



ANNUAL
INTELLECTUAL PROPERTY
REPORT TO CONGRESS

April 2024

Because of the greatness of a country is measured not only by the size of its economy or the strength of its military. It's — the strength of the nation is also measured by its boldness of its science, the quality of its research, and the progress it helps bring forth for not only the country but the whole world.

-- President Joe Biden¹

¹ Remarks by President Biden at National Medal of Science and National Medal of Technology and Innovation Ceremony, October 24, 2023, at <https://www.whitehouse.gov/briefing-room/speeches-remarks/2023/10/24/remarks-by-president-biden-at-national-medal-of-science-and-national-medal-of-technology-and-innovation-ceremony/>.

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 2023.

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DEPARTMENT OF AGRICULTURE

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Department of Agriculture Appendix for FY 2023 Annual Report

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.”

United States Department of Agriculture’s (USDA’s) GI-related Activities during FY 2023

The Foreign Agricultural Service (FAS) of the Department of Agriculture actively works with other Federal agencies, particularly the lead agencies the Office of the United States Trade Representative (USTR) and the United States Patent and Trademark Office (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 2023, 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 but not limited to, Chile, Oman, China, the European Union, and New Zealand 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 2023, 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 FTA negotiations, including:

- **Chile-EU AFA:** On December 9, 2022, the Chilean Government and the European Commission announced an agreement in principle on the Advanced Framework Agreement (AFA). Parallel to the Chile-EU FTA, the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP) entered into force in Chile on February 21, 2023. As a result, Chile must comply with due process and transparency provisions applicable to GIs under the CPTPP regarding any recognition or protection under the Chile-EU FTA. On May 8, 2023, CCFN sent two letters to the Chilean Undersecretariat of International Economic Relations (SUBREI) and the National Institute of Industrial Property (INAPI). The letters sought clarifications about compliance with the CPTPP obligations in relation to the names seeking recognition as GIs under the Chile-EU AFA.

Additionally, as part of the Chile-EU AFA agreement in principle, on June 6, 2023, SUBREI issued a call for prior users of the terms: “parmesano” and “gruyere.” Since the “prior users” were limited to Chilean agents, on June 19, CCFN filed and submitted affidavits on behalf of its members that met the grandfathering dates.

- **Chile-EU AFA Negotiations:** On April 6, 2023, the Chilean Government opened a consultation process inquiring whether any of the names for which Switzerland is seeking recognition as GIs as part of the modernization of the Chile-EU AFA, could undermine any commercial interests. On May 8, CCFN submitted comments and supporting evidence contesting the recognition of “emmental” and “gruyere” as GIs, asserting their frequent and widespread common use in Chile.
- **China-EU GI Agreement:** On December 2, 2022, an opposition period was opened against the recognition of 173 names as GIs, published as part of Phase 2 of the EU-China GIs Agreement. On February 2, 2023, CCFN filed an opposition against the recognition of “fontina” as a GI. The submission included information and evidence provided by CCFN members. A resolution or response from the Chinese authorities is still pending.
- **Vietnam-EU FTA:** During the past several years, CCFN has repeatedly contacted Vietnam’s National Office of Intellectual Property and Ministry of Industry and Trade and the Ministry of Science and Technology to request answers on how Vietnam will implement certain provisions of the Vietnam-EU FTA, with emphasis 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, as well as during the first quarter of 2023, CCFN repeatedly contacted Vietnamese authorities to receive an answer to the request.
- CCFN continued to build relationships with the Director General of the World Intellectual Property Organization (WIPO) and his leadership team.
- CCFN has served as an Observer to the WIPO Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications (SCT) and participated in

the Information Session on Geographical Indications. CCFN was also an Observer for the Working Group on the Development of the Lisbon System. 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 served on INTA’s GI Committee for the 2022-2023 period – on the Governance and the 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.
- During 2023, CCFN participated in INTA Subcommittees’ sessions that took place on May 19 (Governance Subcommittee) and on February 9, April 11, May 19, and June 15 (Expansion & Monitoring Subcommittee), as well as in the GI Committee Meetings held on March 7 and May 19 in order to help inform INTA positions on the issue of GIs and common names. Likewise, CCFN representatives participated in-person at the 2023 Annual Meeting in Singapore in order to advocate for INTA GI Committee workstreams that provide equitable treatment to common names.
- As part of its ongoing engagement in INTA, CCFN was approved by the GI Committee to organize a virtual symposium in October 2023 concerning common names and GIs. The symposium encouraged a dialogue among experts regarding how GI regimes may be constructed to allow for comprehensive protection of GIs, while respecting the rights of users of common or generic names.

CCFN participation in international fora and symposia:

- In collaboration with USPTO, CCFN organized and secured speakers for a session on common names during the Asia Pacific Economic Cooperation (APEC) Intellectual Property Experts Group IPEG meeting in February 2023. This was an opportunity to educate officials from several APEC economies amid negotiations with the EU.
- On April 27, 2023, CCFN worked in collaboration with WIPO staff to organize a Common Names event in Geneva to educate WIPO officials and delegates on the issue. CCFN remarks focused on informing policymakers on best practices for honoring legitimate GIs while protecting the rights of producers to market and sell their products using the common names that have long been part of the public domain.
- CCFN participated in the World Symposium on GIs, organized by WIPO, and co-hosted by the National Intellectual Property Center of Georgia (known as SAKPATENTI) which took place from June 14-16, 2023, in Tbilisi, Georgia. CCFN participated in the panel: “Geographical Indications, Trade and Common Names.”

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

- Mexico: In January and February 2022, CCFN engaged with the Mexican Association for the Protection of Intellectual Property (AMPROPI) by developing comments and recommendations on the draft implementing regulations of the IP law of 2020. During 2022 and 2023, CCFN continued monitoring developments and sharing comments and suggestions to ensure the effective implementation of the USMCA side letters on cheeses and prior users.
- New Zealand: On February 27, 2023, CCFN submitted comments on the final text of the EU-New Zealand FTA to highlight New Zealand’s obligation to comply with CPTPP GI provisions, including making available an opposition process against GIs intended to be protected in the country.
- Philippines: Upon request of the Philippines’ Senate Committee on Trade, Commerce and Entrepreneurship, on July 3, 2023, CCFN submitted comments on the Senate Bill No. 1868-An Act Providing for Protected Geographical Indications of Locally Produced Agricultural or Natural (Unprocessed or Wild) Products, Processed Products, Or Any Products Of Handicraft Or Industry. The Bill includes elements of a new GI regime in the Philippines (which would substitute the Rules and Regulations developed during 2022). CCFN comments focused on safeguarding the free use of common terms, including through transparency and due process guarantees.
- Vietnam: In July 2023, CCFN was notified about the Circular Guiding and Implementing Certain Articles of the Intellectual Property Law of Vietnam, which contained provisions on GIs. CCFN is submitting comments, highlighting Vietnam’s GIs commitments under the CPTPP, as well as the inclusion of measures that do not restrict the free use of common names.

Monitoring of GI and GI-related trademark applications in foreign markets to take appropriate action:

- CCFN developed a trademark logo that can be registered globally to preserve common usage rights with a disclaimer for generic terms. Once these CCFN trademarks are registered and used in countries around the world, this will provide strong protection against later sought bad-faith GI applications. By Q2 2023, trademarks filed via the Madrid Protocol were registered for: “Asiago CCFN” and “Feta CCFN” in Australia; “Bologna CCFN” in Australia and Japan; “Parmesan CCFN” in Canada and Japan; and “Provolone CCFN” in China, Japan, and South Korea. Direct national applications have been granted for “Asiago CCFN” in the U.S.; “Feta CCFN” in Costa Rica, Dominican Republic; and “Feta-Style CCFN” in Canada. Additional applications remain under active consideration by IP authorities.
- Argentina - Opposition to “munster” trademark applications: In September 2020, CCFN filed oppositions against two trademark applications for cheese and cheese-based

foodstuffs. On April 3, 2023, the process resumed for one of the applications and CCFN is reaffirming its opposition to ensure that the trademark does not impinge on the free use of the common term.

- Canada - Opposition filing against “Grana Padano” trademark applications: In December 2022, CCFN filed statements of opposition to two trademark applications for “Grana Padano” intended to expand the scope of the protection of the GI to prevent the use of the common term “grana.” On March 17, 2023, the applicant failed to respond to CCFN’s motion and the original trademark applications were deemed abandoned.
- EU - Ruling on the genericness of the term “emmentaler”: In March 2018, CCFN filed third-party observations against an attempt to trademark the term “emmentaler.” On May 24, 2023, the Court of Justice of the European Union (CJEU) ruled that “emmentaler” is a generic name for a type of cheese and cannot be trademarked.
- India – Opposition to a “feta” trademark application: In 2018, CCFN opposed a trademark application by an Indian company comprising the term “feta.” Due to the Covid pandemic, the process was put on hold. On May 27, 2023, the application was deemed abandoned since the applicant failed to respond to the opposition.

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.

USDA Plant Variety Protection Activities in FY 2023

PVPO received 350 applications for sexually reproduced, tuber propagated, and asexually reproduced varieties during the fiscal year. Among these were more than 20 applications for asexually reproduced varieties including varieties of apple, apricot, avocado, blackberry, calibrachoa, sweet cherry, peach, petunia, rose, and strawberry. PVPO issued 425 certificates of protection and examined 450 applications.

PVPO staff provided presentations on the program, the electronic Plant Variety Protection System, and examination procedures – to participants from the Netherlands and Nigeria. 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.

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

“What’s clear from conversations throughout this past year is that, more than ever, our nation needs the progress and growth that IP protections provide. We need a robust and reliable IP ecosystem that cultivates an innovation mindset and catalyzes inclusive innovation and entrepreneurialism—one that drives economic prosperity, U.S. competitiveness, supply chain resiliency, national security, and creative world problem-solving. We must continue to lead, and work closely with our allies, to realize our potential.”²

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

Department of Commerce Appendix for FY 2023 Annual Report

This appendix discusses the FY 2023 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 2023.

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 the General Counsel’s technical assistance arm, CLDP upholds the Department of Commerce’s mission, as stated in the 2022-2026 Strategic Plan, to “promote accessible, strong, and effective intellectual property rights to advance innovation, creativity, and entrepreneurship.” Pursuant to Strategic Objective 1.5, a critical element for achieving this objective is protecting and enforcing 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.

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.

² Kathi Vidal, *Director’s Blog on One Year of Bringing Innovation to Impact*, April 13, 2023, at <https://www.uspto.gov/blog/director/entry/one-year-of-bringing-innovation>.

Since 2021, USPTO's Global Intellectual Property Academy (GIPA) and CLDP have held monthly coordination meetings to discuss our current and future programs around the world and share best practices and lessons learned.

In FY 2023, CLDP IP activities were conducted for the following countries and regions: Bosnia and Herzegovina, Georgia, Regional Central Asia, Ukraine, Bahrain, the Kyrgyz Republic, Tajikistan, Uzbekistan, Sri Lanka, Tunisia, Algeria, and Pakistan.

As outlined below, CLDP's FY 2023 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 2023 IP PROGRAMS

1. Judicial Capacity Building in IPR Enforcement

Bosnia and Herzegovina

CLDP Hosts Intellectual Property Bench Book Workshop

On November 28-29, 2022, CLDP hosted a two-day workshop with stakeholders from the judiciary, the Intellectual Property (IP) Institute, the private sector, and academia with the goal of updating CLDP's Bosnia and Herzegovina (BiH) IP Bench Book from 2013. The workshop investigated the challenges of IP rights protection in BiH and focused on the development of bench book first drafts, as well as questions in preparation for the March 2023 U.S. study tour (discussed below).

CLDP Hosts Expert IP Group Consultative Visit

From March 20-24, 2023, CLDP hosted a group of IP experts from BiH for a consultative visit on U.S. IP law and practice in Washington, D.C. The delegation of judges, practitioners, professors, and officials met with a number of U.S. federal agencies, including the USPTO, Customs and Border Protection (CBP), ITA, Office of the United States Trade Representative (USTR), as well as with representatives of the judiciary and the private sector. The goal of the visit was to inform the delegation's drafting of the new IP Bench Book and their role in continuing legal education.

Georgia

CLDP Trains Judges to Handle Disputes on Intellectual Property Infringement

On July 29-30, 2023, CLDP facilitated a workshop on the adjudication of civil IP infringement cases for members of the Georgian judiciary. Judges from the U.S. and EU covered the foundational principles in the adjudication of IP infringement and National Intellectual Property Center of Georgia (Sakpatenti) presented country-specific case studies. The workshop increased the capacity and expertise of the Georgian judiciary to handle complex commercial law cases which often involve IP issues.

2. Capacity Building for Institutions that Grant IPR

Georgia

CLDP Recommends Amendments on CMO Law to Parliament

On December 7, 2022, in coordination with USAID's Economic Governance Program, CLDP provided recommendations and next steps in the reform of Georgia's Law on Collective Management Organizations (CMOs) to officials from Georgia's Parliamentary Culture Committee, Sakpatenti, the Georgian Copyright Association, Georgian artists and performers, and private sector representatives. CLDP's recommendations included requiring greater transparency, accountability, and good governance and increasing the regulatory role of Sakpatenti.

CLDP Leads Roundtable on Collective Management

From January 25-27, 2023, in coordination with USAID, the Culture Committee of the Parliament of Georgia, and Sakpatenti, CLDP led a roundtable on policy justifications and amendment language on collective copyright management to better align Georgia's CMO regime with international best practices. The proposed amendments will add cultural, social, and economic value by strengthening fair, efficient, transparent, and accountable process.

CLDP Participates in Public-Private Dialogue on Amendments to Copyright Law

On May 17, 2023, CLDP participated in a Public-Private Dialogue (PPD) on the recently drafted amendments to Georgia's Copyright Law regarding CMOs. The PPD was hosted by the Culture Committee of the Parliament of Georgia, Sakpatenti, and USAID. CLDP and international CMOs provided feedback on the proposed amendments. CLDP will continue to provide assistance through the legislative process.

3. Capacity Building for Institutions that Enforce IPR

Central Asia

CLDP Holds Consultations and Workshop and Combatting Trade in Counterfeit Goods

From February 13-26, 2023, CLDP, in cooperation with the USPTO, CBP, and the U.S. Department of Justice (DOJ), held consultations and a workshop for high-level government officials from Kazakhstan, the Kyrgyz Republic, Tajikistan, Turkmenistan, and Uzbekistan in Geneva, Switzerland. The delegation met with, among others, the World Intellectual Property Organization, the World Trade Organization, the World Health Organization, and the International Road Transport Union, to discuss best practices in combatting illicit trade in counterfeit goods. CLDP then held a workshop for the delegation to determine a series of next steps aimed at combating proliferation of counterfeit goods in Central Asia.

CLDP Hosts Brand Protection and Identification Workshops

On March 9-10 and March 13-14, 2023, respectively, CLDP, in partnership with the U.S. Customs and Border Protection and the anti-counterfeiting network REACT, conducted workshops for officials from customs, law enforcement, and intellectual property agencies on the identification and protection of brands in Dushanbe, Tajikistan and Tashkent, Uzbekistan. The

workshops investigated security features applied to genuine goods, shared methodology on identifying counterfeit goods, and discussed recent trends in counterfeiting.

CLDP Holds Fifth Meeting of the Intellectual Property Working Group

From July 19-21, 2023, in Tbilisi, Georgia, CLDP, in coordination with USTR, CBP, USPTO, DOJ, the Drug Enforcement Administration (DEA), and the Intellectual Property Rights Center (IPR Center), led the fifth meeting of the Central Asia Expert Level Intellectual Property (IP) Working Group. Government officials from Kazakhstan, Kyrgyz Republic, Tajikistan, Turkmenistan, and Uzbekistan discussed best practices in inter-governmental coordination on IP policy and enforcement, as well as how to educate consumers about the dangers of counterfeit goods. The Working Group agreed on a set of recommendations that will be sent to the U.S.- Central Asia Trade and Investment Framework Agreement (TIFA) Council for adoption.

CLDP Hosts 7th Annual International Conference on Counterfeiting and Piracy

On July 24-25, 2023, CLDP partnered with Sakpatenti to hold the 7th Annual International “Georgia Against Counterfeiting and Piracy” Conference in Batumi. Featuring speakers from the World Intellectual Property Organization, the European Union Intellectual Property Office, USPTO, CBP, and Europol, the conference enhances public-private dialogue and improves both interagency and international cooperation in combating counterfeit goods and digital piracy in Georgia and the broader Caucasus, Eastern Europe, and Central Asia.

CLDP Organizes Working Group on Intellectual Property Rights

On July 26, 2023, CLDP and Sakpatenti organized a meeting of the South Caucasus and Eastern Europe Expert-Level Working Group on IP Rights. With representation from Armenia, Georgia, and Moldova, the Working Group identified mutual challenges for the protection and enforcement of IP and discussed opportunities for enhanced regional cooperation and information sharing. This Working Group contributes to predictable, harmonized, and efficient IP protection and enforcement across the region.

CLDP Hosts 2nd Annual Trans-Caspian Intellectual Property Forum

On July 27, 2023, CLDP and Sakpatenti organized the 2nd Annual Trans-Caspian Intellectual Property Forum. Utilizing expertise from the USPTO, CBP, and DOJ, the Forum provided a platform for government officials from the South Caucasus, Eastern Europe, and Central Asia to discuss areas of mutual topics such as customs enforcement, engaging rightsholders, and overcoming challenges in protecting digital intellectual property.

Ukraine

CLDP Holds IP Law and Practice Fundamentals for Ukrainian Lawyers

From November 14-18, 2022, CLDP held a workshop in Warsaw, Poland and online for Ukrainian lawyers and law students on IP law and practice fundamentals. Participants heard from U.S., Ukrainian, and Polish private sector, government, and academic experts on the foundations of IP law, as well as tips for incorporating some aspects of IP into their existing legal practice. The program aims to proliferate appreciation for IP among a broad group of Ukrainian legal practitioners and to provide a skillset that allows those individuals to begin handling some

components of IP legal issues in their day-to-day work. The program also provides a networking opportunity for Ukrainian lawyers who have been affected by the war (either through displacement, inability to work, or working in hostile conditions) and to share best practices for the rebuilding and strengthening of the post-war legal community in Ukraine. This work is a part of CLDP's multi-phase programming to strengthen IP protections in Ukraine and to facilitate greater local and international investment and innovation, which will be essential in the rebuilding process.

4. Development of Innovation Ecosystems/Technology Transfer

Global

CLDP Supports Technology Transfer Professionals at AUTM Annual Meeting

From February 19-22, 2023, CLDP supported government officials, academics, and technology transfer professionals from Algeria, Armenia, Georgia, Pakistan, Sri Lanka, and Tunisia to attend the 2023 AUTM Annual Meeting in Austin, Texas. The AUTM Annual Meeting is a global event for technology transfer professionals to share knowledge and build professional networks. CLDP also provided each delegation guidance on the challenges in building and sustaining successful technology transfer offices.

Bahrain

CLDP Conducts Innovation and Technology Transfer Workshop

On December 12, 2022, CLDP, in cooperation with the Bahrain Ministry of Industry, Commerce, and Tourism and the University of Bahrain, conducted a workshop for faculty, students, and entrepreneurs interested in the services of the Bahrain Innovation and Technology Transfer Center. Utilizing experts from the University of Maryland, George Mason University, and Georgetown University, the workshop focused on best practices in commercializing research-based innovation.

Central Asia

CLDP and USPTO Present IPR Webinar

On March 6-7, 2023, CLDP conducted intellectual property rights (IPR) webinars for students, faculty, and government officials in Uzbekistan and the Kyrgyz Republic. Lawyers from the USPTO provided overviews of basic concepts in patents, trade secrets, trademarks, and copyrights. This program is the opening effort of a multi-year project for CLDP to assist the development of a university-based technology transfer ecosystem in each Central Asian country.

Kyrgyz Republic

CLDP Conducts IPR Workshop to Celebrate World IP Day

On April 25, 2023, CLDP conducted a workshop to celebrate World Intellectual Property Day and educate Kyrgyz stakeholders on topics pertaining to IPR protection. This year's theme was Women in IP, and participants joined sessions that covered IPR's value to society, patents, trade secrets, trademarks, and copyrights. This program is part of a multi-year program designed to

develop a technology transfer office in a Kyrgyz university that will mentor students, faculty, and entrepreneurs to protecting and commercializing their research innovations.

CLDP Conducts Technology Transfer Workshop

On July 27-28, 2023, CLDP conducted a technology transfer workshop for government officials, students, faculty, and entrepreneurs in Bishkek. Utilizing experts from Cornell and Boston University, the workshop discussed invention and intellectual property management, effective transfer of intellectual property rights, and technology transfer in public-private partnerships. This workshop is part of CLDP's ongoing effort to develop a technology transfer office in the Kyrgyz Republic.

Tajikistan

CLDP and USPTO Conduct Intellectual Property Webinar

On March 17, 2023, CLDP in collaboration with the USPTO conducted an intellectual property rights webinar for students, faculty, and government officials. USPTO lawyers provided overviews of basic concepts in patents, trade secrets, trademarks, and copyrights. This program is the opening effort in a multi-year project for CLDP to assist the development of a university-based technology transfer ecosystem.

CLDP Conducts IP Workshop to Commemorate World IP Day

On May 2, 2023, CLDP conducted an intellectual property (IP) rights protection workshop for Tajik stakeholders. The workshop covered IP's value to society in patents, trade secrets, trademarks, copyrights, and the commercialization of research and development. The workshop, opened by the U.S. Ambassador to Tajikistan, is part of a multi-year project designed to develop a technology transfer office in a Tajik university.

CLDP Conducts Workshop on Technology Transfer

On July 20-21, 2023, in Dushanbe, CLDP conducted a technology transfer workshop for various public and private stakeholders. The workshop included presentations on invention and intellectual property management, effective transfer of intellectual property rights, and technology transfer in public-private partnerships, as well as case studies in intellectual property policy and invention disclosure. The workshop is part of an effort to develop a technology transfer office in Tajikistan as a resource for inventors and to foster an effective technology transfer ecosystem that will benefit U.S. and Tajik companies.

Uzbekistan

CLDP Conducts IP Workshop to Commemorate World IP Day

On April 28, 2023, CLDP conducted an IPR protection workshop for Uzbekistani stakeholders. The workshop discussed IP's value to society through patents, trade secrets, trademarks, copyrights, and the commercialization of research and development. This workshop is part of a multi-year project designed to develop a technology transfer office in an Uzbekistani university.

CLDP Conducts Workshop on Technology Transfer

On July 24-25, 2023, in Tashkent, CLDP conducted a technology transfer workshop for various public and private stakeholders. The workshop included presentations on invention and intellectual property management, effective transfer of intellectual property rights, and technology transfer in public-private partnerships, as well as case studies in intellectual property and invention disclosure. The workshop is part of an effort to develop a technology transfer office in Uzbekistan as a resource for inventors and to foster an effective technology transfer ecosystem that will benefit U.S. and Uzbekistani companies.

INTERNATIONAL TRADE ADMINISTRATION (ITA)

Office of Standards & Intellectual Property (OSIP)

STOPfakes.gov

The International Trade Administration's Office of Standards and Intellectual Property (OSIP) leads and manages the United States interagency STOPfakes.gov program including coordinating 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 and includes links to resources supporting the 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 on a specific foreign country. The following information is included on each IP Snapshot: contact information for local IP Offices, country membership in important global IP treaties, the USTR Special 301 Report rankings for the immediate three years prior, 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. The China IP toolkit was recently updated. Additionally, available toolkits include Singapore, Korea, Malaysia, Vietnam, Thailand, Brunei, Brazil, Colombia, Egypt, European Union, Italy, and Peru.

STOPfakes at 2023 Consumer Electronics Show

The STOPfakes team provided in-person IP education and direct outreach to over 2800 attendees during the 2023 Consumer Electronics Show in Las Vegas, Nevada. The STOPfakes engagement included 3 USG interagency STOPfakes partners, including the USPTO, the State Department, and CBP. The Office of the Intellectual Property Enforcement Coordinator (IPEC) participated as well.

STOPfakes at the 2023 SelectUSA Investment Summit

The STOPfakes team provided in-person IP education and direct outreach as part of the U.S. Government pavilion at the 2023 SelectUSA Investment Summit in National Harbor, Maryland. The STOPfakes engagement at SelectUSA included interagency partners from CBP, USPTO, and IPEC.

OSIP Outreach

Baltimore Innovation Week-"Going Global" Panel

OSIP regularly participates in this yearly Innovation Outreach program for SMEs and innovators in Baltimore, Maryland. For FY 2023, OSIP participated in an innovation and intellectual property panel focused on providing SMEs, start-ups and innovators with critical guidance to protect and enforce their intellectual property rights. The outreach program is co-hosted by Baltimore's Emerging Technology Center, in cooperation with U.S. Commercial Service and the U.S. Department of Commerce. As a result of OSIP's participation, the team connected with over 50 businesses.

STOPfakes Roadshows

The [STOPfakes Roadshows](#) 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 help facilitate the seizure of infringing goods at our borders;
- The Federal Bureau of Investigation (FBI) 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.

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

During FY 2023, OSIP coordinated two domestic STOPfakes Roadshows in Milwaukee, Wisconsin and Orlando, Florida. During the Orlando Roadshow, the STOPfakes team also spoke about the importance of intellectual property rights and protection at a brand owner breakfast in Daytona Beach, Florida.

STOPfakes Webinars

During FY 2023, OSIP continued to offer a variety of online 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.

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.

Brand Summit (NYC)

In September 2023, OSIP presented at the Brand Summit USA in New York City to several hundred brand owners about the STOPfakes program including a summary of the program's resources and guidance for brand owners. Several businesses at the Summit had specialized business consultations with OSIP IP following the event.

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, most domain name registration data is no longer openly published on the Internet. The U.S. Government continues playing an active role in the ongoing discussions to establish a sustainable access 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 applications for new generic Top Level Domains, 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

Throughout FY 2023, NTIA followed developments in the Section 1201 rulemaking process and prepared to fulfill its statutory role to engage in consultation with the Copyright Office on exemptions proposed during the ninth triennial rulemaking, which is expected to conclude by late calendar year 2024 (17 U.S.C. § 1201(a)(1)(C)). In particular, NTIA engaged with the Copyright Office on the proceeding and reviewed petitions for renewals and new exemptions. NTIA looks forward to continuing its participation in the rulemaking and sharing its views with the Copyright Office.

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 2023, 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). In March 2023, USPTO attended the 11th Plenary Meeting of the OECD Task Force on Countering Illicit Trade as part of a U.S. delegation that included the Department of State, Customs and Border Protection, and the Department of Homeland Security. USPTO representatives participated in a TF-CIT affiliated expert working group meeting to discuss enforcement efforts and best practices related to countering the trade in counterfeit goods through e-commerce marketplaces.

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

Throughout FY 2023, 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; an enacted Nigerian copyright law; ongoing legislative reform in India and several ASEAN/APEC members; a U.S.-Paraguay Intellectual Property Memorandum of Understanding (MOU); 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 analysis on the state of IP protection and enforcement in 70 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 2023, GIPA provided IP awareness and education programming to over 5,200 U.S. SMEs, U.S. government officials, and other U.S. stakeholders. About 24% of GIPA’s over 140 programs in FY 2023 targeted this domestic audience of IP rights owners, users, and policymakers. During FY 2023, following GIPA’s continued successful 2020 pivot to all-remote outreach and education delivery, thanks to prior investments in technology platforms and e-learning strategies, in-personal and hybrid programming increased significantly in FY 2023 compared to the previous fiscal year.

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, and webinars for U.S. SMEs, as well as continuing 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 Small Business Administration’s (SBA) affiliated organizations and conferences on IP basics, exporting IP overseas, and USPTO resources for entrepreneurs and SMEs; 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 IP and considerations for entrepreneurs for several Small Business Development Centers (SBDCs) in cooperation with many of the USPTO Regional Outreach Offices.

On December 15, 2022, the USPTO participated in the International Trade Administration’s Global Diversity Export Initiative “Opportunities in Africa” event held on the margins of the US-Africa Business Forum to provide SMEs and Minority Business Enterprises (MBEs) with access to information and support for doing business on the African continent.

From February 17-21, 2023, the USPTO organized a “Roundtable on Copyright and Creativity in the Digital Economy: Challenges to Creative Entrepreneurs,” in Palm Springs, California, on the margins of the APEC Intellectual Property Experts Group meeting.

On May 25, 2023, the USPTO participated in the International Trade Administration’s “Maryland Export Day” event, which focused on SMEs engaged in exporting. This year’s event had a special focus on exporting to Africa.

On June 11, 2023, the USPTO supported ITA’s Global Diversity Export Initiative’s Trade Mission to Africa by co-hosting a pre-mission webinar with ITA, “Know Before You Go - Protecting Your Intellectual Property Rights on the African Continent,” for trade mission participants.

On August 8, 2023, the USPTO Southeast Asia Team participated in a “Southeast Asia IP Virtual Roadshow 2023,” jointly organized by the USPTO and the U.S. Department of Commerce International Trade Administration. This webinar provided practical information to SMEs and exporters about IP-related topics in the Southeast Asia region to U.S. businesses and stakeholders.

Finally, the USPTO Attachés throughout the globe provide assistance and answer inquiries from SMEs regularly. These inquiries range from explaining the workings of the intellectual property rights (IPR) system of the foreign country and/or region in order to assist them ensure that their IPR is protected abroad, to providing initial guidance on an infringement matter. In addition, in light of Director Vidal’s efforts to provide support to the US military community by assisting veterans and their spouses pursue entrepreneurial opportunities in the future, the USPTO Attaché for Europe recently joined Director Vidal on a panel at the US Military Base in Rota, Spain, to discuss entrepreneurship and the importance of protecting and enforcing IPR as a business asset.

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 [USPTO’s website](#) and promoted through the USPTO’s social media platforms.

In FY 2023, 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 102,000 views as of September 30, 2023.

The USPTO’s “Go For Real” campaign, a partnership with the National Crime Prevention Council, continued to educate tweens and teens, along with their educators and caregivers, about the dangers of counterfeit goods. The program includes an array of multimedia assets, including

the award-winning “You’re Smart. Buy Smart” public service announcement (PSA) and “The Real McGruff” PSA, which features a 3D animated McGruff the Crime Dog and his nephew Scruff. Together the PSAs have had nearly 240,000 TV airings, more than 1.5 billion impressions, and an ad value of more than \$30 million. In addition, the campaign launched Go For Real TV, a YouTube series developed by USPTO and the National Crime Prevention Council comprising short videos designed to educate our target market about the dangers of counterfeit goods. The first season was awarded first place in the “K-12 Educational Program” category by the National Association of Government Communications (NAGC) Blue Pencil & Gold Screen Awards, and a second season was released in summer 2023. The campaign has an active social media presence, with more than 3 million social media impressions. Finally, the campaign held 12 pop-up events, serving thousands of tweens and teens.

