideas. By highlighting *IP Protect*, an IPR Center initiative launched in 2021 in conjunction with Michigan State's A-CAPP, future creators were given tools to effectively navigate IP rights and enforcement.

Cooperating with Foreign Law Enforcement

As discussed above, DHS law enforcement agencies regularly cooperate with other Federal law enforcement agencies and with law enforcement offices in other countries. Below are especially notable examples of DHS cooperation with foreign law enforcement.

In FY 2022, as discussed above, U.S. law enforcement and Federal agencies – including the IPR Center through HSI, CBP, and FDA – participated in *Operation Pangea*, a global enforcement effort led by INTERPOL that is aimed at disrupting organized crime networks behind the illicit online sale of fake drugs. The majority of Pangea participant countries conducted a week of coordinated enforcement efforts from June 23-30, 2022.

Through the U.S.-China IP Criminal Enforcement Working Group, DOJ and U.S. law enforcement (including HSI and FBI) maintain a steady exchange of information and case leads with Chinese law enforcement, resulting in successful operations to disrupt the manufacture of counterfeit items, such as airbags, pharmaceuticals, batteries, electronic components, and luxury items.

During FY 2022, the IPR Center was again able to physically host foreign government officials with an interest in IP enforcement at the IPR Center. These included delegations from Canada, Indonesia, and Saudi Arabia. The IPR Center also engaged with foreign counterparts in meetings and various outreach and training efforts throughout the world. Among these were representatives from Algeria, Bahrain, Bangladesh, Bhutan, Botswana, Brazil, Bulgaria, Cambodia, Canada, Egypt, Eswatini, India, Indonesia, Kenya, Laos, Lesotho, Malaysia, Maldives, Mongolia, Morocco, Myanmar, Nepal, Oman, Pakistan, Panama, Peru, Philippines, Romania, Saudi Arabia, Senegal, Singapore, South Africa, South Korea, Sri Lanka, Thailand, and Vietnam.

Capacity Building and Training

DHS engages in training and capacity building programs to strengthen intellectual property awareness and enforcement domestically and abroad.

Domestic Capacity Building and Training

The IPR Center works closely with partner USG agencies, as well as state and local officers, to deliver training and support domestic investigative and enforcement capacity throughout the U.S.

In FY 2022, the IPR Center conducted multiple domestic training programs in support of these efforts, as described below.

The *Intellectual Property and Trade Enforcement Investigations* (IPTEI) course is hosted by the IPR Center. The IPTEI offers advanced training with a specific focus on commercial fraud and IP theft. Presenters are CBP and HSI subject matter experts in selected topics and programs. HSI and CBP field personnel are the target audience for this training, which also supports the educational requirement of the Trade Facilitation and Trade Enforcement Act of 2015. Additional attendees may include representatives from the IPR Center partner agencies, DHS, and DOJ, as well as task force officers placed within HSI field offices representing local and federal law enforcement. The course is evaluated through anonymous online surveys which are used to review and enhance the training curriculum.

In FY 2022, due to the COVID-19 pandemic, the IPR Center continued offering the IPTEI training course virtually. Three online sessions (20 training hours each) were held in FY 2022, attracting over 300 participants.

The IPR Center also coordinates and hosts virtual training to partner agencies on the use of USPTO's Trademark Electronic Search System (TESS) and CBP's Intellectual Property Rights Search (IPRS) systems in support of IP enforcement and investigative efforts.

Additionally, the IPR Center delivered multiple IP and commercial fraud-focused trainings to U.S. federal, state, and local officials in FY 2022, including:

- In June 2022, the IPR Center delivered intellectual property training in Henderson, Nevada to HSI, CBP and Nevada state and local authorities. The training included investigative best practices with presenters from the pharmaceutical, apparel, sport apparel, and automotive industries.
- In July 2022, the IPR Center and NCFTA co-sponsored a training workshop focused on counterfeit pharmaceutical and medical supplies investigations in Los Angeles, California to HSI, CBP, and State and Local officials.
- In July 2022, the IPR Center delivered IP enforcement training in San Juan, Puerto Rico to HSI, CBP and FBI officers. The training included presentations from private sector to enhance the investigative capacity and sharing of information in combating IP theft.

Foreign Capacity Building and Training

The IPR Center works closely with partner USG agencies, overseas attachés, and U.S. embassies to deliver training and support capacity building efforts across the globe. These efforts are conducted through multiple channels, including the interagency International Law Enforcement Academy (ILEA) program, INTERPOL programs, and the *Global Intellectual Property Rights Foreign Law Enforcement Training and Technical Assistance Initiative* that is funded through the Department of State's Bureau of International Narcotics and Law Enforcement Affairs (INL).

This initiative – administered cooperatively by the IPR Center, DOJ CCIPS, DOJ OPDAT, and USPTO – is designed to complement the U.S. Transnational and High-Tech Crime Global Law Enforcement Network (GLEN) in developing and delivering training and technical assistance on IPR and computer crimes to foreign partners in the investigative, prosecutorial, judicial, and customs and border enforcement areas. The initiative is designed to strengthen the enforcement capacity of these foreign partners for IPR matters involving transnational organized crime.

Through this initiative, the IPR Center, in conjunction with HSI Attaché offices, directs, organizes, and delivers regional IPR training in the form of lectures and presentations to foreign customs, police, prosecutors, and magistrates. The IPR Center training programs are typically held in person for 3-5 days and focus on the investigation and prosecution of IPR violations and associated crimes like smuggling and money laundering. The training programs are interactive workshops led by subject matter experts and focus particular on health and safety counterfeited items such as pharmaceuticals, electronics, automotive parts, and health and beauty products. With the growing number of e-commerce marketplaces, the training programs also focus on internet investigations. Private sector representatives or associations are invited to participate in many of the training programs to highlight the challenges their industry sector may face in a particular region and to highlight the necessity of government and industry cooperation.

In FY 2022, the IPR Center participated in 50 international training and outreaches in support of these programs. HSI continues to work closely with its foreign law enforcement counterparts, particularly those who received training in IP enforcement. The following are examples of training events that HSI either organized or supported via their international program.

• USPTO-sponsored Online Pharmaceutical IP Enforcement Workshop - Peru – Virtual Webinar

From October 26-27, 2021, USPTO sponsored an online counterfeit pharmaceutical training for Peruvian officials from the National Superintendency of Customs and Tax Administration (SUNAT) and the General Bureau for Medicines, Drugs, and Inputs (DIGEMID), Police (PNP), INDECOPI and other agencies involved in IP prosecutions. HSI provided two case studies on counterfeit pharmaceutical investigations and participated on a panel focused on best practices for combatting the online sale and distribution of counterfeit medicines.

• DOJ ICHIP/IPR Center co-sponsored program – Investigation of Crimes Against Intellectual Property Workshop - Panama City, Panama

From February 22-25, 2022, the National Intellectual Property Rights Coordination Center (IPR Center), the U.S. Department of Justice, International Computer Hacking and Intellectual Property (DOJ/ICHIP) attorney advisor, and Homeland Security Investigations (HSI) Panama City, along with interagency and international partnerships with U.S. Customs and Border Protection (CBP) and the U.S. Department of State (DOS), held an in-person training program in Panama City, Panama. The purpose of the workshop was to share best practices and principles for investigating cases involving trademark and copyright infringement in the hard goods and online contexts. The training also focused on developing investigations of trade-based money laundering (TBML) stemming from the smuggling of counterfeit goods into and through Panama.

Members of Panama's Frontier, Aeronaval, and Maritime Services, along with members of HSI's Trade Transparency Unit (TTU), attended the training. Participants were given the opportunity to learn about authenticating U.S. rights-holders' products during classroom instruction and by participating in an interactive rights-holder trade fair.

International capacity building programs, such as this training, are critical to the U.S. Government, and the international community's efforts in combatting the threats identified in the intellectual property environment, including the increasing health and safety risks posed by counterfeit goods. Providing an overall understanding of the complexities involved in these matters, including challenges related to commodity awareness, interdiction, investigation and prosecution allow investigators and law enforcement professionals to have the greatest impact in disrupting the efforts of transnational criminal networks involved in illicit activities. This in-person program was also crucial in building a working relationship between police, prosecutors, and border officials to better tackle counterfeit smuggling occurring at Panamanian ports.

• Intellectual Property Rights Investigative Methods Training: Egypt – Cairo, Egypt

From March 27-31, 2022, the IPR Center, in collaboration with HSI Cairo, provided intellectual property rights investigative methods training to Egyptian investigators, judges, prosecutors, and customs officials. The training was held in Cairo, Egypt and supported by HSI Computer Crimes Center (C3), HSI Sacramento, HSI New Orleans, HSI Tel Aviv, HSI Toronto, HSI Frankfurt, HSI Nairobi, U.S. Department of State, Bureau of International Narcotics and Law Enforcement Affairs (INL), U.S. Department of Justice, Office of Overseas Prosecutorial Development, Assistance, and Training (OPDAT), FBI, CBP, USPTO, and Interpol.

The training workshop provided participants with an increased understanding of the complexities and threats identified in the intellectual property environment, including the increasing health and safety risks posed by counterfeit goods. The training featured HSI case-study presentations on pharmaceuticals, cell phones, digital piracy, and methods to investigate and combat transnational cyber-enabled intellectual property crime. Industry representatives from Amazon, Apple, General Motors, Moderna, Nike, Philip Morris International (PMI), and Procter & Gamble delivered presentations outlining their enforcement efforts and collaboration with law enforcement to combat counterfeit goods and illicit trade.

The training addressed challenges and best practices related to interdiction, investigation and prosecution of intellectual property crimes to allow law enforcement agencies the greatest impact in disrupting transnational criminal networks involved in these illicit activities. This HSI-led international capacity-building training workshop was funded by the U.S. Department of State, INL.

• South Africa Regional Intellectual Property Rights Investigative Methods Training – Durban, South Africa

From May 9-13, 2022, HSI Pretoria, in coordination with the IPR Center, hosted a training conference in Durban, South Africa for 35 police investigators, customs officials, and prosecutors from South Africa, Botswana, Eswatini, and Lesotho. Opening Remarks were given by Consul General Anne Linnee from the U.S. Consulate in Durban. The participants heard presentations from the IPR Center, DOJ CCIPS, CBP Container Security Initiative (CSI), HSI agents from HSI New York, HSI Phoenix, HSI Houston, and ICE OPR Denver, and multiple private industry brand holders. Additionally, the South African Police Service (SAPS), South Africa Health Products Regulatory Authority (SAHPRA), the South Africa National Prosecuting Authority Asset Forfeiture Unit (NPA AFU), and the South Africa Companies & Intellectual Property Commission (CIPC) presented on the role of each agency in fighting counterfeiting crimes in Southern Africa. The participants left the training conference with an increased capacity to investigate and prosecute IPR crimes, as well as an expanded network of contacts across the stakeholder countries and agencies involved in IPR enforcement in Southern Africa.

• USPTO Global Intellectual Property Academy: Counterfeit Medicines Workshop (Romania/Bulgaria)

On June 9, 2022, the IPR Center provided a presentation on counterfeit pharmaceutical products and international cooperation to delegations from Romania and Bulgaria. This event was part of a 3-day program organized by USPTO and FDA.

• TEAMING UP: Combatting IP Crime in Eastern Europe: ICHIP Romania Enforcement Workshop – Bucharest, Romania

On June 8-9, 2022, the IPR Center, represented by HSI Anchorage and CBP, supported a DOJ ICHIP Romania-led IP Infringement in Sports training workshop hosted in Bucharest, Romania. The IPR Center representatives provided instruction on best practices for small parcel targeting and interdiction, as well as a case-study presentation involving counterfeits and small parcels.

• USPTO-sponsored Customs Workshop – Rabat, Morocco

On June 14-16, 2022, the IPR Center, represented by HSI Houston, supported a USPTO-led Customs Enforcement Workshop for officials from Morocco. The IPR Center representative provided an IP Enforcement case study presentation.

• DOJ /ICHIP African Regional Pharma Crime Working Group – Dakar, Senegal On June 15, 2022, HSI supported a DOJ/ICHIP Abuja-sponsored training event for west African countries to learn and discuss best practices in the identification, interdiction, and enforcement of counterfeit pharmaceuticals in west Africa. HSI provided an introduction of HSI, instruction on IPR Center programs, and a case study/program overview of Operation Stolen Promise.

• USPTO-sponsored Customs Workshop – Algiers, Algeria On June 20-22, 2022, HSI supported a USPTO sponsored IPR border enforcement workshop in Algiers, Algeria with an audience of 40 Algerian Customs, Office of Trade

and Administrative Judges. CBP discussed the workflow of a seizure from targeting to destruction. HSI presented an IPR 101 session, and participated in a panel discussion with DOJ/ICHIP on criminal investigations and prosecution. HSI also participated in a panel discussion with CBP and DOJ on the entire US IPR enforcement timeline.

USPTO Regional Workshop on Enforcement Against Counterfeits – Bangkok, Thailand

On June 28-30, 2022, the IPR Center International Training Program Manager provided instruction at a USPTO-led Indo-Pacific Regional Workshop on Enforcement Against Trade in Counterfeit Goods, in Bangkok, Thailand. The focus of the training workshop was on both the challenges faced by IP rights holders in confronting counterfeits, and the effective practices implemented by law enforcement agencies in enforcing laws against such counterfeit goods, both in physical markets and online. It was attended by 122 individuals, from the private and public sectors, and 21 countries and U.S. territories in the Indo-Pacific region.

- DOJ/ICHIP Tri-Border Regional IPR Enforcement Training Asuncion, Paraguay On August 8-10, 2022, the IPR Center supported a DOJ/ICHIP Brazil-hosted IP Enforcement training for officials from the Tri-Border Region in South America. The program shared best practices and principles for investigating cases involving trademark and copyright infringement in the hard goods and online contexts. The training also focused on developing investigations of trade-based money laundering stemming from the smuggling of counterfeit goods, and investigations of dark web markets involved in counterfeiting. The course provided an opportunity for multilateral engagement with key Southern Cone countries connected to the Tri-Border Area with a special focus on customs enforcement and digital piracy initiatives. Paraguayan, Brazilian, Uruguayan, and Argentinian police, prosecutors, border officials and judges participated.
- USPTO-sponsored Customs Workshop Manama, Bahrain
 On August 28-30, 2022, the IPR Center International Training Program Manager
 provided instruction at a USPTO-led regional workshop on counterfeit enforcement.
 This three-day IPR Border Enforcement Workshop was organized by USPTO-OPIA and
 funded from by the Department of State. The program hosted a total of 29 officials
 consisting of 6 Omani Customs officials, 15 Bahraini Customs officials and 8 Ministry of
 Trade and Commerce officials.
- Department of Commerce, Commercial Law Development Program (CLDP)-sponsored Customs Workshop Tivat, Montenegro

 On September 6-9, 2022, the IPR Center, represented by HSI Toronto, provided presentations for customs, prosecutors, and judicial officials from various Balkan countries at a CLDP-hosted Western Balkans Regional IP Training Workshop in Tivat, Montenegro. The workshop provided anti-counterfeiting strategies involving customs, prosecutorial, and judicial perspectives in the U.S. and Balkans regions.

• Intellectual Property Rights Investigative Methods Training – Kenya – Nairobi, Kenya

On September 12-16, 2022, the IPR Center, in coordination with HSI Nairobi, hosted a training workshop in Nairobi, Kenya for 38 investigators, customs officials, and prosecutors from Kenya. The participants heard presentations from the IPR Center, DOJ CCIPS, USPTO, CBP, and HSI agents, as well as multiple private industry brand holders. Additionally, representatives from the Kenya Revenue Agency, the Office of the Director of Public Prosecutions, Anti-Counterfeit Authority, and Pharmacy and Poisons Board presented on the role of each agency in fighting counterfeiting crimes in Kenya. The participants left the training conference with an increased capacity to investigate and prosecute IPR crimes, as well as an expanded network of contacts across the stakeholder agencies involved in IPR enforcement in Kenya.

• USPTO and DOJ-sponsored IP Enforcement Program – Ulaanbaatar, Mongolia On September 26-30, 2022, the IPR Center pharmaceutical program manager supported a five-day workshop in Ulaanbaatar, Mongolia to train 239 judges, police, Prosecutors on intellectual property rights enforcement. This workshop was DOJ-lead training through the Hong Kong ICHIP and focused on digital forensics, cyber hacking, IP investigative methods and judicial process.

U.S. Customs and Border Protection (CBP)

U.S. Customs and Border Protection engages with stakeholders on a regular basis to educate them about how to best work with CBP to protect their intellectual property rights at the border. A sample of the Office of Trade's (OT) engagement with the trade community in FY 2022 include the following:

- On December 14, 2021, CBP participated in a virtual panel discussion at the US China Intellectual Property Exchange & Development Foundation directed to over 400 importing and exporting companies conducting business in both China and the United States. The discussion focused on IP border enforcement in the United States and how it compares with China.
- On December 14 and 16, 2021, as well as January 24 and 26, 2022, CBP provided webinar sessions to groups of e-Recordation Points of Contacts indicated in the e-Recordation system. The sessions were titled "Webinar for Recordation POCs: Best Practices in Working with CBP to Enforce Your IPR at the Border" and attracted around 200 participants in every session. The goal of these webinars was to educate recordation POCs on CBP enforcement procedures, such as enforcement timelines, disclosure rules, and how best to assist CBP Officers and Import Specialists when they reach out for authenticity assistance.
- On January 7, 2022, OT spoke at the Practicing Law Institute's *Intellectual Property Law Institute 2022* on CBP's enforcement of intellectual property rights at the border. This

- program provided information on key events in all areas of IP, including recent legislation and agency developments in IP border enforcement.
- On January 5-7, 2022, CBP attended the annual Consumer Electronics Show (CES) in Las Vegas as part of International Trade Administration's STOPfakes team. STOPfakes is a 10-agency government initiative aimed at providing U.S. businesses with IP resources and curtailing the trade in counterfeit goods. At CES, CBP interacted with hundreds of conference attendees and discussed their intellectual property concerns in the border enforcement context. CBP shared the IP protection resources available through CBP's e-Recordation program, where trademark and copyright owners can apply to CBP for border enforcement of their IP.
- On January 27, 2022, CBP hosted a sixth webinar as part of the Office of Trade Year of the SME programming, which provides free educational webinars directed to small and medium enterprises on how to protect their intellectual property rights, entitled "Is Gray Market Protection Right for You? Understanding CBP's Gray Market and Lever-rule Enforcement Program." The webinar provided instruction to IP owners on CBP's enforcement of restricted gray market merchandise as well as how to apply for such protection.
- On February 2, 2022, CBP participated in the Department of Commerce's STOPfakes Virtual Roadshow in coordination with the Boise U.S. Export Center on the government resources available to U.S. intellectual property owners experiencing IP theft. The Boise U.S. Export Center garnered an audience of Idaho entrepreneurs, artists, and SMEs in rural and underserved communities through the Idaho Rural Partnership, Idaho Women's Center, Idaho Arts Commission, Idaho Black Community Alliance, Idaho Native American Women Business Alliance and the Idaho Manufacturing Alliance. The STOPfakes Roadshow is organized through the International Trade Administration and includes speakers from other government agencies focused on intellectual property rights protection.
- On February 22, 2022, CBP hosted a webinar entitled "IPR Protection Beyond US Borders: Preventing Infringing Exports from China" as part of the Year of the SME webinar series. The webinar was presented by experts from the U.S. Patent and Trademark Office and provided attendees with information on how to register their IP in China, and then how to work with China's customs administration to prevent exports of infringing merchandise from ever reaching the United States.
- On March 1, 2022, CBP participated in a video interview with the Copyright Alliance, a trade association which represents 1.8 million individual creators and over 13,000 organizations in the United States. The interview covered CBP's IP enforcement regime, as well as best practices for copyright holders who wish to have their copyrights protected at U.S. ports of entry. This event is part of a wider initiative to encourage more copyright owners to record their registrations with CBP, as there are four times as many trademarks recorded with CBP as there are copyrights.

- On April 7, 2022, CBP participated in a panel concerning the intersection of IP violations and consumer health and safety violations at a National Association of Attorneys General (NAAG) Workshop on IP and Consumer Protection, co-sponsored by the U.S. Patent and Trademark Office. Members of the panel included representatives from the U.S. Postal Service, the U.S. Department of Justice, the Consumer Product Safety Commission, and the U.S. Patent and Trademark Office. CBP provided a presentation on IP recordation as well as an overview of CBP's IP border enforcement regime with a focus on the legal aspects that may prove relevant to an IP or consumer protection case brought by an Attorney General.
- On April 29, 2022, CBP participated in a workshop at the International Anti-Counterfeiting Coalition's Annual Meeting in Washington, DC, directed to small and medium enterprises experiencing problems with counterfeiting. On the panel with CBP was Homeland Security Investigations. CBP discussed the IPR e-Recordation Program and other opportunities to work with CBP to combat IP theft. The IACC is a Washington, DC-based non-profit formed in 1979 devoted solely to combating product counterfeiting and piracy.
- On April 30, 2022, CBP participated in the Anticounterfeiting Workshop at the International Trademark Association (INTA) Annual meeting, which consisted of government representatives from various countries as well as some private sector participants. The day-long Workshop focused on "Counterfeits in a Digital World: The Evolution of the Fight Against Fakes."
- On May 2, 2022, CBP participated in a panel at the International Trademark Association
 (INTA) Annual Meeting entitled Customs and Cross Border Synergy: Best Practices in
 IP Border Enforcement Measures in the Americas and the Caribbean Perspectives from
 Government Officials. The panel consisted of representatives from the customs
 administrations of Canada and Trinidad and Tobago and covered the IP border
 enforcement procedures of each country.
- On May 11, 2022, CBP participated in the Automotive Aftermarket Suppliers Association's Intellectual Property Committee Government Roundtable. The Roundtable was hosted by the National IPR Coordination Center and covered a range of topics related to the U.S. government's efforts to curb counterfeiting activities.
- On May 19, 2022, CBP presented during the Miami World Trade Center's International Trade Week, providing an overview of CBP's intellectual property enforcement regime. The members of the audience included representatives of carriers, freight forwarders, importer, customs brokers, and other members of the trade community.
- On May 20, 2022, CBP provided a briefing to members of the American Apparel and Footwear Association (AAFA) on CBP's intellectual property border enforcement regime, including the importance of trademark and copyright recordation, the seizure process, and how to best to assist CBP when field officials reach out for authentication assistance.

- On July 29, 2022, CBP participated in a webinar organized by the World Intellectual Property Organization (WIPO) entitled "The Role of Customs Authorities and Border Measures in the Effective Enforcement of Intellectual Property Rights." The two presenters were the Chief of the Intellectual Property Enforcement Branch at CBP and the Compliance and Technical Officer in charge of IPR, Health, and Safety Program at the World Customs Organization (WCO). The webinar attracted over 200 participants and is part of a WIPO webinar series called "Respect for IP."
- On August 3, 2022, CBP participated in a virtual roundtable event hosted by the Pharmaceuticals, Health, and Chemicals Center, which was attended by representatives of major global pharmaceutical companies that frequently do business with CBP as well as the Food and Drug Administration. CBP provided information to the participants about obtaining gray market protection from CBP and how to share information with CBP.
- On September 7, 2022, CBP co-hosted a workshop at the America's Small Business Development Counsel (SBDC) 43rd Annual Conference in San Diego, California, entitled "Best Practices in Countering Counterfeits Along the Supply Chain." CBP hosted this workshop along with the U.S. Patent and Trademark Office, as part of the week-long conference with over one-thousand attendees. The workshop provided the nuts and bolts of protecting a brand and utilizing all available government resources. America's SBDC represents a nationwide network of Small Business Development Centers (SBDCs) the most comprehensive small business assistance network in the United States and its territories. There are nearly 1,000 SBDC centers available to provide no-cost business consulting and low-cost training to new and existing businesses.
- On September 22, 2002, CBP participated in a workshop in Albuquerque, New Mexico, sponsored by the U.S. Patent and Trademark Office and the New Mexico Bar Association that consisted of one-on-one consultations with local intellectual property rights owners having issues with infringement. The CBP representative presented on methods of obtaining border enforcement against infringing imports and assisted the right holders with recording their IP in real time.

CBP Office of Trade International Engagements

CBP's Office of Trade is also responsible for fulfilling requests made by other government agencies for technical legal experts able to provide capacity building to foreign audiences. The Office of Trade also participates in multi-lateral organization activities central on border enforcement of intellectual property rights. In FY 2022, CBP participated in the following capacity building activities:

• On November 17, 2021, CBP met with members of the U.S. Patent and Trademark Office, the U.S. Department of Justice, and the Mexican Association for the Protection of Intellectual Property (AMPPI) to discuss IPR enforcement in Mexico and share best practices in enforcing IPR at the border.

