



ANNUAL
INTELLECTUAL PROPERTY
REPORT TO CONGRESS

January 2025

Furthermore, we are positioning American workers to lead the world in innovation. I signed the Inflation Reduction Act, the largest investment in clean energy and climate action in history, creating nearly 335,000 clean energy jobs according to outside estimates. I also signed the CHIPS and Science Act to bring semiconductor manufacturing back home and ensure that America’s clean energy jobs go to American workers. To date, we have attracted nearly \$900 billion in private-sector commitments to invest in manufacturing and clean energy. I am proud that this manufacturing boom we ignited is being done with American products and led by American workers — the most highly skilled workers in the world — because of “Made in America” provisions that I championed and my Administration enforced.

-- President Joe Biden¹

¹A Proclamation on Labor Day, 2024, August 30, 2024, at <https://www.whitehouse.gov/briefing-room/presidential-actions/2024/08/30/a-proclamation-on-labor-day-2024/>.

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, Justice, 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 2024.

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DEPARTMENT OF AGRICULTURE

DEPARTMENT OF AGRICULTURE

Department of Agriculture Appendix for FY 2024 Annual Report

Geographical Indications (GIs)

Overview

Article 22(1) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 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 2024

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 2024, 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 with 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. Below are a few examples of CCFN actions that helped contribute toward preserving U.S. exporters’ rights to use common food names.

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

- **Australia – EU FTA:** On October 30, 2023, Australia-EU FTA negotiations stalled due to European unwillingness to grant market access for key Australian products like sugar,

beef, and dairy, diminishing the likelihood of reaching an agreement in the near future. CCFN continues to monitor these developments.

CCFN collaborated with U.S. and Chilean officials to protect U.S. meat and cheese exports from significant restrictions:

- Following the EU-Chile Advanced Framework Agreement (AFA) signed in December 2023, CCFN engaged U.S. and Chilean government officials to ensure that various U.S. meat and cheese exports would be protected against geographical indication claims outlined by the agreement with the EU.
- This engagement helped lead to an agreement with Chile, to provide protections for U.S. producers that export and sell products in Chile using certain cheese and meat terms, such as mozzarella, provolone, brie, salami, and prosciutto, among others. This agreement also allows any current or future U.S. national to continue using certain terms, such as parmesan, that are covered by the latest draft of the prospective EU-Chile Advanced Framework Agreement in the Chilean market.

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

- As part of its international efforts to defend the right to use common terms, CCFN participated in the 65th WIPO Assemblies held in Geneva, Switzerland, from July 9 to 17, 2024 as an Official Observer and met with WIPO staff while there.
- On April 12, 2024, CCFN leadership attended a Chamber of Commerce meeting with Darren Tang, Director General of WIPO. This meeting provided an opportunity for CCFN to emphasize the importance of a balanced approach between GIs and common names.

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

- In late 2023, one of CCFN's international legal advisors was appointed Chair of the International Agreements and Harmonization Subcommittee of the INTA Geographical Indications Committee for the 2024-2025 term. Throughout 2024, CCFN actively participated in INTA's International Agreements Subcommittee sessions and in the full Committee's in-person session during INTA's Annual Meeting in Atlanta in May 2024.

CCFN participation in international fora and symposia:

- A CCFN advisor traveled to Kuala Lumpur, Malaysia, for USPTO's GI education conference in March 2024. CCFN's participation focused on the issues surrounding the exchanging of GI lists through FTA negotiations, and the harm this tactic causes not only to foreign exporters, but also to domestic producers and consumers in EU FTA partner countries, who risk losing significant business opportunities and face fewer consumer choices. CCFN's advisor also moderated a discussion on trends and best practices

employed by the Association of Southeast Asian Nations regarding GIs and common names.

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

- **Canada:** Between late 2023 and early 2024, CCFN assessed the impact of Quebec’s Bill 96, which mandates French translations on all labels, to ensure that the translations of recognized GIs do not negatively affect common terms. CCFN joined other industry associations in signing a February 2024 letter to the Quebec Board of the French Language to cite the inconsistencies of the measures with Canada’s international commitments and the impacts that they may have on consumers and businesses. CCFN also filed individual comments with Quebec on the Bill.
- **China:** With the aim of contributing to a fair and balanced GI regime in China, on November 1, 2023, CCFN filed comments on the draft *Provisions on the Protection of Geographical Indication Products*, a legal instrument replacing the current provisions on the requirements and procedures for the registration of GIs in China.
- **Indonesia:** CCFN organized a May 2024 letter to Indonesia’s Trade Minister, expressing concerns from several US organizations about potential restrictions on the use of common food and beverage names due to the EU-Indonesia FTA.