USPTO celebrates World Intellectual Property Day (WIPD) each year on April 26 to highlight the importance that IP plays to the U.S. economy and the creation of good-paying jobs. This year, the USPTO celebrated WIPD and its theme “Women and IP: Accelerating Innovation and Creativity” by hosting on Capitol Hill a panel of women business leaders and CEOs to discuss the importance of IP for helping women entrepreneurs and SMEs create successful businesses. This seminal event capped a month-long WIPD social media campaign entitled “The Value of Her IP.” The campaign featured nine women Founders and CEOs of SMEs including a biotech company, an independent toy store, a clothing/lifestyle company, a candy company, and a music publisher. Each woman shared about the time, money, and personal sacrifice it took to create their IP and their company, and why it was important that IP be protected and respected to ensure U.S. companies remain competitive in an ever-changing global marketplace. Additionally, U.S. IP Attachés conducted several in-person WIPD events around the globe and many participated in USPTO’s “The Value of Her IP” WIPD social media campaign.

Capacity-Building and Training

The USPTO’s Global Intellectual Property Academy (GIPA)

In FY 2023, 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. Face-to-face training programs increased throughout FY 2023, though the USPTO’s continued leverage of various technologies to provide live online IP training or a combination of in-person and virtual functionality. Through these well-attended and well-received in-person and 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 administrators. In FY 2023, GIPA conducted over 140 IP programs covering all areas of IP. About 72% of these programs targeted foreign officials with IP portfolios, engaging over 4,600 officials from 122 countries and intergovernmental organizations. A complete list of all countries represented at GIPA trainings in FY 2023 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 November 2022, as part of USPTO's continued outreach efforts to small and medium-sized enterprises (SMEs), the USPTO hosted a CLE accredited multi-panel webinar covering patent enforcement fundamentals for SMEs thinking about enforcing their patents. The webinar featured three panels of experts, each addressing different aspects of patent enforcement in the U.S. system. The panelists included judges, in-house counsel, government experts, and litigation counsel, and they addressed litigation before United States District Courts and the United States International Trade Commission, and administrative proceedings before the Patent Trial and Appeal Board.

In May and August 2023, USPTO OPIA presented on USPTO Resources for Law Enforcement and an Overview of the Trademark Electronic Search System ("TESS") for CBP officers, HSI investigators, import specialists, and other field personnel engaged in IP protection and trade enforcement as part of the Intellectual Property and Trade Enforcement Investigations (IPTEI) course organized by the IPR Center.

On July 25-27, 2023, USPTO hosted the "Indo-Pacific Judicial Colloquium on Intellectual Property, Innovation, and Technology," an international event with 130+ participants from public, academic, and private sectors, including 70+ international judges from countries across the Indo-Pacific region (Australia, Brunei, Fiji, India, Indonesia, Japan, South Korea, Malaysia, New Zealand, Philippines, Singapore, Vietnam) and 20+ U.S. Federal judges.

In September 2023, USPTO OPIA participated as a speaker in INTERPOL's 16th International Law Enforcement Intellectual Property Crime Conference, as a panelist on "Eliminating Barriers & Increasing Influence of Women in IP Law Enforcement." USPTO provided insights on ways to challenge cultural and societal norms, increase STEM-based programs and opportunities for women, and highlighted the programs and resources of the USPTO. This year's Conference theme was "Pathways to Solutions," and many sessions focused on keeping pace with current trends and learning technologies that would allow law enforcement to stay ahead of emerging

risks associated with transnational organized IP crime and illicit trade. In particular, many sessions focused on AI, the Metaverse, augmented reality, cryptocurrency and the interplay of law enforcement. There were over 400 delegates from 100 countries representing 200+ cross-sector organizations at this year's conference.

Africa

On February 13-15, 2023, OPIA's Enforcement Team welcomed a delegation of 17 sub-Saharan African officials at GIPA, including government officials from Djibouti, Kenya, Namibia, Gabon, Lesotho, Liberia, Madagascar and Togo, for the "Countering Illicit Trade Amid Expanding Trade Infrastructure Investments" program. The program faculty included participants from USPTO, CBP, DOJ, HSI and the IPR Center. The program was so well-received that a second iteration was held November 13-15, 2023, with participants from Cameroon, Cote d'Ivoire, Ghana, Nigeria, Senegal, and Tanzania.

On March 6-10, 2023, OPIA's Enforcement Team participated in a multi-agency, IPR Center-led training, "Intellectual Property Rights Investigative Methods Workshop: Southern African Development Community – Cross-Border Illicit Trade Enforcement," in Swakopmund, Namibia. The 40 participants hailed from Namibia, South Africa, Malawi, Botswana and Zambia, and included government officials from customs offices, the police and prosecutors.

On April 14, 2023, OPIA's Enforcement Team presented to Sub-Saharan African SMEs an "Overview of IP for Businesses Ready to Conduct Business Under the AfCFTA" as part of CLDP's "Investment and Export Readiness under the AfCFTA" Masterclass Program, held in collaboration with the United Nations Economic Commission for Africa (UNECA), the International Trade Centre and others.

On June 5-7, 2023, OPIA's Enforcement Team conducted a workshop, "Enforcing IP Rights at the Cabo Verde Border," for 26 Cabo Verdean government officials from a variety of government agencies (including prosecutors, customs officers and IP office administration) at the Presidential Palace in Praia, Cabo Verde. The program was co-hosted by CBP and included participation from HSI Senegal.

On June 5, 2023, USPTO met with the Sub-Saharan Africa Pharma Crime Working Group with representatives from 11 countries including Namibia, Niger, Nigeria, Uganda, Botswana, Senegal, South Africa, Ghana, Kenya, Zambia and Sierra Leone to discuss efforts to address counterfeit pharmaceuticals.

On August 11, 2023, OPIA's Copyright and Enforcement Teams conducted a "Mock Business IP Consultation," about copyright rights and clearances required, at the U.S. Department of State's Creative Industries event in Accra, Ghana, "Leveraging Intellectual Property Rights to Grow the Creative Economy."

Eurasia

On October 27, 2022, the IP Attaché for Eurasia gave a presentation at the 2022 Europol IP Crime Conference in Rome, Italy, with a program attendance of over 400 government officials and private sector representatives. He spoke on a panel entitled: “Spotlight on Key Crises: Inter-Influences with IP crime,” where he addressed the IP implications of Russia’s war on Ukraine, including counterfeiting of semiconductors and medical devices.

In November 2022, OPIA’s Enforcement Team participated in a capacity building program in Lithuania for Central Asia, including representatives from Kyrgyz Republic, Kazakhstan, and Turkmenistan, and provided presentations on trade infrastructure associated illicit trade, and participated in panel discussions on customs and illicit trade.

In December 2022, OPIA’s Enforcement and Copyright Teams participated in a capacity building program for the government of Uzbekistan addressing online copyright infringement and enforcement mechanisms to address online copyright enforcement and illicit streaming.

In February 2023, OPIA’s Enforcement Team participated in consultations between five Central Asia countries (Kazakhstan, Kyrgyz Republic, Tajikistan, Turkmenistan, Uzbekistan) and WIPO, WHO, WTO, and industry. The USPTO presented on its public awareness outreach work, including the “Go For Real” campaign. The consultations took place in Geneva, Switzerland.

In March 2023, the IP Attaché for Eurasia, together with the OPIA Enforcement Team, assisted South Carolina-based North American Rescue, LLC, regarding counterfeit medical tourniquets appearing in Ukrainian military supply chain. As a result, the National Intellectual Property Rights Coordination Center (IPR Center) released an Officer Safety Bulletin to American first responders, for them to be aware of potential counterfeit tourniquets and how to identify them.

On May 17, 2023, the IP Attaché for Eurasia, together with the IP Attaché for the EU, conducted a briefing for members of the Digital Creators Coalition (DCC), regarding priority IP issues in their regions. The DCC is a group of more than two dozen associations, companies, and organizations, which represent individual creators, independent producers, small-and-medium-size enterprises, large businesses, and labor organizations from the American creative communities.

On May 31, 2023, IP Attaché for Eurasia participated in the Europe, the Middle East, and Africa (EMEA) Security Conference: “Anti-Counterfeiting & Brand Protection,” which was held in Istanbul, Turkiye. He participated in a panel discussion on “Public Private Partnerships,” which addressed effective ways to coordinate with different stakeholders in the fight against counterfeiting.

On July 19-21, 2023, OPIA’s Enforcement Team participated in the U.S.-Central Asia Expert Level Intellectual Property Working Group meeting in Tbilisi, Georgia. The Working Group is under the auspices of the U.S.-Central Asia Trade and Investment Framework Agreement (TIFA). The USPTO provided presentations and participated in panels on intragovernmental

coordination of enforcement, intragovernmental coordination is setting and following IP policy, and raising public awareness of counterfeit goods.

On July 24-25, 2023, OPIA's Enforcement Team participated in the Seventh Annual International Conference Georgia Against Counterfeiting and Piracy, in Batumi, Georgia. The annual conference is jointly organized by the Georgian Institute for Intellectual Property (SAKPATENTI) and CLDP. The USPTO provided a presentation on "Transnational Illicit Trade: Recent Trends and Emerging Risks" and participated on the panel on "The Status of the Fight Against Counterfeiting & Piracy."

On July 27, 2023, OPIA's Enforcement Team participated in the CLDP-organized Second Annual Trans-Caspian Intellectual Property Forum, in Batumi, Georgia. Discussions focused on Regional Challenges and Progress for IPR Protection and Enforcement.

Latin America and Caribbean

On November 30, 2022, OPIA's Enforcement Team participated in a webinar centered around the latest developments in worldwide IP protection. This webinar was hosted by the World Intellectual Property Organization (WIPO) and the Mexican Institute of Industrial Property (IMPI). During the session, the Enforcement Team shared insights based on the U.S. experience with intellectual property enforcement.

Between January 2023 and June 2023, the IP Attaché's office Lima, in conjunction with the Peruvian Ministry of Production's interagency Commission Against Intellectual Property Crimes and Contraband (CLCPC) and the private sector, organized six training and outreach programs in Peru. These activities were focused on disseminating information about the importance of protecting IPRs. More than 290 government officials (Customs, Police, IP prosecutors and IPOs) benefitted from these IP-focused activities all around Peru (Lima, Callao, Cuzco, Apurimac).

On March 14, 2023, USPTO's Brazil's IP Attaché and Advisor joined representatives from State Econ and the FBI; the governments of the United Kingdom, Japan, Colombia, Singapore, South Africa, and the European Union (and Brazil); and representatives from Microsoft, IFPI, MPA, and Brazil's National Confederation of Industries (CNI) at Brazil's National Integrated Command and Control Center to demonstrate support for the fifth phase of OPERATION 404 and the first instance of the operation to take place under the Lula government. The March 14th operation resulted in the arrest of 11 people in 4 Brazilian states as well as the blocking of 199 websites, 63 illegal streaming applications, and six messaging app channels in Brazil, Peru, and the United Kingdom. Additionally, 32 search and seizure warrants were executed and the targeted sites were de-indexed from Internet search engines and de-referenced from social network profiles and pages

On March 14, 2023, USPTO's OPIA and the IP Attaché based in Mexico organized, hosted and participated in a virtual "Judicial Colloquium on Intellectual Property Rights Enforcement" for approximately 30 Caribbean Community (CARICOM) judges from Barbados, Belize, Jamaica, and Trinidad & Tobago.

On March 21 and April 18, 2023, the USPTO IP Counselor in Mexico City organized, with the OPIA Patent Team, a webinar on utility patents for the government of Honduras, including the IP Office (DIGEPIH) and the Public Ministry.

From March 22-24, 2023, the USPTO's Brazil IP Attaché co-hosted a trade secret event with DOJ. During the activity, the IP Advisor held side meetings with a local judge; UKIPO's Brazil-based IP Attaché on a possible joint event; and representatives of São Paulo's Civil Police and Federal Police on a possible visit and training.

On March 23, 2023, the USPTO IP Counselor in Mexico City organized, with the OPIA Patent Team, a webinar on design patents for the government of Honduras, including the IP Office (DIGEPIH) and the Public Ministry.

In March 2023, USPTO's OPIA, with the support of the IP Attaché's Office in Peru, organized a virtual workshop for approximately 30 Honduran police, prosecutors and customs officials on the "Importance of IP Protection and Enforcement" and "Border Measures for IP."

On March 28, 2023, the USPTO IP Counselor in Mexico City organized with the OPIA Trademark Team a webinar on artificial intelligence and the Metaverse for the government of Honduras, including the IP Office (DIGEPIH) and the Public Ministry.

On March 30, 2023, the USPTO IP Counselor in Mexico City organized with the OPIA Enforcement Team and CBP a webinar on enforcing against counterfeit brands for the government of Honduras, including the IP Office (DIGEPIH) and the Public Ministry.

In March 2023, the IP Attaché Office Lima participated in the VIII Latin American Anti-Smuggling Alliance (ALAC) conference in Bogota by presenting on the impact of counterfeiting on health and safety. More than 200 attendees, including government officials and stakeholders from Pharma, Agricultural and other industries attended the conference.

On March 2023, the IP Attaché Office Lima co-sponsored with Universidad de los Hemisferios – Ecuador, the Ecuadorian Chamber of Commerce and ASIPI a workshop about border measures. IP authorities from the Judiciary, IPO, Customs, Prosecutor Office and Police, actively participated. Later in April 2023, the Legal Advisor gave a presentation at an Illicit Trade Webinar organized by Universidad de los Hemisferios to Ecuadorian journalists. Finally, on May 15, the Legal Advisor participated as a speaker at an "Intellectual Property Enforcement" training program, organized by the IP Attaché office Lima and a Peru-based law firm, targeted at Ecuadorian customs officials. Representatives of well-known trademarks, such as Epson, Nike, Adidas, Puma, Calvin Klein, Levi's, Johnson & Johnson, Tiffany & Co., gave detailed presentations on how to spot counterfeit or fake goods. Sixty-five Ecuadorian Customs Officials attended the workshop.

On April 11, 2023, the USPTO IP Counselor in Mexico City organized with the OPIA Enforcement Team a webinar on "Good Practices Regarding Enforcement" for the government of Honduras, including the IP Office (DIGEPIH) and the Public Ministry.

On April 20, 2023, the USPTO IP Counselor in Mexico City organized with the OPIA Copyright Team a webinar on collective societies for the government of Honduras, including the IP Office (DIGEPIH) and the Public Ministry.

On April 24, 2023, USPTO's Brazil IP Advisor attended the inauguration of the São Paulo CyberGAECO's new Laboratory of Technological Investigations. The laboratory is a public-private partnership modeled after the City of London Police Intellectual Property Crime Unit, and its launch was timed to coincide with World IP Day. An arm of the state prosecutor's office, CyberGAECO is a digital crime-focused Special Action Group for Combatting Organized Crime.

In April 2023, USPTO's OPIA and the IP Attaché based in Mexico, organized a virtual webinar and presented information on "Best Practices in IP Enforcement" for approximately 50 police, prosecutors and customs officials.

On May 22-23, 2023, USPTO's OPIA, the Brazil IP Attaché and Advisor attended and spoke at the "Latin America IP Enforcement Forum for Entertainment Industries" in Los Angeles. The event began with technical visits to several studios to demonstrate the importance of copyright creative industries and set the tone for the remainder of the program, which focused on IP enforcement efforts and resources available in Brazil, Argentina, and Peru for IP enforcement.

On August 1-2, 2023, USPTO's OPIA, in collaboration with the USPTO IP Counselor in Mexico City, organized a Regional Copyright Workshop in Panama City, Panama for government officials from Mexico, Central America and the Caribbean.

In September, 2023, USPTO's OPIA participated in a webinar for Peruvian Judges, presenting on enacted and proposed legislative initiatives in the U.S. to protect and enforce intellectual property, starting with an overview of the key provisions of the INFORM Consumers Act (enacted at 15 U.S.C. § 45f), the Protecting Lawful Streaming Act (enacted at 18 U.S.C. § 2319C), and the Domain Reform for Unlawful Drug Sellers (DRUGS) Act (introduced in 2021), all as a part of an ongoing educational series organized by the Attaché's Office in Peru under the auspices of the MOU between USPTO and Poder Judicial.

On September 7, 2023, the USPTO IP Counselor in Mexico City co-organized a roundtable on enforcement with the creative industry, including the Entertainment Software Association (ESA) and the Motion Picture Association (MPA), for ten members of Mexico's Cyber Police of the National Guard. The roundtable enabled an exchange of best practices on the subject of enforcing copyrights and trademarks in the digital environment for cinematographic and audiovisual works and videogames.

South East Asia

On October 25-28, 2022, the OPIA Enforcement Team co-organized with the ASEAN Intellectual Property Academy, an "Indo-Pacific Regional Workshop on Handling, Storage, Disposal and Destruction of Counterfeit Goods," in Bangkok, Thailand.

From October 31-November 4, 2022, the USPTO co-organized and participated in a Singapore-United States Third Country Training Program (TCTP) course for ASEAN Member States on the “Digital Economy,” in Singapore. The program was co-organized with the Singapore Infocomm Media Development Authority (IMDA) and the Singapore Civil Service College.

In November 2022, the USPTO participated in a “Seminar on Emerging Intellectual Property Enforcement Issues,” organized by the Thai Central Intellectual Property and International Trade Court, in Bangkok, Thailand. Later that same month, the USPTO organized an “ASEAN Workshop on Intellectual Property, Consumer Protection, Unfair Business Practices, and Public Awareness,” in Bangkok, Thailand.

On January 30-February 3, 2023, OPIA’s Enforcement Team participated in the “Intellectual Property Rights Investigative Methods Workshop,” hosted by the National IPR Coordination Center and Homeland Security Investigations, in Jakarta, Indonesia. Approximately 40 Indonesian officials and enforcement authorities participated in the program.

In March 2023, the USPTO participated in an “Interpol Regional Workshop on Enforcement Against Trade in Counterfeit Pharmaceuticals and Illicit Health Products,” as part of the USPTO-funded support for the Interpol Operation Pangea, in Bangkok, Thailand.

In May 2023, the USPTO organized an “Indo-Pacific Workshop on Enforcement Against Food Fraud and Trade in Counterfeit Agricultural Goods,” in Bangkok, Thailand.

Later in May 2023, the USPTO participated in a Pharmaceutical Security Institute-Interpol-INTA “Roundtable on Pharmaceutical Crime,” in Singapore.

On June 29, 2023, USPTO’s OPIA participated in the virtual “Strategies for Success in Asia” webinar, hosted by the U.S. Commercial Service. This event focused on empowering U.S. businesses with essential tools and insights to excel in Southeast Asia’s diverse and promising markets, with particular attention on the opportunities in the Philippines. USPTO’s OPIA underscored the critical need for U.S. companies to protect their innovations, trademarks, and creative works against infringement, counterfeiting, and piracy when exporting to Southeast Asia. Approximately 15 U.S. business representatives participated in the program.

On June 21, 2023, the USPTO Southeast Asia Office participated in a “Seminar on Intellectual Property Rights Enforcement & Technology,” jointly organized by the USPTO, the U.S. Department of Justice, the U.S. Department of Homeland Security, the U.S. Embassy in Bangkok, and Thailand’s Court of Appeal for Specialized Cases in Bangkok, Thailand. The seminar focused on IP in the evolving technological landscape, emphasizing online investigations, digital piracy, and artificial intelligence. Approximately 60 Thai judges and judicial officers participated in the seminar.

From August 29-30, 2023, the USPTO Southeast Asia Office participated in an “Intellectual Property Rights Workshop,” jointly organized by the U.S. Department of Justice (DOJ) and the State Department’s Bureau of International Narcotics and Law Enforcement (INL) in Vientiane, Lao PDR. The Workshop focused on border enforcement for IPR, IP investigations, and

prosecutions. Approximately 40 Lao officials, including police, judiciaries, customs, and law enforcement authorities, attended the workshop.

On September 12, 2023, the USPTO supported and facilitated the 12th meeting of the ASEAN Network of IPR Enforcement Experts (ANIEE) in Bangkok, Thailand. ANIEE consists of representatives from ASEAN member states and is tasked by the ASEAN Working Group on Intellectual Property Cooperation (AWGIPC) to undertake the implementation of the IPR enforcement initiatives under the ASEAN IPR Action Plan 2016-2025 and enhance regional cooperation and effectiveness in combating IP crimes.

From September 13-15, 2023, the USPTO organized an “ASEAN Workshop on Developments in Copyright Law and Enforcement,” in Bangkok, Thailand. The workshop provided an overview and discussion of recent developments in copyright laws for new and evolving approaches to protection and enforcement in the ASEAN region and the United States, including issues raised by AI, legislative revisions, administrative and regulatory changes, judicial case decisions, treaty implementation, public awareness campaigns, ADR and mediation services, and litigation practices. The workshop was attended by approximately 60 officials from the ASEAN members' national copyright offices, creative economy/SMEs/cultural affairs agencies, and criminal law enforcement investigators and/or police officials responsible for copyright piracy and content streaming enforcement.

South Asia

On October 19, 2022, the U.S. IP Counselor for South Asia conducted a lively and interactive outreach session on IPR enforcement with 50 women entrepreneurs organized by the Islamabad Women’s Chamber of Commerce and Industry (IWCCI). During the session, IWCCI leadership and women entrepreneurs underscored the importance of IP protection to their businesses and expressed appreciation for the opportunity to learn about the U.S. policy framework and enforcement regime.

On November 10, 2022, the U.S. IP Counselor for South Asia spoke at the Conference on “International IP Exchange: Enriching Your IP” organized by Associated Chambers of Commerce and Industry of India (ASSOCHAM). The Conference deliberated on IP best practices and developments intersecting around pharmaceuticals, emerging technology, IP transactions, and IP enforcement challenges in dealing with infringers. The IP Counselor’s address stressed the need for sharing and following international best practices for promoting effective protection and enforcement of IP including trade secrets, as well as effective IP commercialization highlighting their importance for the businesses and the economy as a whole. One of the speakers was a Delhi High Court Judge. The program drew over 100 attendees.

On November 21, 2022, USPTO’s South Asia Office, in collaboration with the Prosecutor General's Office, Maldives, hosted a two-hour in-person session on an overview of IP, IP enforcement and its importance for the country’s economy. The session was hosted and delivered at the request of the Prosecutor General’s Office. The objective of the session was to give the Maldivian prosecutors a detailed overview of different categories of IP and ways to differentiate one from the rest. The U.S. IP Counselor for South Asia delivered the lecture and

led the discussion, along with the Senior IP Specialist, highlighting the importance of the role of a prosecutor in supporting an IP ecosystem in the country. The session was very interactive and was attended by twenty prosecutors. Prosecutors shared their interest in having a series of IP sessions with case studies.

On January 18, 2023, the U.S. IP Counselor for South Asia spoke on a Chennai International Book Fair experts panel on “Publishing Trends and Policies in India” at the International Publishing Conference. The IP Counselor’s speech focused on U.S.-India cooperation, and the importance of strong copyright protection and enforcement for the publishing sector.

On March 9, 2023, the U.S. IP Counselor for South Asia along with OPIA hosted an in-depth virtual information session on U.S. IP enforcement and coordination with the senior officials of the Indian IP Office. The USPTO and other USG IP enforcement agencies, namely the Food and Drug Administration (FDA), Customs and Border Protection (CBP), Department of Justice (DOJ), Federal Bureau of Investigation (FBI), Homeland Security Investigations (HSI), the IPR Center, and the Office of the IP Enforcement Coordinator (IPEC) in the Executive Office of the President all provided an overview of their respective agencies, their operations as they relate to the enforcement of intellectual property, as well as their broader coordinating efforts. The Indian delegation included Assistant Controller of Patents & Designs (International Affairs Division), Deputy Registrar of Trade Marks and Geographical Indications, Assistant Registrar of Geographical Indications, Senior Copyright Examiner, and Patent Examiners. Over 25 officials from both sides attended the session.

On April 26, 2023, U.S. IP Counselor for South Asia delivered a special World IP Day (WIPD) address at a panel (called #ChatWithADiplomat) on “IP in Movies and Supporting Women in Innovation and Creative Arts” at a copyright focused educational program hosted by the USPTO and Public Diplomacy Department at Post in partnership with the Motion Picture Association (MPA). The IP Counselor spoke on his role, key priorities and initiatives, his perspectives on the topic of the program and the WIPD 2023 theme, U.S.-India collaboration, and recent developments focused on copyright enforcement including the Cabinet’s approval of the Cinematograph (Amendment) Bill, 2023 that has anti-camcording provisions to tackle film piracy. The Public Diplomacy Officer delivered welcome remarks, and the Senior Director - Copyright & Digital Economy from the MPA India office delivered a presentation on importance of copyright protection and motion picture copyright. The program was followed by a screening of the movie “Shazam! Fury of the Gods.”

On May 15-19, 2023, the USPTO South Asia Office, in collaboration with the U.S. Department of Commerce and the U.S. Department of Homeland Security, hosted a five-day- “South Asia Regional Workshop on Intellectual Property Rights Investigative Methods (IPRIM)” in Kathmandu, Nepal. The objective of the workshop was to help South Asian countries build a comprehensive National Strategy for IP Enforcement with a focus on public health, national security, and the digital economy. The workshop covered presentations from nine U.S. agencies including HSI, DOC, USPTO, DOJ, CBP, HHS, FDA, Defense Criminal Investigative Service (DCIS), and Global Law Enforcement Network (GLEN) on IPR violations, interdictions, investigations, and prosecutions and demonstration of the need for inter-agency and international cooperation and public-private partnerships for effective IP enforcement. In addition to the USG

partners, multiple rights holders also participated and shared their views on the authentication of their products. Customs, Health, Drugs, and other relevant Regulatory Agencies, and IP offices from Six South Asian countries including India, Nepal, Bangladesh, Maldives, Sri Lanka, and Bhutan participated and exchanged ideas at the conference. In total the workshop was attended by 75 participants.

On June 30, 2023, the U.S. IP Counselor for South Asia spoke on “International Arbitration - Analyzing Key Trends for Global Disputes and International Arbitration in 2023 and Beyond” at the Economic Times (ET) Legal Commercial Dispute Conclave hosted by ET LegalWorld. Over 150 legal, IP and alternative dispute resolution professionals from around the world, along with India’s Attorney General and High Court Justices joined the discussion.

On August 2, 2023, the Senior IP Specialist spoke at a seminar on “Innovation and IP” organized by the Public Diplomacy Department of the U.S. Embassy, New Delhi, and Atal Bihari Vajpayee School of Management & Entrepreneurship, Jawaharlal Nehru University. The seminar was part of a 5-city series of programs on IP-driven innovation and women’s entrepreneurship with a focus on IP enforcement. The session was attended by 50 participants.

On August 8, 2023, the U.S. IP Counselor for South Asia and Senior IP Specialist conducted an informative session tailored for Bhutan customs officials. The session focused on various aspects of IP, with a specific emphasis on enforcement relating to border measures such as search and seizure at entry points. The presentation also highlighted some good practices from the South Asia region that have proved helpful for owners and customs officials in safeguarding IP.

On August 9, 2023, the U.S. IP Counselor for South Asia and Senior IP Specialist delivered a presentation on Intellectual Property to the Bhutan Attorney General and Advocates. The presentation emphasized the importance of enforcement in building an innovative ecosystem. It outlined the fundamentals of the IP protection system and delved into different IP regimes applicable for ensuring IP protection.

On August 9, 2023, the U.S. IP Counselor for South Asia and Senior IP Specialist delivered a presentation on intellectual property, including enforcement aspects, to senior officials of the Bhutan Department of Industry, those handling the Invest Bhutan portfolio, as well as Small and Medium Enterprises. The team provided an outline of the fundamentals of the IP protection system, touching on different types of intellectual property regimes available for IP protection. The presentation stressed the importance of IP for the growth of cottage and small industries and for attracting foreign investments and companies to Bhutan.

On August 22, 2023, the U.S. IP Counselor and Senior IP Specialist led the USPTO's “Gujarat State Conference on IPR.” The program supported the economic growth of the Indian people, focusing on geographical indications and trademarks for women entrepreneurs in rural areas, as well as IP enforcement. The conference was held in cooperation with the Consortium of Women Entrepreneurs of India (CWEL) at Karnavati University School of Law in Gandhinagar. It drew participation from start-ups and artisans from different villages and districts across Gujarat, with over 125 participants. The conference also included an exhibition of 40 Gujarati women entrepreneurs displaying their products and creations. The Ministry of Micro, Small & Medium

Enterprises (MSME), the Department of Science and Technology (DST), and the Indian IP Office also joined the conference. During their visit, on August 23rd, the US team conducted field visits where they promoted awareness about IP protection with various artisans and entrepreneurs.

On August 19, 2023, the Senior IP Specialist spoke at a panel on “Counterfeiting of Auto Parts” at the Automobile and IP workshop organized by the Global IP Convention in Pune. The speech focused on the important role of a positive culture of IP in combating counterfeiting, highlighting the functions of the USPTO South Asia Office and its contribution to the IP ecosystem in the region. The session drew 75 attendees.

Middle East/North Africa

On January 23-25, 2023, OPIA’s Enforcement Team conducted a three-day “IPR Judicial Exchange” for 46 Algerian and Tunisian judges held at GIPA. The program leveraged expertise from across the interagency, including two U.S. Federal judges, DOJ and CBP. The program utilized a case study for assessing damages, which encouraged the judges to issue higher penalties and civil compensation than courts in Algeria and Tunisia typically provide.

On February 6-8, 2023, OPIA’s Enforcement Team conducted a three-day workshop for Moroccan Judges and Prosecutors in Marrakech, Morocco. The program hosted 51 officials: 31 judges and 20 prosecutors from across Morocco. The program leveraged expertise from across the interagency, including two U.S. Federal District Court judges, DOJ, HSI, CBP and the Trademark Trial and Appeal Board (TTAB). The program included several practical exercises, which demonstrated that the participants both absorbed the materials and immediately put the lessons into practice. Following the three-day workshop, USPTO conducted a half-day roundtable discussion with Moroccan Industry in close partnership with the Moroccan IP Office. The roundtable discussion hosted 10 participants in person and approximately 25 participants virtually. The program included substantive exchanges on all areas of IP with an emphasis on IP enforcement.

On March 8-9, 2023, OPIA’s Enforcement Team conducted a 2-day Judges and Prosecutors Workshop on Trademark Enforcement for the United Arab Emirates held in Abu Dhabi in close partnership with the UAE Ministry of Justice. The program hosted 12 Department of Economic Development officials, 10 prosecutors, 19 judges and 24 Ministry of Justice officials. In addition to leveraging expertise from two U.S. Federal judges, a U.S. Department of Justice prosecutor and a TTAB judge, the program included a session on state and local prosecutions from a North Carolina Chief Financial Crimes Prosecutor. The program also included a number of UAE speakers organized by the Ministry of Justice. The format facilitated in-depth discussion on UAE’s recently passed Trademark Law and recently revised trademark enforcement initiatives.

On May 15-16, 2023, OPIA’s Enforcement Team conducted a series of consultations with the Saudi IP Authority to gain a deeper sense of their existing, revised IP enforcement processes and procedures. This included sharing extensive substantive information regarding U.S. enforcement practice. Following the May consultations, USPTO hosted a delegation at USPTO August 7-11,

2023. The group met with a number of U.S. interagency experts, including several representatives from CBP, DOJ, the IPR Center, IPEC, and USTR.