- On November 30, 2021, OT, in collaboration with the U.S. Department of Justice, presented to the Africa Joint Pharmacrime Working Group, a group composed of customs and law enforcement officials from multiple African nations, on CBP's e-Recordation system. The e-Recordation system allows U.S. trademark and copyright owners to apply to CBP for border enforcement against infringing imports. Many developing countries do not yet have such a centralized database and are seeking capacity building assistance from the United States in creating one.
- On December 7-8, 2021, CBP provided an overview of CBP's IP Enforcement Regime to the African Intellectual Property Organization (OAPI), which consists of government officials and industry representatives in all sub-Saharan African countries. The webinar was hosted by the U.S. Patent and Trademark Office and focused on topics related to the destruction or disposal of infringing merchandise, which is an issue many developing countries have in their IP enforcement regime.
- On December 14, 2021, CBP provided an overview of CBP's IP Enforcement Regime to the customs administrations of Kuwait and the Kingdom of Bahrain. The program was coordinated by the U.S. Patent and Trademark Office, Global Intellectual Property Academy, and was the first in a series of workshops planned for customs administrations in the Middle East and North African region.
- On December 14, 2021, CBP participated in a technical workshop hosted by the
 Organization for Economic Cooperation and Development (OECD) on creating a
 mechanism to ensure "clean" FTZs that are free of illicit merchandise. CBP previously
 provided substantive comments on the draft document outlining the certification scheme
 proposed by the OECD Task Force on Countering Illicit Trade (TF-CIT). In the meeting
 delegates from OECD member governments discussed implementation of the
 certification scheme.
- On March 16-17, 2022, CBP attended the 10th Plenary Meeting of the OECD Task Force on Countering Illicit Trade as part of a U.S. delegation that included the Department of State, the Department of Homeland Security, the U.S. Patent and Trademark Office, and the National Intellectual Property Rights Coordination Center. At this plenary meeting the Task Force approved the Free Trade Zone (FTZ) Certification Scheme, which sets out a framework for reviewing FTZs and certifying that they are compliant with the Code of Conduct for Clean Free Trade Zones, which was modeled on CBP's Foreign Trade Zone regulations and developed with significant input from CBP. On the second day, the Task Force hosted a thematic dialogue titled "Charting the True Costs of Illicit Trade" and featured several presenters from private and public entities, including a CBP FP&F Officer from the Port of Baltimore, who presented on green destruction of seized merchandise and e-waste.
- On March 30, 2022, CBP met with Thailand customs administration, the U.S. Patent and Trademark Office, the CBP Attaché and Post concerning Thailand's desire to create an online IP recordation module similar to CBP's e-Recordation System. CBP provided capacity building on the preliminary steps required in building a database as well as an

- overview of CBP regulations concerning what data points are required in a recordation application.
- On April 29, 2022, CBP met with a delegation of individuals from the Australian Border Force and the Oceania Customs Organization as part of their visit to Washington, DC. The delegation was organized by the U.S. Patent & Trademark Office, Global Intellectual Property Academy, and sought to learn more about CBP's best practices in IPR border enforcement. The delegation later received a tour of the Dulles, Virginia CBP facilities as well as a tour of the San Francisco laboratory before departing the United States.
- On May 16, 2022, CBP participated in a workshop entitled *Developments in Copyright* and *Enforcement* for Southeast Asian participants organized by the Association of East Asian Nations (ASEAN) Secretariate and the U.S. Patent and Trademark Office. CBP sat on a panel with the Associate Register of Copyrights from the U.S. Copyright Office to discuss "Registration vs. Recordation of Copyrights: Requirements and Legal Effects." The workshop attracted over 150 participants from 10 Southeast Asian countries seeking to strengthen copyright enforcement in their nation.
- On May 24, 2022, CBP participated in an online dialogue entitled "Counter-infringement and Online Marketplaces" with representatives from the intellectual property enforcement offices of all G7 members. The event was organized by the United Kingdom Intellectual Property Office and began with a briefing by the UK on their new strategy on how to counter infringing goods being sold on online platforms and social media sites, which included a discussion of their border enforcement strategy.
- On June 1-3, 2022, CBP co-facilitated an IPR Workshop in Panama City, Panama, alongside the World Customs Organization (WCO) Secretariat, entitled "Combatting Counterfeiting and Piracy: Consumer Health and Safety." The workshop focused on enhancing the skills of nine customs administrations (Argentina, Brazil, Chile, Costa Rica, Mexico, Paraguay, Peru and Uruguay) in IPR border enforcement procedures in advance of an operation planned by the WCO in the Latin America, Central America and Caribbean region. The CBP representative that was asked to co-facilitate this workshop completed an Accreditation Workshop for Technical and Operational Advisers in Intellectual Property Rights Enforcement in March, making her the first IPR Technical Expert in the United States accredited by the WCO.
- On June 8, 2022, CBP participated in a Workshop on the Investigation and Handling of Counterfeit Medicine Cases organized by the Food and Drug Administration, Office of Criminal Investigation, and the U.S. Patent and Trademark Office, and directed to the customs administrations of Bulgaria and Romania. CBP presented on "Customs Procedures for Recordation and Addressing Mail Shipments of Falsified Health and Safety Products" and "Building Cases for Customs Seizure and Forfeiture in Cases Involving Illicit and Illegal Health and Safety Regulated Products."
- On June 14-16, 2022, CBP participated in an IP Rights Border Enforcement Workshop in Rabat, Morocco, co-sponsored by the U.S. Patent and Trademark Office's Global

Intellectual Property Academy and the U.S. State Department's Middle East Partnership Initiative (MEPI). The workshop, attended by government officials from Morocco, Tunisia and Jordan, featured discussions of each country's IP border enforcement procedures, best practices, and challenges for effective enforcement. CBP provided instruction on developing and maintaining a centralized recordation database similar to CBP's e-Recordation database, conducted a gap analysis of the region's customs laws concerning IP enforcement, and presented suggestions on how the region can strengthen their IP enforcement regime.

- On June 17, 2022 CBP participated in a panel presentation to discuss the current trends in IPR enforcement with the European Anti-Fraud Office (OLAF) Spirits and Wine. CBP spoke to international partners on the agency's role and authority in interdicting counterfeit goods, the work in the small package environment, and the "*Truth Behind Counterfeits*" public awareness campaign to educate consumers.
- On June 20-22, 2022, CBP supported the U.S. Patent and Trademark Office in delivering a IPR Border Enforcement Workshop in Algiers, Algeria. CBP provided an overview of the U.S. border enforcement regime, including the importance of establishing a centralized customs database to house all registered rights that are enforceable at the border, *ex officio* enforcement actions and working with brand owners.
- On June 28-30, 2022, CBP participated in a regional workshop organized by the USPTO Global Intellectual Property Academy, ASEAN Intellectual Property Academy, and the U.S. Department of Justice, in Bangkok, Thailand. Participants from 23 southeast Asian nations were present, composed of prosecutors, customs officials, judges/magistrates, and criminal investigators. The workshop provided an overview of the laws available in the United States to combat trade in counterfeit goods, prosecution techniques, collection of electronic evidence and the role of customs in combating IP crime.
- On July 20-22, 2022, CBP participated in a meeting of the Central Asia Regional Expert Level Working Group on Intellectual Property Rights in Tbilisi, Georgia, under the U.S.

 Central Asia Trade and Investment Framework Agreement (TIFA) led by the United States Trade Representative. The Central Asian Working Group consists of governments from the Republic of Kazakhstan, the Kyrgyz Republic, the Republic of Tajikistan, Turkmenistan, and the Republic of Uzbekistan. This was the fifth meeting of the Working Group, which IP protection and enforcement has been a priority since its inception.
- On July 21, 2022, CBP provided an overview of the legal authorities behind CBP's IP border enforcement regime to government officials from the Dominican Republic and Costa Rica, as part of a U.S. Study Tour.
- On August 10-12, 2022, CBP participated in a Workshop on Combatting Digital Piracy Crime in Paraguay organized by the U.S. Department of Justice I-CHIP and the National IPR Coordination Center. CBP provided instruction on CBP's *ex officio* IP enforcement, how CBP enforces copyrights at the border, and how CBP intercepts copyright

- circumvention devices that are subject to seizure pursuant to the Digital Millennium Copyright Act.
- On August 28-30, CBP participated in a regional workshop organized by the USPTO Global Intellectual Property Academy, in Manama, Bahrain. The audience consisted of prosecutors, customs officials, judges/magistrates, and criminal investigators from the region, who were provided an overview of the laws available in the United States to combat trade in counterfeit goods, prosecution techniques, collection of electronic evidence and the role of customs in combating IP crime. Reducing the level of IP theft and IP crime in the Middle East and North Africa (MENA) region remains a priority for the U.S. government, and this workshop furthered the aim of building cross-sector partnerships, sharing knowledge, and promoting law enforcement operations in the region.
- On September 6–9, 2022, CBP participated in the Commercial Law Development Program's Western Balkans Regional Workshop titled "Combatting Counterfeit Goods through Customs Seizures Customs, Prosecutorial, and Judicial Approaches" in Tivat, Montenegro. The workshop, attended by government officials from Montenegro, Albania, Kosovo, Serbia, Bosnia and Herzegovina, and Moldova featured discussions of regional IP border enforcement procedures, best practices, and challenges for effective enforcement. CBP provided instruction on the U.S. legal framework for the border enforcement of IP, discussed CBP's e-Recordation database, and participated in a panel on the administrative approach to customs seizures.
- On September 12-16, 2022, CBP participated in a program organized through the National Intellectual Property Rights Coordination Center on enforcement and investigation methods in intellectual property crime. The training was provided to Kenyan investigators, judges, prosecutors, regulators, and customs officials from the Anti-Counterfeit Authority (ACA), Kenya Revenue Authority (KRA), Office of the Director of Public Prosecutions (ODPP), Pharmacy and Poisons Board (PPB), and the Kenya Bureau of Standards (KEBS). The training was held at the Kenya School of Government in Nairobi, Kenya and was supported by CBP, the U.S. Department of State, Bureau of International Narcotics and Law Enforcement Affairs (INL), U.S. Department of Justice, Office of Overseas Prosecutorial Development, Assistance, and Training (OPDAT), and the U.S. Patent and Trademark Office.
- On September 15-16, 2022, CBP participated in a program co-organized by the FDA and the OECD on combatting the illicit trade in counterfeit medicines and medical products. The program was held at the OECD headquarters in Paris, France, and marked the third in a series of meetings in which IPE offered its expertise in border enforcement of intellectual property rights. The program was enriched by the perspectives of other U.S. government agencies including Homeland Security Investigations, USPTO, the National IPR Center, and the FDA. Additionally, foreign governments, international organizations, and the private sector were well-represented, and each provided valuable insight and recommendations. The topics discussed ranged from sharing examples of successful interdiction in the illicit trade of medical products, identifying gaps in the

global fight against counterfeits, and outlining a path forward for increased cooperation to tackle this complicated issue.

- On September 29, 2022, CBP participated on a panel with HSI at the Premier League Fakes Against Football event in London, UK. The panel focused on showcasing to stakeholders the work CBP does on interdicting counterfeit sports merchandise specifically through our Trade Special Operations.
- On September 28, 2022, CBP participated in a panel at the U.S. Copyright Office's International Copyright Institute, discussing intellectual property enforcement mechanisms within the U.S. Government's Executive Branch. CBP provided an outline of CBP's border enforcement of intellectual property rights, presented on the e-Recordation Program, and took questions from audience about specifically about copyright enforcement. The event was hosted at the Madison Building of the Library of Congress and is one of the Office's premier training events that brings senior-level copyright officials from developing countries and countries in transition to discuss current topics in copyright law and policy. Other panelists represented the Department of Justice, the International Trade Administration, and the Department of State.
- In FY 2022, CBP continued engagement on IPR issues with APEC in the SCCP by briefing the other 20 member economies on updates on our COVID-19 counterfeit goods enforcement efforts and our e-commerce data pilots status. Additional engagement took place at the SCCP2 meeting held in Chiang Mai, Thailand where CBP presented all participating economies on the Truth Behind Counterfeits IPR educational campaign for consumers and its evolution and lessons learned.

Interagency Collaboration

The Office of Trade also collaborates with other federal agencies to further the mission of protecting the country from importations of IP infringing merchandise. Examples of such collaborative efforts in FY 22 are the following:

- On October 21, 2021, CBP met with attorneys from the Computer Crimes and Intellectual Property Section (CCIPS) of the Department of Justice and the Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), to discuss CBP's seizure of fraudulent vaccine cards bearing government seals and insignia, and how to strengthen such enforcement measures.
- On October 22, 2021, CBP delivered a joint webinar with the State Department's Office of Intellectual Property Enforcement (IPE) directed to over 250 State Department officials stationed overseas. The webinar provided an overview of what programs CBP has in place to protect intellectual property rights at the border, and how the US IP border enforcement regime fits into the global landscape of IP protection

- On November 17, 2021, CBP provided an overview of the last Fiscal Year's IP border enforcement updates at the Annual Law Enforcement Industry Meeting organized by the U.S. Department of Justice, Computer Crime and Intellectual Property Section (CCIPS).
- On December 13, 2021 and May 4, 2022, CBP provided a training to HSI agents and CBP Officers enrolled in the IP Trade Enforcement Investigations (I-IPTEI) Course run by the National IPR Coordination Center. The training provided an overview of trademark and copyright enforcement, and also touched upon certain advanced topics such as fair use, refurbished goods, and gray market merchandise.
- On January 20, 2022, CBP met with the U.S. Copyright Office to discuss ways to increase copyright owner participation in CBP's e-Recordation Program. The e-Recordation program allows federal trademark and copyright owners to apply to CBP for border enforcement against infringing imports. Over 85% of CBP's IPR enforcement is based on recorded trademarks as opposed to copyrights. One reason for this discrepancy is that there are much fewer copyrights recorded with CBP than there are trademarks. The two teams discussed ways to educate copyright registration holders on CBP's e-Recordation Program and increase recordation numbers, which would allow CBP to prevent the entry of copyright infringing merchandise.
- On April 1, 2022, CBP met with the Centers for Disease Control and Prevention (CDC), the U.S. Patent and Trademark Office, and the U.S. Department of Justice (DOJ) regarding trademark registrations covering the CDC logo and word mark for use on printed vaccine cards. The group discussed CBP's ongoing seizures of fraudulent vaccine cards and what more could be done to ensure such cards are not circulated in the United States.
- On April 4, 2022, CBP provided a training session directed to HSI agents and CBP Officers enrolled in the IP Trade Enforcement Investigations (IPTEI) training program run by the National IPR Coordination Center. The training provided an overview of trademark and copyright enforcement and also touched upon certain advanced topics such as fair use, refurbished goods, and restricted gray market merchandise.
- On April 7, 2022, CBP participated in a panel concerning the intersection of IP violations and consumer health and safety violations at a National Association of Attorneys General (NAAG) Workshop on IP and Consumer Protection, co-sponsored by the U.S. Patent and Trademark Office. Members of the panel included representatives from the U.S. Postal Service, the U.S. Department of Justice, the Consumer Product Safety Commission, and the U.S. Patent and Trademark Office. CBP provided a presentation on IP recordation as well as an overview of CBP's IP border enforcement regime with a focus on the legal aspects that may prove relevant to an IP or consumer protection case brought by an Attorney General.
- On May 4, 2022, CBP in coordination with USPTO delivered a joint training to HSI agents on how to search for trademarks in the USPTO's Trademark Electronic Search

System (TESS) database and in CBP's e-Recordation internal database (IPRiS). The training covered overall best practices in using the tool for IP enforcement cases.

- On August 3, 2022, CBP participated in a virtual roundtable event hosted by the Pharmaceuticals, Health, and Chemicals Center, which was attended by representatives of major global pharmaceutical companies that frequently do business with CBP as well as the Food and Drug Administration. CBP provided information to the participants about obtaining gray market protection from CBP and how to share information with CBP.
- On September 21, 2022, CBP and an attorney-advisor from the USPTO delivered a joint training to HSI agents and CBP Officers and Import Specialists. The training covered how to search for design marks in the USPTO's TESS database and in CBP's IPRiS database. Approximately 150 HSI and CBP employees attended the training.

CBP Internal Training

The Office of Trade is also entrusted with training CBP personnel stationed at all 328 Ports of Entry in how to recognize intellectual property rights violations and take appropriate enforcement action. Such training initiatives in FY 22 included the following:

- On October 20-21, 2021, CBP provided a two-day training to new CBP Officers and the Port of Los Angeles/Long Beach on IP border enforcement. The training provided an overview of CBP's border enforcement procedure and the different IP violations CBP enforces. The second day focused on advanced topics in IP enforcement such as defenses to infringement, trademark and copyright infringement analysis and best practices in working with recordation holders when seeking assistance with authenticity determinations.
- On May 24 and 26, 2022, CBP, delivered an Advanced Intellectual Property Enforcement Seminar to over 160 personnel from the Apparel, Footwear and Textile Center. The Advanced Intellectual Property Enforcement Seminar introduces students to advanced topics in CBP's IPR enforcement. Each seminar is tailored to address the specific IP enforcement topics that fall within the scope of the particular Center and is presented in a format of attorney-advisor instruction followed by collaborative case studies and exercises.
- On June 23, 2022, CBP Regulations and Rulings (R&R) provided the Advanced Intellectual Property Enforcement Seminar to CBP personnel stationed at the Port comprising the San Juan Field Office.
- On July 12, 2022, CBP R&R provided the Advanced Intellectual Property Enforcement seminar to CBP Officers, Import Specialists and personnel from the Fines, Penalties and Forfeiture office from POEs in the Area Port of Miami.

- On July 13-14, 2022, CBP R&R provided the Advanced Intellectual Property Enforcement Seminar to the Pharmaceutical Health and Chemical (PHC) Center of Excellence and Expertise.
- On August 9, 2022, CBP R&R delivered the Advanced IP Enforcement Seminar to Import Specialists and Entry Specialists at the Petroleum, Natural Gas, and Minerals (PNGM) Center of Excellence and Expertise.
- On August 16, CBP R&R delivered a training in intellectual property border enforcement at the Port of Savannah. The Port of Savannah is the largest seaport on the East Coast and is responsible for a large percentage of CBP's IP enforcement actions. Attorney-advisors provided general instruction sessions followed by small group meetings to discuss specific issue facing the Port.
- On August 16-18, CBP R&R delivered an Advanced IP Enforcement Seminar to
 personnel at the San Francisco Field Office. The three-day training featured instruction
 on advanced topics in intellectual property border enforcement. The training was
 presented in a format of attorney-advisor instruction followed by collaborative case
 studies and exercises.
- On August 19, CBP R&R provided a briefing to the Port of Calexico, California, on best practices in IP border enforcement prior to their undertaking a week-long operation concerning counterfeit sporting equipment, toys and consumer products.
- On September 14-15, CBP R&R delivered a Virtual Advanced IP Enforcement Seminar to Import Specialists and Entry Specialists at the Electronics Center of Excellence and Expertise. The Intellectual Property Enforcement Seminar instructed students on advanced topics in CBP's IPR enforcement. The seminar was tailored to address the specific IP enforcement topics that fall within the scope of the Electronics Center and was presented in a format of attorney-advisor instruction followed by collaborative case studies and exercises.
- On September 22 and 25-27, CBP R&R provided an in-person training to CBP Officers, Import Specialists, Homeland Security Investigations Agents and Fines, Penalties and Forfeiture Officers at the Ports of Albuquerque, Nogales, Tucson, and Phoenix. The Port of El Paso virtually attending the training that was directed to the Port of Albuquerque. The training team included attorneys from the Office of Chief Counsel and featured in depth instruction on proper IP border enforcement procedure.

U.S. Customs and Border Protection and the U.S. Chamber of Commerce Memorandum of Understanding

On May 26, 2021, CBP entered a novel memorandum of understanding (MOU) with the U.S. Chamber of Commerce that underscores the importance of IPR and outlines general terms on connecting resources and sharing information to stop the flow of trade in counterfeit goods. CBP and the Chamber created an implementation plan to further outline how both entities would

contribute to the MOU effort. The MOU consists of has allowed for collaboration across four pillars:

- Outreach- CBP and the Chamber agreed to support outreach efforts related to bringing awareness to the general public about the dangers of counterfeit goods. During the holiday season of 2021, CBP and the Chamber participated in a joint holiday campaign, the *Shop Smart Campaign*, which included a media blitz that reached an audience of over 83 million people. In August 2022, CBP and the Chamber jointly engaged in a consumer awareness effort to alert the public about the harms of purchasing counterfeits around Back to School merchandise. The *Back to School* campaign reached over eight million impressions in just 15 days of the campaign in August 2022.
- CBP IPR Statistics Data Sharing- CBP provides exclusive intellectual property rights (IPR) seizure statistics on a quarterly basis to the Chamber. CBP has provided all of the Fiscal Year (FY) 2021 Quarterly IPR statistics and has provided all of the FY 2022 IPR statistics to the Chamber.
- Training- CBP and the Chamber have agreed to provide bi-directional training to each of their relevant personnel/members. On September 22, 2022, CBP provided Chamber members with an in-depth look at the IPR statistics and provided insight into CBP's data methodology as it relates to IPR.
- Data Pilot- As part of the MOU, CBP is conducting a data sharing pilot with three of the Chamber's member companies, with the hopes of expanding the pilot to include other companies in the future. The current pilot serves as an opportunity to establish best practices for IPR data sharing with the private sector. It also offers CBP the ability to test the viability of data sharing with major brands in an effort toto better target and seize imports of counterfeit and pirated goods and other IPR violative merchandise.

At the end of FY 2022, as part of the MOU, CBP and the Chamber signed on two more member companies and are actively looking to expand the pilot program.

CBP Product ID Guide Webinars

In FY 2022, the CBP Office of Trade hosted nine Product ID Guide webinars, reaching approximately 1035 CBP and HSI personnel. These webinars are an opportunity for rightsholders to engage directly with CBP Officers to introduce their products, present key identifying marks for genuine goods, and highlight counterfeiting trends and areas of risk specific to their products. The webinar recordings and corresponding Product ID Guides are also made available online to all CBP and HSI personnel.

Other Engagements

• CBP's multi-faceted communication with IP stakeholders includes daily interaction with industry regarding enforcement activities, formal meetings involving both trade

facilitation and enforcement efforts, and participation in numerous national trade events. CBP's stakeholder engagement includes:

- Regular conference calls with the IPR working group of the Commercial Customs Operations Advisory Committee (COAC) and quarterly public meetings with COAC members;
- Daily interaction with stakeholders affected by CBP's IP enforcement efforts at the
 ports of entry, and nationally through CBP's ten industry-aligned Centers of
 Excellence and Expertise (Centers), the IP-focused staff at headquarters, and the
 IPR Center in the Washington, DC metro area;
- o Participation in national and local trade events, industry meetings, speaking engagements, and industry-specific rightsholder roundtables.

Throughout FY 2022, CBP collaborated with industry in the form of an e-commerce task force to address the complexities and challenges associated with the increases in small packages due to the worldwide proliferation of online and mobile technologies.

Educating the Public

Changing public attitudes toward infringing activities remains essential to an effective intellectual property enforcement strategy. CBP's activities during FY 2022 included:

- CBP's Centers of Excellence and Expertise have been heavily involved in the development and implementation of the trade intelligence concept, a CBP effort to establish formal linkages with the private sector to develop actionable intelligence. As part of these efforts, the Centers engage in continual dialogue, information sharing, and trend analysis (e.g., with the pharmaceutical industry) in order to safeguard the American public from substandard, counterfeit, or otherwise illegal products. CBP proactively and frequently issues national and local press releases, and social media notifications to educate the public on counterfeiting.
- In FY 2022, CBP continued the *Truth Behind Counterfeits* IPR Public Awareness Campaign designed to educate the public on the negative impacts associated with the purchase of counterfeit goods and highlights how purchasing knockoffs can damage the U.S. economy, destroy American jobs, support criminal activity, and harm the health and safety of consumers. Due to the COVID-19 pandemic, CBP pivoted its consumer education campaign to leverage existing digital platforms and utilize relationships with the trade community to bring awareness to the dangers of counterfeits. During the campaign, CBP utilized its social media presence (e.g., Twitter, Facebook, Instagram, etc.) and leveraged its IPR website by revamping the design and updating information available on CBP.gov and CBP's "Truth Behind Counterfeits" website. Additionally, CBP collaborated with government agencies and trade associations with a nexus to stopping trade in illegitimate goods that violate IPR of American businesses to help further bring awareness to the dangers of fake goods. Throughout FY 22, CBP posted an average of 15 social media posts (Twitter, Facebook, and Instagram) per month about the

dangers of counterfeit goods. These social media posts were available to over 250,000 followers. Additionally, in FY 2022, CBP expanded the campaign to include posting sponsored ads on Instagram with these ads having a total of approximately 50 million impressions.