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

- **EU - Ruling on the genericness of the term “emmentaler”:** In 2018, CCFN filed third-party observations against the Emmentaler Switzerland trademark application in the EU. In May 2023, the European Court of Justice (ECJ) ruled that “emmentaler” is a generic name for a type of cheese and cannot be trademarked. The Swiss appealed, but the Court of Justice of the European Union (CJEU) upheld the ruling in October 2023.
- **EU - Opposition against the recognition of “emmentaler” as a GI:** To preserve its generic status, on August 9, 2024, CCFN filed a submission of opposition against the registration of a GI for “Emmentaler” in the EU as part of the Geneva Act, pointing to the term’s wide-spread generic nature and established Codex standard. The opposition process is ongoing.

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 or to accede to the International Convention for the Protection of New Varieties of Plants, as revised at Geneva on March 19, 1991, to protect U.S. plant breeders' rights across the globe.

USDA Plant Variety Protection Activities in FY 2024

PVPO received 515 applications for sexually reproduced, tuber propagated, and asexually reproduced varieties during the fiscal year. Among these were more than 35 applications for asexually reproduced varieties including varieties of apple, apricot, calibrachoa, chestnut, grapefruit, grapevine, hop, hydrangea, lemon, magnolia, oleander, orange, peach, raspberry, rose, and strawberry. PVPO issued 450 certificates of protection and examined 475 applications. PVPO staff provided presentations on the program, the electronic Plant Variety Protection System, and examination procedures – to delegations from China and Taiwan; and to participants in attendance at conferences held by the American Seed Trade Association (ASTA), AmericanHort, and the International Community of Breeders of Asexually Reproduced Horticultural Plant Varieties (CIOPORA). The presentations reviewed the benefits of the electronic plant variety protection system, an overview of PVPO examination procedures, and an update on the number of asexually reproduced varieties received. PVPO continues to actively work with ASTA, AmericanHort, CIOPORA, the USPTO, 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

“The USPTO advises the President, through the Secretary of Commerce, on a full range of national and international intellectual property (IP) issues, including patents, trademarks, copyright, trade secrets, and enforcement. IP is a critical engine that powers our economy and one reason our Nation is a global leader in innovation and entrepreneurship. As we face humanitarian and environmental crises, and new technologies and globalization present evolving and challenging IP issues, we need to encourage the progress and growth that IP protection can provide. We need an IP ecosystem that will cultivate an innovation mindset and catalyze inclusive innovation and entrepreneurialism, economic prosperity, and U.S. competitiveness, and bring that innovation to positive impact.”²

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

DEPARTMENT OF COMMERCE APPENDIX FOR FY 2024 ANNUAL REPORT

This appendix discusses the FY 2024 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 protection, awareness and enforcement internationally. Additionally, the USPTO provides many different intellectual property capacity building programs to developing and least developed countries as fully described in our TRIPS Article 67 report each year. The following highlights some enforcement activities during FY 2024.

1) COMMERCIAL LAW DEVELOPMENT PROGRAM (CLDP)

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, the 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 of the Plan, a critical element for achieving this objective is protecting and enforcing intellectual property abroad.

The 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 the country a vested interest in enforcing IPR.

² Kathi Vidal, *Statement of Kathi Vidal, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, before the Subcommittee on Intellectual Property Committee on the Judiciary United States Senate*, July 26, 2023, at https://www.judiciary.senate.gov/imo/media/doc/2023-07-26_pm_-_testimony_-_vidal.pdf.

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

Since 2021, the USPTO's Global Intellectual Property Academy (GIPA) and the 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 2024, the CLDP's intellectual property (IP) activities were conducted for the following countries and regions: Armenia, Azerbaijan, Bosnia and Herzegovina, Central Asia, Moldova, Regional South Caucasus, Sri Lanka, Tajikistan, and Uzbekistan.

As outlined below, CLDP's FY 2024 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 2024 IP Programs

Judicial Capacity Building in IPR Enforcement

Bosnia and Herzegovina

CLDP Promotes Publication of IP Bench Book

From May 7 - 10, 2024, CLDP hosted three events to promote the publication of an IP bench book in Bosnia and Herzegovina (BiH). The bench book was drafted by a multidisciplinary, multiethnic working group of judges, professors, and IP practitioners from BiH. The Center for Judicial and Prosecutorial Training of the Federation of BiH and the Center for Judicial and Prosecutorial Training of the Republic of Srpska worked in coordination with CLDP to publish the bench book. On May 7, in Sarajevo, CLDP hosted an author panel for the High Judicial and Prosecutorial Council of BiH, judges of the Court of BiH, and prosecutors from the Prosecutor's Office in BiH. CLDP also hosted events on May 8 and 10, in Sarajevo and Banja Luka, featuring an author panel, a judicial perspectives panel, and presentations by a U.S. federal judge.