On September 12-14, 2023, OPIA's Enforcement Team conducted a three-day "Piracy Workshop" in Amman, Jordan. The program hosted officials from across the Jordanian enforcement space, including the National Library, Judges, Prosecutors, Media Commission and Police. The consultations brought in expertise from the U.S. Federal Judiciary, DOJ, HSI, and industry experts to share best practices in combating online piracy. The program hosted around 55 Jordanian officials and one Iraqi official.

On September 19-21, 2023, OPIA's Enforcement Team conducted a three-day "Border Enforcement" workshop in Dubai, UAE. The program was conducted in close partnership with the UAE Authority for Identity, Citizenship, Customs and Port Security. The program was focused on the importance of coordination on anticounterfeiting processes and procedures and best practices concerning border enforcement. The program hosted 29 Emirati officials and leveraged expertise from CBP and HSI.

In September 2023, the USPTO, in partnership with the IP Attaché Office for the Middle East and North Africa, organized and participated in a Workshop on Investigation and Prosecution of IPR Violations for approximately 45 Jordanian and Iraqi customs officials, regulators, judges, police, and prosecutors, with both criminal and civil authority over IPR enforcement issues, in Amman, Jordan. The workshop focused on enforcement capabilities of the various ministries, coordination between ministries on IP enforcement, forms of digital piracy, identifying pirates, how they capture and distribute unauthorized content, collection and preservation of physical and digital evidence, chain of custody, best practices in investigation and prosecution of digital crimes, and how to achieve deterrent sentencing.

East Asia

The OPIA's China Team engaged regularly during FY 2023 with counterparts in the People's Republic of China (PRC), both directly and through USTR, regarding draft amendments to PRC laws, regulations, and judicial guidance.

The OPIA's China Team conducted regular outreach to U.S. rights holders over the course of FY 2023. The Team organized and executed three in-person China IP Roadshows in a variety of geographic regions, including Greenville, South Carolina, Minneapolis, Minnesota, and Dallas, Texas. These all-inclusive, one-day programs educate rights holders on protecting and enforcing their IP in the United States and China, and feature speakers from private practice, as well as U.S. Government enforcement officials from U.S. Immigration and Customs Enforcement (ICE) / Homeland Security Investigations (HSI), U.S. Customs and Border Protection, the Federal Bureau of Investigation, and the U.S. Attorney's Office.

The China Team hosted webinars providing 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 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 (IACC), and the International Trademark Association (INTA).

The China Team represents the USPTO at investment-promotion events, such as the SelectUSA Investment Summit, held annually at National Harbor in Oxon Hill, Maryland. China Team members have interacted with potential investors, explaining how U.S. IP protection and enforcement laws, protocols, and agencies work together to protect the most important asset of any business, their IP. They also explain that USPTO IP Attachés are stationed around the world, some in the countries where the investors live, and are available for consultation at any time.

Since arriving at post, the Shanghai IP Attaché has led USPTO Shanghai in renewed engagement on IP issues of interest and concern with IP officials and stakeholders throughout her consular district. In FY 2023, USPTO Shanghai accomplished a tremendous amount following a difficult period in the previous year that included a three-plus month ordered departure and a 61-day lockdown due to COVID-19 related measures. Over the past year, the Attaché met with approximately 50 host government officials, including through 10 individual meetings with IP and related officials (including judges and scholars) in Shanghai and in Jiangsu and Zhejiang provinces, and met informally with IP officials from likeminded trading partners. The IP Attaché assisted many U.S. companies on specific issues of concern, spoke on IP protection both in person and virtually at approximately 16 industry events (to about 600 attendees cumulatively), including most recently to a gathering of U.S. aviation stakeholders in the East Asia region.

USPTO Shanghai also deepened sectoral engagement in e-commerce by organizing an Ambassador roundtable in Hangzhou with leading U.S. and China platforms and AmCham Shanghai. USPTO Shanghai and Mission China leadership also took part in ongoing discussions with a major e-commerce platform in the region. USPTO Shanghai also deepened its engagement on pharmaceutical IP protection that included multiple discussions with government, industry, and legal experts, culminating in a flagship event in Shanghai on September 15, 2023 on "Trends in Pharmaceutical IP Protection: U.S. and China Perspectives." The symposium-style event covered China, U.S., and global trends, drawing over 100 persons in attendance and an additional 30 or so who participated online, and was supported by PhRMA, the US-China Business Council, AmCham Shanghai, and the Quality Brands Protection Committee (QBPC).

USPTO Shanghai aided in capacity building and in promoting public awareness on IP. The IP Attaché spoke to government officials and rightsholders during her keynote speech at QBPC's annual forum on IPR enforcement on November 4, 2022. USPTO Shanghai also put on a

successful event on May 19, 2023, in conjunction with World IP Day and USPTO's #thevalueofherIP campaign. The event on "Women in IP: Accelerating Innovation and Creativity" featured three accomplished panelists in a discussion moderated by the Attaché. Furthermore, the Attaché also supported a major U.S. e-commerce platform's World IP Day event for its sellers by speaking to them on the dos and don'ts of registering IP.

USPTO Shanghai continued to advance U.S. Government priorities on IP. USPTO organized a well received 360 IP roundtable hosted by the Consul General and moderated by the IP Attaché in December of 2022, at which a dozen U.S. rightsholders shared their views with the Consul General, the Attaché, and other colleagues. USPTO Shanghai worked with the State Department and other agencies to report on physical and online markets, including by organizing and presiding over an industry listening session (with AmCham support) as well as 4 separate meetings with stakeholders. The Attaché and her team also organized and shepherded meetings with Shanghai IP officials, practitioners, and rightsholders for the first China Team delegation to Shanghai in over four years.

As part of USTR's Notorious Market List research, USPTO Guangzhou enlisted the assistance of the new State Department Consular Officers to visit 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.

OPIA's Enforcement Team played a significant role in advising the Economic Officer at the U.S. Embassy in Korea in planning the "U.S.-ROK 2023 World IP Day Seminar," which took place on April 28, 2023, in Seoul, Korea. In addition, the Enforcement Team represented the U.S. alongside IPEC, the IPR Center, the FBI, HSI Attaches, and State's Intellectual Property Enforcement division, further strengthening the U.S. representation. Together, the group actively engaged in discussions with Korean counterparts from various organizations, including the Korean Intellectual Property Office (KIPO), the Ministry of Culture, Sports, and Tourism (MCST), the National Police Agency, the Korea Institute of Intellectual Property, the Korea

Intellectual Property Protection Agency, the Korea Copyright Protection Agency, and the Prosecutors Office. The discussions centered around aligning long-term IP rules, strategizing the management of trade secret leaks, and celebrating women's participation in IP.

OPIA's Enforcement Team participated in the "WIPO-Ministry of Culture, Sports, and Tourism (MCST) Regional High-Level Meeting on Copyright Enforcement in the Digital Environment," which took place from April 26 to April 27, 2023, in Seoul, Korea. The Enforcement Team represented the United States and provided updates on national developments in online enforcement and regulation during the meeting.

Europe, including the European Union

Building on the efforts in FY 2022, USPTO Brussels continued to engage during FY 2023 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, USPTO Brussels participated in several events on trade in counterfeit products, its negative impact on IP and the economy, and the risks for public health.

In March 2023, the IP Attaché for Europe discussed US efforts to fight counterfeiting in the United States at a meeting of the European Multidisciplinary Platform Against Criminal Threats (EMPACT), highlighting the close collaboration among US government agencies. EMPACT is an initiative driven by EU Member States to identify, prioritize, and address threats posed by organized and serious international crime.

On March 21-22, 2023, USPTO hosted a delegation of judges from Bosnia and Herzegovina (BiH), who were visiting the U.S. as part of a CLDP study tour. The USPTO program on "Judicial Perspective on IP Law" included participation of judges and USPTO subject matter experts, addressing topics such as enforcement of IP rights, copyright in the digital world, trademarks, the function of the PTAB, and the relationship between trade secrets and patents.

In May 2023, USPTO Brussels took part in *Operation Lascar*, an operation launched by U.S. FDA in 2017 to combat trade in illicit products traveling to the U.S. from the U.K. On the margins of the Operation, USPTO Brussels met with representatives of the UK IP Office, UK Border Force, UK HM's Revenue & Customs, and London Police to discuss anti-counterfeiting strategies. USPTO Brussels also organized a two-day on "Dialogue on Customs Enforcement of IP Rights" in Madrid, Spain. The program hosted 23 officials from Spanish Customs, National

Police, Guardia Civil, and the Spanish IP Office to exchange information with USPTO and CBP officials on best practices for customs enforcement of IPR. This effort was further bolstered by a recent visit from USPTO Director Kathi Vidal to Spain. Director Vidal met with heads of those agencies that participated in the program to discuss how the information learned from the program contributes to their work and to discuss possible next steps. Moreover, USPTO Brussels organized together with USPTO HQ and the International Computer Hacking and Intellectual Property (ICHIP) representative in Romania a “Judicial Dialogue on the Protection of Intellectual Property Rights” in Sofia, Bulgaria. This program served as an opportunity for U.S. and Bulgarian judges to discuss effective handling of IP cases. The program hosted 27 participants from the Bulgarian judiciary.

In June 2023, the IP Attaché for Europe provided a briefing to the US aerospace sector on IP protection and enforcement in Europe at the Paris Air Show in Paris, France.

Oceania

In October 2022, the USPTO conducted a virtual training and capacity building workshop on trademark legislation and enforcement for the customs administration members of the Oceania Customs Organization.

In November 2022, the USPTO organized a Technical Assistance and Training Workshop for Oceania Customs Organization customs administration members on trademark legislation and border enforcement, as part of the ongoing OCO-USPTO IPR Legislative Reform Project, in Lautoka, Fiji.

DEPARTMENT OF DEFENSE

DEPARTMENT OF DEFENSE

“The Defense Criminal Investigative Service (DCIS), the law enforcement arm of the Department of Defense (DoD) Office of Inspector General, is fully committed to protecting the integrity of the DoD supply chain. Supplying counterfeit products to the DoD endangers the lives of American service members and betrays the public’s trust. This investigation and subsequent prosecution demonstrate DCIS’ ongoing commitment to working with its law enforcement partners to hold individuals who defraud the DoD accountable.”³

– Patrick J. Hegarty, Special Agent in Charge of the DCIS
Northeast Field Office

Department of Defense Appendix for FY 2023 Annual Report

This appendix discusses the FY 2023 activities of the Department of Defense.

Defense Acquisition University

As a corporate university of the Department of Defense (DoD), the Defense Acquisition University’s (DAU) mission is to provide a global learning environment to develop acquisition professionals.

As noted in the DoD’s 2022 National Defense Strategy, technology is central to today’s geopolitical competition and to the future of U.S. national security, economy, and democracy. Intellectual Property (IP) plays a critical role in allowing the U.S. to maintain technological superiority by acquiring and sustaining advanced warfighting systems. Guided by its FY 2021-2026 Intellectual Property Strategic Plan, DAU continued to develop training and engage in educational initiatives during FY 2023 for the DoD acquisition workforce focusing on three themes:

- (1) DoD’s desire to collaborate with U.S. Government agencies and industry to identify and build partnerships to address strategy development and education in the area of IP and data rights;
- (2) Providing on-demand targeted learning assets and webinars on a range of IP topics critical to acquisition and sustainment of military weapon systems; and
- (3) Identifying emerging issues, such as artificial intelligence, and how they intersect with IP and data rights.

³ DOJ press release, “Leader of a Conspiracy to Manufacture, Import, and Sell Counterfeit Military Clothing and Gear Sentenced” (October 13, 2022) at <https://www.justice.gov/usao-ri/pr/leader-conspiracy-manufacture-import-and-sell-counterfeit-military-clothing-and-gear>.

Key highlights of DAU's initiatives include:

- **DAU's Flexible Acquisition Practices Web Series**
This five-part web series provided the government audience with insights to DoD's Flexible Acquisition Practices, from the tech start-up perspective. The series discussed several hurdles for tech start-ups in dealing with the DoD. One episode discussed the challenges regarding pricing in non-traditional acquisitions – including the pricing of intellectual property rights, from the tech start-up perspective. For more information, see: <https://www.dau.edu/events/pricing-non-traditional-acquisitions>.
- **Engaging USPTO on Training Collaboration**
DAU, in conjunction with other DoD offices (e.g., Office of the Under Secretary for Defense for Acquisition & Sustainment and the Office of the Under Secretary for Research and Engineering), engaged with the USPTO on collaborating on training initiatives for the DoD acquisition and research and engineering workforce. Future initiatives may include use of the USPTO's training resources and subject matter experts in DAU webinars to consult on content for courses and other training and educational initiatives.
- Developing 6 on-demand topical videos (e.g., IP and Supply Chain; Vignettes on IP topics – Artificial Intelligence and IP; Data Driven Product Support Analyses; Other Than Commercial Computer Software; IP and Vendor Lock).
- Deploying a Foundational Software Acquisition and Management Credential (CACQ 011); providing subject expertise on a Product Support Data Requirements Credential (CLCL 018) currently being developed.
- Participated in numerous webinars and in-person events on IP for government and industry (e.g., Aerospace Industries Association (AIA) and National Defense Industrial Association (NDIA) 2023 Technical Data Rights Forum, Contracting for IP and Data Rights (Council on Logistics Engineering Professionals, Open Source Software National Contract Management World Congress)).
- Engaged in mission assistance consultations on IP issues for acquisition and other DoD professionals (NAVAIR CH52K, KC-Y).
- DAU continues to conduct IP Strategy Workshops with several Program Offices across all of the services to assist these offices in the development of program specific IP strategies.
- Ongoing collaboration with the Office of the Secretary of Defense (OSD) in developing a suite of online introductory learning assets on IP, IP strategy development, data markings, and management of post award activities relative to IP and data rights.

**DEPARTMENT OF HEALTH AND HUMAN
SERVICES**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

“Our Office of Criminal Investigations continues to protect consumers and patients by prosecuting and preventing the serious crime of health care professionals tampering with opioids intended for patient use, and preventing illegal online sales of opioids and counterfeit medicines. We also continue to monitor the marketplace for incidents of health fraud, including products fraudulently claiming to prevent, treat, mitigate, or cure opioid addiction and withdrawal.”⁴

– Robert M. Califf, FDA Commissioner

Department of Health and Human Services Appendix for FY 2023 Annual Report

This appendix discusses the FY 2023 activities of the Department of Health and Human Services, through the Food and Drug Administration and the National Institutes of Health.

Food and Drug Administration (FDA)

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 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 public health threats associated with such drugs. FDA also educates consumers and the health care community about the risks of counterfeit drugs, other unapproved new drugs, and substandard drug products. FDA works to minimize consumers’ exposure to these 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 the amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) made by 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 trading partner, and verification requirements for manufacturers, repackagers, wholesale distributors, and

⁴Remarks by FDA Commissioner Robert Califf to the 2023 Rx and Illicit Drug Summit” (April 10, 2023) at <https://www.fda.gov/news-events/speeches-fda-officials/remarks-fda-commissioner-robert-califf-2023-rx-and-illicit-drug-summit-04102023>.

dispensers. The DSCSA also requires critical steps to achieve electronic, interoperable tracing of certain prescription drugs at the package level by November 27, 2023. For more information see: <https://www.fda.gov/news-events/fda-voices/fda-protects-patients-harmful-drugs-through-drug-supply-chain-security-act>. These requirements will help to better identify and trace such prescription drugs that are distributed in the United States. 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 helping improve the detection and removal of potentially dangerous drugs from the supply chain, and by requiring the establishment, by regulation, of national standards for licensure of wholesale distributors and third-party logistics providers.

In FY 2023, amongst other continued stakeholder engagement, FDA held a virtual public meeting in December 2022 for discussion around implementation and readiness for enhanced drug distribution security. FDA continues to work towards finalization of the national standards for the licensure of wholesale drug distributors and third-party logistics providers (3PL), which issued as a proposed rule in February 2022.

In FY 2023, FDA issued six final guidance documents addressing compliance with applicable DSCSA requirements. The guidance documents are summarized below:

- The guidance on “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 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 guidance on “Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product — Compliance Policies” describes FDA’s compliance policies regarding enforcement of requirements for wholesale distributors and dispensers to verify a product’s product identifier in certain circumstances under sections 582(c)(4) and 582(d)(4), respectively, of the FD&C Act.
- The guidance on “Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act” is intended to assist supply chain stakeholders, particularly trading partners, with requirements for enhanced drug distribution security at the package level under section 582(g)(1) of the FD&C Act.
- The guidance on “Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act — Compliance Policies” describes FDA’s compliance policies regarding enforcement of requirements for enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act that went into effect on November 27, 2023.
- The guidance on “Waivers, Exceptions, and Exemptions for the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act” describes the process an authorized trading partner or other stakeholder should use to request a waiver, exception, or

exemption from the requirements of the FD&C Act, as well as the factors FDA intends to consider when evaluating such requests from an authorized trading partner or other stakeholder, and when determining FDA-initiated exceptions and exemptions.

- The guidance on “Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act” is intended to help industry better understand the definitions of “suspect” and “illegitimate” product as defined in the FD&C Act, as amended by the DSCSA. The guidance lays out FDA's current understanding of the following key terms used to define “suspect” and “illegitimate” product: “counterfeit,” “diverted,” “stolen,” “fraudulent transaction,” and “unfit for distribution.”

In FY 2023, FDA issued one untitled letter and one warning related to DSCSA violations. In December 2022, FDA issued an untitled letter to Valisure, LLC, citing past failures to comply with certain wholesale distributor and dispenser verification requirements of section 582 of the FD&C Act, as added by the DSCSA. In June 2023, FDA issued a warning letter to Safe Chain Solutions, LLC for failing to comply with certain wholesale distributor verification requirements and conducting business with an unauthorized trading partner, in violation of section 582(c) of the FD&C Act, as added by the DSCSA.

In addition, we have launched a DSCSA Portal through the FDA’s CDER NextGen that trading partners can use to submit electronic DSCSA documentation in response to FDA inquiries regarding suspect or illegitimate products, such as counterfeits. More information on the portal is available at: <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-dscsa-portal-cder-nextgen>.

See the FDA [Supply Chain Security Act webpage](#) for updates about DSCSA implementation and copies of the guidance documents.

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. Updates to the post-marketing surveillance (PMS) and internet sales sections of the APEC Toolkit were finalized this past April. These updates were made with guidance from the pharmaceutical industry, member states regulators, and the World Health Organization (WHO).

In addition, in April 2023, FDA co-hosted an event with the United States Pharmacopeia (USP): the “Asia-Pacific Economic Cooperation (APEC) Medical Product Supply Chain Dialogue.”

This two-day hybrid event, held at USP’s headquarters in Rockville, MD, aimed to accelerate APEC and global efforts to strengthen the resilience of global medical product supply chains. The meeting was attended by representatives from 45 economies from around the world, including participants from 35 government agencies, and brought together international medical product regulators, multilateral organization representatives, industry and academic professionals to discuss public health priorities, the impact of the COVID-19 pandemic on supply chains, and why the APEC Supply Chain Security Toolkit continues to be a valuable tool to stakeholders.

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 Organisation for Economic Co-operation and Development Multilateral Initiative

In February 2023, the FDA (represented by the Office of Criminal Investigations (OCI) and FDA’s Europe Office) and the Organisation for Economic Co-operation and Development (OECD) held the first steering group meeting for the joint FDA and OECD program titled “Whole of Governments Approach against Illicit Health Products.” FDA and OECD launched this program in May 2022 to highlight the need for extensive collaboration and coordinated efforts, across countries and government entities, to effectively address the threat to public health and safety posed by the trade in illicit pharmaceuticals. The steering group, which is an informal body, is comprised of representatives from FDA, OECD, European Commission, World Customs Organization, World Health Organization, World Trade Organization, Universal Postal Union, and INTERPOL, focused on shaping and driving future work related to countering illicit trade in health products. Furthermore, in August 2023, OCI assigned a representative to the U.S. Mission to the European Union in Brussels, Belgium to partner with FDA’s Europe Office on

this effort. In September 2023, the steering group met for the second time to further refine its initial activities and timelines.

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

Illegal Stimulants, Opioids, and Benzodiazepines 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 misusing prescription opioids. These concerns come against a backdrop of rising mortality from psychostimulant-involved overdoses, which involve illicitly obtained stimulants the vast majority of the time, but sometimes involve the misuse of prescription stimulants.

The drug overdose crisis is an immense public health issue and addressing it is one of FDA's highest priorities. Tragically, over 106,000 Americans died from drug overdoses in the 12 months ending in June 2023.⁵ The illegal online marketing of unapproved opioids is particularly concerning in light of the nation's 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 many overdose deaths documenting involvement of benzodiazepines.

In FY 2023, FDA issued six warning letters to the operators of websites illegally offering for sale one or more or a combination of unapproved and misbranded opioids, stimulants and/or benzodiazepines to U.S. consumers in violation of the Federal Food, Drug, and Cosmetic Act.

In addition, FDA hosted its fourth Online Controlled Substances Summit (formerly called the Online Opioids Summit) virtually on June 8, 2023, as an integral part of FDA's overall efforts to protect the public, including youth, from harm associated with drugs that have abuse potential. Summit attendees from the public and private sector, including those from the internet ecosystem, academia, international organizations, and regulatory entities, gathered to discuss challenges and develop strategic and effective solutions to reduce the availability of controlled substances online.

⁵ Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2023. <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.

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

In October 2022, FDA warned 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 labels. 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 latinfoodsmarket.com 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 Warned Companies of Illegally Selling Unapproved Monkeypox (Mpox) Products

In January 2023, as part of FDA’s [Mpox Response](#), FDA warned four companies and one Amazon associate for illegally selling or promoting the sale products that claimed to cure, treat, mitigate, or prevent human monkeypox (mpox) infection. There are no FDA-approved treatments for mpox. These products were sold online and have not been reviewed by the FDA or proven to be safe and effective to treat mpox or other diseases or conditions. The [recipients of the warning letters](#); Dr. Green Mom, LLC, Noble Elements LLC, Old Tiles Wallpaper, LLC, Organics Heirloom Plants and Monkeypox-Treatment.com were selling or promoting the sale of various vitamins, colloidal silver, Advil, Aleve, children’s ibuprofen, various tinctures, a H2O2 therapy, ivermectin and others to cure, treat, mitigate, or prevent mpox.

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 FDA regulated products, by identifying those responsible, arresting perpetrators, and seizing manufacturing equipment and counterfeit drugs. In FY 2023, CcIU focused resources to counter public health threats, such as the opioid crisis, through enforcement operations such as ***Operation Wild Wild Web***. This Operation is focused on targeting the sale of counterfeit synthetic drugs, such as fentanyl analogues and benzodiazepines, on the clear and dark web, social media platforms, and encrypted communication applications. 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.

In May 2023, OCI successfully partnered with CBP, the USPTO, U.S. Embassy London, the U.K.’s His Majesty’s Revenue and Customs (HMRC), Medicines and Health products Regulatory Agency (MHRA) and the U.K. Intellectual Property Office (UKIPO) to execute ***Operation Lascar-Ancord VI***. Initially launched in 2017, ***Operation Lascar-Ancord*** addresses illicit FDA regulated products being shipped to the U.S. through the U.K.

Since its inception in 2017, **Operation Lascar** has included six unprecedented joint enforcement operations, bilateral training opportunities, and senior-level engagements. 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, OCI has successfully participated in and supported several criminal investigations, including those related to fraudulent COVID-19 and counterfeit products. **Operation Lascar-Ancord VI**, which was conducted in the U.K. from May 21-26, 2023, examined approximately 450 packages of violative medical products 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.

In September 2023, OCI hosted the inaugural meeting of the Post Ancord Working Group. As mentioned above, over the past five years, OCI, together with CBP, the USPTO, U.S. Embassy London, HMRC, MHRA, and UKIPO, have collaborated to combat serious and organized crime that exploits jurisdictional differences to trade in illicit FDA regulated goods globally. This partnership has demonstrated the need for joint efforts across various sectors, including food, medical devices, pharmaceuticals, and more. The Ancord methodology has potential to disrupt global illicit supply chains, posing threats not only to consumers and legitimate businesses but also to national economies. A joint multi-agency working group, building on existing collaboration, will work to address these challenges, supported by evidence-based intelligence products. This initiative aims to foster cooperation, raise awareness, and secure essential resources, while providing a model for future joint efforts.

Outreach to Health Care Providers

FDA provides various online courses to inform healthcare professionals and provide them continuing education opportunities. One of these courses, “Cannabis and Cannabis-Derived Products – For Healthcare Practitioners,” was hosted on March 28, 2023, and is available for access through the FDA website until May 10, 2026.⁶ The course provided a general understanding of the *Cannabis sativa L.* plant and how products are generally produced utilizing cannabis raw materials. The presentation explained why manufacturing controls surrounding cannabis and cannabis-derived products are an integral part of protecting the public health. In addition, the course provided attendees with greater knowledge of the many products available on the marketplace, and included a discussion on potential benefits and risks, ways to report adverse events associated with these products to FDA, as well as suggestions on how to create a safe space to discuss patient use of these products.

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

⁶ The course can be found at <https://www.fda.gov/about-fda/fda-pharmacy-student-experiential-program/cannabis-and-cannabis-derived-products-healthcare-practitioners>.

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 version of the CDx (CD5) was tested by FDA import field staff from October 2019 – December 2022. After the testing period was complete, an evaluation was conducted. Based on user feedback and evaluation findings, the CD5 was returned to the manufacturer in June 2022 for hardware updates. The suggested updates to make the instrument more user friendly have been completed and the CD5s are being re-deployed for FDA staff to screen imported products suspected to be counterfeit pharmaceuticals. As staff are trained on the newly updated CD5, they will be re-deployed to our field offices. Training was provided in April 2023 to nine CSOs at the Miami Sweetwater office; future trainings are planned for the remaining IMFs and will be provided by the Office of Regulatory Science (ORS).

In FY 2023, the CD3(+) was used to screen three products that contained a total of 1,078 tablets and the CD5 was used to screen two products that contained a combined 14 tablets. Two CDx examined samples were sent to FDA's Forensic Chemistry Center for confirmation analysis. The identified products were examined using the CDx, which has a library that includes over 170 pharmaceutical product profiles.

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), FDA and CBP examined over 4,800 FDA regulated products consisting of opioids, controlled substances, and unapproved drugs in FY 2022 and 2023. Through these examinations, approximately 600,000 tablets/capsules/pieces consisting of unapproved drugs and controlled substances were refused, destroyed, or referred to CBP for regulatory action.

The FY 2022 OOOD operational data and results also provided critical information to support the development of FY 2023 OOOD targeting. FY 2023 OOOD consisted of ten operations across nine different ports of entry: four international facilities, three land border ports, and two

express consignment hubs, which included two dedicated operations focused on imports from Guam entering through Honolulu and Los Angeles international mail facilities. FY 2023 OOOD concluded on June 17, 2023; data from FY 2023 OOOD is being analyzed and will inform FY 2024 OOOD operations.

FDA's Forensic Chemistry Center (FCC) continued expansion of field screening efforts. Field-based scientists were specially trained in the use of an established set of instrumentation (toolkit) 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"). The Office of Regulatory Affairs (ORA) expanded collaborative efforts with Federal partners in the fight against illegal/unapproved drugs by establishing satellite laboratories at the Chicago O'Hare and Miami IMFs in partnership with CBP's Laboratories and Scientific Services (LSS). The Chicago satellite laboratory has been operational since June 2021 with the Miami satellite laboratory operational as of August 2023. FDA's FCC provided updated training to 31 chemists to support opening of satellite laboratories at the Miami IMF and other locations projected for FY 2024.

Collaboration with U.S. Customs and Border Protection (CBP) at International Mail Facilities (IMFs)

As part of FDA's Import Operation Strategy, FDA import operations personnel work daily with 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 suspected counterfeit pharmaceuticals, products marketed as foods and/or dietary supplements containing undeclared active pharmaceutical ingredients, other unapproved new drugs, 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 continue to collaborate to utilize FDA's handheld CDx (discussed above) to identify counterfeit pharmaceuticals and other FDA-regulated products. FDA's Office of Import Operations (OIO), in cooperation with the Office of Regulatory Services (ORS), is looking at extending the application of the CDx and exploring 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. In FY 2023, FDA's FCC provided advanced handheld Raman training, followed by an operation to provide real world application to 11 OCI Special Agents and two ORA Health Fraud Branch CSOs. 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 2022, OCI provided an "OCI 101" presentation – on OCI's mission and work – to the Chilean and Colombian Police Attachés to the United Kingdom (U.K.), at the U.S. Embassy in London.

In October 2022, OCI delegates attended the Permanent Forum for Internet Pharmaceutical Crimes (PFIPC) and Europol's Intellectual Property Rights Conference organized in partnership with Guardia di Finanza and the International Anti-Counterfeiting Coalition (IACC). Both the PFIPC and Europol meetings were held in Rome, Italy.

In November 2022, OCI conducted meetings with the U.K.'s HMRC discussing ways for possible future collaboration, training, and operations between the two agencies.

In November 2022, an OCI delegation attended Europol's ***Operation OPSON XI and XII*** meeting in Copenhagen, Denmark. *OPSON* is the annual joint Europol/INTERPOL initiative against fraudulent food and food related products.

In January 2023, OCI provided an "OCI 101" presentation to the Spanish National Police Attaché in the U.K. and the Spanish Department of Interior Attaché at the U.S. Embassy in London.

In January 2023, OCI provided an "OCI 101" presentation at the U.K. Food Crime Unit National Conference.

In February 2023, OCI provided an "OCI 101" presentation at the 11th Annual Pharma Anti-Counterfeit and Serialization 2023 meeting. OCI described the types of investigations OCI conducts, and the OCI resources at the U.S. Embassy in London, to numerous U.K. and European pharmaceutical Global Security members and members of U.K. regulatory agencies.

In February 2023, OCI provided an "OCI 101" presentation to the Commissioner of the Spanish National Police, Crimes Against Persons Central Brigade, and the Principal Commissioner and Head of Specialized and Violent Crimes Unit (UDEV) at the U.S. Embassy in London. UDEV is the Spanish National Police unit which investigates counterfeit, adulterated, misbranded, diverted medical products, foods, tobacco, and veterinary products in Spain.

In March 2023, OCI participated in Europol's ***Operation Shield III Reporting*** and ***Operation Shield IV*** kick off meeting in Madrid, Spain. ***Operation Shield*** is the Europol initiative targeting certain medical related products.

In March 2023, OCI participated in the U.S. Patent and Trademark Office (USPTO) intellectual property enforcement discussions with the Indian IP Office. During the presentation OCI

described the types of investigations OCI conducts, OCI resources, and about the OCI position at the U.S. Embassy in London.

In March 2023, OCI participated in the 11th plenary session of the Organisation for Economic Co-operation and Development's Task Force on Countering Illicit Trade (OECD-TFCIT).