DEPARTMENT OF JUSTICE

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"When companies invest huge amounts of time and money to develop world-class technologies, only to have those technologies stolen, the results are devastating. . . . Crimes like the defendant's threaten both victim companies and the economic security of the nation as a whole. This case should serve as a warning to those entrusted with valuable trade secrets: if you break the law, you will be punished." ¹⁰

 Kenneth A. Polite Jr., Assistant Attorney General, Criminal Division

Department of Justice (DOJ) Appendix for FY 2022 Annual Report

This appendix for the Department of Justice (DOJ) is in two parts. The first part discusses the Department's activities during FY 2022 relating to intellectual property (IP) protection and enforcement. The second part discusses certain IP-related activities of DOJ's Antitrust Division.

The Department of Justice also submits an annual report to Congress pursuant to Section 404 of the Prioritizing Resources and Organization for Intellectual Property Act of 2008 ("PRO IP Act" or "Act"), Pub. L. No. 110-403. The Act imposes a number of annual reporting requirements on the Attorney General, including actions the Department has taken to implement Title IV of the Act ("Department of Justice Programs") and "a summary of the efforts, activities, and resources the [Department] has allocated to the enforcement, investigation, and prosecution of intellectual property crimes." The Act requires similar reporting by the Director of the Federal Bureau of Investigation ("FBI") on its intellectual property ("IP") enforcement efforts pursuant to Title IV of the Act. Copies of the PRO IP Act annual reports are available at https://www.justice.gov/criminal-ccips/ccips-documents-and-reports.

I. IP Protection and Enforcement Activities

The following is a discussion of Department of Justice (DOJ) activities relating to intellectual property (IP) protection and enforcement, including litigation activities in which arrests, charges, indictments, guilty pleas or verdicts, and/or sentencing took place during FY 2022.

COPYRIGHT / PRE-RELEASE / CAMCORDING / COUNTERFEIT LABELS (17 U.S.C. § 506, 18 U.S.C. §§ 2319, 2318)

• Three Defendants Indicted in Massive Software Piracy Scheme. On June 28, 2022, a grand jury indictment was unsealed, charging three individuals with violating federal wire fraud and money laundering statutes in connection with an operation to sell over \$88 million of stolen Avaya Direct International (ADI) software licenses, which were used to unlock features of a popular telephone system used by thousands of companies around the globe. The grand jury charged the following defendants with conspiracy to commit wire fraud and 13 counts of wire fraud: Raymond Bradley Pearce aka Brad Pearce, of Tuttle, Oklahoma;

¹⁰ DOJ press release, "Chemist Sentenced for Stealing Trade Secrets, Economic Espionage and Wire Fraud" (May 9, 2022), at https://www.justice.gov/opa/pr/chemist-sentenced-stealing-trade-secrets-economic-espionage-and-wire-fraud.

Dusti O. Pearce of Tuttle, Oklahoma; and Jason M. Hines aka Joe Brown, aka Chad Johnson, aka Justin Albaum, of Caldwell, New Jersey. In addition, the grand jury charged both Brad Pearce and Dusti Pearce with one count of conspiracy to commit money laundering and money laundering.

According to the indictment, Avaya Holdings Corporation, a multinational business communications company headquartered in California, sold a product called IP Office, a telephone system used by many midsize and small businesses in the United States and abroad. To enable additional functionality of IP Office such as voicemail or more telephones, customers had to purchase software licenses – which Avaya generated – from an authorized Avaya distributor or reseller. Avaya used software license keys to control access to Avaya's copyright-protected software and to ensure that only customers who paid for the software could use it. In addition, Avaya required that each software license on an IP Office system be associated with the system's Avaya Secure Digital (SD) card – a small flash memory card with a unique serial number that plugged into the IP Office manager computer – which the end user had to keep in its possession in order to use the licenses.

According to the indictment, Brad Pearce, a long-time customer service employee at Avaya, allegedly used his system administrator privileges to generate tens of millions of dollars of ADI software license keys that he sold to Hines and other customers, who in turn sold them to resellers and end users around the globe. The retail value of each Avaya software license ranged from under \$100 to thousands of dollars. Brad Pearce also allegedly employed his system administrator privileges to hijack the accounts of former Avaya employees to generate additional ADI software license keys. Furthermore, he allegedly used these privileges to alter information about the accounts to conceal the fact that he was generating ADI license keys, preventing Avaya from discovering the fraud scheme for many years. Brad Pearce's wife, Dusti Pearce, is alleged to have handled accounting and helped run the financial side of the illegal business. Hines operated Direct Business Services International (DBSI), a de-authorized Avaya reseller, in New Jersey. He allegedly bought software licenses from the Pearces under his own name and also using an alias, Joe Brown. Hines was the Pearces's largest customer and significantly influenced how the scheme operated. Hines also received help from Brad Pearce to resell the stolen software licenses. Hines was allegedly one of the biggest users of the ADI license system in the world. (WDOK, FBI)

https://www.justice.gov/usao-wdok/pr/three-defendants-indicted-massive-software-piracy-scheme

• EDVA Seizes Six Websites Providing Illegal Access to Copyrighted Music. On June 27, 2022, the U.S. Attorney's Office for the Eastern District of Virginia announced the seizure of six websites as part of ongoing efforts by Homeland Security Investigations (HSI) and the Department of Justice to combat copyright infringement. According to court records, the United States obtained court authorization to seize six domain names pending forfeiture. Four of those domains – Corourbanos.com, Corourbano.com, Pautamp3.com, and SIMP3.com – were registered with a U.S.-based registry, while two domains – flowactivo.co and Mp3Teca.ws – were registered through a U.S.-based domain registrar. According to court documents, law enforcement identified these six domains as being used to distribute copyrighted material without the authorization of the copyright holders. A law enforcement investigation confirmed that copyright-protected music content was present and available for

streaming or downloading on each of these six websites from the Eastern District of Virginia. (EDVA, HSI, OIA)

 $\underline{https://www.justice.gov/usao-edva/pr/edva-seizes-six-websites-providing-illegal-access-copyrighted-music}$

• ODAI Wireless, LLC Pleads Guilty to Copyright Infringement. On May 26, 2022, ODAI WIRELESS, LLC d/b/a ELITE WIRELESS, located in New Orleans, Louisiana, pleaded guilty to one-count of copyright infringement. According to court records, ODAI WIRELESS, LLC, infringed the copyright of three fashion designers, Gucci, Supreme and Burberry, when it attempted to import for resale and distribution approximately 1,200 counterfeit cloth masks without the authorization of the three fashion designer copyright holders. (EDLA, HSI, ICE)

https://www.justice.gov/usao-edla/pr/odai-wireless-llc-pleads-guilty-copyright-infringement

• *Member Of International Movie Piracy Ring Pleads Guilty*. On November 18, 2021, George Bridi, a citizen of the United Kingdom, pled guilty to his role in the Sparks Group, an international piracy group that illegally distributed movies and television shows on the Internet. Bridi was arrested on August 23, 2020, in Paphos, Cyprus, on charges of conspiracy to commit copyright infringement, wire fraud conspiracy, and conspiracy to commit interstate transportation of stolen property, for his involvement in the Sparks Group. Bridi was extradited from Cyprus on August 31, 2021.

As alleged in the indictment and statements made in open court, between 2011 and the present, Bridi and others known and unknown were members of the Sparks Group, a criminal organization that disseminated on the Internet movies and television shows prior to their retail release date, including nearly every movie released by major production studios, after compromising the content's copyright protections. In furtherance of its scheme, the Sparks Group fraudulently obtained copyrighted DVDs and Blu-Ray discs from wholesale distributors in advance of their retail release date by, among other things, making various misrepresentations to the wholesale distributors concerning the reasons that they were obtaining the discs prior to the retail release date. Sparks Group members then used computers with specialized software to compromise the copyright protections on the discs, a process referred to as "cracking" or "ripping," and to reproduce and encode the content in a format that could be easily copied and disseminated over the Internet. Sparks Group members then uploaded copies of the copyrighted content onto servers controlled by the Sparks Group, where other members further reproduced and disseminated the content on streaming websites, peer-to-peer networks, torrent networks, and other servers accessible to public. The Sparks Group identified its reproductions by encoding the filenames of reproduced copyrighted content with distinctive tags, and also uploaded photographs of the discs in their original packaging to demonstrate that the reproduced content originated from authentic DVDs and Blu-Ray discs.

Bridi arranged for discs to be picked up, mailed, or delivered from distributors located in Manhattan, Brooklyn, and New Jersey to other members of the Sparks Group prior to their official release date. BRIDI then reproduced, and aided and abetted the reproduction of,

these discs by using computer software that circumvented copyright protections on the discs and reproducing the copyrighted content for further distribution on the Internet. (SDNY, DHS-HSI, USPIS, OIA)

https://www.justice.gov/usao-sdny/pr/acting-us-attorney-announces-federal-charges-and-international-operation-dismantle-0

 $\underline{https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-extradition-british-national-participation-online-film$

https://www.justice.gov/usao-sdny/pr/member-international-movie-piracy-ring-pleads-guilty

• Columbia Couple Pleads Guilty to Selling Counterfeit Disney Movies on eBay. On October 12, 2021, Tabitha Nicole Rodgers and her husband, Clint Travis Rodgers, of Columbia, Missouri, pleaded guilty to a scheme to smuggle counterfeit Disney DVDs into the United States and sell them on eBay. Tabitha Rodgers pleaded guilty to one felony count of criminal copyright infringement for profit, and Clint Rodgers pleaded guilty to a misdemeanor count of criminal infringement of a copyright.

In July 2014, Homeland Security Investigations (HSI) received information from the National Intellectual Property Rights Coordination Center indicating that Clint Rodgers had received more than 443 shipments of counterfeit DVDs from companies in Hong Kong known to sell and export counterfeit goods. HSI agents identified two shipments that had been seized prior to delivery to the Rodgers' home in Columbia. One shipment contained 200 counterfeit "Beauty and the Beast" DVDs and another shipment contained 260 counterfeit "Aladdin" DVDs. On Feb. 4, 2015, U.S. Customs and Border Protection agents seized a parcel addressed to Clint Rodgers that contained 200 counterfeit Disney DVDs.

According to court documents, undercover federal agents purchased several counterfeit Disney DVDs from the Rodgers on eBay in February and March 2015. The Rodgers represented that the DVDs were genuine and authentic Disney products, when in reality, they were aware the products were counterfeit. During the investigation, agents contacted two persons who assisted the Rodgers in selling counterfeit DVDs on eBay. They told agents they were aware of numerous complaints from customers, including complaints that the DVDs didn't work. On Aug. 25, 2015, HSI agents executed a search warrant at the Rodgers' residence. Agents seized an assortment of counterfeit goods, including numerous counterfeit Disney DVDs. Tabitha Rodgers admitted that she conducted the day-to-day operation of the business. She corresponded via email with the counterfeit DVD supplier in Hong Kong and placed orders for the DVDs. She also packaged and sent the DVDs to customers and processed customer complaints when DVDs were inoperable. (DWMO, HSI, USDA)

https://www.justice.gov/usao-wdmo/pr/columbia-couple-pleads-guilty-selling-counterfeit-disney-movies-ebay

DIGITAL MILLENNIUM COPYRIGHT ACT (17 U.S.C. §§ 1201, 1204)

• Public Voice and Principal Salesperson for Notorious Videogame Piracy Group Sentenced to 3+ Years in Prison for Conspiracy. On February 10, 2022, the public face of a notorious

video game piracy group was sentenced to 40 months in prison for two federal felonies. Gary Bowser, a Canadian national of Santo Domingo, Dominican Republic, pleaded guilty in October 2021 to Conspiracy to Circumvent Technological Measures and to Traffic in Circumvention Devices, and Trafficking in Circumvention Devices. Bowser was a prominent leader of the criminal enterprise that developed and sold illegal devices that hacked popular videogame consoles so they could be used to play unauthorized, or pirated, copies of videogames. The enterprise targeted popular consoles such as the Nintendo Switch, the Nintendo 3DS, the Nintendo Entertainment System Classic Edition, the Sony PlayStation Classic, and the Microsoft Xbox.

According to court documents, the Team Xecuter criminal enterprise is comprised of over a dozen individual members located around the world, including developers who exploit vulnerabilities in videogame consoles and design circumvention devices; website designers who create the various websites that promote the enterprise's devices; suppliers who manufacture the devices; and resellers around the world who sell and distribute the devices. The indictment alleges that due, to the illegal nature of its business, Team Xecuter continuously sought to evade enforcement efforts by victim companies, financial institutions, and law enforcement. Notably, Team Xecuter attempted to protect its overall business by using a wide variety of brands, websites, and distribution channels, according to the indictment.

From approximately June 2013 through August 2020, Team Xecuter used a variety of product names for its devices, such as the Gateway 3DS, the Stargate, the TrueBlue Mini, the Classic2Magic, and the SX line of devices that included the SX OS, the SX Pro, the SX Lite, and the SX Core. To support their illegal activity, Team Xecuter allegedly helped create and support online libraries of pirated videogames for its customers, and several of the enterprise's devices came preloaded with numerous pirated videogames. According to the indictment, Team Xecuter even required customers to purchase a "license" to unlock the full features of its custom firmware, the SX OS, in order to enable the ability to play pirated videogames.

In September 2020, Louarn and Bowser were arrested abroad in connection with the charges in this case. The United States will seek Louarn's extradition to stand trial in the United States. Bowser was arrested and deported from the Dominican Republic, and appeared on October 2, 2020, in federal court. (WDWA, FBI, HSI, OIA)

 $\underline{https://www.justice.gov/opa/pr/two-members-notorious-videogame-piracy-group-team-xecuter-custody}$

http://www.justice.gov/usao-wdwa/pr/public-voice-and-principal-salesperson-notorious-videogame-piracy-group-sentenced-3

TRAFFICKING IN COUNTERFEIT GOODS (18 U.S.C. § 2320) (Non-Pharmaceutical)

• Las Vegas Store Owner Indicted for Trafficking in Counterfeit Designer Merchandise. On September 14, 2022, Amie Kamara of Las Vegas, Nevada, made her initial court appearance

for allegedly trafficking in more than 3,000 counterfeit designer handbags, clothes, and other merchandise which she offered for sale at her beauty supply store. The defendant is charged with two counts of trafficking in counterfeit goods.

According to the indictment, the defendant owned and operated Aminic Beauty Supply in Las Vegas. At the store, she possessed and intended to sell items bearing counterfeit marks that were identical to the genuine trademarks from Louis Vuitton, Chanel, Gucci, and other designer brands. If convicted, the statutory maximum penalty is 20 years in prison, a term of supervised release, and a monetary fine. (DNV, HSI)

 $\underline{\text{https://www.justice.gov/usao-nv/pr/las-vegas-store-owner-indicted-trafficking-counterfeit-designer-merchandise}$

• CEO of Dozens of Companies and Entities Charged in Scheme to Traffic an Estimated \$1 Billion in Fraudulent and Counterfeit Cisco Networking Equipment. On July 7, 2022, an indictment was returned charging a resident of Florida with running a massive operation over many years to traffic in fraudulent and counterfeit Cisco networking equipment with an estimated retail value of over \$1 billion. According to the indictment, Onur Aksoy, aka Ron Aksoy, aka Dave Durden, of Miami, allegedly ran at least 19 companies formed in New Jersey and Florida as well as at least 15 Amazon storefronts, at least 10 eBay storefronts, and multiple other entities (collectively, the "Pro Network Entities") that imported tens of thousands of fraudulent and counterfeit Cisco networking devices from China and Hong Kong and resold them to customers in the United States and overseas, falsely representing the products as new and genuine. The operation allegedly generated over \$100 million in revenue, and Aksoy received millions of dollars for his personal gain.

According to the indictment, the devices the Pro Network Entities imported from China and Hong Kong were typically older, lower-model products, some of which had been sold or discarded, which Chinese counterfeiters then modified to appear to be genuine versions of new, enhanced, and more expensive Cisco devices. As alleged, the Chinese counterfeiters often added pirated Cisco software and unauthorized, low-quality, or unreliable components – including components to circumvent technological measures added by Cisco to the software to check for software license compliance and to authenticate the hardware. Finally, to make the devices appear new, genuine, high-quality, and factory-sealed by Cisco, the Chinese counterfeiters allegedly added counterfeited Cisco labels, stickers, boxes, documentation, packaging, and other materials. Customers of Aksoy's fraudulent and counterfeit devices included hospitals, schools, government agencies, and the military.

As set forth in the indictment, between 2014 and 2022, U.S. Customs and Border Protection (CBP) seized approximately 180 shipments of counterfeit Cisco devices being shipped to the Pro Network Entities from China and Hong Kong. In response to some of these seizures, Aksoy allegedly falsely submitted official paperwork to CBP under the alias "Dave Durden," an identity that he used to communicate with Chinese co-conspirators. To try to avoid CBP scrutiny, Chinese co-conspirators allegedly broke the shipments up into smaller parcels and shipped them on different days, and Aksoy used at least two fake delivery addresses in Ohio. After CBP seized a shipment of counterfeit Cisco products to Aksoy and the Pro Network

Entities and sent a seizure notice, Aksoy allegedly often continued to order counterfeit Cisco products from the same supplier.

According to the indictment, between 2014 and 2019, Cisco sent seven letters to Aksoy asking him to cease and desist his trafficking of counterfeit goods. Aksoy allegedly responded to at least two of these letters by causing his attorney to provide Cisco with forged documents. In July 2021, agents executed a search warrant at Aksoy's warehouse and seized 1,156 counterfeit Cisco devices with a retail value of over \$7 million. (DNJ, HSI, CBP)

 $\underline{\text{https://www.justice.gov/opa/pr/ceo-dozens-companies-and-entities-charged-scheme-traffic-estimated-1-billion-fraudulent-and}$

Leaders of International Organization that Trafficked in Counterfeit Apple Products Plead Guilty. On June 2, 2022, three brothers from San Diego pleaded guilty, admitting that for eight years, they led an international conspiracy to traffic counterfeit iPhones and iPads. As part of their plea agreements, the Liao brothers – Zhiwei, Zhimin and Zhiting - and their wives - Dao La, Mengmeng Zhang, and Tam Nguyen, who also pleaded guilty - agreed to forfeit their interests in five residences in San Diego, more than \$250,000 in criminal proceeds, and more than 200 Apple iPhones that were counterfeit, fraudulently obtained, or linked to their criminal conspiracy. The Liaos admitted that, from 2011 through at least August 2019, they managed an organization to traffic in counterfeit Apple products. The Liaos imported counterfeit iPhones and iPads from China that looked genuine and included identification numbers that matched identification numbers on real iPhones and iPads that were under warranty and had been previously sold to customers in the United States and Canada. At the direction of the Liao brothers, co-conspirators traveled to hundreds of Apple Stores across the United States and Canada and attempted to exchange more than 10,000 counterfeit iPhones and iPads for genuine iPhones and iPads. The Liaos exported fraudulently obtained iPhones and iPads to individuals in foreign countries for profit. The estimated total infringement amount or loss suffered by Apple was approximately \$6.1 million. (DSCA, FBI, USCPB, HSI, San Diego Police Department, San Diego Sheriffs)

 $\underline{https://www.justice.gov/usao-sdca/pr/leaders-international-organization-trafficked-counterfeit-apple-products-plead-guilty}$

• Ferndale, Washington, Woman Indicted for Trafficking in Counterfeit Goods. On June 1, 2022, Kara Suneva Allen, aka Kara Suneva Mitchell, of Ferndale, Washington, was indicted for multiple counts of trafficking in counterfeit goods. According to records filed in the case, Allen operated a business named 'Keepin Up With Kara' LLC, located in a warehouse space in Ferndale, Washington. As of March 2022, a website associated with the business advertised 467 different items for sale that appeared to be products made by Adidas, Burberry, Cartier, Chanel, Christian Dior, Fendi, Gucci, Hermès, Louis Vuitton, MCM, Nike, Prada, Saint Laurent, Tiffany & Co., Tory Burch, and UGG. All the products were priced substantially below the suggested retail price for the genuine items.

An investigation revealed that in August and September 2021, three shipments destined for Allen and her company were seized from the mail in Oakland, California. The shipments, which originated in China and Hong Kong, contained a wide variety of counterfeit goods,

including handbags, wallets, and jewelry. Allen was notified of these seizures, but never petitioned to have the goods in the shipments released. An analysis of shipping records revealed that between September 2021 and March 2022, approximately 46 shipments from China and Hong Kong had been sent to the Ferndale warehouse where 'Keepin Up With Kara' operated. To document Allen's sale of counterfeit goods, an undercover agent made online purchases from the company's website. In one instance, the agent made an undercover purchase of a Louis Vuitton-branded handbag for \$110. The suggested retail price for that specific authentic Louis Vuitton handbag is \$1,690.00. A Louis Vuitton representative confirmed the handbag purchased from the website was counterfeit. On May 2, 2022, law enforcement executed search and seizure warrants at Allen's place of business, home, and vehicle. Large quantities of counterfeit merchandise were seized. (WDWA, HSI, USCBP, Whatcom County Sheriff's Office)

https://www.justice.gov/usao-wdwa/pr/ferndale-washington-woman-indicted-trafficking-counterfeit-goods

• Bergen County Man Charged for Participating in Multimillion-Dollar Counterfeit Trafficking Conspiracy. On May 20, 2022, Musa Karaman of North Arlington, New Jersey, was arrested on charges of participating in a multimillion-dollar conspiracy to traffic counterfeit computer networking devices. According to documents filed in this case and statements made in court, from at least September 2017 through May 2021, Karaman, Israfil "David" Demir, and another uncharged conspirator, formed and operated numerous entities in the business of selling computer networking equipment, particularly, networking devices manufactured by Cisco Systems Inc., a major U.S. technology conglomerate. Although Karaman and his conspirators advertised the Cisco products they offered for sale as new and genuine, the products were in fact counterfeit Cisco devices that the conspirators procured from various illicit suppliers based in China.