In May 2023, OCI participated in the biannual meeting of the European Heads of Medicines Agencies, Working Group of Enforcement Officers (WGEO) meeting and provided a presentation to its members on OCI's mission and work. 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 May 2023, OCI attended the Intellectual Property Rights Methods Workshop in Kathmandu, Nepal. The workshop was sponsored by the U.S. Department of Justice (DOJ) and Homeland Security Investigations (HSI). OCI presented multiple times.

In May 2023, OCI attended the Indo-Pacific Regional Workshop on Enforcement Against Food Fraud and Trade in Counterfeit Agricultural Products sponsored by DOJ and the USPTO. OCI presented numerous times throughout the workshop.

In September 2023, OCI participated in INTERPOL's 2023 International Property Crime Conference in Oslo, Norway. This law enforcement event included approximately 500 delegates from over 100 countries and over 200 agencies. The Conference focused on intellectual property crimes including counterfeit drugs, devices, and other products that defraud consumers and threaten their health and safety.

In September 2023, OCI conducted a presentation at Oxford University's Centre for Tropical Medicine and Global Health in Oxfordshire, United Kingdom. This presentation was delivered to the teams involved in two critical projects: Forensic Epidemiology and the Impact of Substandard and Falsified Antimicrobials on Public Health (FORESFA), as well as the Vaccine Identity Evaluation (VIE) initiative. FORESFA is focused on identifying counterfeit and substandard medicines, whereas VIE is dedicated to assessing screening devices designed to detect substandard and falsified vaccines within supply chains.

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 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, newly synthesized unapproved and potentially toxic substances including fentanyl and related opioids, ideas for identifying and interdicting products, 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 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 five senior operations managers, two of which are posted internationally, and consists of approximately 15 full-time IOP special agents. The program also includes an operations officer position and is supported by an intelligence research specialist. IOP's priorities include engaging with foreign counterpart agencies and international organizations, responding to U.S. Postal Service International Mail Facilities, 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 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 and participates in multilateral workshops (as evidenced in the international capacity building and training section of this document).

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, after appropriate notice to the owner/consignee. 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. 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. In FY2023, FDA destroyed over 48,000 violative drug products with more than 29,000 (60%) identified as 801(u) products.

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, after appropriate notice to the owner/consignee. 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, etc.) from circulation and has led to more than 3,000 arrests.

Other FDA Enforcement Actions

OCI plays a leading role in combating counterfeit pharmaceuticals and medical devices. Below are notable examples of OCI's enforcement activities. In addition to the operations discussed above, FDA-led enforcement cases during FY 2023 include the following prosecutions:

Three individuals sentenced for trafficking conspiracy involving counterfeit pills pressed with fentanyl. On March 22, 2023, Alex Ogando was sentenced to 12 years in prison for illegal sales of counterfeit pills pressed with fentanyl on various Darknet markets. Two other defendants, Olatunji Dawodu and Luis Spencer, were previously sentenced to 12 years and 12 ½ years, respectively for the same offense. The Darknet operations pumped kilograms of counterfeit pills pressed with fentanyl into communities across the nation over the course of four years, using Darknet markets including AlphaBay, Dream, Wall Street, and Empire to reach a broad customer base. The defendants also used encrypted messaging services to communicate with and sell the counterfeit pills directly to customers. In exchange for cryptocurrency, the defendants sold the counterfeit pills that were shipped via the U.S. Postal Service to buyers in the District of Columbia and all 50 states.

<https://www.justice.gov/usao-dc/pr/three-individuals-sentenced-darknet-narcotics-trafficking-conspiracy-involving>

Ringleader Sentenced to 25 Years for Counterfeit Drug Trafficking Conspiracy. On September 18, 2023, Byron Marshall pleaded guilty to conspiracy, trafficking in counterfeit drugs, and money laundering conspiracy and was sentenced to 300 months (25 years) in federal

prison. According to information presented in court, Marshall used Woodfield Pharmaceutical's manufacturing facility based in Boca Raton, Florida, and employees in Houston to produce more than 500,000 pints of counterfeit cough syrup. Marshall's drug trafficking organization sold the counterfeit drugs 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.

<https://www.justice.gov/usao-edtx/pr/ringleader-sentenced-25-years-counterfeit-drug-trafficking-conspiracy>

National Institutes of Health (NIH)

IP Management and Oversight at NIH/CDC

The NIH manages a large portfolio of inventions arising from intramural research at the NIH and the Centers for Disease Control and Prevention (CDC). The NIH Office of Technology Transfer's Monitoring and Enforcement Unit (MEU) supports enforcement of the government's rights in these inventions. MEU monitors invention licenses for compliance with license terms and leads enforcement actions in cases of non-compliance, including license termination. It also reviews licensee requests for approval of sublicensing, assignments, foreign manufacture, and other issues impacting the government's rights, to ensure that these activities are appropriate and in compliance with the law. In the case of an alleged instance of infringement of NIH- or CDC-owned patent rights, MEU also investigates and works towards the resolution of potential infringement.

Capacity Building Support for Emerging Economies

NIH recognizes the importance of assisting U.S. and foreign institutions in the development of expertise in technology transfer, and particularly intellectual property management. Two examples of NIH's efforts in 2023 to support this are: provision of intellectual property and technology transfer mentoring services to institutions in Bangladesh, via BIO Ventures for Global Health; and participation in a WHO-Southeast Asian Regional Office sponsored regional workshop on accelerating technology transfer for local production and improving access to medical products.

The NIH Defensive Counterintelligence (DCI) and Insider Threat (InTh) Program

The NIH DCI/InTh Program develops and implements initiatives to conduct information integration, analysis, and response activities to detect, identify, and mitigate foreign interference, counterintelligence, and insider threats to NIH research and intellectual property. The program conducts research and analysis using search platforms which focus on the aggregation of information from various sources, such as USG prohibited lists, financial obligations, patent analysis, and foreign partnerships, foreign collaborations, foreign affiliations, and other data points of interest.

DEPARTMENT OF HOMELAND SECURITY

Department of Homeland Security

“The protection of sensitive U.S. technologies has been and continues to be a top priority for HSI. HSI and the partners of the Strike Force will ensure that the U.S. maintains its technologic edge to protect the economic and national security interests of the United States. The Strike Force will be relentless in its pursuit of bad actors that attempt the theft of any sensitive U.S. technologies.”⁷

– James Mancuso, Assistant Director, Homeland Security Investigations and Director of the National Intellectual Property Rights Coordination Center

“HSI will continue to focus on removing websites that facilitate digital piracy, and other intellectual property violations, from the internet. While many may believe that such websites do not constitute serious threats, the infringement upon rights holders of any intellectual property is a growing threat to our economic viability. The impact can be felt across multiple industries, and it can be the conduit to other forms of criminal activity.”⁸

– James C. Harris III, Special Agent in Charge, HSI Baltimore

“Consumers in need of auto repairs should be wary of unscrupulous repair shops and greedy internet vendors that prioritize profits over the safety of their customers. Consumer safety is a top priority to Customs and Border Protection and CBP officers will continue to seize counterfeit goods that threaten the health and safety of American consumers.”⁹

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

Department of Homeland Security Appendix for FY 2023 Annual Report

This appendix discusses the FY 2023 activities of the Department of Homeland Security (DHS). As outlined below, DHS’s activities include 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 coordinates the development and implementation of strategies and policies for the Department, including those related to trade, including illicit trade, intellectual property rights, and counterfeiting and piracy. The DHS Private Sector Office (PSO) coordinates U.S. Government-wide efforts to catalyze and support private sector and non-governmental-based counter-illicit trade activities. On the international stage, PSO coordinates conferences and

⁷ DOJ press release, “Justice Department Announces Five Cases as Part of Recently Launched Disruptive Technology Strike Force: Cases Mark Strike Force’s First Enforcement Actions Since Established” (May 16, 2023) at <https://www.justice.gov/opa/pr/justice-department-announces-five-cases-part-recently-launched-disruptive-technology-strike>.

⁸ DOJ press release, “Maryland U.S. Attorney’s Office Announces the Seizure of 55 Domain Names that Violated Copyrights by Illegally Live Streaming the World Cup” (December 22, 2022) at <https://www.justice.gov/usao-md/pr/maryland-us-attorney-s-office-announces-seizure-55-domain-names-violated-copyrights>.

⁹ CBP press release, “Philadelphia CBP Seizes Nearly \$200K in Counterfeit Auto Parts from China” (March 31, 2023) at <https://www.cbp.gov/newsroom/local-media-release/philadelphia-cbp-seizes-nearly-200k-counterfeit-auto-parts-china>.

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.

This appendix includes two sections – the first on the Homeland Security Investigations (HSI)-led National Intellectual Property Rights Coordination Center (IPR Center), and the second on U.S. Customs and Border Protection (CBP).

National Intellectual Property Rights Coordination Center (IPR Center)

HSI is the principal investigative arm of DHS 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. HSI also 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 can pose a significant threat to 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” (https://www.dhs.gov/sites/default/files/publications/20_0124_plcy_counterfeit-pirated-goods-report_01.pdf).

In the context of the U.S. Government’s acquisition of products and services, 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, taking effective action to prevent 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 U.S. Immigration and Customs Enforcement's (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.

Government Supply Chain Investigations Unit (GSCIU)

In FY 2023, to strengthen its efforts to target and combat the proliferation of counterfeit goods entering the supply chains of the DoD and other U.S. Government agencies, HSI was appropriated an additional \$7.5 million in enhancement funding to establish the Government Supply Chain Investigations Unit (GSCIU) at the IPR Center. The GSCIU has assumed oversight of ***Operation Chain Reaction***, an HSI-led task force that proactively targets counterfeit goods entering the U.S. Government supply chain. The establishment of a dedicated government supply chain security unit will facilitate comprehensive supply chain risk management across the federal government by revitalizing and leveraging key public and private partnerships, modernizing existing infrastructure and processes, and integrating and analyzing interagency data sources to identify and combat threats to our supply chain. These joint efforts aim to maintain the integrity of the government supply chain, advance national and economic security, and protect the safety of the public, our communities, and those that serve them.

In FY 2023, under ***Operation Chain Reaction***, HSI initiated 16 criminal investigations, conducted 8 criminal arrests, and helped secure 9 indictments and 10 convictions, as well as 13 seizure incidents of counterfeit goods with an estimated MSRP (if genuine) of \$3,571,279.

Other notable ***Operation Chain Reaction*** (OCR) activities during FY 2023 included the following.

On October 12, 2022, as a result of an OCR investigation, Ramin Kohanbash was sentenced in the U.S. District Court of Rhode Island to 40 months in federal prison. On June 12, 2019, Kohanbash pleaded guilty to conspiracy to commit wire fraud and trafficking in counterfeit goods (18 U.S.C. § 2320). Kohanbash was the second defendant to be sentenced in the investigation, following Bernard Klein (sentenced on April 9, 2021, to 18 months in federal

prison, plus 3 years of supervised release). The two men, along with a third defendant Terry Roe (sentenced on October 20, 2022, to 24 months in federal prison, plus 3 years of supervised release) caused the manufacture and importation of counterfeit U.S. military uniforms that were then sold to the DoD.

HSI made significant contributions to this case with the Defense Criminal Investigative Service (DCIS) as the lead agency. Additionally, the Air Force Office of Special Investigations (AFOSI), Army Criminal Investigation Service (CID), and the General Services Administration Office of the Inspector General (GSA-OIG) all made notable contributions to the investigation. HSI's investigation overlapped with a DCIS Rhode Island investigation and became a joint wide-ranging conspiracy investigation into the development, manufacturing, and importation of \$20 million USD worth of Chinese-made counterfeit U.S. military uniforms that were sold to the U.S. military. (<https://www.justice.gov/usao-ri/pr/final-defendant-conspiracy-manufacture-import-and-sell-counterfeit-military-clothing-and-gear>; <https://www.justice.gov/usao-ri/pr/leader-conspiracy-manufacture-import-and-sell-counterfeit-military-clothing-and-gear>; <https://www.justice.gov/usao-ri/pr/manufacturer-sentenced-conspiring-manufacture-and-sell-counterfeit-goods>)

Law Enforcement Operations

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

DHS law enforcement efforts during FY 2023 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 2023, the IPR Center expanded collaboration with CBP to disrupt transnational criminal organizations illicitly importing counterfeit pharmaceuticals into the United States by exploiting e-commerce platforms and international mail systems. This was accomplished by synchronizing ***Operation Apothecary*** with CBP's FY 2023 iterations of ***Operation Bitter Pill***, which is an annual CBP Trade Special Operation (TSO) performed in various international mail facilities throughout the year to target inbound counterfeit pharmaceuticals.

In FY 2023, the IPR Center conducted two TSOs, in conjunction with CBP Centers for Expertise and Excellence (CEE) and the CBP National Targeting Center (NTC). During these enhanced TSOs, the IPR Center designed a one-day training to educate HSI special agents, CBP officers, and task force officers on how to target, interdict, and investigate counterfeit pharmaceuticals illicitly entering the United States via the international mail facilities (IMF). A total of 577 parcels were examined; 165 parcels were seized containing counterfeit drugs or related violations, and 323 parcels were referred to the Food and Drug Administration (FDA) for Title

21 violations. HSI has initiated several new investigations into organizations trafficking counterfeit pharmaceuticals into the United States via the mail service.

During FY 2023, under ***Operation Apothecary***, HSI initiated 34 criminal investigations, 16 arrests, 12 indictments, and 7 convictions, as well as 329 seizure incidents of counterfeit items with an estimated MSRP (if genuine) of \$2,528,135.

Operation Genuine Valor

In FY 2023, the IPR Center, in cooperation with its law enforcement partners, initiated ***Operation Genuine Valor*** to ensure the health and safety of U.S. veterans. The operation focuses on combating counterfeits through targeting, interdiction, and investigation. Criminals who undermine U.S. Government compliance regulations by selling counterfeit and non-conforming pharmaceuticals, medical, and surgical supplies to the U.S. Government will be investigated and prosecuted. ***Operation Genuine Valor*** focuses on ensuring that counterfeit pharmaceuticals, medical devices, and surgical supplies do not infiltrate the supply chain of the U.S. Department of Veterans Affairs.

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.

As part of the IPR Center's digital piracy initiative, ***In Our Sites***, special agents from HSI Baltimore seized a total of 71 separate internet domains between December 9 and 18, 2022 for live streaming World Cup matches, an infringement of Fédération Internationale de Football Association (FIFA) copyrights. Individuals visiting the sites saw a message that the site has been seized by the U.S. Government and were redirected to additional information. These seizures were the result of a joint investigation called ***Operation Offsides*** between the IPR Center, HSI Baltimore, Department of Justice, International Computer Hacking and Intellectual Property

(ICHIP) Offices, United States Attorney's Office, District of Maryland and Computer Crimes and Intellectual Property Section (CCIPS).

In FY 2023, under *e-commerce/IOS*, HSI initiated 81 criminal investigations, conducted 5 arrests, helped secure 4 indictments and 8 convictions, and 94 seizures with an estimated MSRP (if genuine) of \$323,893. 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 FY 2023, under *OEN*, HSI initiated 7 criminal investigations, conducted 5 criminal arrests and helped secure 3 indictments. In addition, HSI recorded 65 counterfeit goods seizures incidents with an estimated MSRP value (if genuine) of \$779,091.

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).

In FY 2023, under *OSP*, HSI initiated 11 criminal cases, conducted 8 arrests, and helped secure 4 indictments and 6 convictions, as well as 32 counterfeit goods seizures incidents with an estimated MSRP value (if genuine) of \$2,113,845 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 2023, under ***Operation Body Armor***, HSI initiated 8 criminal cases, conducted 3 criminal arrests, and helped secure 3 indictments and 2 convictions, as well as 8 seized counterfeit goods seizures incidents with an estimated MSRP (if genuine) of \$ 44,975.

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 2023, 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, NBA Championship, NHL Stanley Cup Finals, and National Collegiate Athletic Association (NCAA) Championships.

On February 5-13, 2023, IPR Center representatives traveled to Phoenix, Arizona, to coordinate ***OTP*** enforcement operations targeting the importation and trafficking of counterfeit sports merchandise and media activities related to the NFL’s Super Bowl LVII. These enforcement efforts resulted in 70 seizures of 8,230 items with an estimated MSRP value of \$2,029,942.

In FY 2023, under ***OTP***, HSI initiated 24 criminal cases, conducted 65 arrests, and helped secure 46 indictments and 26 convictions, as well as 186 counterfeit goods seizures incidents with an estimated MSRP value (if genuine) of \$3,011,584.

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).

In May 2023, the IPR Center hosted its First Annual Summit Series featuring keynote addresses and panel discussions in support of a theme of Building a Great Investigation from Lead to Prosecution. The three-day event featured multiple panel discussions emphasizing inter-industry collaboration, case studies, pharmaceutical challenges, protecting trade secrets, and how to effectively build, present and prosecute cases.

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. In FY 2023, ***Operation Joint Venture*** conducted 113 engagements.

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 2023. 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 2023, the IPR Center conducted 113 outreach and training events with 7,920 attendees.

In FY 2023, 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 2023, 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 A2C2 and AASA to provide case-study training addressing counterfeit automobile parts.
- Collaborated with the Department of Justice’s (DOJ) 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.
- In FY 2023, IPR Program Managers were provided access to SIENA, an advanced messaging service provided by the European Union Agency for Law Enforcement Cooperation (EUROPOL) to quickly exchange crime-related operational and strategic data between European Union law enforcement authorities. Utilizing this access, intelligence reports regarding Bulgarian exporters of counterfeit auto parts shipping to the United States were shared with EUROPOL law enforcement partners as part of a new deconfliction process highlighting the collaboration of the IPR Center, the National Cyber Forensics and Training Alliance, and EUROPOL.

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.

Through the U.S.-China IP Criminal Enforcement Working Group, DOJ and U.S. law enforcement (including HSI and the Federal Bureau of Investigations (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 2023, the IPR Center hosted foreign government officials with an interest in IP enforcement at the IPR Center. These included delegations from Denmark, Guatemala, Indonesia, Jamaica, Panama, and Trinidad and Tobago, as well as a multi-national delegation from the African Pharma Crime Working Group. The IPR Center also engaged with foreign

counterparts in meetings and various outreach and training efforts throughout the world. Among these were representatives from Argentina, Bangladesh, Benin, Botswana, Brazil, Bulgaria, Cabo Verde, Chile, Colombia, Costa Rica, Democratic Republic of the Congo, Denmark, Dominican Republic, Ecuador, El Salvador, Ghana, Guatemala, Hungary, India, Indonesia, Jamaica, Kazakhstan, Kyrgyz Republic, Malawi, Malaysia, Mexico, Moldova, Morocco, Namibia, Nepal, Nigeria, Panama, Paraguay, Peru, Philippines, Romania, Senegal, Sierra Leone, South Africa, Sri Lanka, Tajikistan, Thailand, The Gambia, Trinidad & Tobago, Turkey, Turkmenistan, Ukraine, Uruguay, Uzbekistan, and Zambia.

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 U.S. Government agencies, as well as state and local officers, to deliver training and support domestic investigative and enforcement capacity throughout the United States. In FY 2023, 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 2023, the IPR Center hosted one virtual and two in-person IPTEI trainings. The online course attracted 202 participants, while the two-week in-person training was offered to 60 law enforcement personnel from CBP and HSI. Nearly 60 subject matter experts from U.S. law enforcement agencies and private sector partners presented case studies and information on trade fraud detection, interdiction, and disruption investigations.

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 2023. On December 8, 2022, the IPR Center provided training to a group of state and local prosecutors on intellectual property enforcement. The event was hosted by IPR Center partner Michigan State University’s Center for Anti-Counterfeiting and Product Protection (A-CAPP). Presenters included DOJ CCIPS, USPTO,

prosecutors and industry representatives. Attendees included prosecutors from around the United States from state and local agencies.

Foreign Capacity Building and Training

The IPR Center works closely with partner U.S. Government 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's Office of Overseas Prosecutorial Development, Assistance and Training (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 2023, the IPR Center expanded its support of the GLEN through the deployment of a Temporary Duty Assignment International Cyber Hacking and Intellectual Property Agent Advisor (ICHIP Agent) to enhance the ongoing work of the IPR Center and the existing ICHIP network. The ICHIP Agent deployed to Bangkok, Thailand with regional responsibilities to build capacity for foreign law enforcement counterparts, including investigators, police, and prosecutors, policy officials and lawmakers. This capacity building work is accomplished through practical technical training and case-based mentoring focused on efforts to effectively interdict, investigate, and prosecute intellectual property rights crime and related cybercrime in order to protect U.S. national and economic security from Transnational Organized Crime threats. This capacity building work is designed to deliver the technical skills and resources to targeted countries to interdict and investigate intellectual property rights crimes and obtain and preserve evidence at trial.

In FY 2023, the IPR Center and its ICHIP Agent participated in 88 international training and outreaches in support of the International Outreach and Training 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.

- **ILEA Bangkok, Intellectual Property Rights Course: Session 8: Bangkok, Thailand**
From October 3-7, 2022, the International Law Enforcement Academy (ILEA) in Bangkok, Thailand hosted the Intellectual Property Rights Course: Session 8, which was conducted by the IPR Center's HSI. The event focused generally on the interdiction and investigation of Intellectual Property Rights violations, including instruction on cyber-enabled investigative techniques, and included presentations by private industries. Members of the governments of Thailand, the Philippines, Indonesia, and Malaysia were in attendance.
- **DOJ-ICHIP Brasilia IP Enforcement and Illicit Streaming Workshop: Virtual (South America and the Caribbean)**
From October 17-18, 2022, the ICHIP and ICHIP Panama City Staff Attorney conducted a two-day virtual training on sports piracy for approximately 240 Argentinian, Brazilian, Chilean, Colombian, Costa Rican, Dominican Republic, Ecuadorean, Mexican, Panamanian, Paraguayan, Peruvian, and Uruguayan law enforcement officials and public authorities. The program focused on the connections between digital piracy and malware, ransomware, and credential stealing software, and provided best practices and techniques for analyzing digital content from websites using developer tools and open-source software to determine the true source of pirated content. Finally, key partners from Brazil and Peru demonstrated the local impact and importance of IPR protection coupled with innovative methods they have used to combat these offenses. Given the anticipated increase in digital piracy and trademark counterfeiting relating to the 2023 World Cup, the program garnered significant attention from various countries and provided a foundation for the ICHIP's plan for a regional IPR working group in the Western Hemisphere.
- **DOJ-ICHIP Abuja hosted IP Enforcement Workshop: "Train-the-Trainers," Accra, Ghana**
From October 25-27, 2022, HSI Dakar participated in a "Train the Trainers" - IP Enforcement Workshop at the ILEA West Africa Regional Training Center in Accra, Ghana. In attendance were police and IP enforcement officials from Nigeria, Senegal, Sierra Leone, The Gambia, Democratic Republic of the Congo, Benin, Ghana, and Morocco. The program addressed international cooperation, internet piracy, counterfeit pharmacy, and presentation skills. HSI Deputy Attaché Ken Rochford gave presentations on a case study of Operation Stolen Promise and a separate presentation on the IPR Center E-Commerce program and *Operation In Our Sites*. HSI Dakar emphasized the value of our partnerships with other domestic and foreign law enforcement partnerships and the importance of partnering with industry in IPR investigations.

- **Intellectual Property Rights Investigative Methods Training: Indonesia – Jakarta, Indonesia**

From January 30-February 3, 2023, the IPR Center and HSI Jakarta co-hosted the Intellectual Property Rights Investigative Methods Workshop for Indonesian investigators, prosecutors, regulators, and customs officials from the Indonesian Directorate General of Intellectual Property (DGIP), Ministry of Law and Human Rights, Indonesian National Police, Indonesia Customs and Excise, BPOM (Indonesian FDA), Attorney General Office, Ministry of Health (Kemenkes), Ministry of Communication and Informatics (Kominfo), Ministry of Trade, and the Ministry of Research, Culture, Education & Technology (Kemendikbudristek). The training was held in Jakarta, Indonesia and supported by State INL, DOJ OPDAT, FBI, CBP, and USPTO. The program was supported by special agents from HSI Singapore, HSI Bangkok, OPR Denver, and OPR Phoenix. Pharmaceutical Security Institute (PSI) also supported the program, outlining their enforcement efforts and collaboration with law enforcement to combat counterfeit goods and global illicit trade.

The workshop provided participants with an increased understanding of the threats, impacts, and enforcement challenges identified in the intellectual property environment, including the increasing health and safety and economic risks posed by counterfeit goods. It also demonstrated the importance of a whole of government approach to IP enforcement and highlighted the successes of the U.S. IP enforcement framework. The workshop topics and case-studies addressed challenges and best practices related to interdiction, investigation, and prosecution of intellectual property crimes and related trade fraud 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, Bureau of International Narcotics and Law Enforcement Affairs.

- **DOJ-ICHIP Romania hosted Combatting Intellectual Property Crime in Central Asia Workshop: Tashkent, Uzbekistan**

From February 2-3, 2023, the ICHIP-Romania hosted a workshop on Combatting IP crime in Central Asia. This two-day program brought together participants from Kazakhstan, Kyrgyz Republic, Tajikistan, Turkmenistan, and Uzbekistan to focus on combating IP infringement through criminal investigations and prosecutions. The IPR Center supported the program with HSI case agents from HSI Bangkok and HSI Portland, as well as a CBP presentation on small parcel interdiction.

- **USPTO hosted Intellectual Property Rights Prosecutors Workshop: Marrakech, Morocco**

From February 9-10, 2023, the USPTO hosted an IPR Prosecutors Workshop in Marrakech, Morocco. This program was attended by judges and prosecutors from Morocco. The IPR Center supported this program with HSI case agent support and presentation of an IP case.

- **USPTO GIPA Training: “Countering Illicit Trade Amid Expanding Trade Infrastructure Investments”: Alexandria, VA**

From February 13-15, 2023, the USPTO sponsored a three-day program entitled “Countering Illicit Trade Amid Expanding Trade Infrastructure Investments” at the Global Intellectual Property Academy (GIPA) in Alexandria, Virginia for participants from Sub-Saharan African countries. The program was supported by IPR Center Program Managers and case agents. Topics of instruction and class discussions focused on IPR interdictions and investigations as well as related topics on illicit trade, including environmental crimes, forced labor, and the exploitation of foreign trade zones (FTZs).

- **Regional Intellectual Property Rights Investigative Methods Training: Southern Africa – Swakopmund, Namibia**

From March 6-10, 2023, the IPR Center and HSI Pretoria co-hosted the Regional Intellectual Property Rights Investigative Methods Workshop for investigators, prosecutors, regulators, and customs officials from Namibia, Botswana, Malawi, South Africa, and Zambia. The training was held in Swakopmund, Namibia, and included a tour of the Port of Walvis Bay, hosted by the Namibian Revenue Agency (NamRA) and the Namibian Ports Authority. The workshop was supported by instructors from HSI Houston, HSI Burlington, HSI El Paso, DOJ OPDAT and CCIPS, CBP, USPTO, and the Nigerian Federal Ministry of Justice. Industry representatives from Syngenta, Colgate-Palmolive, Phillip Morris International, and a South Africa-based law firm also supported the program, outlining their enforcement efforts and collaboration with law enforcement to combat counterfeit goods and global illicit trade.

The Regional IPR Investigative Methods Workshop provides participants with an increased understanding of the threats, impacts, and enforcement challenges identified in the intellectual property environment, including the increasing health and safety and economic risks posed by counterfeit goods. It also demonstrates the importance of a whole of government approach to IP enforcement and highlights the successes of the U.S. IP enforcement framework. The workshop topics and case-studies address challenges and best practices related to interdiction, investigation, and prosecution of intellectual property crimes and related trade fraud 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, Bureau of International Narcotics and Law Enforcement Affairs.

- **DOJ-ICHIP Romania hosted Combatting Counterfeit Automotive Workshop: Budapest, Hungary**

From April 19-20, 2023, the ICHIP-Romania hosted a workshop on Combatting Counterfeit Automotives. This two-day program was hosted at the ILEA Budapest in Hungary and brought together participants from Hungary, Romania, Bulgaria, Moldova, and Turkey. The program focused on investigative and prosecutorial methods for disrupting and destroying the markets and supply chains for dangerous counterfeit car parts through effective criminal investigations and prosecutions. The IPR Center supported the program with an HSI case agent and IPR Center program manager.

- USPTO and ASEAN IP Academy – Regional Workshop on Food Fraud: Bangkok, Thailand**

From May 9-11, 2023, the ICHIP Bangkok Agent Advisor supported the USPTO hosted Regional Workshop on Food Fraud. The ICHIP Agent participated in a panel discussion on the topic of law enforcement and private sector cooperation in criminal cases. Also on the panel was the ICHIP Bangkok Attorney Advisor, an FDA Agent, and an Interpol Criminal Intelligence Officer. Workshop topics covered food defense strategies and innovating smarter food hygiene; how regulatory agencies and law enforcement work together in food fraud investigations; and false and misleading advertising.
- DOJ-ICHIP Romania hosted the “Border Coordination: Combatting IP Crime” Workshop: Cluj, Romania**

From May 9-10, 2023, the ICHIP-Romania hosted a workshop titled “Border Coordination: Combatting IP Crime,” in Cluj, Romania. This two-day program included officials from Romania, Moldova, and the Ukraine. The IPR Center supported this program with CBP legal advisor support.
- Regional Intellectual Property Rights Investigative Methods Training: South Asia – Kathmandu, Nepal**

From May 15-19, 2023, the IPR Center and HSI New Delhi co-hosted the “Regional Intellectual Property Rights Investigative Methods Workshop” for investigators, prosecutors, regulators, rights-holders and customs officials from India, Bhutan, Maldives, Nepal, Sri Lanka, and Bangladesh. The training was held in Kathmandu, Nepal. The workshop was supported by instructors from the following agencies: the Department of Commerce (DOC), the Department of Health and Human Service (HHS), HSI, DOJ, GLEN, U.S. Embassy New Delhi, FDA, U.S. General Services Administration, Office of Inspector General (OIG), CBP, USPTO, and the DoD DCIS.

In addition to the stateside instructors, our international IP colleagues presented on their respective IP enforcement efforts, cooperation and coordination within and among their counterparts, and challenges they face as developing countries investigating IP: Central Board of Customs and Indirect Taxes (CBIC), New Delhi, Department of Customs, Ministry of Finance, Nepal, the National Board of Revenue, Bangladesh, and the Bangladesh Standards and Testing Institution (BSTI).

Industry representative from the Alliance for Creativity and Entertainment (India Operations), an India-based law firm, and Unilever contributed to the program by providing their insights and perspectives on combatting counterfeit goods and global illicit trade within a developing country and economy.

The IPR Investigative Methods Workshop provides participants with an increased understanding of the threats, impacts, and enforcement challenges identified in the intellectual property environment, including the increasing health and safety and economic risks posed by counterfeit goods. It also demonstrates the importance of a whole of government approach to IP enforcement and highlights the successes of the U.S. IP enforcement framework. The workshop topics and case-studies address challenges

and best practices related to interdiction, investigation, and prosecution of intellectual property crimes and related trade fraud 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, Bureau of International Narcotics and Law Enforcement Affairs.

- **USPTO hosted “Enforcing IP Rights” Workshop: Praia, Santiago, Cabo Verde**
From June 5-7, 2023, HSI Dakar Regional Attaché Marc Sanders and Deputy Attaché Ken Rochford traveled to Praia, Santiago, Cabo Verde to present Intellectual Property Rights Enforcement with CBP. HSI provided training and best practices to the Intellectual Property Directorate, the Cabo Verde Minister of Justice, National Police and Customs. USPTO also sponsored the training. Cabo Verde enforcement agencies were receptive to develop new investigative and enforcement strategies to prevent IPR related fraud in the Cabo Verde Island Chain.
- **US Embassy Bangkok-hosted Seminar on Intellectual Property Rights Enforcement & Technology: Bangkok, Thailand**
On June 21, 2023, the ICHIP Agent for Bangkok and the ICHIP Attorney for Hong Kong gave presentations to Thai judges on the topics of IP, new technologies, and Artificial Intelligence. The ICHIP Agent presented a case study on counterfeit 3M medical respirator masks and the methodology of the online investigation. The second presentation by the ICHIP Agent was an introduction to Artificial Intelligence and how that with new technologies affects the intellectual property industry. The ICHIP Attorney from Hong Kong assisted with the second presentation.
- **Danger and Distilleries: Fighting the Illicit Market for Counterfeit Alcohol Products - DOJ ICHIP-Romania**
From July 11-12, 2023, the IPR Center provided instructional support for a two-day multi-lateral workshop focused on counterfeit alcohol products for law enforcement, border police, and prosecutors from Poland and the Baltic countries. This workshop was held in Warsaw, Poland and sponsored by the DOJ ICHIP-Romania.
- **DOJ-ICHIP Abuja hosted IPR Enforcement Workshop – Botswana: Gaborone, Botswana**
On July 31-August 1, 2023, the DOJ ICHIP Attorney Advisors sponsored a two-day bilateral capacity building program on IP rights for an audience of 36 customs officers and prosecutors from the Botswana Unified Revenue Service and prosecutors from the Botswana Directorate of Public Prosecution. The IPR Center was invited to co-facilitate this collaborative learning experience.
- **DOJ-ICHIP Abuja hosted Africa Regional Pharma Crime Working Group Workshop: Gaborone, Botswana**
On August 2-5, 2023, the DOJ ICHIP Attorney Advisors hosted a three-day bilingual roundtable to assist prosecutors, investigators, customs officials, and regulators in the African Regional Pharma Crime Working Group in developing key partnerships and

relations with industry and other African nations that are investigating and combatting IP crimes and discussing their shared experience. The National IPRC Center, along with Interpol and private industry, joined the ICHIP Attorney Advisors during these dynamic roundtable discussions. The roundtable hosted 40 participants from the following countries: Botswana, Ghana, Kenya, Liberia, Namibia, Nigeria, Sierra Leone, South Africa, The Gambia, Uganda, Zambia, Benin, Burundi, Chad, Niger, Senegal, and Togo.

- **Intellectual Property Rights Workshop - Vientiane, Laos**

From August 30-31, 2023, the IPR Center's ICHIP Bangkok Agent advisor participated in a two-day workshop for Intellectual Property Rights in Vientiane, Laos. Participants consisted of approximately 25 Laotian participants represented by Laos Customs, Economic Crime Bureau police, prosecutors, judges, and the chamber of commerce.

- **Intellectual Property Rights Investigative Coordination Workshop: Maldives Customs – Male, Maldives**

From August 14-15, 2023, the ICHIP Bangkok Agent Advisor assembled an IP training workshop for Maldivian authorities which included 30 officials from Maldives Customs, Maldives Police, and several prosecutors from the Prosecutor General's Office. This 2-day workshop covered topics such as a Threat and Trend analysis for Southern Asia and Southeast Asia, a case study on counterfeit 3M respirator masks, DOJ prosecution overview of IP cases, and methods of collaboration for law enforcement. The presenters for this workshop included the ICHIP Bangkok Agent Advisor, the ICHIP Hong Kong Attorney Advisor, and HSI Delhi investigators.

- **Regional South America Digital Piracy Workshop: Evidence Processing – DOJ ICHIP São Paulo**

From August 14-16, 2023, the IPR Center in conjunction with the DOJ ICHIP conducted a digital piracy workshop in Montevideo, Uruguay. This training included 30 students from Peru, Uruguay, and Argentina, comprised of investigators, judges, and prosecutors. The training consisted of 1 day of classroom instruction covering topics concerning digital piracy investigative methodologies, case studies, evidence collection, and courtroom testimony. The second day had students search and process a staged digital piracy crime scene, a "digital capture the flag" exercise and legal instruction block from Assistant United States Attorneys (AUSAs). Mock trials were held on the third and final day of the training.

- **Regional Applied Trade Enforcement Workshop: Southern Africa – Port of Durban, South Africa**

The National Intellectual Property Rights Coordination Center and HSI Pretoria co-hosted the Applied Trade Enforcement Regional Training Workshop for police services, revenue services, rights-holders and customs officials from South Africa, Namibia, Lesotho, and Botswana. The training was held in Durban, South Africa from September 11-13, 2023, with the support of CBP personnel. The workshop focused on intellectual property rights violations, to include brand authentication, interdictions, and investigations, with a practical interdiction exercise on the third day. Workshop topics highlighted public health and safety issues related to IP crime and demonstrated the need

for inter-agency and international cooperation and public-private partnerships for effective IP enforcement.

- **USPTO Piracy Workshop – Amman, Jordan**
From September 12-14, 2023, the IPR Center supported the USPTO Piracy Workshop in Amman, Jordan with Special Agent case study support.
- **USPTO IPR Border Enforcement Workshop for UAE Federal Authority for Identity, Citizenship, Customs and Port Security**
From September 19-21, 2023, USPTO invited the IPR Center to participate in a comprehensive in-person Intellectual Property event in Dubai, UAE titled IPR Border Enforcement Workshop for UAE Federal Authority for Identity, Citizenship, Customs, and Port Security. The audience was comprised of customs officials and other regulatory professionals involved in the interdiction of illicit goods and investigation of IP crimes. The HSI Regional Attaché gave opening remarks to start the event. An IPR Center Special Agent Program Manager presented an IPR Center 101 highlighting the role and capabilities of the IPR Center and a case study on IPR investigations with emphasis on importance of working with Rights Holders.

U.S. Customs and Border Protection (CBP)

CBP engages with stakeholders on a regular basis to educate on how to work with CBP to protect their intellectual property rights (IPR) at the border. A sample of the Office of Trade's (OT) engagement with the trade community in FY 2023 include the following:

On October 12, 2022, OT participated in a webinar entitled "Experts Demystify CBP's Detention and Seizure (FP&F) Process as it Relates to Intellectual Property Rights (IPR)" directed to the Florida Customs Brokers and Freight Forwarders Association (FCBF) on CBP's intellectual property enforcement regime. OT provided instruction on the types of intellectual property violations enforced by CBP, the detention and seizure process, how to respond to CBP's requests for information, and best practices in conducting due diligence prior to importing merchandise that might present an intellectual property infringement issue.

On November 2, 2022, OT served as panelists at DOJ's 16th Annual Law Enforcement and IP Industry Meeting. The annual meeting provides members of the IP industry with an opportunity to communicate openly with senior law enforcement officials, including agents and prosecutors, who are directly responsible for federal criminal enforcement of IP law at the national level.

On November 8-9, 2022, OT participated in panels at the American Conference Institute's 11th Advanced Forum on Import Compliance and Enforcement. The Conference gathered CBP and industry to assess the Uyghur Forced Labor Prevention Act (UFLPA) and other U.S. and international regulatory changes impacting import and customs compliance strategy.

On November 18, 2022, OT participated in a DOC STOPfakes program in Orlando, Florida attended by local businesses. OT's objective in participating in these programs is to educate businesses, consumers, government officials, and the general public about CBP's intellectual property rights border enforcement mission, and how trademark and copyright owners can partner with CBP in preventing the importation of infringing goods through the e-Recordation program.

On January 5-8, 2023, OT attended the Consumer Electronics Show (CES) in Las Vegas, Nevada, as part of the STOPfakes exhibition booth. The STOPfakes booth was staffed by an interagency team consisting of ITA, the USPTO, the Department of State, HSI, CBP, and the Office of the Intellectual Property Enforcement Coordinator (IPEC). The team highlighted the government resources available to intellectual property owners to help protect their intellectual property rights.

On March 23, 2023, OT participated as an expert in the "China IP Road Show" event held in Minneapolis, Minnesota, that was led by the USPTO and the U.S. Commercial Service. The OT expert provided an overview of how businesses can record their intellectual property through the e-Recordation program to receive border enforcement against infringing imports originating from China. The "China IP Road Shows" are free one-day events that represent a collaboration between the USPTO, universities, business groups, state and local governments, and other federal agencies, to bring local businesses and stakeholders the expertise and knowledge of the USPTO's China specialists as well as that of special invited guests.

On April 4-6, 2023, OT participated in a panel at the International AntiCounterfeiting Coalition (IACC) discussing best practices on Trade Seminars, Webinars, and working with CBP on recordation, registration, and e-allegations.

On April 17-18, 2023, OT participated in the National Automotive Service Task Force (NASTF) ToolTech Conference, hosted by the Equipment and Tool Institute (ETI) in Albuquerque, New Mexico. The event brought together representatives from original equipment manufacturers (OEM) and aftermarket automakers and tool manufacturers to discuss trends in safety, technology, and law enforcement, including intellectual property theft.

On May 1-4, 2023, OT participated in the DOC's SelectUSA Investment Summit at the Gaylord National Resort and Convention Center at National Harbor, Maryland. OT staffed the STOPfakes exhibition booth to discuss the importance of IP protection and enforcement in the United States with potential investors, including recording federally registered trademarks and copyrights with CBP, and on May 3, spoke on a panel along with representatives from ITA and the USPTO on U.S. government resources available to IP owners.

On May 4, 2023, OT participated in a panel discussion at the IPR Center in Crystal City, Virginia, as part of the three-day Summit entitled "Building a Great Investigation, From Lead to Prosecution." The audience consisted of approximately 80 members of the trade

community including brand owners. OT discussed CBP's e-recording program and best practices for compiling product authentication manuals for use by CBP officials.

On May 10, 2023, OT participated in a panel discussion entitled "Customs Seizures: Best Practices to Improve Your Rate of Seizure of Counterfeit Goods" as part of the NCFTA Disruption Conference in Pittsburgh, Pennsylvania. OT covered CBP's e-Recordation procedure and best practices in responding to CBP's requests for authentication assistance.

On May 18, 2023, OT provided a virtual presentation during the Miami World Trade Center's International Trade Week event on CBP's intellectual property enforcement regime. The audience consisted of approximately 300 individuals representing carriers, freight forwarders, importer, customs brokers, and other members of the trade community in the Miami area.

On June 10, 2023, OT participated in a panel presentation at the 2023 Annual Meeting of the State Bar of Georgia in Savannah, Georgia. OT presented on a panel entitled "Intellectual Property Rights Enforcement: What Businesses That Manage, Transport, Import and Export Goods Need to Know." OT's contribution focused on CBP's IPR e-Recordation system and provided an overview of CBP's enforcement of IPR at the border. The audience included legal practitioners licensed by the State Bar of Georgia.

On June 14, 2023, OT addressed the U.S. Chamber of Commerce Global Brand Council as part of the Chamber's "Speaker Series." OT provided members with updates on CBP's e-Recordation program, which is an essential element in any company's intellectual property protection efforts.

On June 15, 2023, OT participated in the USPTO's "China IP Roadshow" in Dallas, Texas. The China IP Road Shows are a USPTO initiative that offers U.S. businesses and rights holders, especially small and medium-sized businesses and new-to-market exporters, the unique opportunity to learn how to better protect their IP in China. OT's contribution focused on protecting one's IP at U.S. borders by preventing the importation of infringing goods through the e-Recordation program.

On June 21, 2023, OT participated in the American Apparel and Footwear Association's Brand Protection Seminar held in New York, New York, sitting on the Government Anti-Counterfeiting IP Roundtable and discussing how the U.S. Government is working to combat counterfeiting in the apparel and footwear industry. OT was accompanied by representatives from IPEC and USPTO.

On August 29-30, 2023 OT presented at the "Workshop on IP and Consumer Protection" in San Jose, California, that was co-organized by the National Association of Attorneys General (NAAG) Center for Consumer Protection and the USPTO. The two-day event featured prominent speakers from the federal government, such as the Federal Trade Commission, the Consumer Products Safety Commission, HSI, and FDA, as well as from industry, such as the American Toy Association and the American Apparel and Footwear

Association, who discussed what government resources existed in combatting intellectual property theft and furthering consumer protection. The trade industry shared their best practices in working with U.S. Government agencies, while CBP focused on its robust IP border enforcement regime, which begins with e-Recordation.

On September 8, 2023, OT presented on CBP's intellectual property enforcement regime at the Korea Trade Investment Promotion Agency's (KOTRA) 14th Annual IP Strategy Seminar in Los Angeles, California. The audience consisted of representatives of Korean companies which do business in the United States and are looking for trends and strategies to combat trade in counterfeit merchandise. Other speakers at the event included a representative from the USPTO, as well as the IP Attaché and the Customs Attaché from the Embassy of Korea.

On September 18, 2023, OT moderated a panel on anti-counterfeiting measures along the supply chain at the annual meeting of IP Watchdog in Dulles, Virginia.

On September 20, 2023, OT moderated as well as participated on a panel at the Michigan State University's Center for Anti-Counterfeiting and Product Protection program at the IPR Center in Arlington, Virginia. The panel concerned the downstream effects of the purchase of counterfeit goods on society.

On September 20, 2023, OT presented to the Pharmaceutical Research and Manufacturers of America during their monthly Product Security Coordination meeting to discuss the benefits of working with CBP through the e-Recordation program as well as seeking gray market or *Lever*-rule protection against the importation of gray market merchandise.

CBP OT International Engagements

OT is also responsible for fulfilling requests made by other government agencies for technical legal experts able to provide capacity building to foreign audiences. OT also participates in multi-lateral organization activities centered on border enforcement of intellectual property rights. In FY 2023, CBP participated in the following capacity building activities:

On November 7-9, 2022, OT participated in the DOC, Commercial Law Development Program's (CLDP) International Anti-Counterfeiting "Workshop on Combatting Trafficking in Counterfeit Goods." The Workshop was held in Vilnius, Lithuania and included Lithuanian Customs authorities as well as delegates from the Central Asia Working Group. OT presented on international intellectual property border enforcement standards as well as the United States' implementation of these international standards.

On December 6 -7, 2022, OT joined the U.S. delegation at the Argentina-US Innovation and Creativity for Economic Development Forum led by the Office of the United States Trade Representative (USTR). CBP presented on how to enhance border enforcement of IP rights through statutory and regulatory reform, as Argentina was a Priority Watch List country on the 2022 USTR Special 301 Report.

On January 24, 2023, OT participated in a USPTO Judicial Exchange program in Alexandria, Virginia. OT provided instruction on CBP's trademark infringement analysis at the border, directed to Algerian and Tunisian judges.

On February 6-10, 2023, OT participated in a program hosted by the USPTO in Marrakech, Morocco, directed toward Moroccan judges and prosecutors involved in IP enforcement. The OT speaker provided instruction on the agency's infringement analysis at the border concerning protected trademarks and copyrights, as well as CBP's regulatory intellectual property border enforcement process.

On February 13-15, 2023, OT participated in a workshop sponsored by the USPTO directed towards customs officials from multiple Sub-Saharan African nation entitled "Countering Illicit Trade Amid Expanding Trade Infrastructure Investments." The attendees included customs personnel from Togo, Lesotho, Namibia, Madagascar, Liberia, and Kenya.

On February 13-16, 2023, OT participated in consultations and a workshop with government officials from Kazakhstan, Kyrgyz Republic, Tajikistan, Turkmenistan, and Uzbekistan in Geneva, Switzerland, sponsored by CLDP. All government officials met with representatives of the World Intellectual Property Organization, the World Trade Organization, the World Health Organization, International Road Transport Union, the Anti-Counterfeiting Network REACT and Transnational Alliance to Combat Illicit Trade to discuss combatting imports/exports of and illicit trade in counterfeit goods.

On March 9, 2023, OT presented virtually at the DOC CLDP's Intellectual Property Workshop in Dushanbe, Tajikistan. OT presented on the U.S. legal framework for the border enforcement of intellectual property rights in the context of counterfeit medical products.

On March 9, 2023, OT participated in an online information session for India's Office of the Controller General of Patents, Designs, & Trade Marks. The event was hosted by the USPTO and featured speakers from DOJ, FBI, USTR, IPEC, and HSI. CBP presented an overview of the U.S. *ex officio* border enforcement model, tying organizational structure, operational capabilities, and IPR e-recording to border security and the rule of law.

On March 13, 2023, OT presented virtually at the DOC CLDP's Intellectual Property Workshop in Tashkent, Uzbekistan. OT presented on the U.S. legal framework for the protection of IP rights at the border in the context of counterfeit medical products.

On March 20, 2023, OT participated in an interactive workshop on CBP's intellectual property enforcement regime at the DOC, CLDP headquarters as part of CLDP's Bosnia and Herzegovina (BiH) IP Benchbook Study Trip for Expert Working Group. The Expert Working Group is an interethnic, interdisciplinary group of intellectual property (IP) attorneys from BiH that are in Washington, DC to study all aspects of U.S. IP law.

On March 30, 2023, OT, in coordination with the USPTO, provided a virtual capacity building workshop to Honduran prosecutors, police, and customs officials involved in intellectual property enforcement. The program reviewed international standards for IP enforcement and provided an overview of U.S. best practices.

On April 14, 2023, OT participated in a discussion with government officials from the Kenyan Anti-Counterfeit Authority, the Kenya Industrial Property Institute and the Kenya Copyright Board, to discuss the implementation of IP border enforcement provisions in Kenya's 2008 Anti-Counterfeiting Act. OT joined representatives from the USPTO and USTR in developing formal recommendations on how Kenya could improve their IP border enforcement system.

On April 19, 2023, OT, in coordination with the USPTO, provided a webinar to government officials from Guatemala that are responsible for enforcing IP rights at the border. OT reviewed international standards, the U.S. border enforcement system, and CBP's e-Recordation program.

On April 27, 2023, a representative of OT was one of three women featured on a virtual panel hosted by the World Intellectual Property Organization (WIPO) entitled "Respect for Women in IP," in honor of the 2023 World IP Day theme "Women and IP". The panel was moderated by the WIPO's Senior Advisor on IP and Gender and featured three speakers: CBP's IPE Branch Chief, the Senior Manager of Copyright and IP Enforcement in South Africa's Department of Trade and Industry, and the Deputy Attorney General of the IP Unit in the Dominican Republic's Attorney General's Office. Each speaker shared their experience in building a government career in IP enforcement, a field where women are traditionally underrepresented.

On May 2-4, 2023, OT participated in a DOC/CLDP Intellectual Property Workshop in Dushanbe, Tajikistan directed to five Central Asians nations. The Workshop was part of USTR's US-Central Asia Trade and Investment Framework Agreement (TIFA) with Kazakhstan, the Kyrgyz Republic, Tajikistan, Turkmenistan, and Uzbekistan, the goal of which is to expand trade, connectivity and investment between and among the TIFA member countries with benefits that are broadly shared, inclusive of women and youth, supportive of micro, small, and medium enterprises, and beneficial to regional economic security and connectivity.

On May 3-4, 2023, OT presented at a Workshop organized by the DOC CLDP in Ashgabat, Turkmenistan. The audience included 70 members of the Turkmen customs authority and intellectual property office. OT presented on the customs enforcement framework in the United States, as well as on the unique threats presented by counterfeit medical products and how our customs framework helps the U.S. address this challenge.

On May 9-10, 2023, OT participated in a joint DOJ International Computer Hacking and Intellectual Property (ICHIP) and Department of State (State) Bureau of International Narcotics and Law Enforcement Affairs (INL) program on "Combatting Intellectual Property Crime" in Cluj-Napoca, Romania. Participants included customs, police, and

judicial authorities from Romania, Moldova, and Ukraine, who were trained by U.S. delegates from CBP, DOJ, FBI, and HSI.

On May 10-11, 2023, OT participated in a dialogue on customs enforcement of intellectual property rights in Madrid, Spain, organized by the USPTO's regional attaché to the European Union. The audience included members of the Spanish customs authority, the Spanish civil police, and the Spanish intellectual property office. OT presented on the IPR e-Recordation system, the customs enforcement framework in the United States, and best practices for enforcing intellectual property rights at the border.

On May 15-19, 2023, OT participated in a joint DOJ ICHIP and HSI Investigative Methods Workshop in Kathmandu, Nepal, entitled "Building a Comprehensive National Strategy for IP Enforcement, Pharmaceuticals, Government Supply Chains and Digital Piracy." The workshop was attended by customs officials and personnel from national intellectual property authorities from Nepal, India, Bangladesh, Maldives, and Sri Lanka. OT presented on international standards in IP border enforcement, the U.S. legal framework, and CBP's e-Recordation enforcement tool.

On June 5-7, 2023, OT participated in a training of government officials in Praia, Cabo Verde titled "Enforcing Intellectual Property Rights at the Border." The program was organized by CBP's Office of International Affairs and the USPTO, and included instruction by CBP's Office of Chief Counsel, Office of Field Operations, and OT. The training was delivered to high level government officials and policy makers in Cabo Verde, including representatives of the Ministry of Justice, the Intellectual Property and Quality Standards Agency, the Customs Administration, the Ministry of Health, the Federal Police and their comprehensive market regulation agency, Agência Reguladora Multisectorial da Economia.

On June 6, 2023, OT, in coordination with CBP's Office of International Affairs and Office of Chief Counsel, addressed fifteen customs attorneys from ten African countries visiting the United States on a Study Tour concerning IP enforcement. The African delegates were members of the DOJ's Africa Joint Pharmacrime Working Group, a DOJ OPDAT initiative aimed at improving IP enforcement efforts in the region, including the quality of IP seizures and prosecutions involving counterfeit pharmaceuticals, as well as to connect U.S. right holders to African government officials. OT presented on international standards in IP border enforcement and the U.S. IP border enforcement laws, regulations, and enforcement procedure, as they relate specifically to seizure of pharmaceutical products.

On July 11-12, 2023, OT participated in the "Dangerous Distilleries: Fighting the Illicit Market for Counterfeit Alcohol Products" program presented by the DOJ ICHIP network in Warsaw, Poland. This two-day program brought together prosecutors, law enforcement, and customs officials representing Poland, Latvia, Lithuania, and Estonia to discuss investigative and prosecutorial methods for disrupting and destroying the markets and supply chains for dangerous counterfeit alcohol products, with an eye toward effective criminal investigations and prosecutions. OT gave presentations concerning

CBP's civil IP enforcement procedures, as civil enforcement in the United States is often the precursor to any criminal investigation. OT also provided instruction on post-seizure procedure in the United States including administrative review, penalty assessment and destruction. In addition to OT attorneys, panelists at the event included attorneys from the ICHIP network; the HSI Deputy Attaché, Frankfurt; and private industry representatives. Approximately 30 people attended the program.

On July 19-21, 2023, OT participated in a meeting of the Central Asia Regional Expert Level Working Group on Intellectual Property Rights under the U.S. – Central Asia TIFA. TIFAs are led by USTR and provide strategic frameworks and principles for dialogue on trade and investment issues between the United States and the other parties to the TIFA. 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. Five delegates from each of the Central Asian nations in the Working Group were invited to take part in the meeting. The delegates consisted of heads of customs administrations, heads of intellectual property registration authorities, chief border enforcement officers and customs attorneys.

On July 24-25, 2023, OT presented at the 7th Annual International Conference on “Georgia Against Counterfeiting and Piracy” in Batumi, Georgia. The program, hosted by the National Intellectual Property Center of Georgia (SAKPATENTI) and the DOC CLDP was attended by 120 participants from both the private and public sectors, including representatives from the governments of Georgia, Armenia, Moldova, Kazakhstan, Uzbekistan, Turkmenistan, Tajikistan, and the Kyrgyz Republic. OT presented on CBP's recordation program and the intellectual property border enforcement procedures utilized by CBP, and moderated a panel on public-private partnership.

On July 27, 2023, OT participated as an expert at the 2nd Annual Trans-Caspian Intellectual Property Forum in Batumi, Georgia. The program included delegations from Georgia, Armenia, Moldova, Kazakhstan, Uzbekistan, Turkmenistan, Tajikistan, and the Kyrgyz Republic. Organized by the National Intellectual Property Center of Georgia (SAKPATENTI) and the DOC, CLDP, the Forum provided an opportunity for collaborative dialogue, sharing of information regarding each country's border enforcement framework for intellectual property, and established targets for the next session of the working group.

On August 9, 2023, CBP met for a full day with executives of the Saudi Authority for Intellectual Property (SAIP) during their week-long Enforcement Consultations with U.S. Government agencies involved in intellectual property enforcement. The week-long Enforcement Consultations program was organized by the USPTO and included meetings with State, USTR, DOJ, HSI, CBP, and IPEC. OT's morning sessions included topics related to CBP's intellectual property border enforcement regime and establishing an e-recordation database. The afternoon sessions included topics related to international information sharing and intelligence analysis, followed by an open round table on any remaining points. SAIP indicated they would like further assistance from OT in fine tuning their e-Recordation system, which launched during the last week of August, 2023.

On August 30-31, 2023, OT presented at an “Intellectual Property Crime Workshop” organized by the DOJ ICHIP and State, in Vientiane, Laos. The audience included representatives from Laotian police, prosecutors, criminal investigators, and customs. OT presented on the customs enforcement framework in the United States, as well as international minimum standards in IP border enforcement pursuant to the WTO-TRIPS Agreement. OT sat on multiple panels and shared best practices with the Laotians.

On September 11, 2023, OT met with the USPTO IP Attaché in Bangkok, Thailand, regarding regional capacity building programs focusing on Cambodia and Laos. On September 12, OT provided opening remarks at an ASEAN Network of Intellectual Property Enforcement Experts (AIMEE) meeting.

On September 13-15, 2023, OT attended and spoke at a “Copyright Enforcement Workshop” organized by the ASEAN Secretariat and the USPTO in Bangkok, Thailand. On September 15, OT met with Thai Customs’ officials responsible for the border enforcement of intellectual property to discuss enhancements to their recordation system and how they help strengthen IP border enforcement in the region.

On September 19-22, 2023, OT participated in an “IPR Border Enforcement Workshop” for the United Arab Emirates (UAE) Federal Authority for Identity, Citizenship, Customs, and Port Security, organized by the USPTO and State. OT provided technical legal expertise on the U.S. legal framework for the border enforcement of intellectual property rights through in depth presentations and participation on several moderated panels.

On September 27, 2023, OT was featured as a panelist at the “16th International Law Enforcement IP Crime Conference” hosted by INTERPOL and the Norwegian Police in Oslo, Norway. The panel concerned illicit trade in Free Trade Zones, and how the OECD Clean Certification Scheme can help mitigate the risk of illicit trade flowing through these less regulated zones.

In FY 2023, CBP continued engagement on IPR issues with the Asia Pacific Economic Cooperation (APEC) in the Subcommittee on Customs Procedures (SCCP) by coordinating an IPR mutual enforcement operation focused on counterfeits and their lack of sustainability. Nine APEC economies participated in the joint operation (Australia, Chile, Japan, Mexico, New Zealand, Singapore, Chinese Taipei, Thailand, the United States) and shared practices and statistics in a report that was presented at the SCCP 2 meeting in Seattle, Washington.

Interagency Collaboration

The Office of Trade OT 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 2023 are the following:

On December 8, 2022, OT presented to U.S. Government stakeholders in the IP

enforcement field at the Annual IP Attaché Consultations held by the USPTO. The program featured updates from program offices in various agencies that enforce IP rights, such as the U.S. Copyright Office, and the USPTO Office of Policy and International Affairs. The OT representative led an in-depth discussion of recent trends and challenges in IP border enforcement around the world.

On March 8, 2023, OT, in coordination with USPTO, delivered a joint virtual training to ICE, HSI Agents, on how to utilize the USPTO's Trademark Electronic Search System (TESS) database and in CBP's e-Recordation internal database (IPRiS) for IP enforcement cases. Approximately 150 HSI Agents attended the training, which covered best practices in searching and digesting information contained in CBP's proprietary database that houses all trademark and copyright recordations.

On April 27, 2023, OT was honored as part of an interagency team presented with a *NIOSH Science and Service Award 2023* in the *Intervention* category for "Protecting the NIOSH Brand: Registering, Monitoring, and Enforcing Certification Marks to Combat Counterfeit and Respirators Misrepresenting Being NIOSH Approved". During the peak of the COVID-19 pandemic OT proactively reached out to the trademark attorneys from HHS, Centers for Disease Control and Prevention, to inform them about how they can record their certification marks through CBP's e-Recordation program to obtain protection against infringing imports. Once NIOSH recorded its certification marks, CBP was able to seize millions of unbranded respirator marks falsely bearing these filtration designations.

From May 23-24, 2023, OT provided advanced joint training to personnel at the Port of Savannah, along with the Office of Field Operations Jones Act Division of Enforcement (JADE) and Atlanta Office of Chief Counsel. The training covered the legal and regulatory overview of the coastwise and navigation laws, including the Jones Act, coastwise law enforcement training, and restricted merchandise (*i.e.*, drug paraphernalia, forced labor, and cultural property) and yacht chartering enforcement, as well as advanced topics in the border enforcement of intellectual property rights and Office of Chief Counsel's role in IPR issues.

On June 6, 2023, OT participated in the HSI Intellectual Property and Trade Enforcement Investigations (IPTEI) training course. The IPTEI course offers advanced training with a specific focus on commercial fraud and IP theft. OT speakers discussed CBP's intellectual property border enforcement regime and the process of making a seizure based on an intellectual property rights violation.

On June 6-7, 2023, OT delivered an Advanced Border Security and Trade Compliance Division (BSTCD) training directed to the Office of Fines, Penalties, & Forfeitures (FP&F) at JFK Airport. The training covered advanced topics in the border enforcement of intellectual property rights and restricted merchandise enforcement and included attorney-advisor instructors from other OT offices. This Advanced Training also included instructors from the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), DOJ, HSI, ICE Bulk Cash Smuggling Center (BCSC), as these restricted merchandise topics

were identified as enforcement areas of particular concern at FP&F JFK. Approximately 30 FP&F personnel and 10 CBP Cargo Officers attended the training.

On July 26, 2023, OT provided training on international intellectual property border enforcement, to new State Department Foreign Service Officers and Economic Officers scheduled to deploy that summer. The training began with an overview of the guiding legal documents governing IP border enforcement, minimum international standards, and the United States' implementation of WTO-TRIPS Agreement. Next, the State Department personnel were given a tour of the Port of Dulles Airport where they received a briefing on CBP's IP border enforcement procedures, to include an examination of imported merchandise and procedures used in enforcing IP at the border.

On August 22, 2023, OT provided a training to HSI agents and CBP Officers enrolled in the I-IPTEI Course run by the IPR Center. The training provided an overview of trademark and copyright enforcement and touched upon advanced topics such as fair use, refurbished goods, and gray market restricted merchandise.