In May 2021, federal agents executed a search warrant at a Woodland Park, New Jersey, warehouse used by Karaman and his conspirators as their business headquarters and discovered thousands of counterfeit Cisco devices, including 7,260 counterfeit Cisco transceivers with a total manufacturer's suggested retail price of approximately \$13.77 million. From September 2017 to May 2021, approximately \$3.8 million worth of counterfeit Cisco products were seized, containing in over 20 shipments sent by illicit Chinabased suppliers to various locations under the control of Karaman and his conspirators, including their warehouse and home addresses, often under bogus names. (DNJ, HSI, USCBP)

https://www.justice.gov/usao-nj/pr/bergen-county-man-charged-participating-multimillion-dollar-counterfeit-trafficking

• Mother and son indicted for dealing counterfeit goods. On March 22, 2022, a federal grand jury returned a two-count indictment against Bok Nyo Kim, a legal permanent residing in Laredo, Texas, and Henry Yuseok Kim, also of Laredo. Both were originally charged by criminal complaint. The investigation began when Henry Kim, part-owner of Fashion Outlet, allegedly sold a counterfeit t-shirt purporting to be Louis Vuitton. Authorities then seized approximately 346 items of counterfeit merchandise from the store, according to the

charges. The indictment alleges that, during the seizure, Bok Kim identified herself as part-operator of Fashion Outlet. According to the complaint, both admitted to selling counterfeit clothing at Fashion Outlet for financial gain and shared control over the business. Bok Kim allegedly admitted to purchasing counterfeit merchandise from wholesalers in California. The indictment further alleges both individuals had knowledge of a prior seizure notice authorities had sent. (SDTX, HSI)

https://www.justice.gov/usao-sdtx/pr/mother-and-son-indicted-dealing-counterfeit-goods

Philadelphia Man Charged with Trafficking Counterfeit Airbags from China. On February 2, 2022, Emiliano Rodriguez, a citizen of the Dominican Republic residing in Philadelphia, Pennsylvania, was arrested and charged by Indictment with one count of trafficking in counterfeit goods, and two counts of causing the delivery of hazardous materials by air carrier in connection with a scheme to utilize counterfeit goods in used vehicles, which he then resold to unsuspecting customers. The Indictment alleges that from at least January 2017 through October 2019, the defendant, who is a trained auto mechanic, fraudulently imported counterfeit airbags from China and installed these unproven parts in salvaged autos which were then reintroduced to the consumer market. China has been identified as the largest exporter of counterfeit commodities, including counterfeit airbags. Persons involved in the trade of counterfeit airbags engage in this practice in an effort to increase profits from their sales by decreasing the cost of the parts used to replace the original items. Unsuspecting motorists purchase used or salvaged vehicles unaware of the history of the part(s) used in the vehicle reconstruction. Once purchased, the vehicles are driven on public roads and expose the driver, passengers and general public to potential hazards associated with the use of counterfeit parts. In this case, federal agents recovered more than 450 counterfeit airbags and parts from the Rodriguez's residence and business. (EDPA, HSI, DOT)

http://www.justice.gov/usao-edpa/pr/philadelphia-man-charged-trafficking-counterfeit-airbags-china

• Omaha Woman Sentenced for Trafficking in Counterfeit Goods. On December 10, 2021, Paw Moo of Omaha, Nebraska, was sentenced for to probation for a term of three years trafficking in counterfeit goods. In February 2021, U.S. Customs and Border Protection in Anchorage, Alaska, seized a shipment of counterfeit designer purses destined for Moo's residence in Omaha, Nebraska. On March 23, 2021, Homeland Security Investigations (HSI), using an undercover officer, executed a controlled delivery of the seized package to Moo's residence in Omaha. Moo accepted the package and HSI agents executed a search of her residence where numerous items with counterfeit marks were located. The items were handbags, clothes, blankets, phone cases, belts, and a wallet from brands to include Louis Vuitton, Chanel, Gucci, Yves St. Laurent, Michael Kors, Coach and Nike. The total manufacturers' suggested retail price of the seized merchandise exceeded \$118,000. Moo stated she began to sell items online from her residence in the beginning of March 2020 and began selling counterfeit items in the Fall of 2020, a timeframe that was consistent with her importation history. (DNE, HSI)

https://www.justice.gov/usao-ne/pr/omaha-woman-sentenced-trafficking-counterfeit-goods

Texas Vape Shop Owner Pleads Guilty to Unlawful Importation of Counterfeit Vaping **Products.** On November 23, 2021, Texas vape shop owner Muhammad Uzair Khalid (Uzair) of Garland, Texas, pleaded guilty to one count of trafficking in counterfeit goods relating to the importation of counterfeit vaping products. Uzair admitted that, from October 2017 to November 2019, he intentionally and unlawfully imported counterfeit vaping-related items from China, including counterfeit vaping atomizers, labels, boxes, and bags for vapingrelated products. During a November 2019 search of a Texas vape shop owned by Uzair, Homeland Security Investigations (HSI) special agents seized counterfeit vaping-related items, as well as a machine used to fill vape cartridges, several items that tested positive for THC, and an injector mechanism with an amber substance containing Vitamin E acetate. In pleading guilty, Uzair admitted that he regularly communicated with Chinese manufacturers about the production and sale of counterfeit vaping products. In particular, Uzair consulted with Chinese manufacturers on methods to imitate the branding and logos of well-known American vape companies and imported and sold imitation vaping devices, labels, and packaging. Uzair further admitted that he adopted and used those counterfeit marks to boost his sales. Uzair also sold numerous other counterfeit goods at his vape shop. (NDTX, HSI, CPB)

 $\underline{https://www.justice.gov/opa/pr/texas-vape-shop-owner-pleads-guilty-unlawful-importation-counterfeit-vaping-products}$

Norristown Man Indicted On Charges Of Trafficking In Counterfeit Merchandise. On
October 19, 2021, Alpha Jalloh of Norristown, Pennsylvania, was indicted by a federal grand
jury on charges of trafficking in counterfeit merchandise. The indictment alleges that, on
December 9, 2020, and February 26, 2021, Jalloh possessed and sold counterfeit designer
merchandise, including Gucci, Nike/Air Jordan and Michael Kors items in Luzerne County.
(MDPA, HSI, Pennsylvania State Police)

https://www.justice.gov/usao-mdpa/pr/norristown-man-indicted-charges-trafficking-counterfeit-merchandise

TRADE SECRET THEFT (18 U.S.C. § 1832)

• Engineer Sentenced to Eight Months In Prison For Theft Of Trade Secrets. On September 20, 2022, Peter Kisang Kim of Ben Lomond, California, was sentenced to eight months in prison for trade secret theft involving Broadcom trade secrets following a guilty plea. Broadcom is headquartered in San Jose and its products include networking chips used in equipment sold worldwide, including for enterprise and data center networking. In July 2020, the defendant left Broadcom after having been employed for over twenty years including work as a principal design engineer at the company. He worked on various Broadcom products during his time at the company, including the Trident family of chips frequently used in high-volume data centers. Less than two weeks after he left Broadcom, the defendant began working as IC Design Verification Director for a start-up company based in the People's Republic of China (PRC). He acknowledged in his plea agreement that the company was seeking to become a leading chip designer focused on the PRC's domestic market for networking chips at the time. During the defendant's employment at his new

company, he repeatedly accessed and referenced the Broadcom trade secrets on his personal electronic devices as well as the laptop issued by his new employer. (NDCA, FBI)

https://www.justice.gov/usao-ndca/pr/former-broadcom-engineer-charged-theft-trade-secrets

https://www.justice.gov/usao-ndca/pr/former-broadcom-engineer-sentenced-eight-months-prison-theft-trade-secrets

• Lexington Man Convicted of Possessing Stolen Trade Secret. On May 26, 2022, Haoyang Yu of Lexington, was convicted of possessing a stolen trade secret, the first-ever conviction following a criminal trial of this kind in the District of Massachusetts. Yu was convicted following a month-long jury trial of possessing the prototype design of a microchip, known as the HMC1022A, which was owned and developed by Analog Devices, Inc. (ADI), a semiconductor company headquartered in Wilmington. The chip is used in aerospace and defense applications. From 2014 to 2017, Yu worked at ADI, where he designed microchips used by the communications, defense and aerospace industries. As a result of his work, Yu had access to ADI's present and future microchip designs, including their schematic files, design layout files and manufacturing files. While he was an ADI employee, Yu started his own microchip design firm, Tricon MMIC, LLC, and used the stolen HMC1022A design to manufacture a knock-off version of ADI's chip. Yu began selling his version of HMC1022A prior to ADI's release of its chip. (DMA, HSI, FBI, NCIS, CBP)

https://www.justice.gov/usao-ma/pr/lexington-couple-and-their-semiconductor-company-indicted-charges-theft-trade-secrets

https://www.justice.gov/usao-ma/pr/lexington-man-convicted-possessing-stolen-trade-secret

PH.D. Chemist Sentenced To 168 Months For Conspiracy To Steal Traded Secrets, Economic Espionage, Theft Of Trade Secrets, And Wire Fraud. On May 9, 2022, Dr. Xiaorong You, aka Shannon You, of Lansing, Michigan was sentenced to serve 168 months in prison and ordered to serve three years of supervised release and pay a \$200,000 fine. In April 2021, a federal jury convicted You of conspiracy to commit trade secret theft, conspiracy to commit economic espionage, possession of stolen trade secrets, economic espionage, and wire fraud. According to court documents and evidence presented at trial, You stole valuable trade secrets related to formulations for bisphenol-A-free (BPA-free) coatings for the inside of beverage cans. You was granted access to the trade secrets while working at The Coca-Cola Company in Atlanta, Georgia, and Eastman Chemical Company in Kingsport, Tennessee. The stolen trade secrets belonged to major chemical and coating companies, including Akzo-Nobel, BASF, Dow Chemical, PPG, Toyochem, Sherwin Williams, and Eastman Chemical Company, and cost nearly \$120,000,000 to develop. You stole the trade secrets to set up a new BPA-free coating company in China. As witnesses from the chemical and coating companies testified at trial, developing these BPA-free alternatives was a very complex, expensive, and time-consuming process. You and her Chinese corporate partner, Weihai Jinhong Group received millions of dollars in Chinese government grants to support the new company. Documents and other evidence presented at trial, showed You's intent to benefit not only Weihai Jinhong Group, but also the governments of China, the Chinese province of Shandong, and the Chinese city of Weihai, as well as her intent to benefit the Chinese Communist Party.

Evidence presented at trial showed that from December 2012 through Aug. 31, 2017, You was employed as Principal Engineer for Global Research at Coca-Cola, which had agreements with numerous companies to conduct research and development, testing, analysis, and review of various BPA-free technologies. Because of You's extensive education and experience with BPA and BPA-free coating technologies, she was one of a limited number of Coca-Cola employees with access to BPA-free trade secrets belonging to Akzo-Nobel, BASF, Dow Chemical, PPG, Toyochem, and Sherwin Williams. From approximately September 2017 through June 2018, You was employed as a packaging application development manager for Eastman Chemical Company in Kingsport, Tennessee, where she was one of a limited number of employees with access to trade secrets belonging to Eastman. (EDTN, CCIPS, NSD-CES, FBI)

https://www.justice.gov/opa/pr/one-american-and-one-chinese-national-indicted-tennessee-conspiracy-commit-theft-trade

 $\underline{https://www.justice.gov/usao-edtn/pr/one-chinese-national-and-one-american-indicted-east-tennessee-conspiracy-commit-theft}$

 $\underline{https://www.justice.gov/opa/pr/phd-chemist-convicted-conspiracy-steal-trade-secrets-economic-espionage-theft-trade-secrets}$

 $\underline{https://www.justice.gov/usao-edtn/pr/phd-chemist-sentenced-168-months-conspiracy-steal-traded-secrets-economic-espionage}$

• Swiss Scientist Convicted by Federal Jury of Conspiracy to Steal Trade Secrets Belonging to GlaxoSmithKline. On May 2, 2022, Gongda Xue, formerly a resident of Allschwil, Switzerland, a legal permanent resident of Switzerland and citizen of China, was convicted of charges related to his participation in a conspiracy to steal trade secrets from GlaxoSmithKline (GSK) pertaining to biopharmaceutical products under development from January 2010 to January 2016. Xue worked as a scientist at the Friedrich Miescher Institute for Biomedical Research (FMI) in Switzerland, which is affiliated with Novartis. His sister, Yu Xue, worked as a scientist at GSK in Pennsylvania. Both the defendant and his sister conducted cancer research as part of their employment at these companies. Their research was sensitive and confidential. Consequently, GSK and FMI required Yu Xue and Gongda Xue respectively to sign confidentiality agreements as part of their employment. While the defendant performed basic research for publication in journals, the defendant's sister performed research relating to GSK's anti-cancer drugs under development. Evidence presented at trial showed that the defendant knew that GSK's research could prove incredibly valuable, and that it was proprietary and confidential.

While working for their respective entities, the defendant and his sister betrayed their employers and shared confidential information for their own personal benefit. Gongda Xue created Abba Therapeutics AG in Switzerland and Yu Xue and her associates formed Renopharma, Ltd., in China. Both companies intended to develop their own

biopharmaceutical anti-cancer products. Renopharma received direct funding and support from the government of China. Gongda Xue stole FMI research into anti-cancer products and sent that research to Yu Xue. Yu Xue, in turn, stole GSK research into anti-cancer products and sent that to Gongda Xue. Yu Xue also provided hundreds of GSK documents to her associates at Renopharma. Renopharma then attempted to re-brand GSK products under development as Renopharma products and attempted to sell them for billions of dollars. Renopharma's own internal projections showed that the company could be worth as much as \$10 billion based upon the stolen GSK data.

In January 2016, the FBI arrested Yu Xue and her Renopharma associates, seized e-mail accounts containing the stolen GSK data, and seized the funds in a Renopharma bank account in order to prevent Renopharma from achieving its goals and monetizing the stolen GSK information. Gongda Xue was charged in 2018 and extradited from Switzerland to the United States in December 2019. Two former GSK employees, Yu Xue and Lucy Xi, have pleaded guilty for their roles in sending GSK trade secrets to Renopharma. Yu Xue's sister, Tian Xue, pleaded guilty to a money laundering conspiracy for agreeing to launder the substantial ill-gotten gains which Renopharma expected to receive. One of the directors of Renopharma, Tao Li, also pleaded guilty for his role in conspiring to steal GSK trade secrets. The other director of Renopharma, Yan Mei, is a fugitive who currently resides in China. (EDPA, FBI, OIA)

https://www.justice.gov/usao-edpa/pr/swiss-scientist-convicted-federal-jury-conspiracy-steal-trade-secrets-belonging

Fourth Defendant Pleads Guilty to Stealing Trade Secrets from GlaxoSmithKline to Benefit Chinese Pharma Company. On January 3, 2022, Lucy Xi, formerly a resident of Malvern, PA, pleaded guilty to stealing trade secrets from GlaxoSmithKline (GSK) to benefit a Chinese pharmaceutical company named Renopharma. Xi's co-defendants, Yu Xue, Tao Li and Yan Mei, established Renopharma to research and develop anti-cancer drugs. In reality, the company was used as a repository of information stolen from GSK. Renopharma received financial support and subsidies from the government of China. At the time, Lucy Xi (who was married to Yan Mei) and Yu Xue were employed as scientists at a GSK facility in Upper Merion, PA, which worked on developing biopharmaceutical products. These products typically cost in excess of \$1 billion to research and develop. In January 2015, Lucy Xi sent Yan Mei a GSK document that contained confidential and trade secret data and information. The document provided a summary of GSK research into monoclonal antibodies at that time. In the body of the e-mail, Lucy Xi wrote, "You need to understand it very well. It will help you in your future business [RENOPHARMA]." Yu Xue, her sister, Tian Xue, and Tao Li have all pleaded guilty for their roles in this conspiracy. Yan Mei is a fugitive who currently resides in China. (EDPA, FBI)

 $\underline{https://www.justice.gov/usao-edpa/pr/fourth-defendant-pleads-guilty-stealing-trade-secrets-glaxosmithkline-benefit-chinese$

• Former CEO And COO Of JHL Biotech Sentenced For Conspiring To Steal Trade Secrets And Commit Wire Fraud Exceeding \$101 Million. On March 15, 2022, Racho Jordanov, the co-founder and former Chief Executive Officer of JHL Biotech, and Rose Lin, another of the company's co-founders and former Chief Operating Officer, were sentenced for their

respective roles in conspiring to commit trade secret theft and wire fraud. Jordanov was sentenced to a term of imprisonment of twelve months and one day, to be followed by a term of supervised release of 36 months, a condition of which shall be to serve nine months in home confinement. Lin was sentenced to a term of imprisonment of twelve months and one day, to be followed by a term of supervised release of 36 months.

Both defendants pleaded guilty to the charges on August 24, 2021. According to the plea agreements, in 2012, Racho Ivanov Jordanov, also known as "Racho" Jordanov, of Rancho Santa Fe, Calif., and Rose Lin, also known as Rose Sweihorn Tong, of South San Francisco, Calif., co-founded JHL Biotech, Inc., a biopharmaceutical start-up in Taiwan. Between 2011 and 2019, Jordanov, as President and CEO of JHL Biotech, obtained and possessed confidential, proprietary, and trade secret information from Genentech, and used it to accelerate the timeline for and to reduce the costs of JHL Biotech's development and production of Genentech biosimilars and to enhance JHL Biotech's ability to meet various regulatory requirements related to the same. By various means, Jordanov obtained for JHL Biotech's use many confidential and proprietary documents from Genentech without authorization, some of which contained trade secret information. In so doing, he worked with multiple people within JHL Biotech to possess and use confidential, proprietary, and trade secret information he knew JHL Biotech was not authorized to have.

According to the plea agreement, Jordanov hired former Genentech employees to work at JHL Biotech, several of whom he learned surreptitiously brought, without authorization, confidential and proprietary documents with them from Genentech to JHL Biotech. The company used only some of the stolen documents, but Jordanov tolerated this practice by the employees of JHL Biotech and made no effort to discourage its employees from using the documents or information they brought with them. The employees Jordanov hired provided the Genentech documents and information to JHL Biotech, which, at times, allowed the company to cheat, cut corners, solve problems, provide examples, avoid further experimentation, eliminate costs, lend scientific assurance, and otherwise help JHL Biotech start-up, develop, and operate its business secretly using the intellectual property and scientific know-how taken from Genentech. Jordanov admitted that he suspected that some or all the stolen information was brought to JHL Biotech in violation of relevant Genentech non-disclosure agreements and employment contracts, but he made no effort to verify whether that was true.

In January 2014, Lin arranged for Xanthe Lam, a Principal Scientist working full-time at Genentech, to secretly work as the head of formulation for JHL Biotech. Lin encouraged JHL Biotech scientists to ask Xanthe Lam for assistance or information when they ran into problems. Throughout this time, Lin knew that Xanthe Lam continued to work for Genentech and was not authorized to work for JHL Biotech. Lin also knew that Xanthe Lam did not want Genentech to learn of her work for JHL Biotech. Lin agreed to pay Xanthe Lam's consultancy fee and communicate through her husband, Allen Lam.

Between 2014 and 2018, Jordanov sometimes personally used and instructed others to use confidential, proprietary, trade secret Genentech documents and information relating to Genentech's complex technology transfer procedures and processes. He used Genentech's

confidential and tech transfer documents in the development, construction, and operation of new facilities for JHL Biotech including its manufacturing facility in Wuhan, China.

In early-December 2016, Jordanov and Lin met with representatives of Sanofi S.A., the multi-national French pharmaceutical company, for approximately one week, during which they reviewed the strategic partnership agreement to be entered into by Sanofi and JHL Biotech. During this week-long meeting, Jordanov and Lin reviewed the prospective partnership agreements, which involved JHL Biotech representing to Sanofi that it had developed and was conducting its biosimilar operations without infringing the intellectual property rights of other companies or using other companies' proprietary information. Jordanov and Lin knew that if they had not concealed that JHL Biotech had relied upon intellectual property, including confidential, proprietary, and trade secret information that it stole or received without authorization, Sanofi would not have agreed to the corporate transaction and invest approximately \$80 million in JHL Biotech securities pursuant to the subscription agreement and approximately \$21 million pursuant to Biologics Products Options Agreement (BPOA) for a total investment by Sanofi in JHL Biotech of approximately \$101 million.

On June 1, 2021, a federal grand jury indicted Jordanov and Lin, charging both defendants with: (1) conspiracy to commit theft of trade secrets and wire fraud; (2) wire fraud (three counts each defendant); (3) international money laundering (nine counts against Jordanov and five counts against Lin); and (4) conspiracy to obstruct justice. In addition, the indictment charges Jordanov with two counts of theft of trade secrets and charges Lin with one additional count of making false statements to a government agency. Pursuant to the plea agreements, both defendants pleaded guilty to count one of the indictment, conspiracy to commit theft of trade secrets and wire fraud. The remaining charges were dismissed at sentencing. (DNCA, IRS, FBI)

https://www.justice.gov/usao-ndca/pr/former-ceo-and-coo-jhl-biotech-charged-conspiracy-steal-trade-secrets-and-commit-wire

https://www.justice.gov/usao-ndca/pr/former-ceo-and-coo-jhl-biotech-convicted-conspiracy-steal-trade-secrets-and-commit-wire

 $\frac{https://www.justice.gov/usao-ndca/pr/former-ceo-and-coo-jhl-biotech-sentenced-conspiring-steal-trade-secrets-and-commit-wire$

• Federal Indictment Charges PRC-Based Telecommunications Company with Conspiring with Former Motorola Solutions Employees to Steal Technology. On February 7, 2022, a federal indictment was unsealed, charging a telecommunications company with conspiracy to commit theft of trade secrets. The indictment alleges that a telecommunications company conspired with former employees of Chicago-based Motorola Solutions Inc. to steal digital mobile radio (DMR) technology developed by Motorola. According to court documents, Motorola Solutions developed the DMR technology through years of research and design. Motorola Solutions marketed and sold the radios, which are sometimes referred to as "walkie-talkies," in the United States and elsewhere.

The indictment alleges that PRC-based Hytera Communications Corp. LTD recruited and hired Motorola Solutions employees and directed them to take proprietary and trade secret information from Motorola without authorization. The charges allege that, while still employed at Motorola, some of the employees allegedly accessed the trade secret information from Motorola's internal database and sent multiple emails describing their intentions to use the technology at Hytera. As alleged, from 2007 to 2020, Hytera and the recruited employees used Motorola's proprietary and trade secret information to accelerate the development of Hytera's DMR products, train Hytera employees, and market and sell Hytera's DMR products throughout the world, the indictment states. According to the indictment, Hytera paid the recruited employees higher salaries and benefits than what they received at Motorola. The 21-count indictment charges Hytera with conspiracy to commit theft of trade secrets. Hytera and others are also charged with individual counts of possession or attempted possession of stolen trade secrets. (NDIL, FBI, NSD)

 $\underline{https://www.justice.gov/opa/pr/federal-indictment-charges-prc-based-telecommunications-company-conspiring-former-motorola}$

Owners Of Florida Teacher Certification Preparation Company Sentenced To Federal Prison For Racketeering Conspiracy And Conspiracy To Commit Theft Of Trade Secrets. On January 25, 2022, Kathleen M. Jasper and Jeremy M. Jasper, of Estero, Florida, were sentenced to ten months and four months in federal prison, respectively, plus six months of home confinement, after previously pleading guilty to charges of racketeering conspiracy and conspiracy to commit theft of trade secrets. Court documents reflect that, since January 2016, the Jaspers, who are both certified Florida teachers, stole content and conspired with others to steal content from the Florida Teacher Certification Exams (FTCE) and the Florida Educational Leadership Exam (FELE) and included the stolen content in the test preparation materials and services that were sold through their business, NavaEd, LLC ("NavaEd") for personal profit. NavaEd, LLC, was a company that offered tutoring and training to prepare prospective Florida educators to successfully take and pass the FTCE and the FELE, which are required for certification in the state of Florida. NavaEd offered training publications for sale worldwide directly through its website and through third-party e-commerce websites, such as Amazon and Shopify. Both Kathleen and Jeremy Jasper took the FTCE and FELE multiple times – after having already passed the exams – in order see and memorize, or harvest, as many different exam questions as possible. The Jaspers also directed NavaEd employees and independent contractors to take the FTCE and FELE for the purpose of harvesting exam questions and answers. The Jaspers and NavaEd customers shared the stolen FTCE and FELE test content with each other through email, phone, video conferencing, and messaging applications. The Jaspers republished the stolen FTCE and FELE test content – verbatim and almost verbatim – into NavaEd publications that were written to prepare future Florida teachers and school administrators for the certification exams. These publications and other NavaEd FTCE and FELE preparation materials were disseminated and used during NavaEd training seminars and tutoring sessions. (DNFL, USDE, FL Dept. of Law Enforcement)

https://www.justice.gov/usao-ndfl/pr/owners-florida-teacher-certification-exam-preparation-company-plead-guilty-racketeering

http://www.justice.gov/usao-ndfl/pr/owners-florida-teacher-certification-preparation-company-sentenced-federal-prison

• Former GE Engineer Sentenced to 24 Months for Conspiring to Steal Trade Secrets. On November 10, 2021, Jean Patrice Delia, of Montreal, Canada, was sentenced to 24 months in prison for conspiring to steal trade secrets from the General Electric Company (GE). As part of his guilty plea entered on December 10, 2019, Delia admitted that he conspired with his business partner and co-defendant, Miguel Sernas, to compete against GE using trade secrets Delia stole from GE while employed by GE in Schenectady, New York. Delia admitted that he and Sernas, operating as ThermoGen Power Services, used the stolen trade secrets, as well as stolen marketing data, pricing information, and other confidential GE documents, to compete against GE around the world. Delia, who was employed by GE as an engineer from 2001 through 2012, admitted to conspiring with Sernas from 2008 through 2019. Delia was also ordered to pay \$1.4 million in restitution. (NDNY, FBI)

https://www.justice.gov/usao-ndny/pr/former-ge-engineers-charged-conspiring-steal-trade-secrets

https://www.justice.gov/usao-ndny/pr/former-ge-engineer-pleads-guilty-conspiring-steal-trade-secrets-0

 $\underline{https://www.justice.gov/usao-ndny/pr/former-ge-engineer-sentenced-24-months-conspiring-steal-trade-secrets}$

ECONOMIC ESPIONAGE (18 U.S.C. § 1831)

• Chinese National Sentenced for Economic Espionage Conspiracy. On April 7, 2022, Xiang Haitao, a Chinese national formerly residing in Chesterfield, Missouri, was sentenced to 29 months in prison followed by three years of supervised release and a \$150,000 fine for conspiring to commit economic espionage. Xiang pleaded guilty to the charge in January 2022. According to court documents, Xiang conspired to steal a trade secret from Monsanto, an international company based in St. Louis, for the purpose of benefitting a foreign government, namely the People's Republic of China. In November 2019, Xiang was indicted by a federal grand jury on one count of conspiracy to commit economic espionage, three counts of economic espionage, one count of conspiracy to commit theft of trade secrets, and three counts of theft of trade secrets.