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 2023 included the following:

On October 12, 2022, OT provided a virtual IPR enforcement training to new cargo officers stationed at the Port of Los Angeles/Long Beach Harbor. The course provided an overview of how Officers may utilize their seizure authority to prevent the importation of infringing goods.

On November 18, 2022, OT provided training to frontline CBP Officers at Orlando Airport, Florida. The training covered an overview of CBP's IPR enforcement authority, a tutorial on CBP's IPR e-Recordation System, and best practices for undertaking an IPR enforcement action at the border.

On March 28, 2023, OT divisions delivered advanced training to FP&F Officers, Paralegal Specialists, and Seized Property Specialists of the Atlanta Field Office in Atlanta, Georgia. OT provided instruction on proper IP enforcement procedures, an overview of the entire FP&F process, and covered issues in civil and criminal investigations and seized property management. The training enhanced the Atlanta Field Office's expertise in FP&F enforcement, resources, and risk management.

On May 16-17, 2023, OT participated in a joint training at the Port of San Juan with DHS Law Enforcement Programs Branch of JADE. The training was delivered to CBP personnel as well as members of the U.S. Coast Guard and HSI agents. The training covered the legal and regulatory overview for the Jones Act, coastwise law enforcement training, and restricted merchandise enforcement, as well as advanced topics in the border enforcement of intellectual property rights. Approximately 20 HSI and CBP employees

and 20 U.S. Coast Guard members attended this inaugural joint training between CBP and DHS JADE.

From May 23-24, 2023, OT provided advanced joint training to personnel at the Port of Savannah, along with the Office of Field Operations JADE and Atlanta Office of Chief Counsel. The training covered the legal and regulatory overview of the coastwise and navigation laws, including the Jones Act, coastwise law enforcement training, and restricted merchandise (*i.e.*, drug paraphernalia, forced labor, and cultural property) and yacht chartering enforcement, as well as advanced topics in the border enforcement of intellectual property rights and Office of Chief Counsel's role in IPR issues.

On June 6-7, 2023, OT delivered an advanced BSTCD training directed to the Office of FP&F JFK. The training covered advanced topics in the border enforcement of intellectual property rights and restricted merchandise enforcement and included attorney-advisor instructors. This Advanced Training also included instructors from the Bureau of Alcohol, Tobacco, Firearms, and Explosives, DOJ, and the ICE BCSC.

On June 15, 2023, OT delivered BSTCD training to the Laredo, Texas, Office of FP&F and the Atlanta Georgia, Office of Associate Chief Counsel. Four Branches in BSTCD provided instruction on advanced topics in the enforcement IP rights, exclusion order enforcement, petition adjudication, penalty assessment, and restricted merchandise enforcement.

On June 21, 2023, OT delivered advanced hybrid joint training with two Consumer Product Safety Commission (CPSC) investigators to personnel at the Cargo Clearance Center in Miami, Florida. The audience included the Miami and Tampa Offices of FP&F, the Miami Office of Chief Counsel (OCC), and HSI agents. Four Branches in BSTCD provided instruction on advanced topics in the enforcement of IP rights, exclusion order enforcement, petition adjudication, penalty assessment, coastwise and navigation laws (including the Jones Act), and restricted merchandise enforcement.

On June 27-29, 2023, OT participated in the Advanced Intellectual Property and Restricted Merchandise Enforcement Seminar in Honolulu, Hawaii. The training was attended by CBP Officers and FP&F personnel at the Honolulu port office and Daniel K. Inouye International Airport. From BSTCD, the Intellectual Property Enforcement Branch presented on best practices in IPR enforcement, OT presented on best practices in reviewing administrative petitions for relief, enforcement of commingled goods, mitigation, and post-seizure disposition of merchandise and presented on exclusion order enforcement. OT also presented on cargo carrier violations.

On July 18-19, 2023, OT provided training directed to Import Specialist and Entry Specialists from the Machinery Center on advanced topics in the border enforcement of intellectual property rights and restricted merchandise enforcement. The content was provided by OT attorney-advisor instructors from each of the other BSTCD Branches: the Seizures and Penalties Branch, the Exclusion Order Enforcement Branch, and the Cargo Security, Carriers, and Restricted Merchandise Branch and covered enforcement topics

specifically related to the commodities falling within the Center. Approximately 90 students attended the training.

On August 1, 2023, OT provided training directed to Import Specialist and Entry Specialists from the Apparel, Footwear, and Textile Center (AFT) and Consumer Product and Mass Merchandise Center (CPMM) on advanced topics in the border enforcement of intellectual property rights and restricted merchandise enforcement.

On August 8, 2023, OT in coordination with the CPSC, provided a hybrid training at the Port of Charleston, South Carolina, directed to CBP Officers, Import Specialists and personnel from the FP&F Office on advanced topics in the border enforcement of IP rights and restricted merchandise. The content covered enforcement topics specifically requested by the Port, and included a session delivered by the CPSC on merchandise restricted pursuant to their regulatory authority.

On August 22, 2023, OT provided a training directed to the Detroit FP&F Office and local Import Specialists and CBP Officers at the Port. The course covered an introduction to CBP's intellectual property border enforcement regime, such as the IP violations CBP enforces, how to utilize the Intellectual Property Rights Internal Search System (IPRiS), and how to process a seizure of merchandise infringing recorded trademarks and copyrights. Over 70 students attended.

On August 24, 2023, OT provided advanced intellectual property and restricted merchandise training to personnel from the Portland, San Francisco and Anchorage Fines, Penalties and Forfeiture Offices. The content was provided by OT attorney-advisor instructors and covered advanced enforcement topics in intellectual property, restricted merchandise, forced labor, and petition adjudication.

On August 29-30, 2023, OT provided advanced intellectual property and restricted merchandise training to personnel from the Automotive and Aerospace Center and the Pharmaceuticals, Health and Chemicals Center. The content was provided by OT attorney-advisor instructors and covered advanced enforcement topics in intellectual property, restricted merchandise, forced labor, and petition adjudication, that fell within their Centers. Approximately 160 students attended the interactive training.

On September 21, 2023, OT provided advanced IPR and Restricted Merchandise training to the Petroleum, Natural Gas & Minerals Center for Excellence and Expertise. The audience was comprised of roughly 50 import specialists and Center staff.

On September 20-21, 2023, OT provided trainings to the officers, import specialists, and FP&F Offices at the Port of Champlain, New York. Day One of the training was a hybrid training with speakers presenting on their branch's respective subject area. Day Two was a broader overview of IP enforcement. Approximately 25 participants attended the two-day training session.

On September 27, 2023, OT conducted an advanced IPR and Restricted Merchandise training at the Port of Buffalo, New York. In addition to OT, three partner government agencies, including the CPSC, National Highway Traffic Safety Administration, and the FDA provided presentations. The hybrid audience was comprised of FP&F personnel, import specialists, and frontline officers, totaling roughly 50 attendees.

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

On May 26, 2021, CBP entered into a memorandum of understanding (MOU) with the U.S. Chamber of Commerce (Chamber) 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. On August 10, 2023, CBP held a MOU Renewal Ceremony at the JFK Port of Entry to celebrate the renewal of the MOU for an additional five years. The event included a signing ceremony between CBP and the Chamber, a tour of JFK's International Mail Facility, and a roundtable discussion with CBP. The MOU 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 2022 holiday season, CBP and the Chamber once again participated in the Shop Smart Campaign. This campaign included representatives from CBP, the Chamber, and industry collaborating to speak with stations across the country to discuss how counterfeit goods are a problem for consumers. Specifically, the campaign was focused on the higher demand for consumer goods during the holiday season and the importance of buying genuine products. This media tour reached over 73.5 million people with 827 airings of the content. From August through September 2023, CBP and the Chamber participated in a back-to-school IPR awareness campaign. CBP radio recordings for the effort reached an audience of 54 million people through more than 1,700 airings on 1,200+ stations and network affiliates.
- **CBP IPR Statistics Data Sharing:** CBP provides intellectual property rights seizure statistics on a quarterly basis to the Chamber. CBP has provided all FY 2023 statistics to the Chamber.
- **Training:** CBP and the Chamber have agreed to provide bi-directional training to each of their relevant personnel/members. On March 16, 2023, CBP provided an IPR Statistics training to the Chamber's Global Brand Council that included an overview of the FY2023 Q1 statistics. Additionally, in FY 2023, CBP began conducting the "CBP Speaker Series" to educate Chamber members on CBP initiatives and programs. On April 27, 2023, the IPR & E-Commerce Division provided an overview of CBP's e-Commerce Initiatives. On June 7, 2023, CBP's Green Trade Division provided an overview of CBP's new Green Trade Strategy.

On June 14, 2023, CBP's IPR Enforcement Branch, discussed CBP's e-recordation program for rightsholders as well as CBP's authority to protect IP.

- **Data Pilot:** As part of the MOU, CBP is conducting a data sharing pilot with Chamber 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 to better target and seize imports of counterfeit and pirated goods and other IPR violative merchandise. Currently the pilot consists of five companies including Apple, Pfizer, Burberry, the NBA, and MLB.

CBP Product ID Guide Webinars

In FY 2023, the CBP Office of Trade hosted thirteen Product ID Guide webinars, reaching approximately 1300 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

The CBP Office of Trade's IPR Operations Branch also began in-person instructor lead trainings (ILTs) to the field. In FY 2023, the Office of Trade held 19 in person and 4 virtual trainings. Approximately 341 field personnel were trained.

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 culminated in the submission of nine recommendations from the COAC IPR working group at the September 2023 public COAC meeting. These nine recommendations were focused in five key areas: automation of the administrative enforcement processes, enhancement to the ACE portal, green trade, alternatives to seizure, and funding for an IPR portal.
- 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.

- Participation in national and local trade events, industry meetings, speaking engagements, and industry-specific rightsholder roundtables.

The Office of Trade started monthly Priority Trade Issues IPR meetings with the IPR Coordinators in the field. During these meetings, speakers from Trade Special Operations share their findings, what worked, what did not, and the outcomes. Other speakers are also brought in from different areas of CBP, such as the Labs, the Library and General Counsel to discuss their contributions to IPR-related issues. In FY2023, 10 meetings were held.

Throughout FY 2023, 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.

On September 20, 2023 the Office of Trade participated in the Port of New Orleans “Know Before You Throw” Trade Compliance Summit. The event provided an opportunity for almost 50 members of the trade community to gain more knowledge about counterfeit goods. During the event, the Office provided a presentation on what counterfeit goods are, the dangers they pose, what marks CBP enforces, and initiatives and program available in CBP to better help interdict counterfeits.

Educating the Public

Changing public attitudes toward infringing activities remains essential to an effective intellectual property enforcement strategy. CBP’s activities during FY 2023 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 2023, the “Truth Behind Counterfeits” public awareness campaign continued educating consumers about the many negative impacts associated with the purchase of counterfeits through social media posts and engagement. The campaign and its “Fake Goods, Real Dangers” messages continued to highlight that purchasing these illegitimate goods damages this U.S. economy, threatens consumer health and safety, supports criminal activity, and negatively impacts the environment. The campaign expanded its sponsored social media content to include three platforms (Instagram, Facebook, and X [formerly Twitter]) with approximately 130 million impressions. Additionally, CBP continued to leverage its existing social media presence with monthly posts on CBP Twitter and Facebook accounts. These IPR focused posts were available to over 530,000 followers. In FY 2023, CBP also created a consumer

awareness video that is located at <https://www.cbp.gov/newsroom/video-gallery/video-library/truth-behind-counterfeits>.

DEPARTMENT OF JUSTICE

DEPARTMENT OF JUSTICE

“These charges demonstrate the Justice Department’s commitment to preventing sensitive technology from falling into the hands of foreign adversaries, including Russia, China, and Iran. We will not tolerate those who would violate U.S. laws to allow authoritarian regimes and other hostile nations to use advanced technology to threaten U.S. national security and undermine democratic values around the world.”¹⁰

– Matthew G. Olsen, Assistant Attorney General, DOJ
National Security Division

“The theft of technology and trade secrets from U.S. companies is a threat to our economic and national security. The charges announced today aren’t the only instances of foreign adversaries trying to steal our technology. Combating the illegal transfer of technology is one of the FBI’s highest priorities, and we will continue to work with our federal partners, including the Department of Commerce, to investigate those who steal U.S. technology to ultimately use it in weapons that threaten us and our allies.”¹¹

– Suzanne Turner, Assistant Director, FBI
Counterintelligence Division

Department of Justice Appendix for FY 2023 Annual Report

This appendix for the Department of Justice (DOJ or the Department) is in two parts. The first part discusses the Department’s activities during FY 2023 relating to intellectual property (IP) protection and enforcement. The second part discusses certain IP-related activities of DOJ’s Antitrust Division. In addition, the FBI is a founding partner of the National Intellectual Property Rights Coordination Center (IPR Center) and plays an important role in disrupting the production, distribution, and sale of counterfeit and pirated goods, and the misappropriation of trade secrets. Please see the Department of Homeland Security’s appendix for more information on the work of the IPR Center.

The Department 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>.

¹⁰ DOJ press release, “Justice Department Announces Five Cases as Part of Recently Launched Disruptive Technology Strike Force: Cases Mark Strike Force’s First Enforcement Actions Since Established” (May 16, 2023) at <https://www.justice.gov/opa/pr/justice-department-announces-five-cases-part-recently-launched-disruptive-technology-strike>.

¹¹ Id.

I. IP Protection and Enforcement Activities

The following is a discussion of DOJ activities relating to IP protection and enforcement, including litigation activities in which arrests, charges, indictments, guilty pleas or verdicts, and/or sentencing took place during FY 2023.

INTELLECTUAL PROPERTY CASES FY2023

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

- ***Minnesota Man Sentenced to Three Years in Prison for Scheme to Commit Computer Intrusion and Illegally Stream Content from Four Major Professional Sports Leagues.*** On March 16, 2023, Joshua Streit, a/k/a Josh Brody, was sentenced in Manhattan federal court for conducting intrusions into Major League Baseball (MLB) computer systems and illegally streaming copyrighted content from MLB, the National Basketball Association (the NBA), the National Football League (the NFL), and the National Hockey League (the NHL) on a website that Streit operated, which offered the illegally streamed content to the public for profit. Beginning in or about 2017 to in or about August 2021, Streit operated a website which streamed copyrighted content, primarily livestreamed games from major professional sports leagues, including MLB, the NBA, the NFL, and the NHL, which STREIT had no authorization to stream. Streit obtained the copyrighted content by gaining unauthorized access to the websites for those sports leagues via misappropriated login credentials from legitimate users of those websites. One of the victim sports leagues sustained losses of approximately \$3 million due to Streit's conduct. In addition, at the same time Streit was illicitly streaming copyrighted content from MLB, Streit attempted to extort approximately \$150,000 from MLB via a threat from Streit to publicize unrelated vulnerabilities in MLB's internet infrastructure. Specifically, in multiple communications with MLB employees, Streit claimed that he knew MLB reporters who were "interested in the story," and stated that it would be bad if the vulnerability were exposed, and MLB was embarrassed. In October 2021, Streit was charged with the computer intrusions, wire fraud, interstate threats to extort, and illicitly streaming copyrighted content, and in July 2022, he pleaded guilty to computer intrusion. In addition to the prison sentence, Streit, was sentenced to three years of supervised release and ordered to pay \$2,995,272.64 in restitution and \$500,000 in forfeiture. (SDNY, FBI, MLB, NBA, NFL, NHL)
<https://www.justice.gov/usao-sdny/pr/minnesota-man-sentenced-three-years-prison-scheme-commit-computer-intrusion-and>
- ***Leader of Illegal Copyright Infringement Scheme Sentenced to 5 ½ Years' Imprisonment.*** On March 8, 2023, Bill Omar Carrasquillo of Swedesboro, NJ, was sentenced to 66 months' imprisonment, five years of supervised release, more than \$30 million in forfeiture, and more than \$15 million in restitution for crimes arising from a wide-ranging copyright infringement scheme that involved piracy of cable TV, access device fraud, wire fraud, money laundering, and hundreds of thousands of dollars of copyright infringement. As the Indictment set forth, from about March 2016 until at least November 2019, Carrasquillo along with his co-defendants operated a large-scale internet

protocol television (IPTV) piracy scheme in which they fraudulently obtained cable television accounts and then resold copyrighted content to thousands of their own subscribers, who could then stream or playback content. The defendants also made fraudulent misrepresentations to banks and merchant processors to obtain merchant processing accounts. During the period of their scheme, the defendants earned more than \$30 million. Carrasquillo, in particular, converted a large portion of his profits into homes and dozens of vehicles, including high-end sports cars. When agents attempted to seize those items pursuant to judicially-authorized warrants, Carrasquillo made false statements about and attempted to hide some of those vehicles, including a Freightliner recreational vehicle and a McLaren sports vehicle. Carrasquillo was convicted of one count of conspiracy; one count of violating the Digital Millennium Copyright Act; one count of reproduction of a protected work; three counts of public performance of a protected work; one count of access device fraud; one count of wire fraud; one count of making false statements to a bank; one count of money laundering; one count of making false statements to law enforcement officers; and one count of tax evasion. In addition to a sentence of 66 months' imprisonment, the court ordered Carrasquillo to pay \$10.7 million in restitution to the victim cable companies, more than \$5 million in restitution to the IRS, and to forfeit over \$30 million in illegal proceeds that he reaped from the scheme. (EDPA, FBI, Internal Revenue Service-Criminal Investigation, CCIPS) <https://www.justice.gov/usao-edpa/pr/leader-illegal-copyright-infringement-scheme-sentenced-5-12-years-imprisonment>

- ***Columbia Couple Sentenced for Selling Counterfeit Disney Movies on eBay.*** On February 8, 2023, a Columbia, MO., couple was sentenced in federal court for a scheme to smuggle counterfeit Disney DVDs into the United States and sell them on eBay. Tabitha Nicole Rodgers and her husband, Clint Travis Rodgers were sentenced in separate appearances. Tabitha Rodgers was sentenced to four years in federal prison. Clint Rodgers was sentenced to one year in federal prison. The court also ordered Tabitha Rodgers to pay \$26,573 in restitution to the government for Supplemental Nutrition Assistance Program (SNAP) benefits she was not entitled to receive. The court ordered Clint Rodgers to pay a \$10,000 fine. The sentencing followed Tabitha Rodgers' guilty plea to one felony count of criminal copyright infringement for profit, and Clint Rodgers' guilty plea to a misdemeanor count of criminal infringement of a copyright. According to court documents, the majority, if not all, of the Rodgers' income was derived from this criminal activity. They had been notified by Beachbody and Otter Products to cease and desist from selling counterfeit products yet continued to sell counterfeit goods. eBay cancelled a number of the Rogers's accounts due to counterfeit merchandise being sold, but they recruited others to sell the products. Although they derived substantial income from selling counterfeit goods, Tabitha Rodgers sought and obtained SNAP benefits from the government to which she was not entitled. Her fraudulent conduct in obtaining benefits was considered by the court in determining an appropriate sentence and in ordering restitution. (WDMO, HSI, U.S. Department of Agriculture) <https://www.justice.gov/usao-wdmo/pr/columbia-couple-sentenced-selling-counterfeit-disney-movies-ebay>

- Maryland U.S. Attorney’s Office Announces the Seizure of 23 More Domain Names that Allegedly Violated Copyrights by Illegally Live Streaming the World Cup.*** On December 18, 2022, the U.S. Attorney’s Office for the District of Maryland announced the seizure of 23 websites for allegedly live streaming World Cup tournament games, an infringement of Fédération Internationale de Football Association (FIFA) copyrights. Individuals visiting the sites now see a message that the site has been seized by the federal government and are redirected to another site for additional information. This was the second round of seizures related to FIFA World Cup match streaming. On December 12, 2022, 55 websites were seized. FIFA is the international governing body of association football and holds the exclusive rights to sanction and stage the FIFA World Cup 2022, which was hosted in multiple cities in Qatar. Beginning in September 2022, HSI received information from a representative of FIFA identifying multiple sites being used to distribute and transmit copyright-infringing content, without FIFA’s authorization. After the initial round of seizures executed on December 10, HSI Agents in Maryland observed public internet messages and social media posts identifying additional, alternate sites offering illicit streams of World Cup matches. Agents then reviewed World Cup games and other infringing content being offered through these sites and confirmed a list of additional domain names subject to seizure. As detailed in the affidavit, free access to live sports-related copyright-protected content can attract heavy viewing traffic, which makes websites offering such content a potentially lucrative way to serve advertisements. Based on the pervasive use of advertising on each site, the affidavit alleges that the purpose for distributing the infringing content is the private financial gain to these websites’ operators. By seizing the subject domain names, the government prevents third parties from acquiring the name and using it to commit additional crimes, or from continuing to access the websites in their present forms. (MD, HSI, the National Intellectual Property Rights Coordination Center, the National Cyber-Forensics and Training Alliance, CCIPS)

<https://www.justice.gov/usao-md/pr/maryland-us-attorney-s-office-announces-seizure-23-more-domain-names-allegedly-violated>; <https://www.justice.gov/usao-md/pr/maryland-us-attorney-s-office-announces-seizure-55-domain-names-violated-copyrights>
- Two Russian Nationals Charged with Running Massive E-Book Piracy Website.*** On November 16, 2022, in federal court in Brooklyn, an indictment and a complaint were unsealed charging Russian nationals Anton Napolsky and Valeriia Ermakova with criminal copyright infringement, wire fraud and money laundering for operating Z-Library, an online e-book piracy website. The pair was arrested on November 3, 2022, in Cordoba, Argentina at the request of the United States. At the same time, Z-Library’s network of online domains was taken offline and seized by the U.S. government, pursuant to a court order. As alleged in the indictment and court filings, Z-Library bills itself as “the world’s largest library” and claims to offer more than 11 million e-books for download. Z-Library, which has been active since approximately 2009, offers e-book files in a variety of file formats, stripped of their copyright protections, and encourages users to upload and download titles. Many of the e-books offered by Z-Library are protected intellectual property for which authors hold copyrights and publishers hold exclusive distribution rights, and which Z-Library has no license or authorization to

distribute, and which are available elsewhere only with anti-circumvention measures applied. As such, a central purpose of Z-Library is to allow users to download copyrighted books for free in violation of U.S. law. In addition to its homepage, Z-Library operates as a complex network of approximately 249 interrelated web domains. As part of this action, those domains were taken offline and seized by the U.S. government. (EDNY, OIA, CCIPS, FBI, Argentine authorities)
<https://www.justice.gov/usao-edny/pr/two-russian-nationals-charged-running-massive-e-book-piracy-website>

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

- ***Leader of Illegal Copyright Infringement Scheme Sentenced to 5 ½ Years’ Imprisonment.*** As noted above, On March 8, 2023, Bill Omar Carrasquillo of Swedesboro, NJ, was sentenced to 66 months’ imprisonment, five years of supervised release, more than \$30 million in forfeiture, and more than \$15 million in restitution for crimes arising from a wide-ranging copyright infringement scheme that involved violations of the Digital Millennium Copyright Act, piracy of cable TV, access device fraud, wire fraud, money laundering, and hundreds of thousands of dollars of copyright infringement. (EDPA, FBI, Internal Revenue Service-Criminal Investigation, CCIPS)
<https://www.justice.gov/usao-edpa/pr/leader-illegal-copyright-infringement-scheme-sentenced-5-12-years-imprisonment>

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

- ***CEO of Dozens of Companies Pleads Guilty to Massive Scheme to Traffic in Fraudulent and Counterfeit Cisco Networking Equipment.*** On June 5, 2023, Onur Aksoy, 39, a Florida resident and dual citizen of the United States and Turkey pleaded guilty in the District of New Jersey to running an extensive operation over many years to traffic in fraudulent and counterfeit Cisco networking equipment. According to documents filed in this case and statements made in court Aksoy ran at least 19 companies formed in New Jersey and Florida, as well as approximately 15 Amazon storefronts and at least 10 eBay storefronts (collectively, the “Pro Network Entities”), that imported from suppliers in China and Hong Kong tens of thousands of low-quality, modified computer networking devices with counterfeit Cisco labels, stickers, boxes, documentation, and packaging, all bearing counterfeit trademarks registered and owned by Cisco, that made the goods falsely appear to be new, genuine, and high-quality devices manufactured and authorized by Cisco. The devices had an estimated total retail value of hundreds of millions of dollars. Moreover, the Pro Network Entities generated over \$100 million in revenue, and Aksoy received millions of dollars for his personal gain. 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. 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 added counterfeited Cisco labels, stickers, boxes, documentation, packaging, and other materials. Fraudulent and counterfeit products sold by the Pro Network Entities suffered from numerous performance, functionality, and safety problems. Often, they would simply fail or otherwise malfunction, causing significant damage to their users' networks and operations – in some cases, costing users tens of thousands of dollars. Customers of Aksoy's fraudulent and counterfeit devices included hospitals, schools, government agencies, and the military. Between 2014 and 2022, 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 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 broke the shipments up into smaller parcels and shipped them on different days, and Aksoy used 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 often continued to order counterfeit Cisco products from the same supplier. Between 2014 and 2019, Cisco sent seven letters to Aksoy asking him to cease and desist his trafficking of counterfeit goods. Aksoy 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. Aksoy pleaded guilty to (1) conspiring with others to traffic in counterfeit goods, to commit mail fraud, and to commit wire fraud and (2) mail fraud. He is scheduled to be sentenced on Nov. 6, and under the plea agreement that the court conditionally accepted yesterday pending sentencing, faces a sentence of four to six and a half years in prison. Also pursuant to the plea agreement, Aksoy must forfeit \$15 million in illicit gains from his scheme and make full restitution to his victims. The court will determine the final sentence after considering the U.S. Sentencing Guidelines and other statutory factors. (NJ, CCIPS, HSI, U.S. Department of Defense, Defense Criminal Investigative Service, General Services Administration Office of Inspector General, Naval Criminal Investigative Service, and CBP) <https://www.justice.gov/opa/pr/ceo-dozens-companies-pleads-guilty-massive-scheme-traffic-fraudulent-and-counterfeit-cisco>

- ***Ferndale, Washington Woman Sentenced to Six Months for Trafficking Hundreds of "Knock-off" Designer Goods.*** On April 7, 2023, a Ferndale, WA woman was sentenced to three months in prison and three months home confinement for trafficking in counterfeit goods. Kara Suneva Allen, aka Kara Suneva Mitchell, pleaded guilty in October 2022. According to records filed in the case, Allen operated a business named 'Keepin Up With Kara' LLC. The business was located in a warehouse space in Ferndale, WA. 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 by Homeland Security Investigations, U.S. Customs and Border Protection (CBP), and the

Whatcom County Sheriff's Office revealed that in August and September 2021, three shipments destined for Allen and her company were seized from the mail in Oakland, CA. 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. Over 1,800 items of suspected counterfeit merchandise were seized, including purses, scarves, belts, luggage tags, sunglasses, tumblers, and other accessories. In total, between June 2021 and May 2022, Allen acquired, attempted to acquire, or sold more than 1,900 counterfeit items with an estimated retail value of \$185,842. Her profit over that time was approximately \$43,430. (WDWA, HSI, CBP, the Whatcom County Sheriff's Office, U.S. Postal Inspection Service, the Ferndale Police Department, the National Intellectual Property Rights Center)

<https://www.justice.gov/usao-wdwa/pr/ferndale-washington-woman-sentenced-six-months-trafficking-hundreds-knock-designer>

- ***Five Family Members Sentenced to Prison and Ordered to Forfeit a Combined \$51.9 Million in Proceeds from Their Fraudulent Sale of Counterfeit Trademarked Cellular Phones and Accessories.*** On March 21- 23, 2023, five family members were sentenced to prison for their roles in a conspiracy to commit wire fraud, mail fraud, and conspiracy to traffic in counterfeit trademarked goods, all in connection with their online sale of counterfeit cellphones and accessories. On August 1, 2022, a jury found Pavel Babichenko, Piotr Babichenko, Timofey Babichenko, David Bibikov, and Mikhail Iyerusalimets guilty after a three-month trial. Pavel Babichenko, Piotr Babichenko, Timofey Babichenko, David Bibikov, and Mikhail Iyerusalimets operated a multi-million-dollar scheme wherein they sold counterfeit cellphones and cellphone accessories on Amazon.com and eBay.com that the defendants misrepresented as new and genuine Apple and Samsung products. The counterfeit cellphones and cellphone accessories were obtained in bulk from manufacturers in Hong Kong, repackaged in the Treasure Valley, ID, and then individually resold to consumers online as genuine and new. Pavel Babichenko was sentenced to 72 months in federal prison, a \$21,000 fine, and three years of supervised release. A \$33,708,700.30 forfeiture money judgment was entered against him. Piotr Babichenko was sentenced to serve 48 months in federal prison, a \$10,000 fine, and three years of supervised release. A \$3,316,882.40 forfeiture money judgment was entered against him. Timofey Babichenko was sentenced to serve 48 months in federal prison, a \$10,500 fine, and three years of supervised release. A \$953,411.95 forfeiture money judgment was entered against him. (ID, FBI, HSI, IRS-Criminal Investigation, the U.S. Postal Inspection Service, the U.S. Marshals Service, Treasure

Valley Metro Violent Crimes Task Force, the Ada County Sheriff's Office, the Boise Police Department, and the Meridian Police Department)

<https://www.justice.gov/usao-id/pr/five-family-members-sentenced-prison-and-ordered-forfeit-combined-519-million-dollars>

- ***Man Caught with Counterfeit Designer Phone Cases Heads to Federal Prison.*** On February 16, 2023, a man from Fairfield, IL was sentenced to 33 months in prison after he admitted to importing more than 800 counterfeit designer phone cases from Hong Kong to resell in the United States. Trevor J. Edwards pleaded guilty to two counts of trafficking counterfeit goods. In addition to his prison sentence, he is subject to three years of supervised release and ordered to pay \$1,367.20 in restitution and \$500 in fines. In February 2021, CBP seized 500 counterfeit designer cellphone cases when the shipment reached the U.S. border from Hong Kong. According to court documents, Edwards was listed on the box as the recipient. The phone cases were counterfeit Chanel, Louis Vuitton, Burberry and Gucci and retailed an estimated \$212,500. Once intercepted, the government sent a receipt to Edwards to notify him of his illegal activity. Months later in May 2021, Edwards was pulled over by law enforcement in Washington County and a search of his vehicle found 336 counterfeit designer cell phone cases, \$241,000 in cash and 2,909 vape pens and cartridges containing cannabis. The phone cases retail value is estimated at \$101,340. (SDIL, HSI)
<https://www.justice.gov/usao-sdil/pr/man-caught-counterfeit-designer-phone-cases-heads-federal-prison>
- ***Happy Valley Man Sentenced for Illegally Trafficking Counterfeit Gun Parts for Use as Airsoft Accessories.*** On December 13, 2022, a Happy Valley, OR man was sentenced to federal probation for illegally trafficking counterfeit gun accessories, including suppressors, scopes, grips, and sights, from China for resale as airsoft gun accessories. Johnny Li was sentenced to five years' federal probation, including 180 days of home detention, and ordered to pay \$281,628 in restitution. According to court documents, sometime in 2019, Li began trafficking counterfeit gun parts he purchased from China—often through Alibaba.com, one of the world's largest online commerce companies—into the United States for resale online via his website SupplyAirsoft.com. In December 2019, CBP seized 35 counterfeit laser sights, labeled as "Toy Telescopes," sent from a Chinese company to Li's home in Happy Valley. CBP sent Li a letter notifying him of the seizure. Several months later, in May 2020, CBP seized additional rifle sights en route to Li and again notified him of the seizure. On October 27, 2020, federal agents executed a search warrant on Li's residence and seized hundreds of counterfeit firearm parts and accessories. Altogether, the counterfeit items seized had an estimated value of more than \$281,000. On November 9, 2021, a federal grand jury in Portland returned an indictment charging Li with trafficking in counterfeit goods. On June 23, 2022, he pleaded guilty to the single charge. (OR, HSI, the Portland Police Bureau, the Oregon Intellectual Property Task Force)
<https://www.justice.gov/usao-or/pr/happy-valley-man-sentenced-illegally-trafficking-counterfeit-gun-parts-use-airsoft>