According to the indictment, Xiang was employed by Monsanto and its subsidiary, The Climate Corporation, from 2008 to 2017, where he worked as an imaging scientist. Monsanto and The Climate Corporation developed a digital, on-line farming software platform that was used by farmers to collect, store, and visualize critical agricultural field data and increase and improve agricultural productivity for farmers. A critical component to the platform was a proprietary predictive algorithm referred to as the Nutrient Optimizer. Monsanto and The Climate Corporation considered the Nutrient Optimizer a valuable trade secret and their intellectual property. In June 2017, the day after leaving employment with Monsanto and The Climate Corporation, Xiang bought a one-way plane ticket to China. Before he could board his flight, Xiang was intercepted at the airport by federal officials who seized copies of the Nutrient Optimizer. (EDMO, NSD-CES, FBI)

https://www.justice.gov/opa/pr/chinese-national-who-worked-monsanto-indicted-economic-espionage-charges

https://www.justice.gov/opa/pr/chinese-national-pleads-guilty-economic-espionage-conspiracy

https://www.justice.gov/opa/pr/chinese-national-sentenced-economic-espionage-conspiracy

• Former GE Power Engineer Convicted of Conspiracy to Commit Economic Espionage Following Four-Week Trial. On March 31, 2022, Xiaoqing Zheng of Niskayuna, New York, was convicted of conspiracy to commit economic espionage following a four-week jury trial. Zheng was employed at GE Power & Water in Schenectady, New York, as an engineer specializing in sealing technology. He worked at GE from 2008 until the summer of 2018. The trial evidence demonstrated that Zheng and others in China conspired to steal GE's trade secrets surrounding GE's steam and gas turbine technologies, knowing or intending to benefit the People's Republic of China (PRC) and one or more foreign instrumentalities, including China-based companies that research, develop, and manufacture parts for turbines.

https://www.justice.gov/opa/pr/former-ge-engineer-and-chinese-businessman-charged-economic-espionage-and-theft-ge-s-trade

https://www.justice.gov/usao-ndny/pr/former-ge-power-engineer-convicted-conspiracy-commit-economic-espionage-following-four

• Jury convicts Chinese official of espionage crimes, attempting to steal trade secrets from Cincinnati company. On November 5, 2021, a Chinese Ministry of State Security (MSS) operative, Yanjun Xu, aka Qu Hui, was found guilty on all counts, including conspiring to and attempting to commit economic espionage and stealing trade secrets. Xu was the first Chinese intelligence agent ever to be extradited to the United States to stand trial. Xu is a deputy division director at the Chinese Ministry of State Security (MSS), which is the intelligence and security agency for China. According to court documents and trial testimony, beginning in at least December 2013, Xu targeted specific companies in the United States and abroad that are recognized as leaders in the field of aviation. He identified individuals who worked for the companies and recruited them to travel to China, often initially under the guise that they were traveling to give a presentation at a university. Xu and others paid the individuals stipends on top of covering travel costs.

According to the conviction, Xu attempted to steal technology related to GE Aviation's exclusive composite aircraft engine fan – which no other company in the world has been able to duplicate – to benefit the Chinese state. In March 2017, a GE Aviation employee in Cincinnati was solicited to give a report at a university in China. The employee traveled to China two months later to present at the university and was introduced to Xu. Xu and others paid the employee's travel expenses and a stipend. In January 2018, Xu requested "system specification, design process" information from the employee and – with the cooperation of the company, who was working with the FBI – the employee emailed a two-page document from the company that included a label that warned about the disclosure of proprietary information. In February 2018, Xu began discussing with the employee the possibility of

meeting in Europe during one of the employee's business trips and asked the employee to send a copy of the file directory for his company-issued computer. Xu traveled to Belgium on April 1, 2018, to meet with the employee and was arrested. Xu was extradited to the United States on October 9, 2018, and charges were announced on October 10, 2018. (SDOH, NSD-CES, OIA, FBI)

 $\underline{https://www.justice.gov/opa/pr/chinese-intelligence-officer-charged-economic-espionage-involving-theft-trade-secrets-leading}$

 $\underline{https://www.justice.gov/usao-sdoh/pr/jury-convicts-chinese-official-espionage-crimes-attempting-steal-trade-secrets}$

ALTERNATIVE CHARGES

FALSE MARKETING OF PESTICIDES

New Jersey Business Owner Admits Defrauding Over 75 Victims of More Than \$2.7 Million in Nationwide Scheme to Sell Pesticides Falsely Billed as Registered with EPA and Approved to Kill Coronavirus. On June 9, 2022, Paul Andrecola of Maple Shade, New Jersey, pleaded guilty to various charges stemming from his sale of more than \$2.7 million worth of various unregistered pesticides to numerous victims based on false representations that these products were registered pesticides with the Environmental Protection Agency (EPA), and on EPA's "List N: Disinfectants for Use Against SARS-CoV-2" that EPA deemed to be effective against SARS-CoV-2 (Coronavirus). Andrecola pleaded guilty to an information charging him with one count of knowingly distributing or selling an unregistered pesticide in violation of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), one count of wire fraud, and one count of presenting false claims to the United States. According to documents filed in this case, and statements made in court, Andrecola, who owns and operates three companies based in Mount Laurel, New Jersey, manufactured various disinfectant products, including liquids and wipes, under the brand name "GCLEAN." GCLEAN products were unregistered pesticides under FIFRA and none of the products were on EPA's "List N of Disinfectants for Use Against SARS-CoV-2." Rather, Andrecola placed another company's EPA Registration Numbers on his company's products, and falsely marketed that his products were EPA-approved to kill Coronavirus by creating numerous false documents to support his claims. Specifically, Andrecola, or others at his behest, would provide this falsified documentation to potential customers, falsely representing that various sanitizer and wipe products in the names GCLEAN and/or GC200 were EPA-registered products on EPA's "List N: Disinfectants for Use Against SARS-CoV-2," to persuade them to purchase the unregistered pesticide products. From approximately March 2020 through May 2021, Andrecola used these fraudulent representations to make more than 150 sales of unregistered pesticides for a profit of more than \$2.7 million. The purchasers of these unregistered pesticides included a police department in Delaware, a fire department in Virginia, a medical clinic in Georgia, a janitorial supply company in New York, a school district in Wisconsin, as well as numerous U.S. government agencies (namely, the U.S. Marshal's Service, Moody Air Force Base, the Department of Veterans Affairs and the National Forest Service). (DNJ, EPA, HSI, NCIS, Mount Laurel Police Department)

https://www.justice.gov/opa/pr/new-jersey-business-owner-admits-defrauding-over-75-victims-more-27-million-nationwide-scheme

TRAFFICKING IN COUNTERFEIT PHARMACEUTICALS CONTAINING CONTROLLED SUBSTANCES

• Pharmaceutical President and Company Guilty in Counterfeit Drug Trafficking Conspiracy. On August 22, 2022, Adam P. Runsdorf of Boca Raton, Florida, pleaded guilty to conspiracy, trafficking in counterfeit drugs, and money laundering conspiracy. According to the indictment, from April 2014 until August 2021, Runsdorf conspired with drug traffickers in Houston, Texas, to distribute misbranded and counterfeit cough syrup. Runsdorf's company, Woodfield Pharmaceutical LLC, pleaded guilty to the same charges.

According to information presented in court, Byron A. Marshall of Houston utilized Woodfield Pharmaceutical's manufacturing facility and employees in Houston to produce more than 500,000 pints of counterfeit Actavis cough syrup, which had been discontinued due to its abuse by recreational drug users. The counterfeit syrup was sold across Texas, Louisiana, Mississippi, Alabama, Georgia, South Carolina, Tennessee, Wisconsin, California, Florida, Arkansas, and Ohio. Prices generally ranged from \$100 to more than \$1,000 per one-pint bottle. Depending on the market and brand of cough syrup, prices went as high as \$3,800 to \$4,000 per pint. Six codefendants have already pleaded guilty and are awaiting sentencing.

The case was investigated by the Drug Enforcement Administration; U.S. Food and Drug Administration Office of Criminal Investigations; Internal Revenue Service-Criminal Investigation; Federal Bureau of Investigation; U.S. Marshals Service; Houston Police Department; Galveston Police Department; Galveston County Sheriff's Office; Dickinson Police Department; League City Police Department; Pearland Police Department; Pasadena Police Department; Texas City Police Department; Harris County Precent #2; Brazoria County Sheriff's Office; Fort Bend County Sheriff's Office; Liberty County Sheriff's Office; and the Texas National Guard. (EDTX, DEA, FDA OCI, FBI, US Marshals)

 $\underline{http://www.justice.gov/usao-edtx/pr/florida-based-pharmaceutical-president-indicted-counterfeit-promethazine-codeine-drug}$

https://www.justice.gov/usao-edtx/pr/pharmaceutical-president-and-company-guilty-counterfeit-drug-trafficking-conspiracy

• *Nine Indicted in Counterfeit Promethazine-Codeine Drug Trafficking Conspiracy.* On November 3, 2021, a federal grand jury in Beaumont, Texas, returned a three-count indictment charging nine individuals in drug trafficking conspiracy. The indictment charges the defendants with conspiracy, trafficking in drugs with a counterfeit mark, and money laundering conspiracy. The following individuals have been indicted and arrested: Tunji Campbell, a/k/a Mike, of Webster; Byron A. Marshall, a/k/a Robert Griffin, a/k/a Dr. Griffin, of Houston; Cheryl A. Anderson of League City; Ashley A. Rhea, a/k/a Ashley A. Johnson,

of Houston; Chauntell D. Brown, a/k/a Juan Brown, of Manvel; Willis Reed of Richmond; Kalpen D. Patel of Richmond; Jonathan R. Shaver of Richmond; and Gina Acosta of Fresno. According to the indictment, from April 2014 until August 2021, the defendants conspired to traffic misbranded and counterfeit drugs, specifically promethazine-codeine cough syrup. The indictment alleges the conspiracy resulted in approximately \$52,736,000 in drug trafficking proceeds. (EDTX, FBI, DEA, CPB)

 $\underline{\text{https://www.justice.gov/usao-edtx/pr/nine-indicted-counterfeit-promethazine-codeine-drugtrafficking-conspiracy-0}$

• Stamford Men Sentenced for Trafficking Counterfeit Oxycodone Pills Containing Fentanyl. On August 8, 2022, two residents of Stamford, Connecticut, were sentenced for manufacturing and distributing counterfeit oxycodone pills containing fentanyl analogues, to which they had previously pled guilty. Arber Isaku was sentenced to 51 months of imprisonment and three years of supervised release, and Vincent Decaro was sentenced to 48 months of imprisonment and three years of supervised release. According to court documents and statements made in court, Isaku and Decaro purchased fentanyl analogues from suppliers in China and, working out of Decaro's residence in Stamford, pressed the drug into counterfeit oxycodone pills, which they sold to customers on dark web markets. David Reichard, who lived for a short time at Decaro's residence (and also pled guilty), helped Isaku and Decaro press pills and mail the pills to customers. (D.Conn, OIA, USPIS, DEA)

 $\underline{\text{https://www.justice.gov/usao-ct/pr/stamford-men-sentenced-trafficking-counterfeit-oxycodone-pills-containing-fentanyl}$

• Boston Man Arrested in Counterfeit Fentanyl Pills Conspiracy. On July 6, 2022, Alexis Radhames Diaz Tejeda was charged with one count of conspiracy to distribute and to possess with intent to distribute 400 grams or more of fentanyl. According to the charging document, in October 2021, law enforcement began an investigation into the drug trafficking and money laundering activities of Diaz Tejeda and others. On March 7, 2022, during a video-recorded controlled purchase in Dorchester, Diaz Tejeda was allegedly captured providing a confidential source with 30 counterfeit fentanyl pills as a sample. It is alleged that, on June 1, 2022, Diaz Tejeda again met with the confidential source during a controlled purchase in Lawrence, this time providing the source with 1,000 counterfeit fentanyl pills weighing approximately 152 grams. On July 5, 202,2 in Dorchester, Diaz Tejeda allegedly agreed to sell another 4,000 fentanyl pills to the confidential source and arranged for the deal to occur the following day in Dorchester. Diaz Tejeda was arrested on July 6, 2022, after greeting the source for the arranged deal. It is alleged that approximately 4,000 fentanyl pills weighing approximately 513 grams were recovered during a subsequent search of Diaz Tejeda's residence. (DMA, DEA, Massachusetts State Police)

https://www.justice.gov/usao-ma/pr/boston-man-arrested-counterfeit-fentanyl-pills-conspiracy

Two Evansville Men Indicted for Trafficking Fentanyl and Allegedly Manufacturing Fentanyl-Laced Counterfeit Pills Using a Pill Press. On July 5, 2022, a federal grand jury returned an indictment charging two men with conspiracy to distribute fentanyl, illegal distribution of a tableting machine, and illegal possession of a tableting machine. According to court documents, Ethan Parker of Evansville, Kentucky, allegedly obtained pound quantities of fentanyl powder from an unknown source of supply in the Louisville area and manufactured fentanyl-laced counterfeit pills using a pill press. Parker then allegedly supplied Joshua Harvey, of Evansville, and others, with fentanyl-laced counterfeit pills. Harvey also allegedly transported Parker to the Louisville area to acquire pound quantities of fentanyl powder to facilitate the manufacture and distribution of fentanyl-laced counterfeit pills. During the investigation, it is alleged that Parker and Harvey displayed a high degree of technological sophistication, utilizing encrypted messaging applications to purchase, advertise, and sell fentanyl-laced counterfeit pills, as well as utilizing the "Dark Web" and cryptocurrency to pay for drug transactions. As of the indictment, authorities had seized approximately 140 grams of fentanyl-laced counterfeit pills and powder, two pill presses, and various dies and punches utilized to press pills. (SDIN, DEA, Evansville Police Department)

 $\underline{https://www.justice.gov/usao-sdin/pr/two-evansville-men-indicted-trafficking-fentanyl-and-allegedly-manufacturing-fentanyl}$

Woodbridge Man Pleads Guilty to Illegally Possessing a Firearm and Over 14,500 Counterfeit Pills Containing Fentanyl. On June 30, 2022, Keyshone Stephan Hogan of Woodbridge, Virginia, pleaded guilty to possession with intent to distribute fentanyl and possession of a firearm in furtherance of drug trafficking. According to court documents, between the end of November and beginning of December 2021, Hogan worked with a coconspirator to distribute counterfeit pressed pills containing fentanyl from a hotel room in Manassas. On December 2, 2021, Hogan was arrested after he and his co-conspirator exited the hotel and entered Hogan's car in the hotel parking lot. At the time of his arrest, Hogan was concealing a loaded Glock handgun in his waistband. Law enforcement recovered over 250 counterfeit Percocet pills containing fentanyl from Hogan's driver side door and several boxes of ammunition from the trunk of the vehicle. A search of the hotel room, registered under Hogan's name, revealed over 14,000 counterfeit Percocet pills containing over 1,500 grams of fentanyl in 14 plastic zipper bags. Two loaded mini Draco AK47 pistols and one loaded micro Draco AK47 pistol were in the hotel room. After his arrest and during processing at the local jail, Hogan was found to be hiding an additional 50 counterfeit Percocet pills containing fentanyl in his pants. (EDVA, ATF)

 $\underline{https://www.justice.gov/usao-edva/pr/woodbridge-man-pleads-guilty-illegally-possessing-firearm-and-over-14500-counterfeit}$

• Four Windsor Men Charged with Trafficking Counterfeit Oxycodone Pills Containing Fentanyl. On June 29, 2022, four men from Windsor, Connecticut, were arrested on federal narcotics distribution charges primarily related to the large-scale trafficking of counterfeit fentanyl pills containing fentanyl: Michael Lee, Alexander Lee, Daryl Beaufort, and Justin Little. As alleged in court documents and statements made in court, authorities have been investigating a drug trafficking organization led by Michael Lee and his brother Alexander

Lee. The investigation, which included court-authorized wiretaps, controlled purchases of narcotics, and the seizure of drugs that had been shipped through the U.S. Mail, revealed that Michael Lee, Alexander Lee, and others received thousands of counterfeit oxycodone pills containing fentanyl, and other controlled substances, from a source of supply on the west coast of the U.S., and then distributed the drugs to various street-level distributors in Connecticut, including Beaufort and Little, and numerous drug customers. During the investigation and in association with the arrests, investigators seized more than 15,000 counterfeit oxycodone tablets containing fentanyl, more than 1,800 alprazolam tablets (commonly referred to as "Xanax"), approximately 25 pounds of marijuana, seven firearms, and thousands of dollars in cash. The defendants were arrested on criminal complaints charging each with conspiracy to possess with intent to distribute controlled substances, and possession with intent to distribute and distribution of controlled substances. (DCT, DEA, ATF, Connecticut State Police)

https://www.justice.gov/usao-ct/pr/four-windsor-men-charged-trafficking-counterfeit-oxycodone-pills-containing-fentanyl

• Multi-Year Investigation Leads to Indictment of 26 Defendants and Seizure of Nearly 500,000 Counterfeit Pills Laced with Fentanyl. A two-year investigation has led to the indictment of 26 defendants for international drug smuggling, drug trafficking, and related conspiracy offenses. On June 13, 2022, one of the defendants, Raul Barajas-Padilla, appeared in federal court for an initial appearance on the indictment. As of that date, 17 defendants had been arrested, and efforts were ongoing to apprehend the remaining defendants.

According to publicly filed documents, an investigation was undertaken into a drugtrafficking conspiracy extending from Sinaloa, Mexico into the United States. Agents identified Mexico-based traffickers who coordinated shipments of counterfeit pharmaceutical pills laced with fentanyl, powder fentanyl, heroin, methamphetamine and cocaine into the United States. These efforts yielded seizures of more than 478,000 counterfeit pharmaceutical pills laced with fentanyl, as well as about 51 kilograms of methamphetamine, 10 kilograms of cocaine, 4 kilograms of powder fentanyl, and 4 kilograms of heroin. Agents also seized about \$230,000 in assets. According to the indictment, law enforcement agents also identified the distributors in the U.S.; the couriers who were responsible for transporting drugs; the people who managed stash houses; the people who smuggled the illicit proceeds back to Mexico; and other dealers. (SDCA, DEA, HSI, San Diego Sheriff's Department)

 $\underline{https://www.justice.gov/usao-sdca/pr/multi-year-investigation-leads-indictment-26-defendants-and-seizure-nearly-500000}$

• Drug Dealer Pleads Guilty to Selling Counterfeit Pills that Caused Death of Thirty-Five-Year-Old. On June 1, 2022, Saul Caro pleaded guilty, admitting that he sold the fentanyl that caused the fatal overdose of a thirty-five-year-old San Diego resident, identified in court records as M.S. According to his plea agreement, on April 11, 2021, Caro and the victim exchanged text messages to coordinate the sale of counterfeit oxycodone pills laced with fentanyl. Caro delivered the pills to M.S.'s residence. M.S. died in his apartment sometime

on the evening of April 11, 2021. Caro admitted that the pills he gave to M.S. caused his death. When a search warrant was executed at Caro's residence, a loaded, unregistered, semi-automatic privately manufactured firearm with no serial number, or "ghost gun" was located along with other drugs and drug paraphernalia. Prior to this meeting, Caro had sold the counterfeit oxycodone pills to M.S., and the victim had told Caro that some of the pills had caused him severe unintended effects. (SDCA, DEA, FBI, HSI, San Diego Police Department, CA Department of Health Care Services)

 $\underline{https://www.justice.gov/usao-sdca/pr/drug-dealer-pleads-guilty-selling-counterfeit-pills-caused-death-thirty-five-year-old}$

• Lowell Man Sentenced in Trafficking Conspiracy Involving Counterfeit Pills Containing Methamphetamine. On May 19, 2022, Vimoon Sortsoy of Lowell, Massachusetts, was sentenced to five years in prison and four years of supervised release for his role in a drug trafficking conspiracy involving methamphetamine disguised as counterfeit Adderall pills. On Dec. 15, 2021, Sortsoy pleaded guilty to conspiracy to distribute and possession with intent to distribute 50 grams or more of a mixture or substance containing methamphetamine. Sortsoy conspired to distribute counterfeit prescription pills pressed to resemble Adderall that in fact contained methamphetamine in the Lowell area. In a series of controlled purchases conducted by law enforcement between approximately September 2019 and August 2020, Sortsoy sold hundreds of counterfeit pills containing methamphetamine, totaling over 400 grams. (DMA, DEA, Massachusetts State Police)

 $\underline{https://www.justice.gov/usao-ma/pr/lowell-man-pleads-guilty-drug-conspiracy-involving-counterfeit-pills-containing}$

https://www.justice.gov/usao-ma/pr/lowell-man-sentenced-trafficking-conspiracy-involving-counterfeit-pills-containing

• Fresno Fentanyl Pill Dealer Sentenced to 6 Years in Prison for Illegal Possession of Counterfeit M30 Pills and a Loaded Firearm. On April 18, 2022, Jose Jesus Torres Garcia of Fresno, California, was sentenced to six years in prison for illegally possessing fentanyl pills and a firearm. According to court documents, in May 2021, law enforcement obtained evidence that Torres Garcia was using his social media account to advertise the sale of "M30" pills, which are counterfeit oxycodone pills laced with fentanyl. Based on that information, federal officers executed a search warrant at Torres Garcia's residence and found a loaded, short-barrel rifle and several hundred fentanyl pills packaged for sale. Torres Garcia was charged with possessing fentanyl with intent to distribute it and possessing a firearm in furtherance of a drug trafficking crime. He pleaded guilty to both charges on Sept. 27, 2021. (EDCA, DEA, HSI, Fresno Police Dept.)

https://www.justice.gov/usao-edca/pr/fresno-fentanyl-pill-dealer-sentenced-6-years-prison-illegal-possession-counterfeit-m30

• San Fernando Valley Man Who Sold Counterfeit Prescription Pills Containing Fentanyl Admits Causing Overdose Death of U.S. Marine. On April 15, 2022, Gustavo Jaciel Solis of Sylmar, California, pleaded guilty to two federal drug trafficking offenses, one of which

stemmed from a 2020 transaction in which he sold bogus oxycodone pills laced with fentanyl that caused a U.S. Marine stationed at Camp Pendleton to suffer a fatal overdose. Solis was charged in 2020, along with an active-duty United States Marine stationed at Camp Pendleton and two other alleged co-conspirators, with being part of a ring that distributed narcotics to civilians and members of the United States Marine Corps. In a plea agreement, Solis admitted that he advertised controlled substances for sale through his Snapchat account and provided various controlled substances, including LSD, MDMA, cocaine, and purported oxycodone pills containing fentanyl, to customers directly, through couriers, or through the United States mail.

On May 22, 2020, after obtaining approximately 1,000 counterfeit oxycodone pills containing fentanyl from a co-defendant, Solis admitted using his Snapchat account to advertise the pills by posting a picture of several pills with the caption, "Who f*** with M30s? Tapp in." Solis subsequently sold approximately 10 of the counterfeit oxycodone pills, and a 20-year-old U.S. Marine identified in court papers as "L.M." died after consuming some of the fentanyl-laced pills. Solis also admitted in his plea agreement orchestrating other narcotics transactions, some of which were conducted with an undercover agent with the Naval Criminal Investigative Service. The transactions with the undercover agent involved several types of narcotics, including counterfeit oxycodone containing fentanyl, cocaine and LSD. Solis was arrested on July 29, 2020, at which time investigators seized narcotics and several firearms – including a 9mm "ghost gun" – from his residence. Perez pleaded guilty to conspiring to distribute narcotics on January 26. (CDC, NCIS, DEA, FBI, USPIS)

https://www.justice.gov/usao-cdca/pr/san-fernando-valley-man-who-sold-counterfeit-prescription-pills-containing-fentanyl

• 12 Members of Drug Trafficking Organization Indicted for Distributing Counterfeit Oxycodone Pills Containing Fentanyl, Laundering Proceeds. On March 15, 2022, 12 people were indicted on federal charges for conspiring to distribute counterfeit oxycodone pills containing fentanyl in the Pacific Northwest, and laundering millions in drug proceeds. According to court documents, beginning in fall 2021, federal agents based in Portland began investigating a drug trafficking organization led by Luis Antonio Beltran Arrendondo of Las Vegas, Nevada, who was suspected of importing counterfeit oxycodone pills containing fentanyl and heroin from Mexico into California, and transporting it to Oregon and Washington State for distribution. Arrendondo formerly resided in Oregon, but later relocated to Las Vegas with his significant other and accomplice Jacqueline Paola Rodriguez Barrientos. Barrientos was also indicted as the chief money launderer for the Arrendondo organization.

As the investigation continued, agents interdicted couriers transporting fentanyl pills and heroin to Oregon. In total, their enforcement actions resulted in the seizure of approximately 115,000 counterfeit oxycodone pills suspected to contain fentanyl and stamped "M/30", 41 pounds of methamphetamine, and more than 57 pounds of heroin. A parallel financial investigation revealed that Barrientos laundered money generated by the Arrendondo organization through the Mazatlán Beauty Salon in Tualatin, Oregon, and by buying real estate. Since February 2021, members of the Arrendondo organization purchased a total of

nine residential properties in Oregon and Nevada with an estimated total value of more than \$4.6 million. All nine properties were purchased outright with no mortgages. On February 17, 2022, DEA agents arrested Arrendondo and Barrientos at their Las Vegas residence. Both Arrendondo and Barrientos are in custody pending trial. As of the indictment, all ten of Arrendondo and Barrientos' co-conspirators had been arrested and were also pending trial in the District of Oregon. (DOR, DEA, FBI, HSI, IRS-CI)

https://www.justice.gov/usao-or/pr/12-members-drug-trafficking-organization-indicted-distributing-counterfeit-oxycodone

• Lynn Woman Pleads Guilty to Role in Counterfeit Pill Trafficking Organization. On February 28, 2022, Laurie Caruso of Lynn, Massachusetts, pleaded guilty to her role in a large-scale drug trafficking organization that manufactured and distributed hundreds of thousands of counterfeit Percocet pills containing fentanyl. She pleaded guilty to one count of conspiracy to manufacture, distribute, and possess with intent to distribute fentanyl and other controlled substances. Laurie Caruso was sentenced in June 2022 to nine years in prison and four years of supervised release.