- Leader of a Conspiracy to Manufacture, Import, and Sell Counterfeit Military Clothing and Gear Sentenced.*** On October 13, 2022, a Brooklyn, NY, clothing and goods wholesaler who directed the development, manufacture, and importation of \$20 million worth of Chinese-made counterfeit U.S. military uniforms and gear that were passed off as genuine American-made products was sentenced to forty months in federal prison and ordered to forfeit the \$20 million in proceeds that he obtained from the sale of the counterfeit goods. Ultimately, substandard, counterfeit goods manufactured in China were sold to the U.S. Government to be worn or carried by Airmen in the U.S. Airforce. Some of these products lacked crucial safety features or failed to meet safety specifications, endangering the health and safety of the military personnel who wore them. At least 13,332 counterfeit jackets visible to night vision goggles and 18,597 non-flame-resistant hoods were among the counterfeit products that entered the military supply chain destined for U.S. Air Force bases around the world. Ramin Kohanbash pleaded guilty in June 2019 to conspiracy to commit wire fraud and trafficking in counterfeit goods. Kohanbash agreed to make restitution totaling \$750,000 to the individual companies victimized by his conduct, including a Rhode Island company that reported a loss of more than \$639,000 in profits and significant damage to its relationships with long-standing military clients due to the distribution of counterfeit products distributed by Kohanbash. A co-defendant in this matter, Bernard Klein of Brooklyn, was sentenced in April 2021 to eighteen months of incarceration to be followed by three years of federal supervised release; ordered to pay a fine of \$15,000; and to pay restitution in the amount of \$400,000. In tandem with the criminal case, Klein also entered into a civil settlement agreement under which he has paid \$348,000 to resolve liability to the United States under the federal False Claims Act for goods sold to certain government purchasers. A third defendant, Terry Roe of Burlington, ND pleaded guilty in February 2022 to conspiracy to commit wire fraud and traffic in counterfeit goods, and on October 20, 2022, Roe was sentenced to 24 months in federal prison. Roe, a now-former manager at a North Dakota supplier that purchased counterfeit clothing and gear from members of the conspiracy, acted as the point-of-contact with personnel at military Base Supply Centers. (RI, U.S. Defense Criminal Investigative Service, Northeast Field Office, General Services Administration Office of Inspector General, New England Regional Investigations Office, Army Criminal Investigation Division, Major Procurement Fraud Field Office, the U.S. Air Force Office of Special Investigations, Office of Procurement Fraud Detachment 6, Joint Base Andrews, MD, HSI, Newark, NJ, CBP, New York Field Office)

<https://www.justice.gov/usao-ri/pr/leader-conspiracy-manufacture-import-and-sell-counterfeit-military-clothing-and-gear>

<https://www.justice.gov/usao-ri/pr/final-defendant-conspiracy-manufacture-import-and-sell-counterfeit-military-clothing-and>

TRAFFICKING IN COUNTERFEIT PHARMACEUTICALS

- Ringleader Sentenced to 25 Years for Counterfeit Drug Trafficking Conspiracy.*** On September 18, 2023, Byron A. Marshall pleaded guilty to conspiracy, trafficking in counterfeit drugs, and money laundering conspiracy, and was sentenced to 300 months in federal prison. Tunji Campbell, who partnered with Marshall to hatch the scheme, was

sentenced to 135 months imprisonment. Cheryl A. Anderson pleaded guilty to conspiracy and was sentenced to 60 months imprisonment. According to the indictment, from April 2014 until August 2021, Marshall conspired with ten others including Adam P. Runsdorf, the owner and president of Woodfield Pharmaceutical LLC based in Boca Raton, FL. According to information presented in court, Marshall utilized Woodfield Pharmaceutical's manufacturing facility and employees in Houston to produce more than 500,000 pints of counterfeit cough syrup. Marshall's drug trafficking organization sold the counterfeit drugs 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. During the conspiracy, Marshall communicated directly with Runsdorf regarding production of the counterfeit cough syrup. At Runsdorf's request, Marshall paid Woodfield Pharmaceutical in cash only, and Woodfield employees mailed the cash directly to Runsdorf in Boca Raton. (EDTX, DEA, FBI, Organized Crime Drug Enforcement Task Forces, U.S. Food and Drug Administration (FDA) Office of Criminal Investigations, Internal Revenue Service-Criminal 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 Precinct #2, Brazoria County Sheriff's Office, Fort Bend County Sheriff's Office, Liberty County Sheriff's Office, the Texas National Guard)

<https://www.justice.gov/usao-edtx/pr/ringleader-sentenced-25-years-counterfeit-drug-trafficking-conspiracy>

TRADE SECRET THEFT (18 U.S.C. § 1832)

- ***Former Engineer Sentenced for Possessing Stolen Semiconductor Trade Secret.*** On June 1, 2023, a Lexington, MA man was sentenced in Boston federal court for possessing the stolen prototype design of a microchip, known as the HMC1022A, which was owned and developed by his former employer, Analog Devices, Inc. (ADI), a semiconductor company headquartered in Wilmington, MA. This chip is used in both aerospace and defense applications. Haoyang Yu was sentenced to six months in prison to be followed by three years of supervised release, during which he may not work in the microchip industry. Yu was also ordered to pay a fine of \$55,000 and restitution to be determined at a later date. In May 2022, following a month-long trial, a federal jury convicted Yu of possessing ADI's stolen trade secret. The jury acquitted Yu of alleging possession of other stolen trade secrets, wire fraud, immigration fraud, and the illegal export of controlled technology. Between 2014 and 2017, Yu worked at ADI, where he designed microchips used by the communications, defense, and aerospace industries. Through his employment, Yu had access to various kinds of ADI intellectual property, including present and future microchip designs, schematics, layouts, modeling files, customer lists, and ordering histories. While employed at ADI, Yu used this information to start his own microchip business, Tricon MMIC, LLC. Forensic analysis later showed that Yu's personal, at-home computer held exact, bit-for-bit copies of hundreds of ADI intellectual property files. Trial evidence showed that Yu had accessed these files on ADI's secure

servers, copied them, changed their filenames – often to those of cartoon characters, and then saved them on his personal electronic accounts and devices. Trial evidence showed that all of the chips Yu’s business sold were built with ADI’s stolen intellectual property. In particular, Yu used the stolen HMC1022A design to manufacture two knock-off versions of ADI’s chip. Yu then began selling his versions of the HMC1022A to ADI’s customers and others even before ADI went to market with its own completed design. In all, before his arrest, Yu manufactured about 10,000 chips built with stolen ADI property and grossed about \$235,000. ADI cooperated fully in the government’s investigation. (MA, Department of Commerce, Bureau of Industry and Security, Office of Export Enforcement, Boston Field Office; HSI; FBI; Naval Criminal Investigative Service, Northeast Field Office; CBP; Coast Guard Investigative Service; Defense Criminal Investigative Service; Massachusetts State Police; Lexington and Hingham Police Departments; NSD’s Counterintelligence and Export Control Section)
<https://www.justice.gov/usao-ma/pr/former-engineer-sentenced-possessing-stolen-semiconductor-trade-secret>

- ***Bixby Man Sentenced to Serve Five Years in Federal Prison for Conspiracy to Steal Trade Secrets from Oklahoma City Oil and Gas Company.*** On November 15, 2022, Joshua Decker of Bixby, OK, was sentenced to serve 60 months in federal prison for conspiracy to steal trade secrets. On May 26, 2021, the government filed a one-count Superseding Information charging Decker with conspiracy to steal, download, and possess trade secrets. According to the Superseding Information, Decker was a controller for the valve division of an oil and gas company that serves customers engaged in drilling and production. With its valve operations headquartered in Oklahoma City, the company manufactures compact manifold ball valves sold across the United States. In March 2017, while employed as the controller at the company, Decker registered with the Oklahoma Secretary of State a new company called Legacy Valve Systems (Legacy). He then recruited co-workers at the victim company to join him at Legacy. On June 2, 2021, Decker pleaded guilty to conspiracy to steal trade secrets. Decker admitted that the victim company undertook several measures to protect their information as trade secrets. Decker admitted that he, along with others, planned to take and use the drawings of the victim company’s valves to create products for Legacy. He also admitted that he possessed many of the drawings on his own laptop. Decker also admitted that he instructed those working with him to delete their communications about the drawings they took. At the sentencing hearing, Decker was sentenced to serve 60 months in federal prison for his conduct, followed by three years of supervised release. Decker was also ordered to pay a total of \$1,116,885.49 in restitution to the victim oil company. (WDOK, FBI)
<https://www.justice.gov/usao-wdok/pr/bixby-man-sentenced-serve-five-years-federal-prison-conspiracy-steal-trade-secrets>
- ***Engineer Sentenced to Federal Prison After Admitting Conspiracy to Steal Aircraft Design Secrets.*** On October 20, 2022, a South Carolina man who led a conspiracy to steal trade secrets from aircraft companies was sentenced to nearly seven years in prison. Gilbert Basaldua, of Hilton Head, SC, was sentenced to 80 months in prison after previously pleading guilty to Conspiracy to Steal Trade Secrets and Interstate

Transportation of Stolen Property. Basaldua was also ordered to serve three years of supervised release after completion of his prison term. As spelled out in court documents and testimony, Basaldua worked as a numerical control engineer contractor for an aircraft manufacturer from October 2016 through November 2018. During that time, Basaldua conspired with his co-conspirators to steal valuable proprietary aircraft wing designs and anti-icing testing information from various aircraft manufacturers, including the company where Basaldua worked. The conspirators intended to use the stolen information to accelerate the process of obtaining Federal Aviation Administration certification for another company's product. Basaldua was on trial on the charges in September 2021 when he pleaded guilty during the second day of testimony. (SDGA, FBI)

<https://www.justice.gov/usao-sdga/pr/engineer-sentenced-federal-prison-after-admitting-conspiracy-steal-aircraft-design>

ECONOMIC ESPIONAGE (18 U.S.C. § 1831)

- ***Former GE Power Engineer Sentenced for Conspiracy to Commit Economic Espionage.*** On January 3, 2023, a New York man was sentenced to 24 months in prison for conspiring to steal General Electric (GE) trade secrets, knowing or intending to benefit the People's Republic of China (PRC). Xiaoqing Zheng of Niskayuna, NY, was convicted of conspiracy to commit economic espionage, following a four-week jury trial that ended on March 31, 2022. According to court documents, Zheng was employed at GE Power in Schenectady, NY, as an engineer specializing in turbine 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 ground-based and aviation-based turbine technologies, knowing or intending to benefit the PRC and one or more foreign instrumentalities, including China-based companies and universities that research, develop, and manufacture parts for turbines. Zheng was also sentenced to pay a \$7,500 fine and serve one year of post-imprisonment supervised release. (NDNY, NSD, FBI, HSI)
<https://www.justice.gov/opa/pr/former-ge-power-engineer-sentenced-conspiracy-commit-economic-espionage>
- ***Chinese Government Intelligence Officer Sentenced to 20 Years in Prison for Espionage Crimes, Attempting to Steal Trade Secrets from Cincinnati Company.*** On November 16, 2022, the first Chinese government intelligence officer ever to be extradited to the United States to stand trial was sentenced in federal court in Cincinnati, OH. Yanjun Xu was sentenced to 20 years in prison. Xu targeted American aviation companies, recruited employees to travel to China, and solicited their proprietary information, all on behalf of China. On November 5, 2021, a federal jury in Cincinnati convicted Xu on all counts: conspiracy to commit economic espionage, conspiracy to commit trade secret theft, attempted economic espionage and attempted trade secret theft. Xu was a career intelligence officer, beginning in 2003 and rising to the rank of deputy division director at the Chinese Ministry of State Security (MSS), 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. Xu used aliases, front companies, and universities to deceive aviation employees and solicit information. 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 in addition to covering travel costs. The scheme was executed with full coordination between the MSS and China's aviation entities. Xu worked with others in the MSS to hack or copy computers in hotel rooms while the aviation employees – his “guests” – were taken to dinner by the MSS. Xu also openly talked about efforts to obtain U.S. military information in addition to commercial aviation trade secrets. The evidence at trial showed Xu recruited insiders within a French aircraft engine manufacturer's facility in China who were willing to spy on Xu's behalf. Xu and his assets targeted a French employee of the company that often traveled to the facility in China for work. In 2013, Xu directed one of his assets within the company to plant malware on the French employee's work computer, with the ultimate goal of being able to infiltrate the company's network in France. The evidence at trial also showed Xu's integral role in the installation of the malware, his instructions to destroy the malware, and Xu's monitoring of the success and cover-up of the operation. (SDOH, NSD's CES, OIA, NDIL, AZ)
<https://www.justice.gov/usao-sdoh/pr/chinese-government-intelligence-officer-sentenced-20-years-prison-espionage-crimes>

ALTERNATIVE CHARGES

CUSTOMS VIOLATIONS (18 USC §§ 542, 545)

- ***Phoenix Man Sentenced for Importing Counterfeit N95 Masks from Asia.*** On December 21, 2022, Mark Forrest Cohn was sentenced to one year of probation and ordered to pay restitution, to include \$8,028 in unpaid taxes and tariffs to CBP. Cohn pleaded guilty to one felony count of Entry of Goods by Means of False Statements. On October 29, 2020, Cohn fraudulently imported counterfeit 3M manufactured N95 masks into the United States from China using shipping labels and papers that falsely represented the merchandise. The false representations disguised the merchandise as goods not subject to duties and inspection by the FDA. Once the shipment arrived at a Phoenix mail facility, a box imported by Custom Glass and Synthetic was targeted for inspection as part of an enforcement operation conducted by Homeland Security Investigations (HSI) and CBP's Office of Field Operations officers. When the box was opened, HSI and CBP officers found masks branded as 3M with pixelated photos on the packaging. Working together, HSI and CBP officers scanned and transmitted images of the shipment of purported N95 masks to 3M. On November 3, 2020, 3M advised the N95 masks were in fact counterfeit. Counterfeits create risks to the user because the seals can be ill-fitting and the masks less effective. On November 23, 2020, Department of Veterans Affairs Office of Inspector General agents and a 3M representative inspected the masks located at a Veterans Affairs Medical Center (VAMC) warehouse in Minneapolis, Minnesota. The counterfeit masks were identified and seized before they made their way to front line workers. The N95 mask is designed for health care workers as the fit and seal minimize the transference of COVID. Cohn sold over 20,000 masks to

a third-party vendor that supplied equipment to the VAMC warehouse in Minnesota. The third-party vendor did not know that the masks were counterfeit. (AZ, HSI, CBP, Department of Veterans Affairs)

<https://www.justice.gov/usao-az/pr/phoenix-man-sentenced-importing-counterfeit-n95-masks-asia>

TITLE 21 NARCOTICS VIOLATIONS

- ***Ohio Man Sentenced for Wheeling Traffic Stop that Yielded Counterfeit Fentanyl Pills, Methamphetamine.*** On May 3, 2023, a Thornville, OH man was sentenced to nine years in prison for having a large amount of methamphetamine on Wheeling Island. Christopher W. Thomas pleaded guilty to a possession with intent to distribute charge in May 2022. During a traffic stop of Thomas's vehicle, officers found 79 grams of methamphetamine and more than 240 grams of fentanyl, some of which was in the form of counterfeit Xanax pills. Thomas also had other items to manufacture the pills, including a metal pill press with hydraulic jack, cutting agents and a portable mixer. Officers also recovered a loaded 9mm pistol, a box of ammunition, and nearly \$5,000 in cash. (NDWV, The Marshall County Drug Task Force, West Virginia State Police, ATF) <https://www.justice.gov/usao-ndwv/pr/ohio-man-sentenced-wheeling-traffic-stop-yielded-counterfeit-fentanyl-pills>
- ***Cumberland Man Sentenced to Ten Years in Federal Prison in Largest Counterfeit Pill Seizure.*** On February 23, 2023, Dylan Rodas, who admitted to possessing approximately 665,728 methamphetamine-laced counterfeit Adderall pills, the largest known seizure of its kind in the country, was sentenced to ten years in federal prison. At the time of his arrest, Rodas immediately provided Drug Enforcement Administration (DEA) agents with information about his drug trafficking activities, including the location where he packaged and stored narcotics and that he was in possession of a number of firearms, assorted ammunition and other illegal substance. Upon searching this location, agents seized approximately 665,728 methamphetamine-laced counterfeit Adderall pills, weighing a total of approximately 660 pounds; approximately eleven kilograms of methamphetamine powder; fake Oxycodone fentanyl-laced pills; two motorized pill presses; 250 grams of cocaine; \$15,000 in cash; and seven handguns, including two "ghost guns." (RI, DEA) <https://www.justice.gov/usao-ri/pr/cumberland-man-sentenced-ten-years-federal-prison-largest-counterfeit-pill-seizure>
- ***Drug Dealer Sentenced to 78 Months for Conspiracy to Distribute Approximately 90,000 Counterfeit Pills Containing Fentanyl.*** In early February 2023, Eduardo Flores-Diaz was sentenced to 78 months in prison. Flores-Diaz pleaded guilty to Conspiracy to Possess with Intent to Distribute Fentanyl. In April 2022, Flores-Diaz, traveled from Tucson, AZ, with three co-conspirators. The conspirators were subsequently stopped in Scottsdale, AZ, by federal agents and troopers from the Arizona Department of Public Safety (DPS), during a buy/bust operation. Approximately 90,000 counterfeit oxycodone pills containing fentanyl were discovered in their possession. (AZ, HSI, ATF, Arizona Department of Public Safety)

<https://www.justice.gov/usao-az/pr/drug-dealer-sentenced-78-months-conspiracy-distribute-approximately-90000-counterfeit>

- ***Las Vegas Man Sentenced to Prison For Distributing Fentanyl-Laced Counterfeit Pills.*** On November 29, 2022, Daniel Anguiano was sentenced to 10 years in prison for distributing counterfeit pills that contained fentanyl – a powerful synthetic opioid – that resulted in the overdose death of another person. Anguiano pleaded guilty in June 2021, to distribution of a controlled substance, specifically fentanyl and acetyl fentanyl. (NV, DEA)
<https://www.justice.gov/usao-nv/pr/las-vegas-man-sentenced-prison-distributing-fentanyl-laced-counterfeit-pills>
- ***Portland Man Sentenced to 10 Years in Federal Prison for Trafficking Large Quantities of Methamphetamine and Counterfeit Fentanyl Pills.*** On November 8, 2022, Jonathan James Lawson was sentenced to federal prison after he was found driving on Interstate 5 in Southern Oregon with more than ten pounds of methamphetamine, nearly three pounds of counterfeit pills containing fentanyl, and two firearms. He was sentenced to 120 months in federal prison and five years’ supervised release. According to court documents, on March 6, 2021, law enforcement learned Lawson was traveling from Southern California to Josephine County, Oregon with a large quantity of drugs. The next day, law enforcement spotted Lawson driving northbound on Interstate 5 near Grants Pass, Oregon and conducted a traffic stop. Inside Lawson’s vehicle, officers located a large tool case containing approximately ten pounds of methamphetamine, 700 grams of counterfeit pills containing fentanyl, body armor, and a revolver. Officers located an additional 480 grams of fentanyl pills, ammunition, drug paraphernalia, and a second firearm elsewhere in the vehicle. On May 4, 2021, Lawson was charged by criminal complaint with possessing with intent to distribute controlled substances and possessing a firearm in furtherance of a drug trafficking crime. Later, on March 15, 2022, Lawson was charged by criminal information with possessing with intent to distribute methamphetamine. On May 9, 2022, he pleaded guilty to the single charge. (USAOR, ATF, the Rogue Area Drug Enforcement (RADE) task force, Grants Pass Police Department, Oregon State Police)
<https://www.justice.gov/usao-or/pr/portland-man-sentenced-10-years-federal-prison-trafficking-large-quantities>
- ***23 Individuals Charged With Trafficking Counterfeit Prescription Pills.*** On October 26, 2022, twenty-three individuals in Massachusetts were charged in connection with a North Shore-based drug trafficking organization (DTO) that allegedly manufactured and distributed tens of thousands of counterfeit prescription pills containing narcotics. The defendants were charged with conspiracy to possess with intent to distribute and to distribute controlled substances. According to the charging documents, in 2018, law enforcement identified brothers Lawrence Michael Nagle and Christopher Nagle as leaders of a DTO distributing various controlled substances throughout the North Shore region of Massachusetts. It is alleged that the Nagle DTO distributed significant quantities of various controlled substances, including, Adderall both pharmaceutical-grade pills and counterfeit pills containing methamphetamine), methamphetamine,

Xanax, Oxycodone (both pharmaceutical-grade and counterfeit pills containing fentanyl), cocaine and marijuana, among others. The Nagle DTO allegedly distributed controlled substances to a small network of individuals who would then redistribute the drugs to other traffickers, including separate, but interconnected, organizations headed by Nelson Mora, Javier Bello and Anthony Bryson. It is alleged that Mora, Bello, and Bryson obtained their drug supply from other sources at times and that Mora and Bryson had access to pill press machines used to create counterfeit pills. The investigation resulted in numerous seizures of controlled substances, including: over 74,000 counterfeit Adderall pills containing methamphetamine, weighing more than 24 kilograms; 591 counterfeit Adderall pills containing methamphetamine; 1,000 counterfeit Oxycodone pills containing fentanyl; and 101 counterfeit Oxycodone pills containing fentanyl. Three defendants, Erick Solis Lopez, Melvin Nieves, and Justin Westmoreland have been sentenced following guilty pleas. Lopez was sentenced on January 25, 2024, for 62 months imprisonment followed by 3 years supervised release. Nieves was sentenced on January 22, 2024, to 27 months imprisonment followed by 3 years supervised release. Westmoreland was sentenced on September 26, 2023, to 57 months imprisonment followed by 3 years supervised release. Defendant Savannah Lee Bartone’s sentencing is set for May 6, 2024. (MA, OCDEFT, State/Local LE)
<https://www.justice.gov/usao-ma/pr/23-individuals-charged-trafficking-counterfeit-prescription-pills>

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

Interagency Initiatives

In March 2023, consistent with President Biden’s Executive Order on Promoting Competition,¹² the Antitrust Division began participating in an interagency working group, along with the U.S. Patent and Trademark Office (USPTO), United States Department of Agriculture (USDA), and the Federal Trade Commission (FTC) to discuss ways to protect competition and prevent anticompetitive licensing practices in agricultural products including seeds. Following the first working group meeting, Assistant Attorney General Kanter stated that “Protecting competition and the rule of law in agricultural markets – including in seeds – is core to the work of the Antitrust Division . . . The Antitrust Division is committed to ensuring that anticompetitive practices do not diminish those benefits or lead to undue market concentration or unlawful monopolies in these critical agricultural markets. We are grateful for the leadership of our partners at USDA on this issue, and look forward to working with FTC, USDA, and USPTO to enforce the antitrust laws and protect farmers.”¹³

¹² Executive Order 14036 on “Promoting Competition in the American Economy” (July 9, 2021) at <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/> and <https://www.govinfo.gov/content/pkg/FR-2021-07-14/pdf/2021-15069.pdf>.

¹³ [USDA Launches Interagency Working Group on Competition and Intellectual Property in Seeds | Agricultural Marketing Service](#) (March 23, 2023).

In addition, the Antitrust Division has submitted two public comments in support of the USPTO's efforts to expand access to the patent bar and improve patent quality, which, as the Division's comments explain, have the potential to promote competition and enhance consumer choice.¹⁴

International Advocacy

The Antitrust Division engaged in international competition advocacy and technical assistance to promote the application of sound competition principles to cases involving IP rights. This advocacy takes place in multinational fora, such as the Organization for Economic Cooperation and Development (OECD), as well as on a bilateral basis with antitrust enforcement counterparts in jurisdictions such as Canada, China, the European Union, India, Japan, and Korea, and the United Kingdom. During this fiscal year, the Antitrust Division worked collaboratively with other enforcers to contribute to the OECD's revised principles for competition enforcement involving intellectual property rights.¹⁵

¹⁴ [Comment of the Antitrust Division in Docket No. PTO-P-2022-0027-001, PTO-P-2022-0032-0001 \(Jan. 31, 2023\)](#); [Comment of the Antitrust Division in Docket No. PTO-P-2022-0025-0134 \(Feb. 28, 2023\)](#).

¹⁵ See [OECD Legal Instruments](#), Recommendation of the Council on Intellectual Property Rights and Competition (adopted July 6, 2023).

DEPARTMENT OF STATE

DEPARTMENT OF STATE

“So throughout this week, this group has heard from leaders across the U.S. Government on why the United States is the best place in the world to invest: our culture of innovation and entrepreneurship, driving new products and solutions at scale; a world-class system of universities and colleges, fueling ideas and fostering talent; our rule of law, protecting intellectual property, worker rights, fostering growth.”¹⁶

– Anthony J. Blinken, Secretary of State

“You need to protect ideas and you need to protect Intellectual Property, so that those that devote years of education and hard work, long days and long nights, physical exertion, mental focus, are incentivized to do so by having the ability to harvest the fruits of their efforts.

When ideas are protected in this way, you get more ideas. When ideas are protected in this way, you get better ideas. When ideas are protected in this way, you have ladders of opportunity that allows creators and innovators to climb – and to have the rest of their societies join with them.”¹⁷

– Ramin Toloui, Economic Bureau Assistant Secretary

Department of State Appendix for FY 2023 Annual Report

In FY 2023, 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

¹⁶ “Closing Remarks at the 2023 SelectUSA Investment Summit” (May 4, 2023) at <https://www.state.gov/secretary-antony-j-blinken-closing-remarks-at-the-2023-selectusa-investment-summit/>.

¹⁷ “Day One Closing Remarks at the U.S.-Africa Leaders Summit” (December 13, 2022) at <https://www.youtube.com/watch?v=kcdPDEWSGtc&t=26532s> (the Assistant Secretary’s closing remarks begin at the 7:22:00 mark; the quoted passage begins at the 7:27:28 mark).

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. Department of State 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) 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 vaccine allowed in-person work and travel throughout the fiscal year. The Department of State operated under a hybrid telework/in-person status as health conditions improved. Based on local geographic conditions, the Department of State maintained the 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 2023.

Argentina: Embassy Buenos Aires celebrated National Entrepreneurship Month in November 2022. Highlights included an IP roadshow aimed at entrepreneurs, assessing the gender gap in the entrepreneurial ecosystem, and STEAM week engagement with a local university. Activities

helped advance post's Integrated Country Strategy goal of encouraging sustainable and inclusive economic growth, particularly in new economy areas that could help the country diversify. In December, U.S. and Argentine officials met for the seventh annual Innovation and Creativity for Economic Development Forum (ICED Forum). The continued interest by the Argentine government to hold the Forum and the participation of a broad array of ministries demonstrated engagement on mutual concerns in IP protection. Argentine officials were interested in cooperation with the U.S. on improving public outreach and awareness campaigns, best practices in interagency cooperation and working with the private sector, technical trainings for police investigators and customs personnel, and trainings for prosecutors and judges.

Canada: IP experts from Canada, Taiwan, and the United States shared concerns and advice for Canadian businesses operating in the Chinese market during a hybrid panel presentation organized by the Taipei Economic and Cultural Office (TECO) and U.S. Consulate General Vancouver. This IP panel supported the Department's policy to advance a substantive relationship with Taiwan through regular meetings and by collaborating with TECO on activities akin to those administered through the Global Cooperation and Training Framework. The panel helped advance goals of the Mission's Integrated Country Strategy to improve North American competitiveness and provide a platform for the Canadian public to better understand U.S. policies.

Honduras: Embassy Tegucigalpa hosted a meeting with several IP offices in the Honduran government to discuss Honduras' mention in this year's Special 301 Report and agreed to setup a regular working group to address these issues. To advance and improve Honduras' capacity to enforce IPR, Embassy Tegucigalpa worked closely with USPTO to develop and deliver a series of five virtual training sessions for over 70 Government of Honduras officials, including court officials and prosecutors, on IPR infringement and enforcement. The embassy has also actively nominated relevant Government of Honduras officials to participate in in-person trainings throughout the region and in Washington D.C.

Portugal: Embassy Lisbon leveraged the Regional China Officer program to invite a research security expert from Georgetown University's Center for Security and Emerging Technology (CSET) who engaged with researchers, university students, and government officials. The subject matter expert emphasized PRC scientific collaboration must be viewed in the context of the autocratic system in which it sits and the PRC's technology transfer tools that invalidate foreign patents and other intellectual property rights. They underscored that governments and academics must enter PRC research collaboration with their "eyes wide open" and offered CSET's free Mandarin translation services and data sets to "demystify due diligence" before working with the PRC.

Sweden: Seven representatives from leading Swedish universities participated in a Public Diplomacy initiated study tour focused on "Academic Integrity and National Security". The program focused on how U.S. universities and institutions establish standards and guidelines to counter foreign interference in academic research and prevent intellectual property theft and forced technology transfer. The group met with universities in Washington, D.C., and Boston; Department of State offices including STAS and OES; the U.S. Patent and Trademark Office; and DHS' National Intellectual Property Rights Coordination Center. Participants praised the

timeliness of the study tour, noted that several of their universities were currently working on new strategies, and observed that U.S. institutions had faced similar issues and were in the process of developing measures to protect national security.

Vietnam: Organized by the USPTO in partnership with the Ministry of Science and Technology (MOST), the Ambassador’s Roundtable in Hanoi and the Consul General’s Roundtable in Ho Chi Minh City brought together government and industry representatives during the week of September 26 to underline the important role IPR protection and enforcement plays in driving economic growth, particularly in the digital economy. In addition to remarks by Ambassador Knapper, the Hanoi roundtable featured representation at the Vice Minister level from MOST, the Supreme People’s Procuracy, and the Ministry of Culture, Sports, and Tourism, as well as a representative from the Ministry of Public Security’s cybersecurity division. In Ho Chi Minh City, the roundtable gathered 80 judges, law enforcement officers, legal experts, and brand owners from across southern Vietnam, as well representatives from MOST and the Directorate of Market Surveillance (DMS). The speakers drew connections between IPR protection and incentivizing creativity and innovation, as well as protecting consumers and fighting organized crime. Industry-led panels on digital content piracy and online sales of counterfeit goods discussed regional trends in copyright and trademark infringement and highlighted private sector efforts to protect IPR.