On June 30, 2021, Laurie Caruso was arrested and charged along with co-conspirators Vincent Caruso, Ernest Johnson, and Nicole Benton. According to the charging documents, Laurie Caruso was a member of a large drug trafficking organization (DTO) operated by her son, Vincent Caruso, a self-admitted Crip gang member, that included Johnson and Benton, among others. The DTO allegedly sold counterfeit prescription pills containing fentanyl – produced using multiple large pill presses capable of generating thousands of pills per hour – to street gangs for further distribution on the North Shore of Massachusetts. Laurie Caruso admitted to being a primary distributor for the DTO, which historically manufactured its own counterfeit fentanyl pills when it was based in Saugus. Laurie Caruso admitted to trafficking over 30 kilograms of fentanyl, sold in the form of hundreds of thousands of counterfeit Percocet pills containing pressed fentanyl. As part of her plea agreement, Laurie Caruso also agreed to forfeit over \$100,000 in cash seized from the DTO that were the proceeds of drug trafficking.

On September 30, 2021, Benton pleaded guilty to conspiracy to manufacture, distribute, and possess with intent to distribute fentanyl and other controlled substances. Vincent Caruso and Johnson have pleaded not guilty. Vincent Caruso was indicted on January 19, 2022, for his role in the conspiracy and faces additional charges. (DMA, FBI, ATF, OCDETF)

https://www.justice.gov/usao-ma/pr/lynn-woman-pleads-guilty-role-counterfeit-pill-trafficking-organization

• Lawrence Man Sentenced for Distributing Counterfeit Prescription Pills Containing Fentanyl. On February 17, 2022, Ruben Mejia of Lawrence, Massachusetts, was sentenced to 45 months in prison and two years of supervised release in connection with distributing counterfeit pills containing fentanyl. On September 9, 2021, Mejia pleaded guilty to one count of possession with intent to distribute and distribution of fentanyl and heroin; two counts of possession with intent to distribute and distribution of 40 grams or more of fentanyl

and heroin; and one count of possession with intent to distribute 400 grams or more of fentanyl and heroin. Mejia distributed fentanyl pressed into pills designed to resemble actual pharmaceutical-grade oxycodone. End users of Mejia's product could reasonably believe they were ingesting legitimate oxycodone pills, unaware that they were in fact consuming street fentanyl of uncertain dosage. Mejia personally delivered or attempted to deliver approximately 6,000 pills, in total containing over 980 grams of fentanyl, to an undercover agent. (DMA, DEA)

 $\underline{https://www.justice.gov/usao-ma/pr/lawrence-man-sentenced-distributing-counterfeit-prescription-pills-containing-fentanyl}$

• Reno Man Sentenced For Selling Hundreds Of Counterfeit Oxycodone Pills Laced With Fentanyl. On December 7, 2021, Octavio Mendoza Jr. of Reno, California, was sentenced to 34 months in prison after pleading guilty to selling hundreds of counterfeit oxycodone pills containing the powerful synthetic opioid fentanyl. According to court documents, from June 12 to September 2, 2020, Mendoza Jr. sold counterfeit oxycodone pills stamped with "M30" containing fentanyl and, after observing him using drugs in a vehicle in downtown Reno, law enforcement arrested Mendoza on September 6. During a search of the vehicle, law enforcement found approximately 374 counterfeit oxycodone pills containing fentanyl. Mendoza pleaded guilty in November 2021 to seven counts of distribution of fentanyl and one count of possession with intent to distribute 40 grams or more of fentanyl. (DNV, FBI)

 $\underline{https://www.justice.gov/usao-nv/pr/reno-man-pleads-guilty-selling-hundreds-counterfeit-oxycodone-pills-laced-fentanyl}$

 $\underline{https://www.justice.gov/usao-nv/pr/reno-man-sentenced-selling-hundreds-counterfeit-oxycodone-pills-laced-fentanyl}$

• El Cajon Resident Sentenced to 15 Years for Selling Counterfeit Pills with Fentanyl that Caused 19-Year-Old's Death. On November 24, 2021, Olatunde James Temitope Akintonde of El Cajon, California, was sentenced in federal court to 15 years in prison for selling fentanyl-laced pills that caused the death of a 19-year-old Santee man in March of 2019. Akintonde previously admitted that, on February 28, 2019, he sent messages to the man through social media to coordinate a sale of what the victim believed to be oxycodone pills. Later that evening, Akintonde delivered to the man two counterfeit oxycodone pills laced with fentanyl. After the meeting, Akintonde sent additional messages to the man through social media warning that he should only take one of the pills because they were "strong." Akintonde further admitted that the pills he gave to the man caused his death. According to other filings in the case, the man died in his home sometime in the evening of February 28, 2019, or the early morning hours of March 1, 2019. (DSCA, DEA)

 $\underline{https://www.justice.gov/usao-sdca/pr/el-cajon-resident-pleads-guilty-selling-counterfeit-pills-caused-death-nineteen-year$

https://www.justice.gov/usao-sdca/pr/el-cajon-resident-sentenced-15-years-selling-counterfeit-pills-fentanyl-caused-19-year

• Oregon Man Charged with Possessing Counterfeit OxyContin Pills Containing Fentanyl. On November 18, 2021, a federal grand jury returned a two-count indictment against Jose Antonio Nunez De Jesus of Portland, Oregon, charging him with conspiracy to distribute and possess with the intent to distribute fentanyl and possession of fentanyl with the intent to distribute. According to court documents, a law enforcement officer on routine patrol saw that the vehicle being driven by Nunez De Jesus had committed a traffic violation. After pulling the vehicle over, a narcotics K-9 alerted to the odor of a controlled substance in the vehicle. Officers found approximately 34,020 counterfeit OxyContin pills that weighed a total of 7.5 pounds. Nunez De Jesus told the officer that he had picked up what he believed to be drugs in Los Angeles at the request of a friend and was returning to Oregon with the pills. A presumptive test of the pills showed that they were fentanyl. (EDCA, CA Highway Patrol)

https://www.justice.gov/usao-edca/pr/oregon-man-charged-possessing-counterfeit-oxycontin-pills-containing-fentanyl

II. IP-related activities of the Justice Department's Antitrust Division

Withdrawal of the 2019 SEP Policy Statement

President Biden's Executive Order on Promoting Competition in the U.S. Economy asked the Department to "conside[r] whether to revise the Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments issued jointly by the Department of Justice, the United States Patent and Trademark Office, and the National Institute of Standards and Technology on December 19, 2019."¹¹

The Antitrust Division worked in partnership with the U.S. Patent and Trademark Office (USPTO) and the National Institute of Standards and Technology (NIST) to develop of a draft of a revised Policy Statement, which the Division released for public comment on December 6, 2021. Based on a review of the public comments, and after further consideration of the issues, the three agencies decided to withdraw the 2019 Statement on Remedies for Standard Essential Patents Subject to FRAND commitments (2019 Statement). In announcing their decision on June 8, 2022, the agencies explained that withdrawal of the 2019 Statement was the best course for promoting competition and innovation. The Division indicated that it will evaluate conduct by standards-essential patent (SEP) holders or standards implementers on a case-by-case basis to determine if either party is engaging in practices that result in the anticompetitive use of market power or other abusive processes that harm competition.¹²

¹¹ Executive Order 14036 on "Promoting Competition in the American Economy" (July 9, 2021) at https://www.govinfo.gov/content/pkg/FR-2021-07-14/pdf/2021-15069.pdf.

¹² On the Antitrust Division's request for public comments on a draft of a revised Policy Statement, see DOJ's press release on "Public Comments Welcome on Draft Policy Statement on Licensing Negotiations and Remedies for

Standards-Essential Patents Subject to F/RAND Commitments" (December 6, 2021) at https://www.justice.gov/opa/pr/public-comments-welcome-draft-policy-statement-licensing-negotiations-and-remedies-standards. On the agencies' withdrawal of the 2019 Policy Statement, see the press releases issued by DOJ, USPTO, and NIST on June 8, 2022, at https://www.justice.gov/opa/pr/justice-department-us-patent-and-trademark-office-and-national-institute; and https://www.nist.gov/news-events/news/2022/06/department-justice-us-patent-and-trademark-office-and-national-institute.

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"So as we make sure the next wave of innovation is unleashed by the United States and our allies and partners, we'll also protect ourselves against efforts to siphon off our ingenuity or imperil our security."¹³

"Investing in the United States is the smartest decision an investor can make—we are one of the most open markets in the world, with a predictable and transparent legal system, intellectual property rights, and a culture of entrepreneurship and innovation." ¹⁴

- Anthony J. Blinken, Secretary of State

Department of State Appendix for FY 2022 Annual Report

In FY 2022, the Department of State continued to promote international economic environments conducive to strong intellectual property (IP) regimes and thereby protect the products of U.S. ingenuity through efforts in Washington, DC, and in embassies and consulates around the world. The Department of State advocates for strong IP protection and enforcement in bilateral policy dialogues and in multilateral fora; collaborates with bilateral, interagency, and private sector partners on capacity building; monitors the state of IP protections and enforcement around the world to better address problem areas; and educates public and official audiences on the value of IP both to generate economic growth and to improve people's quality of life. Aligned with the Biden-Harris Administration's foreign policy for the middle class, better IP protection and enforcement abroad allows U.S. companies, including small to medium enterprises, to conduct business around the world with greater confidence.

The Department of State's lead on IP issues is the Office of Intellectual Property Enforcement (IPE), located in the Trade Policy and Negotiations Division in the Bureau of Economic and Business Affairs (EB) in Washington, DC. IPE participates in a range of interagency bilateral and multilateral efforts, conducts research and outreach, and serves a central support function on all IP matters for the agency's personnel. Areas in which U.S. embassies work with their host governments include increasing political will for strengthening copyright, patent, trademark, and other IP protections and their associated enforcement, as well as combatting forced technology transfer, online copyright piracy, and the production and sale of counterfeit goods. United States embassies and consulates report year-round on IP issues to keep Department of State headquarters and relevant U.S. government agencies up to date on key developments.

Department of State economic sections at embassies also liaise with local and global representatives of creative industries, manufacturers, and others about IP issues and advocate for U.S. rightsholders. State Department officials working on IP issues overseas collaborate with, and receive support from, many agencies, including the U.S. Patent and Trademark Office (USPTO) IP Attachés, the Department of State Bureau for International Narcotics and Law Enforcement Affairs (INL), which funds and co-manages the U.S. Transnational and High-Tech Crime Global Law Enforcement Network (GLEN) composed of Department of Justice (DOJ)

¹³ Speech of May 26, 2022, on "The Administration's Approach to the People's Republic of China" at https://www.state.gov/the-administrations-approach-to-the-peoples-republic-of-china/.

¹⁴ Statement of June 28, 2022, during the SelectUSA Investment Summit at https://twitter.com/SecBlinken/status/1541840099188436992.

International Computer Hacking and Intellectual Property (ICHIP) advisors, Global Cyber Forensics Advisors and long-term agent mentors, and Department of Homeland Security (DHS) Homeland Security Investigation (HSI) representatives.

The COVID-19 pandemic continued to limit in-person work and travel throughout the fiscal year, and the Department of State operated under a maximum telework status for most of the year, but began shifting to a hybrid telework/in-person status as local health conditions improved. With in-person activities limited based on local pandemic conditions, the Department of State maintained widespread use of video-conferencing and other technologies. This enabled the Department of State to continue crucial bilateral dialogues, create and participate in a broad range of IP-related events and activities, discuss IP issues with interagency partners, and advance U.S. IP priorities overseas. What follows are illustrative examples of the broad, diverse range of work the Department of State performed on IP issues during the reporting period.

Diplomacy to Advance and Protect IP Rights

The United States has more than 270 diplomatic missions around the world. In addition to IPE efforts in Washington, DC, embassies and consulates feature Foreign Service Officers (FSOs) and locally employed staff who work to advance IP protection and combat IP infringement. They advocate for U.S. rightsholders and alert Department of State headquarters and relevant U.S. government agencies about opportunities to collaborate with foreign governments and others, including to improve IP conditions by reviewing legislative and judicial matters, policy changes, and economic and political conditions that affect the IP environment. In addition to fulfilling Department of State activities on IP issues, the embassies and consulates support the overseas work of other U.S. government agencies through their economic sections, public affairs sections, and other Department of State offices. This assistance takes many forms including information gathering, diplomatic engagement to facilitate and coordinate bilateral discussions, participation in public IP-related events, organizing official U.S. government delegations addressing IP issues, and leading follow-up activities to high-level, IP-focused bilateral meetings.

Below are illustrative examples of the work that Department of State staff undertook during FY 2022.

Argentina: The U.S. Embassy in Buenos Aires assembled interagency partners and industry representatives at an event to inform local judges and prosecutors about the Protect Lawful Streaming Act (PLSA), which was enacted in December 2020 and established enhanced ("felony streaming") penalties for large-scale commercial digital piracy of copyrighted material. In addition to strengthening IP enforcement in the US, the PLSA serves an example for other countries of a law that updates IP protections for today's digital environment while being carefully tailored to apply only to large-scale commercial infringers. The PLSA added 18 U.S.C. § 2319C, and it was enacted in P.L. 116-260, Div. Q, Title II, Sec. 211.

Bahrain: With U.S. Embassy support, the University of Bahrain launched the Bahrain Innovation and Technology Transfer Center (BITTC), established to secure intellectual property protection for any discoveries made by University of Bahrain's faculty, negotiate

partner/licensing arrangements, and assist in the commercialization process to develop products and services that meet Bahrain's economic development priorities. The U.S. Department of Commerce's Commercial Law Development Program (CLDP) and the U.S. Patent and Trademark Office (USPTO) provided training with funding from the State Department's U.S. Middle East Partnership Initiative (MEPI) program.

Bulgaria: Investigation and prosecution of Intellectual Property Rights (IPR) legal cases is a challenge in Bulgaria. Economic Officers (ECONOFFS) from Embassy Sofia continue to support interagency U.S. experts that are assisting the government with IPR capacity building across a broad range of audiences, from university students and entrepreneurs to investigators, prosecutors, and judges. ECONOFFS note that industry representatives have stated that IPR protection concerns are part of Bulgaria's larger rule of law problems. To help strengthen patent protection, embassy officials and other U.S. government personnel have been assisting Bulgaria in joining the U.S. Google Patents platform, which provides information about patents from around the world. In addition, embassy officials and other U.S. government personnel have been assisting in rule of law reform that would also strengthen IPR protections.

Kenya: In February 2022, State Department IP enforcement officials organized meetings between the Washington IP interagency, U.S. Embassy Nairobi, U.S. Congressional leaders, and Kenyan Parliamentarians to discuss the global trade effects of proposed Kenyan Copyright legislation. Through the interactions, Kenyan parliamentarians discovered that their new draft Copyright legislation would weaken IP protections for American and Kenyan creators and threaten existing important internet service provider (ISP)-related liability provisions. As a result of the engagement, Kenyan leaders were able to successfully pass legislation that protects Kenyan and global IP interests, uphold ISP-related liability provisions needed to combat digital piracy, and position Kenya to be in compliance with internationally accepted copyright best practices.

Korea: U.S. Department of State personnel in Seoul continue to engage with the Korea Atomic Industrial Forum (KAIF) in working with interlocutors to encourage and track cooperation on nuclear Small Modular Reactor (SMR) innovation that is dependent upon strong U.S.-Korea engagement on intellectual property rights (IPR) protection, and enforcement. Collaboration between U.S. and ROK industries is already underway for global SMR deployment including \$2.4 billion of current contracts. This U.S.-Korea partnership is essential to meeting rising global demand for nuclear power plant construction in combatting climate change.

Kuwait: Embassy Kuwait personnel met with the Ministry of Commerce and Industry's (MOCI) in October 2021. The meeting highlighted the development of an online system to streamline the infringement complaint process and facilitate quicker enforcement responses.

Mongolia: There will be more Mongolian inspectors at the PRC border specializing in Intellectual Property Rights (IPR) as U.S. and Mongolian officials set goals for joint IPR protection initiatives for the remainder of 2022 and beyond. Subsequent to discussions with the U.S. Ambassador and ECONOFF, the Intellectual Property Office of Mongolia (IPOM) is working closely with Post on IPR events and training for Mongolian judges, digital service providers and entrepreneurs. Further, engagement by the U.S. Ambassador resulted in the

Director General of IPOM to confirm that they will work with Mongolian Customs to better implement Mongolia's WTO TRIPS obligations.

Pakistan: In July 2022, the State Department's Special Representative for Commercial and Business Affairs traveled to Pakistan where he met with business and government leaders and pressed them to make improvements to the country's business climate, specifically highlighting the need to address IPR protection and enforcement regimes.

People's Republic of China: In September 2022, the U.S. Embassy in Beijing hosted an IP roundtable discussion with the U.S. Ambassador that covered a wide range of consumer good and industry sectors. Discussions focused on obtaining effective IP enforcement through China's civil, criminal, and administrative channels.

Romania: U.S. Embassy officers continue to work with their IP interlocutors to improve IPR protection and enforcement in Romania. Working closely with the INL-supported DOJ ICHIP based in Bucharest, Embassy officers continue to engage with Romanian officials on their National Intellectual Property (IP) Strategy and execution of their intellectual property rights (IPR) work plan. As a result of its "taking significant actions to improve IP protection and enforcement," Romania was removed from the Special 301 Report's "watch list" in April 2022. ¹⁵ In addition, the USG's engagement has established the United States as the key coordination partner on IPR with one of our most valuable strategic allies in the Black Sea region. U.S. Department of State and interagency experts are continuing efforts to enhance IPR protection and enforcement, which further supports growth in our rapidly blossoming Romania-U.S. commercial relationship.

Taiwan: In cooperation with Taiwanese interlocutors, U.S. Department of State personnel in Taiwan continue to track the semiconductor industry to prevent overcapacity, inadvertent technology transfer, and intellectual property theft. This work is especially important given the potential significance of compound semiconductor chips in military systems and aerospace applications. The work of U.S Department of State Foreign Service Officers with Taiwan's industry leaders helps inform the discussion around export controls and other measures to prevent PRC exploitation of this industry.

Thailand: Thailand's new copyright act, which was modeled on the United States' Digital Millennium Copyright Act, went into force in August 2022 after technical assistance by USPTO and advocacy by both U.S. Department of State officers and the Regional IP Attaché based at the U.S. Embassy in Bangkok. Of note, the updated Copyright Act includes a notification system by which rights holders can make direct requests to online platforms to remove IP infringing content. Thailand is also in the process of amending its Patent Act to meet international standards and speed up the patent registration process.

coordination of IP working group sessions."

¹⁵ USTR press release, "USTR Releases 2022 Special 301 Report on Intellectual Property Protection and Enforcement" (April 27, 2022), at https://ustr.gov/about-us/policy-offices/press-office/press-releases/2022/april/ustr-releases-2022-special-301-report-intellectual-property-protection-and-enforcement. As the press release explains, Romania's actions "include the appointment of its first-ever national IP enforcement coordinator, establishment of a new department of the economic police dedicated to online piracy cases, dedication of additional officers to IP investigations, and the General Prosecutor Office Intellectual Property Coordination Department's resumed

Vietnam: Due to advocacy and interagency engagements by U.S. Department of State officers, Vietnam's National Assembly amended Vietnam's intellectual property law and legal frameworks to better enforce IPR, in concert with their inter-ministerial committee. As commercial relationships continue to rapidly expand, State Department officers with Mission Vietnam and other U.S. government representatives continue to be the partners of choice, including through establishing strong partnerships with the private sector, industry associations, academia, and IP agencies from Thailand and the Philippines. In September, Embassy Hanoi sponsored an IP roundtable and workshop.

United States Mission to the Africa Union (USAU): In Spring 2022, State Department Officials, including USAU Mission leadership and representatives from the Bureau of Cyberspace and Digital Policy, met with the DOJ International Computer Hacking and Intellectual Property Officer (ICHIP) for an extended discussion on engaging with the African Union on issues related to enhancing cybersecurity measures and enforcing against cybercrime. There is an overlap in both areas sufficient for the ICHIP to appear at certain cybersecurity-focused events hosted by the AU, as was done in 2021.

World Intellectual Property Day

The Department of State promotes the awareness of Intellectual Property through ongoing events and activities at embassies around the world. The flagship annual engagement is the celebration of World Intellectual Property Day (World IP Day) on April 26.

As the theme for 2022 World IP Day, the World Intellectual Property Organization (WIPO) selected "IP and Youth: Innovating for a Better Future." In support of the WIPO theme, the Department of State's Bureau of Economic and Business Affairs' IP Enforcement Office (IPE) hosted a virtual private sector panel of four young inventors under age 35 who had experienced the process of obtaining a patent, trademark, or copyright. This inspirational panel discussion was open to the public and targeted specifically at our embassies and their guests. The recorded event was posted on the Economic Bureau's website and on social media.

In addition, IPE created a social media Toolkit for all embassies that were interested in using pre-cleared, ready-made content for various social media platforms. The Bureau also executed a 10-day countdown campaign on social media, posting content to generate excitement and interest for the April 26th event.

The IPE Director recorded a special video message, in both English and Spanish, highlighting the importance of IP. IPE sent the video to all our embassies. And, for the second year in a row, the video message was the Economic Bureau's top media tweet for April.

The Department of State also marked World IP Day by engaging in a wide range of activities around the world, which included the following:

Argentina: Entrepreneurs, business students, and business leaders attended U.S Embassy Argentina's World IP Day "Intellectual Property and Entrepreneurship" event. The hybrid online-in-person event targeted local entrepreneurs in the software industry, emphasizing the

importance of IP rights for business development. Speakers from the Argentine Copyright Office, the local Software Chamber, the USPTO IP Attaché regional team, and State helped raise awareness about the importance of IP rights for economic development.

Botswana: Embassy Gaborone planned a variety of activities surrounding World IP Day. Post led the U.S. Government partnership with Botswana's Ministry of Trade and Industry, the Intellectual Property Authority, and the Government of Botswana's innovation body in an April 26 event focused on "Intellectual Property and Youth." Botswana's Minister of Trade and Industry celebrated Botswana's potential for innovation and encouraged Botswana's youth to harness creativity and government initiatives to extend Botswana's creative industry to international markets. In the run up to World IP Day, Post held a competition for students from high schools and technical colleges. The students were asked to develop a prototype for a product that provides a practical solution to a problem within defined parameters in line with the students' area of interest. In addition, Post worked with USPTO to create radio advertisements and short videos of inspiring young people who have navigated IP journeys and who could point to copyright protections as the critical element that led to their success. These first-hand narratives of life lessons were very motivating and inspiring to Botswanans under the age of 25, who make up more than half of the nation's population.

Estonia: Embassy Tallinn, in cooperation with the Estonian Organization for Copyright Protection (EOCP) and the Baltic Film, Media and Arts School (BFM) of Tallinn University, and with support from the Ministry of Education and Research, launched an information campaign targeted at Estonian youth, to raise awareness about copyright and related IPR issues in a digital environment, focusing on how illegal use of digital content may harm digital safety. The project targeted children in all general education schools in Estonia in the 10 to 15-year-old age group, where the basic habits of internet use are formed. The EOCP held a contest for second year BFM students to create an original digital campaign poster to teach the importance of copyright, related intellectual property rights, and digital safety. Campaign organizers displayed the winning works in schools, and all contestants received academic credit for their work. The project reached about 40,000 young people and helped raise awareness of copyright issues and the importance of the honest consumption of legitimate digital content by pointing out the risks of downloading content from illegal sources.

Indonesia: Embassy Jakarta worked with the Indonesian Anti-Counterfeiting Society (MIAP) to hold an interactive virtual discussion with local creators and innovators, ages 18-35, to build awareness of intellectual property rights protection and to share knowledge of best practices on managing creative portfolios within a digital platform. The Embassy invited local officials and influencers, including the Governor of West Java Province (who shared his experience as a local creator), the Ministry of Law and Human Right's Director for Investigation and Dispute Settlement (who shared a regulatory perspective), and other speakers including IP practitioners, local creators and inventors, and representatives from digital platforms. The speakers shared best practices on the protection of IP rights across digital platforms, case studies, and the regulation and enforcement of IP protections on digital platforms. Post was able to reach participants from creative communities, start-ups and small medium enterprises, college students, related IP stakeholders (association and government representatives), and media representatives.