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.

This year WIPO’s theme was “Women and IP: Accelerating Innovation and Creativity.” IPE, in collaboration with the Office of Economic Policy Analysis and Public Diplomacy (EPPD) awarded funding to two posts, Luanda and Vientiane. The funding supported their World IP Day programming efforts featuring two workshops. The first workshop brought together key Angolan IP representatives, Angolan National Union of Artists & Composers, and women trademark and patent holders who offered their expertise and discussed why it is important for creators to protect their ideas within a legal framework. The second was an exchange workshop for artisans and designers in Laos which connect rural and urban creators to promote ethical and cultural collaboration while highlighting IP protections in Laos. Many other posts around the world also engaged in their own post-funded roundtable discussions, IP-focused speaker series programs, and other large scale social media campaigns to celebrate World IP Day. Back in Washington, Department of State’s IPE organized a special podcast in collaboration with the Secretary’s Office of Global Women’s Issues on Women and IP Protection as it relates to climate change and the advances that women are making in order to safeguard our planet. The IPE Director delivered a World IP Day video message and Diplomatic Note Blog highlighted on the Department’s public facing website. IPE, in collaboration with the Foreign Press Center team, also organized a tour of the National IPR Center for Foreign Press Center journalists. 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 Department of State also marked World IP Day by engaging in a wide range of activities around the world, which included the following:

Costa Rica: The State/INL funded DOJ ICHIP based in São Paulo provided keynote remarks at a conference on criminal and customs enforcement of IP rights. The event, the first of its kind in seeking to increase cooperation between private sector rightsholders and prosecutors and customs officials, was held to celebrate this year's World IP Day. The ICHIP focused on the importance of IP in the economy, and U.S. anti-counterfeiting efforts, and stressed rightsholders support throughout criminal investigation as a necessary component of IPR enforcement. The ICHIP also met with representatives of the Costa Rica Attorney General's Office, criminal investigators and the Finance Ministry's fiscal police to discuss the importance of large-scale criminal IP cases.

Honduras: Embassy Tegucigalpa's Deputy Chief of Mission (DCM) participated in a World IP Day event hosted by the American Chamber of Commerce. Speaking to over 50 attendees, the DCM highlighted the importance of IP, encouraged young Honduran inventors and artists, particularly women, to utilize IP protections, and raised concerns about IP protection in Honduras.

Mexico: Embassy Mexico City, together with the USPTO IP Attaché, had two activities for World IP Day. USPTO co-hosted a program with Mexican Institute of Industrial Property, AmCham Mexico IP Committee, and innovation think tank Center for Analysis for Innovation Research (CAIINNO) to highlight two women in the innovation space. The program was directed towards university students throughout Mexico. U.S. Embassy Mexico hosted a social media campaign titled "The Value of Her IP" – highlighting a women photographer that started her own business.

Pakistan: Embassy Islamabad, in collaboration with the USPTO, marked 2023 World IP Day with a women empowerment-focused IPR panel event and IPR best practices knowledge sharing with officials from Pakistan's Patent and Design Office and Federal Bureau of Revenue.

Panama: Embassy Panama City celebrated World IP Day with a social media campaign and an in-person event held at the Panama American Center (PAC) in Panama's City of Knowledge - an incubator for innovation among Panamanian businesses, scientists, thinkers, artists, and community leaders. Public Affairs and Economic officers worked closely with to craft materials for release on social media that highlighted the success of the event. The campaign reached nearly 5,000 people on Instagram, 3,000 people on Twitter, and 6,000 people on Facebook. Presenters spoke during a workshop about Panama's IPR legal framework, how women could use IPR tools to close the gender gap, and the impact of artificial intelligence on IPR both in Panama and globally. A moderated panel discussion with three women entrepreneurs who founded tech startups in Panama was another highlight. Attendees reported that the event was both practical and motivational, and expressed a demand for future programs on similar topics at the PAC. Both Post and the PAC promoted World IP Day the following

month, continuing to advocate for the strong protection of IPR in Panama. They also stressed the importance of IP as a tool for creative and innovative entrepreneurs to build their businesses and close the digital divide between women and men.

Peru: Embassy Lima’s IP Attaché Office organized three successful events surrounding World IP Day. The IP Attaché Office worked together with Embassy Lima’s Public Affairs Section (PAS) to co-sponsor a comics workshop targeted at young creators with the municipality of Lima. A prominent Peruvian artist and writer led a workshop to teach over 70 Peruvian children and teenagers how to draw comics. The IP Attaché gave a presentation on key copyright concepts in Peru, including how to protect intellectual creations. The office also sponsored a WIPD event with the Peruvian judiciary titled, “Women and IP: Accelerating Innovation and Creativity” for nearly 100 participants. A Peruvian Supreme Court Justice provided opening remarks, while a former Supreme Court Justice gave a presentation on WIPO recommendations for gender equality. The IP Attaché shared information on the resources that the USPTO provides to help close the gender gap in intellectual property and presented guests with a Spanish translation of a U.S. manual on prosecuting IP crimes. Finally, Embassy Lima’s WIPD-related social media campaign celebrated artists who brought local music to the global stage. The four social media posts attracted over 110k impressions on Facebook and a reel on Instagram that reached over 7,000 accounts.

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.

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, Department of State regional and functional bureaus, and interagency partners on the range of U.S. government technology transfer and capacity building activities around the world. IPE prepares the Article 66.2 Report annually, and USTR submits the Report to the WTO TRIPS Council. 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 2023 on proposals related to the COVID-19 pandemic response, including continuing discussions on whether to extend the Ministerial Decision on the TRIPS Agreement to COVID-19 diagnostics and therapeutics. In December 2022, USTR requested the USITC conduct an investigation into COVID-19 diagnostics and therapeutics and provide information on market dynamics to help inform the discussion around the supply and demand, price points, the relationship between testing and treating, and production and access. The USITC published its report in October 2023. IPE oversaw the Department of State’s response to inquiries on U.S. policy, including by supporting and coordinating with U.S. embassies and consulates around the world. IPE continues to provide input to USTR and the broader U.S. Government IP interagency regarding WTO TRIPS Council issues.

Other activities that the Department of State participated in during FY 2023 include the following:

OECD Task Force on Countering Illicit Trade

Department of State’s IPE leads the U.S. delegation to the OECD Working Party on Countering Illicit Trade (WP-CIT). In March 2023, IPE’s Director led the U.S. Delegation to the WP-CIT plenary meeting. The United States communicated with private and public sector stakeholders on methods to enhance international collaboration in combating illegal activities that undermine the integrity of global supply chains, supporting legitimate commerce and trade. There was a particular highlight of activities harmful to public health and safety, including COVID-19 related fraud. The United States discussed its whole-of-government approach to countering illicit trade and reiterated its support for the OECD Free Trade Zone Certification Scheme. WP-CIT was formerly the Task Force on Countering Illicit Trade (TF-CIT).

Investment Climate Statements

Every year, Economic Officers at U.S. embassies and other diplomatic missions abroad prepare Investment Climate Statement (ICS) Reports 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’s market and includes a chapter on IP. These ICS Reports also form a chapter of the Department of Commerce’s Country Commercial Guides and together form a broad description of the investment and business environments in foreign economies. The Department of State continues to work with the Department of Commerce to further align the complementary Statements and Guides for a more unified experience for the end user.

Interagency Policy Cooperation

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, U.S. embassies and consulates 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.

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; São Paulo, Brazil; Bucharest, Romania; Dar es Salaam, Tanzania; Bangkok, Thailand; and Kuala Lumpur, Malaysia. In addition, two ICHIPs are deployed out of Washington, DC, to specifically address darkweb/cryptocurrency and internet fraud and public health-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 Department of State. For example, at the ICHIP Industry Forum for IP Rights Protection on December 7, 2023 INL Acting Deputy Assistant Secretary Margaret Nardi said: *“The GLEN and its ICHIPs demonstrates how the State Department and DOJ can adapt and evolve new responses to the challenges of transnational crime threats that are fluid, borderless and take full advantage of emerging technologies. It is also a wonderful example of the indispensable partnership between the Justice and State Departments to address the broader range of criminal threats internationally.”*

To deliver foreign law enforcement training and technical assistance to complement the work of the GLEN, INL also provides funding to the National Intellectual Property Rights Coordination Center (IPR Center) of the U.S. Department of Homeland Security, U.S. Immigration and Customs Enforcement’s Office of Homeland Security Investigations (DHS ICE/HSI). DHS-delivered workshops ensure that patent and trademark agencies and foreign border and customs agencies receive IP enforcement capacity building tailored to their missions. DHS 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 organized several workshops and trainings to elevate IP issues among Romanian law enforcement, judges, and prosecutors. In April, the ICHIP Bucharest delivered an IP-themed, virtual training for Romanian prosecutors and judges, as part of the Romanian National Institute of Magistracy’s continuing legal education curriculum. Speakers detailed Romania’s criminal legal framework with respect to copyright, as well as the current ways that counterfeit goods make their way through Romania. In June, 2023, the ICHIP delivered a regional, sports-themed digital piracy/physical goods workshop at the Romanian Football Federation’s House of Football in Bucharest. Prosecutors, law enforcement, and judges from multiple countries in Eastern Europe gathered to participate in the program, which included speakers from major sports leagues around the globe. In October, 2022, the ICHIP brought a delegation of 12 Romanian government officials to Washington, D.C. for a study tour. The delegation met with, among others, Assistant Attorney General

Polite, CCIPS, FBI, USPTO, USTR, INL, OPDAT, and IPEC. In late October and early November 2022, the ICHIP participated with CBP and the Defense Threat Reduction Agency (DTRA) in an assessment of Romania's northwestern border areas.

- The ICHIP Latin America and the Caribbean offices kitted out numerous teams of law enforcement, prosecution and private rightsholders in the leadup to the 2022 World Cup with essential skills and techniques needed to tackle sports-related IPR theft, including digital piracy in the live event arena. The INL-funded ICHIP, based in Consulate General São Paulo, Brazil, with the support of the USPTO IP Attaché Office for Mercosur, French Guiana, Guiana, and Suriname, based in Rio de Janeiro, Brazil, provided skills training programs, including a two-day Sports and IPR training in October 2022.
- On November 7 and 8, 2022, the ICHIP São Paulo provided a two-day in-person course in to approximately 40 members of the Brazilian Federal Judiciary, prosecutors, and police on best practices in tracing and seizing cryptocurrency. The audience included members of the National Council on the Judiciary and investigating judges for the Supremo Tribunal da Justiça and the Supremo Tribunal Federal and a special committee of judges representing each federal appellate district that focused on analyzing the judicial approach to cryptocurrency. The training featured U.S. District Judge Virginia Covington (Middle District of Florida), members of the DOJ's National Cryptocurrency Enforcement Team, Internal Revenue Service-Criminal Investigations (IRS-CI), and FBI's primary response teams on virtual currency.
- In November 2022, Brazil completed accession to become the 68th state party to the Budapest Convention on Cybercrime. At the request of the Government of Brazil, GLEN, the Bureau of Cyberspace and Digital Policy (CDP) and INL worked extensively with the Brazilian government through both diplomatic engagement and capacity building initiatives to assist Brazil in completing accession to Budapest. INL also launched a new \$1 million Southern Cone Cybercrime project led by the United Nations Office on Drugs and Crime (UNODC) to provide additional technical assistance. Brazil also participates in the White House Counter-Ransomware Initiative and in the DOJ ICHIP-led Regional Cryptocurrency Working Group for the Western Hemisphere.

In addition, in FY 2023, IPE coordinated the IP training programs that multiple federal agencies conduct overseas to ensure they're generating meaningful results. 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 2023, IPE partnered with USPTO's Global IP Academy (GIPA), the IPR Center, and CBP to provide a three-day in-person training course on IP issues for U.S. government officials. Participants included U.S. foreign service officer diplomats preparing for onward assignments domestically or overseas, civil servants, and locally employed staff of U.S. overseas diplomatic posts. Experts and stakeholders briefed attendees on IP fundamentals, current IP 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 foreign service officers, 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 THE TREASURY

DEPARTMENT OF THE TREASURY

Department of the Treasury Appendix for FY 2023 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 the Department of Homeland Security (DHS) and is carried out by Customs and Border Protection (CBP) and Immigration and Customs Enforcement (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 (E.O.) of September 15, 2022 ensures, among other things, the robust consideration by CFIUS of risks associated with foreign investment in U.S. businesses involved 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 to review certain transactions, including non-controlling investments by foreign persons in U.S. businesses that produce, design, test, manufacture, fabricate, or develop critical technologies, and this review may consider aspects of a technology's underlying intellectual property.

Transaction parties are required to file a declaration or notice with CFIUS for certain transactions involving a U.S. business that produces, designs, tests, manufactures, fabricates, or develops one or more critical technologies if 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 CFIUS regulations define critical technology by referencing 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 the 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 E.O. 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 E.O. 13694, as amended by E.O. 13757. The E.O. 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://ofac.treasury.gov/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

“Innovation and creativity are at the heart of American competitiveness. That is why the Biden-Harris Administration’s new story on trade includes lifting up the 60 million jobs and workers in our IP-intensive industries through robust IP protection and enforcement in foreign countries.”¹⁸

– Ambassador Katherine Tai, U.S. Trade Representative

Office of the U.S. Trade Representative Appendix for FY 2023 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.

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

¹⁸ USTR press release, “USTR Releases 2023 Special 301 Report on Intellectual Property Protection and Enforcement” (April 26, 2023), at <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2023/april/ustr-releases-2023-special-301-report-intellectual-property-protection-and-enforcement>.

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 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 supports 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.¹⁹

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 2023, the U.S. continued to engage with Free Trade Agreement (FTA) partners (including Bahrain, Chile, Colombia, Costa Rica, Dominican Republic, Korea, and Morocco) 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 2023 Special 301 Report in April 2023. (The 2023 Report is at <https://ustr.gov/sites/default/files/2023-04/2023%20Special%20301%20Report.pdf>, and the related press release is at <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2023/april/ustr-releases-2023-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 or pressured technology transfer policies that may unfairly disadvantage U.S. right holders in markets abroad; and (e) other ongoing, systemic issues regarding IP protection and enforcement, as well as market access, in many trading partners around the world. Combatting such unfair trade policies will encourage domestic investment in the United States,

¹⁹ 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 right holders to address counterfeiting and piracy. Several markets have also ceased operations or have been the focus of government enforcement efforts.

The 2022 Notorious Markets List was issued in January 2023. (The NML is at [https://ustr.gov/sites/default/files/2023-01/2022%20Notorious%20Markets%20List%20\(final\).pdf](https://ustr.gov/sites/default/files/2023-01/2022%20Notorious%20Markets%20List%20(final).pdf), and the related press release is at <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2023/january/ustr-releases-2022-review-notorious-markets-counterfeiting-and-piracy>.) The 2022 NML includes an Issue Focus section that examines the impact of online piracy on U.S. workers.

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 2023, the United States advanced its IP and Innovation agenda in the TRIPS Council by focusing on cross-border intellectual property cooperation and collaboration. The United States is working with WTO Members including Australia; Canada; Chile; Chinese Taipei; the European Union; Japan; Hong Kong, China; 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 fora during FY 2023, including the Organisation for Economic Co-operation and Development (OECD), World Intellectual Property Organization (WIPO), Asia-Pacific Economic Cooperation (APEC) forum, and various U.N. bodies.

In 2023, the United States hosted the Asia-Pacific Economic Cooperation (APEC) with a host year theme of “Creating a Resilient and Sustainable Future for All.” 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 organized workshops on the margins of the IPEG Meeting. The “Roundtable on Copyright and Creativity in the Digital Economy” provided diverse perspectives from independent creators, producers, and union workers on the importance of copyright protection and enforcement for promoting inclusive growth for individuals and small and medium-sized enterprises (SMEs) in the creative industries. The “Workshop on Geographical Indications and Preservation of Common Names” fostered a dialogue on inclusive trade by featuring SME producers and other stakeholders who spoke about the economic benefits of preserving the use of common names and the problems they encounter when common names are not preserved. The United States, which continues to lead an initiative on industrial design protection, also organized a workshop on “Leveraging Industrial Design Protections for Small-and-Medium Sized Enterprises,” which highlighted industrial design protection as 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. The United States also organized a “Green Technology One Day Program,” bringing together policymakers and individuals involved in the research, development, and commercialization of green technologies. With IPEG delegates, they discussed the importance of IP protection and enforcement as essential tools for their work and outlined issues associated with fostering a green economy.

Examples of Additional Areas of IP Rights Engagement

Trade and Investment Framework Agreements (TIFAs) and other similar arrangements between the United States and more than 50 trading partners and regions around the world have facilitated discussions on IP protection and enforcement.

For example, in December 2022, the United States-Argentina Innovation and Creativity Forum for Economic Development held its seventh meeting to discuss IP issues that are essential to the success of each country's innovation economy. Also, the United States and Egypt held a TIFA meeting in December 2022 and discussed the new National IP Strategy, as well as efforts to combat unlicensed content on satellite channels.

In January 2023, at the thirteenth Ministerial-level meeting of the United States-India Trade Policy Forum (TPF), India clarified certain aspects of its patent and trademark system reforms. Additional IP Working Group meetings under the TPF took place in February, August, and September, 2023. Also, a February 2023 United States-Pakistan TIFA Ministerial meeting included engagement on updates to Pakistan's IP laws and Pakistan's progress on joining IP treaties. In addition, an IP technical working group under the U.S.-Saudi Arabia TIFA met ahead of the March 2023 TIFA meeting to discuss private-public engagement on IP issues, enforcement best practices, and updates on Saudi Arabia's planned accession to several IP treaties.

In July 2023, the United States-Central Asia TIFA IP Working Group met to continue engagement on IP issues and help improve IP regimes in the Central Asia region. In September 2023, at the United States-Paraguay Trade and Investment Council meeting, Paraguay and the United States continued work on implementing the Intellectual Property Work Plan that serves as a roadmap to address issues on the protection and enforcement of intellectual property rights in Paraguay.

From July to September 2023, the United States engaged with the Dominican Republic to strengthen and better coordinate IP enforcement, support capacity building, and increase transparency across Dominican Republic agencies, to support the Dominican Republic's efforts to address concerns raised under the Special 301 Report. Other engagements include with Nepal and Indonesia in May 2023 and with Thailand and Sri Lanka in September 2023.

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.²⁰ In addition to requesting comments from the public and holding a public hearing on IP matters, IP trade policy figured heavily in USTR's broader stakeholder and Congressional outreach, including in a range of domestic and international fora.

²⁰ In 2023, 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.

UNITED STATES COPYRIGHT OFFICE

U.S. COPYRIGHT OFFICE

U.S. Copyright Office Appendix for FY 2023 Annual Report

This appendix summarizes some of the key enforcement-related activities taken by the United States Copyright Office during Fiscal Year 2023.

Overview

The U.S. Copyright Office continued to work on important public initiatives during FY 2023, including marking the one-year anniversary of the new Copyright Claims Board (CCB), announcing its Artificial Intelligence (AI) Initiative, completing several policy studies, conducting rulemakings to implement provisions of the Copyright Act, and continuing technological modernization of its services. The Office also provided legal and policy advice to Congress, the federal courts, and executive branch agencies on domestic and international copyright matters in addition to conducting expanded public outreach and education initiatives. Please visit <https://www.copyright.gov/> for more information on all of the Office's activities.

Copyright Claims Board

In December 2020, Congress directed the Copyright Office to establish the Copyright Claims Board (CCB) through the enactment of the Copyright Alternative in Small-Claims Enforcement Act of 2020 (CASE Act). As the first copyright small claims tribunal in the United States, the CCB is a voluntary, alternative forum to the federal courts for copyright disputes involving claims of up to \$30,000. The CCB began accepting claims on June 16, 2022. Through the CCB's 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.

The following are some of the CCB's key features:

- The CCB is accessible to anyone, with or without an attorney. CCB proceedings are intended 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 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:
 - claims of infringement of a copyright;
 - claims seeking declarations that specific activities do not infringe copyright; and

- 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. Statutory damages are also available, but are limited to \$15,000 for each work infringed.
- No injunctive relief is available. The CCB cannot award injunctive relief. However, a respondent can agree to stop the complained-of conduct, which agreement can be part of the final decision.

At its first-year anniversary on June 26, 2023, 485 claims had been filed with the Board. Of the three types of claims that can be brought before the CCB, claims for infringement were the most prevalent. The majority of claims involved pictorial, graphic, and sculptural works. Motion picture and audiovisual works, literary works, and sound recordings were also the subjects of claims. By June 2023, the CCB had issued to claimants approximately forty-five compliance notices and over forty orders to amend for noncompliance. Additional summary information on the first eighteen months of CCB activities is posted at <https://blogs.loc.gov/copyright/2023/11/checking-in-with-the-copyright-claims-board-nearly-eighteen-months-after-opening-day/>. For more information on the CCB, visit <https://www.ccb.gov/>.

Initiative on Copyright and Artificial Intelligence

Going back decades, the Copyright Office has considered the copyright status of machine-generated works. More recently, the rapid development of AI systems has resulted in significant public attention on the copyright implications of generative AI. In a December 2022 letter to Senators Thom Tillis and Chris Coons, the Office explained that it was actively considering legal and policy measures related to AI, and would continue to provide public outreach, internal training, and, ultimately, a notice of inquiry seeking public comment on the many legal and policy questions raised (<https://www.copyright.gov/laws/hearings/Letter-to-USPTO-USCO-on-National-Commission-on-AI-1.pdf?loclr=licop>).

In early 2023, the Office publicly announced its AI Initiative, observing that the rapid development of AI technology, particularly systems capable of generating expressive material, raises many questions about its interplay with copyright law. There are several elements to this initiative. First, to address the copyrightability and registration issues raised by generative AI, the Office issued new registration guidance, “Copyright Registration Guidance: Works Containing Material Generated by Artificial Intelligence,” in March 2023 (available at <https://www.govinfo.gov/content/pkg/FR-2023-03-16/pdf/2023-05321.pdf>). This guidance clarifies that applicants have a duty to disclose the inclusion of more than de minimis AI-generated content in works submitted for registration and outlines how to update pending applications or correct the public record on copyright claims that have already been registered without the required disclosure.

Second, in April and May 2023, the Office hosted four virtual, public listening sessions on the use of AI to generate works in creative fields. The sessions focused on literary works, including

print journalism and software; visual arts; audiovisual works; and music and sound recordings. Participants included a wide range of individual artists, legal practitioners, technology companies, academic experts, and industry associations. The Office has posted transcripts and videos of each of the listening sessions on its website.

Third, in June and July 2023, the Copyright Office hosted two virtual, public webinars. The first focused on applying the Office’s March registration guidance for works containing generative AI-material. The second webinar explored international developments on AI and copyright law, and a video is posted on the Office’s website. Collectively, webinars and listening sessions reached over 8,000 people, breaking engagement records.

Finally, the Office issued a notice of inquiry about copyright and the use of generative-AI on August 30, 2023. The public comment period closed in December 2023, and over 10,000 comments were submitted in this docket.

More information about the Office’s AI Initiative can be found at www.copyright.gov/ai.

Reports and Studies

As directed by title 17, section 701(b)(1) of the U.S. Code, the Copyright Office advises Congress on national and international issues relating to copyright through technical analyses on legislation and policy studies on various aspects 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 opportunities to participate and contribute to the Office’s policy studies, reports, and recommendations.

During FY 2023, the Office worked on three studies relating to emerging technologies, copyright protection, and enforcement.

Joint Study with USPTO on Non-Fungible Tokens

Senators Patrick Leahy and Thom Tillis sent a letter to the Copyright Office and the U.S. Patent and Trademark Office (USPTO) on June 9, 2022, asking both Offices to undertake a public study assessing the various intellectual property law and policy issues associated with NFTs. The letter requested the Offices to “consult with the private sector, drawing from the technological, creative, and academic sectors.”

On November 23, 2022, both Offices issued a Federal Register notice seeking public comments to assist in preparing the study, and announcing public roundtables for patents, trademarks, and copyrights. The Offices requested comments on issues, such as (a) the current use of NFTs in commentators’ fields or industries and the potential future application of NFTs in these fields and industries; (b) how NFT markets affect the production of materials subject to IP protection; (c) how and to what extent NFTs are used by or could be used by IP rights holders; and (d) how and to what extent NFTs can present challenges or opportunities for IP rights holders. The Copyright Office held public roundtables on copyright and NFTs on January 31, 2023.

The final report was published on March 12, 2024. The report and additional materials (such as public comments, recordings and transcripts of the roundtables) can be found at <https://www.copyright.gov/policy/nft-study/>.

Standard Technical Measures and Section 512 (letter 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 online service provider’s liability for infringement if the provider meets certain conditions. One of these conditions is that the service provider “accommodates and does not interfere with standard technical measures” (STMs) to identify or protect copyrighted works. 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).

The Office issued a notice of inquiry in April 2022 to gather additional information on the development and use of STMs. While the comments shared some common themes, the Office found a lack of consensus on the value of STMs and disagreement about proposals for legislative or regulatory action. Nevertheless, in a December 2022 letter addressed to Senators Tillis and Leahy, the Office recommended several changes to section 512(i) that could facilitate the adoption of STMs. These proposed amendments would clarify the meaning of “broad consensus” and “multi-industry” as well set forth a list of factors for weighing whether a particular measure imposes substantial costs and burdens on service providers.

The letter and additional materials (such as public comments) can be found at <https://www.copyright.gov/policy/stm/>.

Technical Measures Consultations (letter issued in December 2022)

Separate from the study on STMs under Section 512(i), the Office conducted a series of consultations on voluntary technical measures, with a final letter issued in December 2022. The Copyright Office’s May 2020 report, Section 512 of Title 17, acknowledged the important role that technical measures can play in addressing internet piracy. The Office noted that stakeholders had engaged in a range of voluntary collaborations and technical measures to supplement the enforcement framework, but that further discussion and collaboration would help ensure that these measures provide a reasonable, effective, and flexible approach for all involved. In a letter dated June 24, 2021, Senators Patrick Leahy and Thom Tillis requested 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. The Office held the first public plenary session on February 22, 2022, a series of moderated sessions in June 2022, and a concluding public plenary session on October 4, 2022.

On December 20, 2022, the Copyright Office published a letter to Senators Leahy and Tillis outlining the outcomes from this year-long public consultation process. After reviewing the public comments and outcomes from the two plenary sessions and smaller consultation discussions, the Office found that stakeholders broadly agree that there is not a one-size-fits-all approach to voluntary technical measures. While points of contention remain, particularly concerning expectations about resources and access as well as the role of automation, these debates serve as important opportunities for further education and conversations.

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/>.

Rulemakings

The Copyright Office has the statutory responsibility to implement many provisions of the Copyright Act via rulemaking. During FY 2023, the Office engaged in a number of such rulemakings; a list of both active and closed rulemakings is available at <https://www.copyright.gov/rulemaking>. An illustrative list appears below.

Copyright Claims Board: District Court Referrals; Proof of Service Forms; Default Proceedings; Law Student Representation

The Office issued a final rule regarding certain CCB procedures on July 31, 2023. This final rule concluded the rulemaking process to implement the CASE Act that began with a March 26, 2021 notice of inquiry and continued through several notices of proposed rulemaking that addressed various aspects of the CCB's operations and procedures. After receiving public comments, the Office published final rules and the CCB began receiving claims on June 16, 2022. On December 19, 2022, the Office again published and sought public comment on an interim rule that clarified the rules governing representation by law students of parties before the CCB, added a rule to address district court referrals, and amended the rules governing proof of service forms and default proceedings. The final rule issued on July 31, 2023 adopts the interim rule as final.

Copyright Claims Board: Agreement-Based Counterclaims

The Office issued a Notice of Proposed Rulemaking on May 3, 2023, seeking public comment on a proposed rule governing the CCB proceedings to address the filing of agreement-based counterclaims and related discovery requirements. Agreement-based counterclaims are counterclaims based on an agreement pertaining to the same transaction or occurrence that is the subject of a claim of infringement if the agreement could affect the relief awarded to the claimant. The proposed regulations set out the requirements for the content of such counterclaims and any responses to them. The regulations also provided for standard interrogatories and standard requests for the production of documents for use in connection with such counterclaims. Because the Office did not receive comments recommending changes to the proposed rule, it was adopted as final on July 27, 2023.

Fair Use Index

The Copyright Office hosts and maintains the Fair Use Index on its website, originated in coordination with the Intellectual Property Enforcement Coordinator a decade ago. This online tool provides a searchable index of notable cases from U.S. courts that comment on fair use law. The Index contains more than 200 cases. The Office 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. In FY2023, the Index saw nearly 339,000 visits and over 56,600 resource downloads, an increase over FY2022’s total engagement levels.

The Fair Use Index is hosted at <https://www.copyright.gov/fair-use>.

Advise Executive Branch Agencies on International Copyright & Trade Matters

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. It participated in meetings 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, on bilateral matters and international issues affecting intellectual property enforcement and other IP topics.

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 2023, the Office 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, and other programs such as those in the G7/G20, OECD and APEC that involve copyright and related matters.

Copyright Office IT Continuous Development

Working with the Library of Congress’s Office of the Chief Information Officer (OCIO), the Copyright Office is engaged in ongoing continuous development of its information technology to provide a more user-centered and flexible design for its public-facing electronic registration, recordation, and public record systems. The Library also hosts biannual, public meetings of the Copyright Public Modernization Committee (CPMC). More information about the Office’s IT modernization and continuous development work can be found at <https://www.copyright.gov/copyright-modernization/>.

Public Outreach

The Copyright Office implements a full program of outreach and communications activities to educate the public regarding copyright protections, and to provide important updates about the practicalities of important changes in the law such as the Music Modernization Act and the CASE Act, and major Office initiatives, like Artificial Intelligence and Copyright. The Office's outreach activities are data-driven, and 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 has expanded promotional efforts and works to identify and reach out to new audiences and to create a variety of easily accessible educational resources. In fiscal year 2023, Copyright Office staff fielded over 129,500 public inquiries on copyright topics ranging in complexity, and midway through the year launched a new best-in-class multimodal contact center to manage demand for information. The Office provided thought leadership and educational outreach by speaking about copyright to a variety of audiences at 185 external-facing events in virtual, hybrid and in-person modes – reflecting a marked year-on-year increase in the public demand for information about the copyright system. The Office has responded to this interest not only by continuing to roll out new educational materials, such as a new set of Spanish-language materials (available at <https://www.copyright.gov/espanol>), but by hosting and recording hybrid or virtual events to raise awareness and expand reach. For example, in September 2023, the Office partnered with the National Library Service for the Blind and Print Disabled (NLS), also within the Library of Congress, to provide a public program in celebration of the tenth anniversary of the adoption of the Marrakesh Treaty and its impact – reaching around 200 people in person and online. A recording of the program is available online at <https://www.copyright.gov/events/marrakesh-treaty-tenth-anniversary/>.