Jamaica: The Jamaica Intellectual Property Office (JIPO) launched its Intellectual Property Week with the WIPO theme of "IP and Youth: Innovating for a Better Future." WIPO's Assistant Director General of the Global Challenges and Partnerships Sector participated virtually in JIPO's launch event and commended Jamaica for encouraging its Caribbean Community (CARICOM) colleagues to allow for regional IPR registration instead of making rights holders register in each Caribbean country. Post's Economic Officer gave remarks at the event about the importance of intellectual property rights for the U.S.-Jamaica trade relationship. Embassy Kingston and JIPO referenced their longstanding partnership in promoting intellectual property rights, including Jamaica's pre-pandemic participation in the State Department's Arts Envoy Program.

Kenya: Embassy Nairobi worked with the Industrial Property Institute (KIPI), a parastatal under the Ministry of Industrialization, Trade and Enterprise Development, to organize a conference-style event targeted at young innovators who wanted to exhibit their innovations and learn about important IP issues. The event included a panel discussion with representatives from different institutions who spoke on the benefits of IP and innovation for youth, why and how to protect their IP, and how to access the relevant government offices. The event also included a competition element, with judges voting on the best exhibited innovation. Several government offices and non-government organizations participated including The Ministry of ICT, Innovation and Youth Affairs, the Ministry of Industrialization, Trade and Enterprise Development, ICT Authority, universities, Technical, Vocational and Educational (TVET) institutions, Young Scientists Kenya, and Youth in Motion, among others. During the day, there were physical and virtual celebrations led by the Cabinet Secretary Ministry of Industrialization, Trade and Enterprise Development. The celebration event targeted 200 in-person participants and over 10,000 on the U.S. Embassy's and KIPI's social media platforms.

Nigeria: Embassy Abuja, in collaboration with the network of government IP agencies, the American Business Council (ABC), the International Trademark Association (INTA), and the Anti-counterfeiting Collaboration (ACC), held a two-day symposium for the community, highlighting Nolly-wood and IP awareness within the film industry. The symposium featured two interactive discussions, bringing together young innovators and government agencies handling IP issues in the science, technology, and business sectors: "Making Nigeria's IP Ecosystem Work for the Innovative Nigerian Youth" and "Negotiating Global Opportunities for Nigeria's Budding Entertainment Industry." The symposium also included presentations on "Digital Environment Education for Youths by a U.S. Speaker" and "Tracking Pending IPR Legislation at the National Assembly." In addition, prior to the symposium, the U.S. Embassy in Nigeria held a video competition requesting video submissions of less than three minutes from undergraduate students on innovative IP solutions to one of Nigeria's problems. The winners showcased their solutions during the event, and a few secondary schools from Lagos held live debates arguing for or against the relevance of IP for Nigeria's better future. U.S. Embassy staff livestreamed the event on U.S. Mission and other social media pages, allowing the message to reach a broad audience.

Panama: Embassy Panama City celebrated World IP Day on April 26 with two events: a virtual conference with over 40 entrepreneurs on how the Panamanian judicial system protects intellectual property rights, and an invitation for Panamanian students to attend WIPO's "Young

Experts Program" to help build innovation ecosystems around the world. Conference participants reported that the program was practical, complete, and useful to protect their businesses. Several Panamanian students noted interest in registering for the "Young Expert Program" for 2023.

Poland: Embassy Warsaw, in a partnership with the local organization called the Legal Culture Foundation, organized a cultural event to celebrate World IP Day. The event drew attention to the ethical aspects of intellectual property. To attract a young audience, organizers linked the event to the release of a new Polish film called "Songs about Love," winner of the Golden Lion at the 46th Polish Film Festival in Gdynia. There were four parts of the event: a short lecture by IP law specialists on the ethical principles of using IP in culture; a meeting and discussion with the film's creators (the director and two lead actors) about the importance of IP; the lead actress's short, live performance from the film's soundtrack; and a screening of the film. Embassy organizers livestreamed the event on its Facebook page and the Foundation's website, allowing them to reach a larger audience.

Uzbekistan: Embassy Tashkent celebrated World IP Day for an entire month, with trainings, roundtables, lectures, American Space "Chai Chats," and social media campaigns to support IPR in Uzbekistan. Post's goal was to make a broad spectrum of Government of Uzbekistan (GOU) interlocutors, private sector businesses, legal firms, and individuals aware of IPR issues, and to further strengthen enforcement capacity across Uzbekistani society. On April 26, the U.S. Embassy in Uzbekistan held a U.S. panel discussion for university students learning the basics of IP. Embassy staff translated the event in several languages and reached an audience of about 100, many of whom were learning about IP for the first time.

Zimbabwe: In observance of World IP Day and in furtherance of a key mission goal to build an inclusive economy, the U.S. Embassy in Harare hosted American musician and IP activist James Barraque Monfils Evangelista on a five-day exchange visit. The Embassy collaborated with leading arts organization Magamba Network, which curated the exchange that featured IP workshops, public performances, and networking sessions with musicians and music producers. As a result, the Mission deepened its network of contacts with emerging and established musicians, music producers, and the arts regulatory bodies, and increased the appreciation of the importance of IP for protecting creative works.

Multilateral Engagement

The Department of State works closely with our interagency partners to ensure U.S. views are known and incorporated in global regulatory, standard-setting bodies and in trade-focused organizations. The Department of State participates in U.S. delegations to multilateral forums and international organizations with global IP protection and enforcement implications including the World Trade Organization's (WTO's) Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council), the World Health Organization (WHO), the Organization for Economic Co-operation and Development (OECD) Task Force on Countering Illicit Trade, the World Intellectual Property Organization (WIPO), the World Customs Organization (WCO) Enforcement Committee, the Intellectual Property Rights Experts Group (IPEG) of the Asia-

Pacific Economic Cooperation (APEC) Forum, the Group of 7 (G7), the Group of 20 (G20), and various United Nations (UN) bodies.

Within such multilateral fora, State IPE participates in interagency processes to review resolutions, declarations, and other statements and ensure that U.S. IP priorities are accurately reflected. Depending on the venue and in the event that multiple rounds of negotiations do not result in a document that reflect U.S. views, an Explanation of Position or an Explanation of Vote may be issued to clarify U.S. policies. A few examples of multilateral documents containing IP equities issued in 2022 include the UN Human Rights Council's *Access to medicines, vaccines and other health products in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*; the Zero Draft of the G20 Roadmap to Stronger Recovery and Resilience in Developing Countries, LDCs and SIDS; multiple resolutions from the Seventy-fifth World Health Assembly, including the resolution on Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination; and the UN's Report of the Committee on Information.

The United States reports on its incentives to promote and encourage technology transfer to least-developed country (LDC) WTO members in the annual Article 66.2 Report. IPE receives input from U.S. missions overseas, State Department regional and functional bureaus, and interagency partners on the range of U.S. government technology transfer and capacity building activities around the world. IPE submits the Article 66.2 Report to the WTO TRIPS Council annually. The broad range of activities covered in this report – including laboratory-based scientific collaboration, capacity building and education, and IP enforcement activities – highlight the United States' efforts to promote effective and voluntary transfer of technology to LDC members.

The United States also continued to engage at the WTO TRIPS Council in FY 2022 on proposals related to the COVID-19 pandemic response. In June 2022, after difficult and protracted negotiations throughout the last year, WTO Members came together to reach an agreement on an IP response to the COVID-19 pandemic that is intended to help get safe and effective vaccines to those who need it most. IPE oversaw the Department of State's response to inquiries on this policy, including by supporting and coordinating with U.S. embassies and consulates around the world. Following the June 2022 meeting of the WTO TRIPS Council, IPE continues to provide input to the broader U.S Government IP interagency regarding whether or not to extend a TRIPS waiver to COVID-19 related therapeutics and diagnostics.

Other activities that the Department of State participated in during FY 2022 include the following:

OECD Task Force on Countering Illicit Trade

Department of State Office of Intellectual Property Enforcement (IPE) leads the U.S. delegation to the OECD Task Force on Countering Illicit Trade (TF-CIT). In March 2022, IPE's Acting Director led the U.S. Delegation for the TF-CIT Task Force Trade plenary meetings in which the United States helped garner multilateral support for the Task Force's work on the development

of an OECD Certification Scheme for Free Trade Zones, a novel and innovative policy tool that sets voluntary standards for FTZs that want to join forces in countering illicit trade, promote trade transparency and rules based international order.

Investment Climate Statements

Every year, economic officers at U.S. embassies and other diplomatic missions prepare Investment Climate Statements analyzing more than 170 foreign markets to help U.S. companies make informed business decisions regarding overseas investments and operations. Each Investment Climate Statement focuses on an individual country market and includes a chapter on IP. These Statements also form a chapter of the Department of Commerce's Country Commercial Guides and can be read together with those guides for a broad description of the investment and business environments in foreign economies. The State Department continues to work with the Commerce Department to further align the complementary Statements and Guides for a more unified experience for the end user.

Science and Technology Agreements (STAs)

In 2022, the United States signed joint statements with Denmark, Finland, France, Sweden, and Switzerland for cooperation in quantum information science and technology. ¹⁶ These statements referenced existing STAs, which included IP annexes.

Interagency Policy Cooperation

Department of State IPE, working with U.S. embassies and consulates around the world, engages with U.S. stakeholders and foreign governments to ensure that the U.S. government's positions are informed by the full range of views on pertinent issues, and encourages trading partners to engage fully and transparently with the full range of IP stakeholders. These thorough "on-the-ground" explorations of overseas IP environments support bilateral policy decisions by deepening U.S. departments' and agencies' knowledge. For example, the Department of State provided extensive support to the Office of the U.S. Trade Representative (USTR) and interagency colleagues for USTR's IP-related reports, including the annual Special 301 Report and Review of Notorious Markets for Counterfeiting and Piracy. At IPE's request, posts around the world submitted detailed analyses of IP protection and enforcement conditions, as well as insights into trademark counterfeiting, protection of trade secrets, and copyright piracy.

¹⁶ The US-Denmark joint statement is at https://www.state.gov/joint-statement is at https://www.state.gov/joint-statement-of-the-united-states-and-finland-on-cooperation-in-quantum-information-science-and-technology/. The US-Swiss joint statement is at https://www.state.gov/joint-statement-of-the-united-states-of-america-and-switzerland-on-cooperation-in-quantum-information-science-and-technology/. At time of drafting, the US-France statement was not yet posted.

The U.S. Transnational and High-Tech Crime Global Law Enforcement Network

The U.S. Transnational and High-Tech Crime Global Law Enforcement Network (GLEN) consists of DOJ International Computer Hacking and Intellectual Property Advisors (ICHIPs), Global Cyber Forensic Advisors (GCFAs), and long-term agent mentors. The GLEN works with foreign countries to strengthen IP protection and enforcement leading to more effective investigation and prosecution of IP offenses.

The ICHIPs are experienced DOJ prosecutors who strengthen global and regional law enforcement coordination and deliver capacity building training. Ten ICHIPs are posted overseas in Panama City, Panama; Zagreb, Croatia; Addis Ababa, Ethiopia; The Hague, Netherlands; Hong Kong, China SAR; Sao Paulo, Brazil; Bucharest, Romania; Abuja, Nigeria; Bangkok, Thailand; and Kuala Lumpur, Malaysia. In addition, two ICHIPs are deployed out of Washington, DC, to specifically address dark market/cryptocurrency and online consumer protection-related aspects of cybercrime and IP theft.

The GLEN is almost entirely funded and managed by the Department of State Bureau of International Narcotics and Law Enforcement Affairs Office of Global Programs and Policy (INL/GPP). The two exceptions are ICHIP Kuala Lumpur, which is funded by the INL Office of Europe and Asia (INL/EA), and ICHIP Bangkok, which is funded by the Department of Justice Office of International Affairs (DOJ/OIA). INL and DOJ consult closely with IPE in GLEN program development and implementation.

The GLEN has global and regionally focused responsibilities. The ICHIPs: (1) assess the capacity of law enforcement authorities throughout the region to enforce IP; (2) develop and deliver training and other capacity building formats designed to enhance the capacity of justice sector personnel to enforce IP; (3) assist in developing or strengthening institutions dedicated to enforcing IP; (4) monitor regional trends in IP protection and computer crimes; and (5) provide expert assistance in support of U.S. IP and computer crimes policies and initiatives in the region. The GCFAs, in coordination with ICHIPs, deliver digital forensics training for investigators, while the long-term federal agent mentors are designed to be paired with an ICHIP to deliver sustained mentoring to foreign counterparts.

Recognition of the importance of international capacity building takes place at the highest levels of the State Department. For example, at the ICHIP Industry Forum for IP Rights Protection on February 23, 2022, INL Assistant Secretary Todd D. Robinson said: "Intellectual property crime is often marginalized based on a misconception that it is less serious. U.S. foreign law enforcement capacity building programs emphasize how intellectual property crime endangers public health, undermines investment and job creation, and erodes trust in public institutions."

To deliver foreign law enforcement training and technical assistance to complement the work of the GLEN, INL also provides funding to the United States Patent and Trademark Office (USPTO) and to the National Intellectual Property Rights Coordination Center (IPR Center) of the United States Department of Homeland Security, U.S. Immigration and Customs Enforcement's Office of Homeland Security Investigations (DHS ICE/HSI). DHS and USPTO-delivered workshops ensure that patent and trademark agencies and foreign border and customs

agencies receive IP enforcement capacity building tailored to their missions. DHS and USPTO programming is closely coordinated with the work of the GLEN. INL funds also support DHS providing U.S. trainers to participate in INTERPOL-managed IP workshops around the world.

Capacity Building and Training

As noted, the Department of State, using foreign assistance anti-crime funds managed by INL, has a longstanding program to provide U.S. government capacity-building training and technical assistance to foreign law enforcement partners to combat IP crime and to deter widespread commercial-scale pirated and counterfeit goods and services. The Department of State works with other agencies to prioritize assistance to developing countries that are named in USTR's Special 301 Report as countries of concern.

Examples of roundtable discussions, lectures, and training successes through the ICHIP program include the following.

- ICHIP Bucharest and officials from the U.S. Department of Commerce's Commercial Law Development Program (CLDP) participated in meetings and roundtable discussions with Kazakh public and private sector IP stakeholders in Nur-Sultan, Kazakhstan. The ICHIP met with officials from the IPR Department (Ministry of Justice), the Industrial Property Division (Justice), the Directorate for Copyright and Related Rights (Justice), the Department of Intellectual Property Rights (Justice), the Department of Services and Investments (Trade), and the independent National Institute of Intellectual Property. These officials are part of Kazakhstan's delegation to the Central Asia Trade and Investment Framework Agreement (TIFA) IP Working Group.
- ICHIP Hong Kong delivered a series of four virtual cybercrime programs for Vietnamese police and prosecutors from Ho Chi Minh City, Vietnam. At the webinar, about 40 Vietnamese prosecutors learned about online investigations in a hybrid workshop. The virtual workshop built on previous ICHIP programs on electronic evidence and digital piracy.
- ICHIP Panama City and ICHIP Dark Web and Cryptocurrency (DWC) assembled the first-ever ICHIP regional cryptocurrency working group in Western Hemisphere. Approximately thirty officials from Colombia, Panama, Mexico, Chile, and Costa Rica learned fundamentals of cryptocurrencies during a multi-day virtual program delivered by a blockchain analytics company that assists primarily financial institutions and governmental organizations with tracing various cryptocurrencies to services that may possess valuable suspect information.
- ICHIP São Paulo: In March 2022, a team of Rio de Janeiro- based organized crime prosecutors trained by the ICHIP for Latin America and the Caribbean used best practices to effectively impeach a corrupt police officer who perjured himself while testifying in defense of another corrupt police officer. During a hearing against a former police chief accused of running a protection racket against counterfeit vendors, the witness claimed to have no knowledge of an attempt by the defendant to frame internal affairs officers

involved in the investigation. The prosecutors used ICHIP-taught best methods to obtain cloud-based evidence and used online backups of WhatsApp chats between the witness and the defendant in which they actively discussed framing the internal affairs officer. When presented with this contradictory evidence, the judge spontaneously found the witness perjured himself and detained him pending sentencing.

• ICHIP Zagreb participated in a lecture from the Department of Commercial and Company Law at the Faculty of Law Zagreb. The lecture covered many concepts related to blockchain technology and associated legal issues, including a comparison of blockchain versus central data systems, the possibility of a blockchain server serving as a central depository, different types of tokens, issues related to the public offering of investment tokens that can trigger SEC oversight, and U.S. case law concerning virtual assets and securities.

In addition, in FY 2022, IPE assumed a coordinating role to generate meaningful results of the IP training programs that multiple federal agencies conduct overseas. Working with interagency partners, IPE compiled a list of the IP-related trainings, identified priority countries where the United States may be able to make real progress, and started the process of developing coordinated training plans to maximize both U.S. resources and impact.

Internal Education Activities

The Department of State is committed to educating its employees about IP issues. In July 2022, IPE partnered with USPTO's Global IP Academy (GIPA) to provide a two-day virtual training course on IP issues for U.S. government officials. The course was held in-person at the USPTO, after being held virtually the prior two years because of the COVID-19 pandemic. Most participants were U.S. foreign service officer diplomats (FSOs) preparing for onward assignments domestically or overseas. The training also included civil servants and locally employed staff of U.S. overseas diplomatic posts. Experts and stakeholders briefed attendees on IP fundamentals, U.S. government positions on current IP "hot topics," and U.S. industry priorities. These officials are now better equipped to advocate for U.S. rightsholders and to articulate U.S. government policy positions in bilateral discussions and in international fora.

IPE also trained FSOs, locally employed staff, and representatives from various U.S. government agencies in sessions of the Foreign Service Institute's classes on Commercial Tradecraft. The training provided participants with the latest U.S. policy perspectives on international IP issues, enabling them to advocate better for U.S. rightsholders overseas.

DEPARTMENT OF TREASURY

DEPARTMENT OF TREASURY

Department of the Treasury Appendix for FY 2022 Annual Report

Treasury IP-related efforts on Customs

Treasury authority for border enforcement of intellectual property laws, along with certain other customs revenue functions, has been delegated to DHS and is carried out by CBP and ICE (see Treasury Order 100-16 and 6 U.S.C. §§ 212, 215). Under the delegation, Treasury retains the sole authority to approve any regulations concerning copyright and trademark enforcement at the border and works closely on these promulgations with DHS and its components.

Treasury efforts to identify and address certain IP-related risks to national security through the CFIUS process

The Secretary of the Treasury serves as Chairperson of the Committee on Foreign Investment in the United States (CFIUS). CFIUS is an interagency committee authorized to review certain transactions in order to determine their effect on the national security of the United States. The President's Executive Order of September 15, 2022 ensures, among other things, the robust consideration by CFIUS of risks associated with foreign investment in U.S. businesses with technologies that are fundamental to national security (E.O. 14083 is at https://www.govinfo.gov/content/pkg/FR-2022-09-20/pdf/2022-20450.pdf). CFIUS has the authority, among others, to review certain non-controlling investments by foreign persons in U.S. businesses that produce, design, test, manufacture, fabricate, or develop critical technologies, and this review may include aspects of a technology's underlying intellectual property. The Department of the Treasury continues to accept declarations and notices under its regulations.

Among other things, these regulations mandate the filing of a declaration with CFIUS for certain foreign investment transactions involving a U.S. business that produces, designs, tests, manufactures, fabricates, or develops one or more critical technologies based on whether certain U.S. Government export control authorizations would be required to export, re-export, transfer (in country), or retransfer such U.S. business's critical technology to certain transaction parties or their owners. The regulations defining critical technology reference certain control lists of U.S. export control agencies, such as the Department of Commerce. This makes the CFIUS definition of critical technology dynamic.

CFIUS does not enforce intellectual property laws. If, however, during its review of a transaction CFIUS identifies a risk to U.S. national security arising from a foreign person's acquisition of, or access to, the intellectual property of a U.S. business, and if other authorities are not adequate or appropriate to address the identified risk, CFIUS will seek to mitigate such risk. Mitigation measures could take a variety of forms, including but not limited to placing the intellectual property in escrow; controlling the foreign person's access to the intellectual property; requiring mechanisms to monitor and enforce such access controls; and ensuring U.S. Government access to, or insight into, the intellectual property. If CFIUS determines that the identified risk cannot be resolved through mitigation, CFIUS may refer the transaction to the

President, who can, in accordance with section 721 of the Defense Production Act of 1950, as amended, suspend or prohibit certain transactions that threaten to impair the national security of the United States.

Treasury authority to impose sanctions under Executive Order 13694, as amended, in response to certain malicious cyber-enabled activities, including the theft of trade secrets for commercial or competitive advantage or private financial gain.

Treasury continues to encourage referrals from relevant departments and agencies, including law enforcement and intelligence agencies, regarding targets for potential designation by the Office of Foreign Assets Control (OFAC) pursuant to Executive Order (E.O.) 13694, as amended by E.O. 13757. The Executive Order authorizes the imposition of sanctions on individuals and entities determined to be responsible for or complicit in, or to have engaged in, certain malicious cyber-enabled activities, including those "causing a significant misappropriation of funds or economic resources, trade secrets, personal identifiers, or financial information for commercial or competitive advantage or private financial gain." (The two executive orders are available at https://home.treasury.gov/policy-issues/financial-sanctions/sanctions-programs-and-country-information/sanctions-related-to-significant-malicious-cyber-enabled-activities.)

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

"The global trade in counterfeit and pirated goods undermines critical U.S. innovation and creativity and harms American workers. This illicit trade also increases the vulnerability of workers involved in the manufacturing of counterfeit goods to exploitative labor practices, and the counterfeit goods can pose significant risks to the health and safety of consumers and workers around the world." ¹⁷

- Ambassador Katherine Tai, U.S. Trade Representative

USTR Appendix for FY 2022 Annual Report

One avenue to promote intellectual property (IP) protection and enforcement abroad is through engagement with our trading partners. Through such engagement, the Administration advocates for strong IP protection and enforcement in other countries for, *inter alia*, creative works, brands, designs, trade secrets, and inventions by U.S. creators, inventors, artists, and businesses. Through direct engagement with foreign counterparts, the Office of the U.S. Trade Representative (USTR) emphasizes the importance that the U.S. government places on protecting and enforcing IP, and presses for concrete action by trading partners to protect and enforce IP rights, which includes those owned by Americans.

To advance the Administration's objectives, USTR uses a broad range of trade policy tools to promote strong IP rights protection and enforcement, including Section 301 of the Trade Act; the annual Special 301 review of IP protection and enforcement and related market access issues; trade agreement negotiations; monitoring and enforcement of those agreements; trade and investment framework agreements; participation in the TRIPS Council at the World Trade Organization; and high-level engagement in multilateral and bilateral meetings.

Given the international competitiveness of U.S. innovative and creative industries, the United States considers strong and effective protection and enforcement of IP rights as critical to U.S. economic growth and American jobs. According to the U.S. Department of Commerce, 63 million American jobs in 2019 were directly or indirectly supported by "IP-intensive" industries, and these jobs paid higher wages to their workers, relative to workers in non-IP-intensive industries. In addition, in 2019, these IP-intensive industries accounted for \$7.8 trillion in value added and 41 percent of the U.S. GDP. (See Department of Commerce, *Intellectual Property and the U.S. Economy: Third Edition* (2022), https://www.uspto.gov/sites/default/files/documents/uspto-ip-us-economy-third-edition.pdf.) Innovation and creativity are key export strengths for the United States. Combatting unfair IP trade policies will encourage domestic investment in the United States, foster American innovation and creativity, and increase economic security for American workers and families.

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¹⁷ USTR press release, "USTR Releases 2021 Review of Notorious Markets for Counterfeiting and Piracy" (February 17, 2022), at https://ustr.gov/about-us/policy-offices/press-office/press-releases/2022/february/ustr-releases-2021-review-notorious-markets-counterfeiting-and-piracy.

The USTR initiatives that have advanced IP protection and enforcement include the following.

Section 301 Investigation on China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property and Innovation Law

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 July 2018, and a panel was established to hear the case at the United States' request in November 2018. In March 2019, China revised certain measures that the United States had challenged, including the Administration of Technology Import/Export Regulations. The United States considered that China's actions had sufficiently addressed U.S. concerns, and after 12 months, the authority of the panel expired on June 8, 2021.

As part of the United States-China Economic and Trade 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.

The United States, Mexico, and Canada Agreement (USMCA)

The United States-Mexico-Canada Agreement (USMCA) entered into force on July 1, 2020. The USMCA will support mutually beneficial trade leading to freer markets, fairer trade, and robust economic growth in North America. It includes a modernized, high-standard IP chapter, which breaks new ground in U.S. trade and IP policy. It contains comprehensive protections against misappropriation of trade secrets, including by state-owned enterprises. It provides the most robust border enforcement mechanisms of any prior FTA. In addition, strong copyright protection and enforcement, more transparency in the grant of geographical indications (GI) protection or recognition, and full national treatment also promote the strong and effective

protection and enforcement of IP rights that is critical to driving innovation, creating economic growth, and supporting American jobs. ¹⁸

The United States continues to engage with Canada and Mexico to ensure full implementation of the IP protection and enforcement obligations.

Ongoing Trade Agreement Implementation and Enforcement

In FY 2022, the U.S. continued to engage with Free Trade Agreement (FTA) partners (including Australia, Bahrain, Chile, Colombia, Costa Rica, and Korea) to ensure that FTA obligations, including those related to IP, are being implemented.

USTR Special 301 Report

Each year, pursuant to statute, USTR issues the Special 301 Report on the adequacy and effectiveness of protection and enforcement of IP by our trading partners. The Special 301 Report is an important tool to engage with our trading partners to promote strong protection for U.S. creative and innovative industries, as well as to promote compliance with trade commitments. USTR actively employs the Special 301 process to identify and address key IP challenges for American businesses and to document and encourage continued progress in countries that undertake legislative and enforcement reforms following engagement under Special 301.

USTR released the 2022 Special 301 Report in April 2022. (The 2022 Report is at https://ustr.gov/sites/default/files/IssueAreas/IP/2022 Special 301 Report.pdf, and the related press release is at https://ustr.gov/about-us/policy-offices/press-office/press-releases/2022/april/ustr-releases-2022-special-301-report-intellectual-property-protection-and-enforcement.) In the report, USTR highlighted serious and ongoing concerns with respect to the environment for IP rights protection and enforcement in China, India, Indonesia, Russia, and other markets.

The Special 301 Report provides an opportunity to put a spotlight on foreign countries and the laws, policies, and practices that fail to provide adequate and effective IP protection and enforcement for U.S. inventors, creators, brands, manufacturers, and service providers, which, in turn, harm American workers whose livelihoods are tied to America's innovation-driven sectors. The Report identifies a wide range of concerns, including (a) challenges with border and criminal enforcement against counterfeits, including in the online environment; (b) high levels of online and broadcast piracy, including through illicit streaming devices; (c) inadequacies in trade secret protection and enforcement in China, Russia, and elsewhere; (d) troubling "indigenous innovation" and forced technology transfer policies that may unfairly disadvantage U.S. rightsholders in markets abroad; and (e) other ongoing, systemic issues regarding IP protection and enforcement, as well as market access, in many trading partners around the world. Combatting such unfair trade policies will encourage domestic investment in the United States,

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¹⁸ United States—Mexico—Canada Trade Fact Sheet: Modernizing NAFTA into a 21st Century Trade Agreement (October 1, 2018), https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2018/october/united-states%E2%80%93mexico%E2%80%93canada-trade-fa-1.

foster American innovation and creativity, and increase economic security for American workers and families.

Notorious Markets List

The Notorious Markets List (NML) highlights select online and physical marketplaces that reportedly engage in or facilitate substantial copyright piracy or trademark counterfeiting. USTR has identified notorious markets in the Special 301 Report since 2006. In 2010, USTR announced that it would begin publishing the NML separately from the annual Special 301 Report, pursuant to an Out-of-Cycle Review. USTR first separately published the 2010 NML in February 2011, and has published an NML for every year since.

In the NML, USTR highlights markets not only because they exemplify global concerns about counterfeiting and piracy, but also because the scale of infringing activity in such markets can cause significant economic harm to U.S. IP rightsholders. Some of the identified markets reportedly are host to a combination of legitimate and unauthorized activities. Others reportedly exist solely to engage in or facilitate unauthorized activity. The NML does not purport to be an exhaustive list of all physical and online markets worldwide in which IP rights infringement takes place.

A goal of the NML is to motivate appropriate action by the private sector and governments to reduce piracy and counterfeiting. The operators of several websites identified in past NMLs have begun to work with rightsholders to address counterfeiting and piracy. Several markets have also ceased operations or have been the focus of government enforcement efforts.

The 2021 Notorious Markets List was issued in February 2022. (The NML is at https://ustr.gov/sites/default/files/IssueAreas/IP/2021%20Notorious%20Markets%20List.pdf, and the related press release is at https://ustr.gov/about-us/policy-offices/press-releases/2022/february/ustr-releases-2021-review-notorious-markets-counterfeiting-and-piracy.) The 2021 NML includes an Issue Focus section that examines the adverse impact of counterfeiting on workers involved with the manufacture of counterfeit goods.

India

The U.S. maintains bilateral engagement with India on IP issues through the IP Working Group under the United States—India Trade Policy Forum (TPF). USTR, working with its interagency partners (USPTO, U.S. Copyright Office, ITA, DOJ, Health and Human Services, FTC, and others), sustained revitalized engagement on IP issues with Indian government counterparts during FY 2022, including through IP Working Group meetings held in October 2021 and July 2022, and a Ministerial-level meeting of the TPF in November 2021. These exchanges and activities centered on the robust protection of IP and enforcement of IP rights, with a focus on areas such as copyright, trade secrets, trademarks, patents, enforcement, and promoting innovation and creativity through high-level government policies.

World Trade Organization Council on Trade-Related Aspects of Intellectual Property Rights (TRIPS Council)

The World Trade Organization (WTO) provides an additional venue for USTR to lead engagement with trading partners on IP rights issues, including through accession negotiations for prospective Members, the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council), and the Dispute Settlement Body.

In FY 2022, the United States advanced its IP and Innovation agenda in the TRIPS Council by focusing on intellectual property and financing. The United States is working with WTO Members including Australia, Canada, Chile, Chinese Taipei, the European Union, Japan, Hong Kong, Singapore, South Korea, Switzerland, New Zealand, and the United Kingdom, examining how IP protection and enforcement promote innovation and creativity to meet societal challenges and needs.

World Trade Organization Accession

Governments in the process of negotiating the terms for accession to the WTO work with WTO Members, including the United States, to appropriately update and strengthen their IP regimes as well as to expand trade and enhance the investment climate for innovative and creative industries.

Other Fora

In addition to the WTO (which is the principal forum for addressing trade-related aspects of intellectual property), the United States also advanced these issues in other for during FY 2022, including the OECD, WIPO, APEC forum, and various U.N. bodies.

In the APEC Intellectual Property Experts Group (IPEG), the United States continued to lead an 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 continued to lead an initiative on industrial design protection, including the benefits of the Hague System, which can be a critical component of IP portfolios for competitive businesses in the modern innovation economy, particularly for small and medium-sized businesses in the APEC region.

Examples of Additional Areas of IP Rights Engagement

During FY 2022, USTR, coordinating with interagency subject matter experts, engaged meaningfully with Ukrainian counterparts on next steps for addressing longstanding areas of concern such as the administration of the system for collective management organizations, online piracy, and government use of unlicensed software. At the United States-Ukraine Trade and Investment Council meeting 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. Ukraine also participated in the Special 301 process in early 2022. However, due to Russia's premeditated and unprovoked further invasion of Ukraine in February 2022, the Special 301 review of Ukraine was suspended.

At the United States-Paraguay Trade and Investment Council meeting held in September 2022, Paraguay and the United States agreed on an Intellectual Property Work Plan that will serve as a roadmap to address issues on the protection and enforcement of intellectual property rights in Paraguay. The two countries, with the relevant agencies coordinating, will implement the Work Plan, and review this implementation on an ongoing basis.

The Central Asia IP Working Group serves as an important mechanism to provide sustained engagement on IP issues and help improve IP regimes in the region. The Working Group met in Tbilisi, Georgia in July 2022.

The United States held TIFA intersessional meetings with Pakistan in March 2022 and with Taiwan in May 2022, and held a TIFA Council meeting with Algeria in June 2022. The United States also held technical meetings under the United States-Indonesia TIFA in November and December 2021; and an Innovation and Creativity Forum with Argentina in November 2021. These meetings discussed a range of issues relating to IP protection and enforcement, such as combatting the sale of counterfeit and pirated goods.

Engagement with Stakeholders and the Public

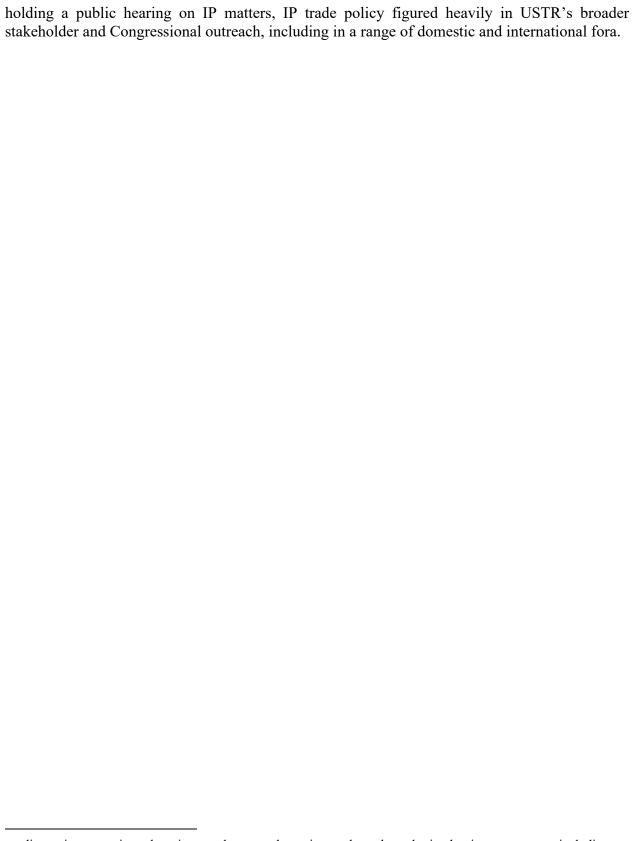
USTR frequently seeks public input from all sectors of society, including private citizens, non-governmental organizations, academia, consumer groups, small and medium-size businesses, and the business community (including innovators, content providers, and technology and other service providers).

To this end, USTR holds public hearings; seeks written comments regarding negotiation objectives through *Federal Register* notices; chairs regular sessions with designated public advisory committees; and disseminates trade policy materials such as press releases, factsheets, and statements on the USTR website. These dialogues are critical at every stage of USTR's work, including in connection with the process of negotiating, implementing, and enforcing trade rules.

USTR also seeks public input for the annual Special 301 and Notorious Markets List processes. The annual Special 301 Report identifies countries that fail to adequately and effectively protect or enforce IP rights or use unfair barriers to limit market access for U.S. businesses that rely on IP. The Notorious Markets List highlights prominent online and physical marketplaces that reportedly engage in or facilitate substantial copyright piracy or trademark counterfeiting. USTR publishes requests for public comment in the *Federal Register* that provide opportunities for public input and rebuttals, and the submitted comments are available online. In addition, USTR holds a public hearing for the Special 301 process.¹⁹ In addition to requesting comments from the public and

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¹⁹ In 2022, due to the COVID-19 pandemic, USTR fostered public participation via written submissions rather than an in-person hearing with the interagency Special 301 Subcommittee of the Trade Policy Staff Committee (TPSC)



sending written questions about issues relevant to the review to those that submitted written comments, including to representatives of foreign governments, industry, and non-governmental organizations.

COPYRIGHT OFFICE

U.S. COPYRIGHT OFFICE

Copyright Office Appendix for FY 2022 Annual Report

This appendix summarizes some of the key enforcement-related activities taken by the United States Copyright Office during Fiscal Year 2022.

Overview

During FY 2022, the Copyright Office continued to work on many important public initiatives, including the launch of the Copyright Claims Board; the completion of several policy studies; and continued efforts to modernize the Office's operations. The Office also provided law and policy advice to Congress, provided expert advice to the federal courts and executive branch agencies on domestic and international copyright matters, and conducted public outreach and education efforts. Please visit https://www.copyright.gov/ for more information on all of the Office's activities.

Copyright Claims Board

In December 2020, Congress enacted the Copyright Alternative in Small-Claims Enforcement Act of 2020 (CASE Act) to establish a new Copyright Claims Board (CCB) that would be a voluntary "small copyright claims" tribunal comprised of three Copyright Claims Officers who will have the authority to render determinations and serve as an accessible and efficient option for resolving copyright disputes.

On June 16, 2022, the CCB began accepting claims as the first U.S. copyright small claims forum via its new website, https://www.ccb.gov/. Through the CCB website, potential claimants can access and create an account with eCCB, the CCB's electronic filing and case management system, submit or respond to a claim, opt out of a proceeding, and contact the CCB with questions. The CCB website also provides users access to the CCB Handbook materials for guidance on the CCB's rules and how to navigate the CCB procedures.

As of September 30, 2022, 181 claims were filed with the Board. No proceeding has yet resulted in a final determination, but there are a few noteworthy trends. Of the three types of claims that can be brought before the CCB, claims for infringement are the most prevalent. In regard to the types of works at the heart of these claims, the majority of claims involve pictorial, graphic, and sculptural works. Motion picture and audiovisual works, literary works, and sound recordings are also the subjects of a number of claims. Additionally, to date, the CCB has issued to claimants approximately forty-five compliance notices and over forty orders to amend for noncompliance.

The following are some of the CCB's key features:

• The CCB is accessible to anyone, with or without an attorney. CCB proceedings are designed to be clearly understood and usable by anyone, even without legal training. Users of the CCB are permitted to have an attorney but can also represent themselves.

- **Participation is voluntary.** Both claimants and respondents can decide whether or not to participate in CCB proceedings.
- Only certain types of claims can be brought before the CCB. Unlike federal court, the CCB's jurisdiction is limited to certain copyright-related claims. Only three types of claims can be brought:
 - o claims of infringement of a copyright;
 - o claims seeking declarations that specific activities do not infringe copyright; and
 - o claims of "misrepresentation" in notices sent under the Digital Millennium Copyright Act (DMCA).
- Monetary damages are capped at \$30,000. A party cannot bring a claim before the CCB seeking more than \$30,000 in total damages.
- No injunctive relief is available. However, a respondent can agree to stop the complained-of conduct, which agreement can be part of the final decision.

For more information, visit https://www.ccb.gov/.

Reports & Studies

The Copyright Office advises Congress on national and international issues relating to copyright. 17 U.S.C. § 701(b)(1). This advice includes providing requested opinions on pending and existing legislation as well as providing analyses on areas of copyright law. The Office seeks to ensure that all members of the copyright community – including copyright owners, technology companies, consumers, public interest groups, academics, and the general public – have robust opportunities to participate and contribute to the Office's policy studies, reports, and recommendations.

During FY 2022, the Office worked on three studies that involved issues related to copyright protection and enforcement. All three studies have now been completed.

Study on Ancillary Copyright Protections for Publishers (report issued in June 2022)

In response to a series of congressional hearings on reforms to digital copyright law, Senators Thom Tillis, Patrick Leahy, John Cornyn, Mazie Hirono, Amy Klobuchar, and Christopher Coons sent a letter to the Copyright Office on May 3, 2021, asking the Office to undertake a public study to assess the viability of establishing "ancillary copyright" protections for press publishers, similar to protections being implemented in Europe, that would require online news aggregators to pay publishers for excerpts of content they provide for others to view.

The Copyright Office issued a notice of inquiry requesting comments on issues, such as a) the effectiveness of current protections for press publishers under U.S. law; b) whether additional

protections for press publishers are desirable and, if so, what the scope of any such protections should be; and c) how any new protections for press publishers in the U.S. would relate to existing rights, exceptions and limitations, and international treaty obligations. The Office held a public roundtable in December 2021 via Zoom.

The final report was released on June 30, 2022. The Office recognized that adequate funding for journalism may currently be at risk and that there are implications for the press's essential role in our system of government. However, the Office recommended against adopting any new copyright protections for press publishers, finding that press publishers have significant protections under existing law and that the challenges of funding journalism in the internet era do not appear to be copyright-specific.

The full report and any additional materials (such as public comments, recordings and transcripts of the roundtables) can be found at https://www.copyright.gov/policy/publishersprotections/.

Technical Measures Consultations (report issued in December 2022)

In the hopes that further discussion and collaboration would help ensure that technical measures that identify or protect copyrighted works online provide a reasonable, effective, and flexible approach for all stakeholders involved, Senators Patrick Leahy and Thom Tillis sent a letter in June 2021 requesting the Office to "convene a representative working group of relevant stakeholders to achieve the identification and implementation of technical measures."

The Office issued a notice of inquiry on December 22, 2021, soliciting comments and statements of interest to participate in the consultations on voluntary technical measures that identify or protect copyrighted works online. These consultations addressed current and forthcoming technologies for identifying or protecting works, including the technologies' availability, their use-cases, and their limitations. The Office received over 6,000 comments and over 40 statements of interest to participate. Based on the responses received to the notice of inquiry and the outcome of the plenary session, the Office identified specific industry-sector based groups that formed the basis for a subsequent series of smaller sessions. After holding a plenary session in February 2022, the Office held a series of smaller consultations in June 2022, which included six moderated sessions and six 'office hours' meetings, in order to dive deeper into the issues identified during the plenary. The Office hosted a closing plenary session for the public on October 4, 2022.

A letter addressed to Congress detailing the study's findings was released on December 20, 2022.

The letter and additional materials (such as public comments, agendas for the consultations, and recordings of the plenary session) can be found at https://www.copyright.gov/policy/technical-measures/.

<u>Standard Technical Measures and Section 512</u> (report issued in December 2022)

The Copyright Office's 2020 report, "Section 512 of Title 17," examined section 512's "safe harbor" framework, which limits an internet service provider's liability for infringement if the provider meets certain conditions. One of these conditions is that the internet service provider "accommodates and does not interfere with standard technical measures" to identify or protect copyrighted works. Recall that in September 2020, the Copyright Office held virtual stakeholder discussions covering the legal foundation of standard technical measures (STMs), current technologies and their potential for adoption as STMs, and means of identifying or developing STMs going forward. In June 2021, Senators Thom Tillis and Patrick Leahy asked the Office to further explore the identification and implementation of STMs under section 512(i).

As a result of this Senate request, the Office issued a notice of inquiry in April 2022 to gather additional information on the development and use of standard technical measures for the protection of copyrighted works, as defined by the statutory framework in section 512(i). This notice of inquiry on standard technical measures is separate from and complements the Office's Technical Measures Consultations for identifying or protecting copyrighted works online. Whereas the consultations focus on the voluntary development of technical measures to identify and protect copyrighted works online generally, this notice of inquiry focuses on standard technical measures as defined in section 512(i) specifically. Sixty public comments were received by the May 27, 2022 deadline.

A letter addressed to Congress detailing the study's findings was released on December 20, 2022.

The letter and additional materials (such as public comments) can be found at https://www.copyright.gov/policy/stm/.

Rulemakings

During FY 2022, the Copyright Office engaged in a number of rulemakings. A list of both active and closed rulemakings is available at https://www.copyright.gov/rulemaking/. An illustrative list of enforcement-related closed rulemakings appears below.

<u>Section 1201 Exemptions to Prohibition Against Circumvention of Technological Measures</u>
<u>Protecting Copyrighted Works</u>

On June 22, 2020, the Office initiated the eighth triennial rulemaking proceeding under the Digital Millennium Copyright Act (DMCA), which provides that the Librarian of Congress, upon the recommendation of the Register of Copyrights, may adopt temporary exemptions to section 1201's prohibition against circumvention of technological measures that control access to copyrighted works. In accordance with the statute, the Librarian's determination to grant an exemption is based upon the recommendation of the Register of Copyrights, who also consults with the National Telecommunications and Information Administration (NTIA) of the Department of Commerce. The ultimate goal of the proceeding is to determine whether there are particular classes of works as to which users are, or are likely to be in the next three years,

adversely affected in their ability to make non-infringing uses due to the prohibition on circumventing access controls.

The following are a few types of activities which the Register recommended exemptions:

- Excerpts of motion pictures for criticism or comment and educational uses.
- Motion pictures, for the provision of captioning and/or audio description by disability services offices or similar units at educational institutions for students, faculty, or staff with disabilities.
- Literary works, for the purpose of deploying text and data mining techniques on a corpus of literary works for scholarly research and teaching by researchers at institutions of higher education.
- Computer programs for purposes of investigating a potential infringement of free and open-source computer programs.

The Register did not recommend adopting of the following proposed exemptions:

- Audiovisual works, for purposes of creating clips to be used in text messages
- Audiovisual works, for purposes of livestream recording
- Audiovisual works, for purposes of space-shifting

The Register's full recommendation and the final rule issued by the Librarian of Congress were published in the Federal Register on October 28, 2021. The exemptions will be in place for the next three years, until October 2024. Information on this entire proceeding is available at https://www.copyright.gov/1201/2021/.

Fair Use Index

The Copyright Office hosts and maintains the Fair Use Index, which was undertaken in coordination with the Intellectual Property Enforcement Coordinator. This searchable database contains notable cases from U.S. courts that comment on fair use law. The Index contains more than 200 cases. The Office continually updates the Index to keep practitioners and the public informed of new or prominent issues in fair use law, the application of fair use to a variety of types of works, and the law across appellate jurisdictions in the United States. The Index contains clear and concise language describing the facts and outcome of each case, making the Index accessible to the general public and providing valuable information—including a full legal citation—to aid a viewer in further research. The Fair Use Index is hosted at https://www.copyright.gov/fair-use/.

International Activities

Throughout the year, the Copyright Office continued to provide outreach and education regarding copyright issues to foreign officials, mostly via video meetings. The Office also hosted international programs to discuss and exchange information on the U.S. copyright system and significant international copyright issues. The Office works with other agencies, including the Office of the U.S. Trade Representative (USTR), the U.S. Patent and Trademark Office (USPTO), and the State Department to participate in meetings, ranging from bilateral matters to international issues affecting various issues affecting intellectual property enforcement and other IP topics.

International Copyright Institute

Every two years, the Copyright Office and WIPO co-host the International Copyright Institute, a week-long program designed to provide representatives from developing countries and countries in transition with a deeper understanding of copyright law in the digital age. Held from September 26-30, this year's program, *Copyright and Related Rights in the Digital Environment for Developing Countries and Countries in Transition*, invited participants from twenty-one countries to discuss emerging issues in the copyright field, including issues such as treaty obligations, modern copyright registration systems, the rapidly changing digital environment, the intergovernmental coordination necessary to build an effective enforcement system, training and public education, as well as issues on collective managements, licensing digital works and library issues.

Advise Executive Branch Agencies on International Copyright & Trade Matters

The Copyright Office supports USTR and other executive branch agencies by serving on official delegations and negotiating teams, as part of its statutory duties (17 U.S.C § 701(b)). In FY 2022, the Office supported the U.S. government delegations to the World Intellectual Property Organization (WIPO) where the Standing Committee on Copyright and Related Rights (SCCR) discussed, among other topics, a draft treaty that would protect broadcasting organizations against signal piracy. The Office also participated in the annual Special 301 review facilitated by USTR (including the Notorious Markets out-of-cycle review), and engaged in regular consultation with executive branch agencies on copyright law and enforcement developments in other countries, including draft legislation and guidance documents, compliance efforts, World Trade Organization trade policy reviews and accessions, the TRIPS waiver, and other programs.

Copyright Office Modernization

Over the past several years, the Copyright Office has engaged in several modernization efforts to provide a more user-centered and flexible design for the Office's electronic registration, recordation, and public record streams. More information about the Office's modernization efforts can be found at https://www.copyright.gov/copyright-modernization/. The Office also hosts a bimonthly webinar series that focuses on various aspects of the modernization process, which can be found at https://www.copyright.gov/copyright-modernization/webinar/.

Public Outreach

The Copyright Office implements a full program of outreach activities to educate the public regarding copyright protections. The Office's outreach programs cover a wide range of formats and media, including live presentations, video tutorials, social media, and participation in programs hosted by outside organizations. The Office regularly produces events to educate stakeholders and the general public, including events to reach music and songwriter communities with information about the MMA. In fiscal year 2022, Copyright Office staff fielded over 152,000 public inquiries on copyright topics ranging in complexity, and hosted or spoke about copyright to a variety of audiences at nearly 150 events in virtual, hybrid and in-person modes. The Office has expanded promotional efforts to reach out to new audiences and to create a variety of easily accessible educational resources. These materials provide plain-language explanations of copyright law and specific information relating to the MMA and copyright issues for musicians. The Office hired a diversity outreach specialist focused on reaching underserved communities.

Illustrative examples of public events include the following.

Public events: In April 2022, the Copyright Office celebrated World Intellectual Property Day with a program, *Engage Your Creativity: Copyright and IP for Young Professionals*, which reflects the World Intellectual Property Organization's 2022 theme. Panelists explored the intellectual property rights creators enjoy daily and discussed young artists' experience with IP, their career stories, and links to copyright relevance.

<u>Legal audience events</u>: The Register of Copyrights and senior staff spoke on a wide number of issues at several events with legal audiences and at other legal and academic venues throughout the fiscal year.