Capacity Building for Institutions that Enforce IPR

Armenia

CLDP Holds Roundtable on Framework for Intellectual Property Rights

On June 17 - 18, 2024, CLDP, in close cooperation with the IP Office and the Ministry of Economy of the Republic of Armenia, held the *Public Private Roundtable on Enhancing the Protection and Enforcement of IP Rights* in Yerevan, Armenia. The Roundtable enabled government officials, private attorneys, and IP rights holders to discuss the obstacles to a national system of IP protection and enforcement and highlighted the intersections between IP rights, public health and safety, and economic growth.

CLDP Leads Roundtable Meetings on Technology Transfer and IP Commercialization

CLDP addressed the potential and challenges for developing institutions capable of delivering technology transfer services to Armenia's university researchers and other inventors during a September 17 - 19, 2024 roundtable on technology transfer and commercialization of IP in Armenia. Participants included representatives from the Armenian Government, universities and public research institutions, entrepreneurs, and other key stakeholders. The group identified several challenges, including gaps in the legal framework, lack of IP policies at public sector research institutions, and lack of awareness among researchers, inventors, and other key stakeholders. By creating effective pathways for technology transfer and IP commercialization, Armenia would fully benefit from the new inventions and cutting-edge technologies that are developed by its public sector research institutions.

Azerbaijan

CLDP Hosts Intellectual Property Best Practices Workshop

On January 30, 2024, CLDP co-hosted a workshop on the protection and enforcement of IPR with the American Chamber of Commerce in Azerbaijan. Over 60 private sector representatives, lawyers, and officials from the Azerbaijan Intellectual Property Agency discussed the current system of IPR in Azerbaijan, learned about regional and international best practices, and strategized on how to strengthen Azerbaijan's IPR protection and enforcement. CLDP supports economic growth in Azerbaijan by encouraging creativity, innovation, consumer-protection, and investment and by promoting a competitive, fair, and balanced marketplace.

CLDP Holds Anti-Counterfeiting Workshop for Rights Holders and Legal Professionals

On August 26 - 27, 2024, CLDP held a workshop on the protection and enforcement of IPR, with an emphasis on anti-counterfeiting, for private sector representatives. Discussions focused on protecting against counterfeit products in the distilled spirits, fashion and apparel, automotive, pharmaceutical, and household cleaning products industries. International experts shared tips and strategies for protecting intellectual property and highlighted their work with law enforcement and government agencies to counter the production of fake goods. On August 28, 2024, CLDP hosted an introductory session for law students on intellectual property law. Protecting and enforcing IPR supports economic growth in Azerbaijan by encouraging creativity, innovation, consumer-protection and investment and by creating a competitive, fair, and balanced marketplace.

Central Asia

CLDP Convenes U.S.-Central Asia Intellectual Property Working Group

From July 16 - 18, 2024, in Kazakhstan, CLDP convened the U.S.-Central Asia Intellectual Property Working Group. Consisting of government officials from Kazakhstan, the Kyrgyz Republic, Tajikistan, Turkmenistan, and Uzbekistan, as well as experts from the USPTO, the Office of the U.S. Trade Representative (USTR), and U.S. Customs and Border Protection (CBP), the group discussed developments in each country toward implementing the intellectual property rights criteria of the U.S.-Central Asia Trade and Investment Framework Agreement and Uzbekistan's removal from the Watch List in the 2024 Special 301 Report issued in April 2024 (<https://ustr.gov/sites/default/files/2024%20Special%20301%20Report.pdf>).

Moldova

CLDP Leads Workshop on Intellectual Property Rights Enforcement

From December 18 - 20, 2023, CLDP conducted a workshop on brand protection and identification of genuine and counterfeit goods. The workshop was attended by country delegations from the Caucasus and Eastern Europe Expert Level Working Group on IPR and a wider audience from Moldova that included market inspectors, customs agents, and police officers. The workshop included sessions on security features applied on genuine goods, methodologies on distinguishing genuine goods from counterfeit, and relevant procedures for targeting suspect shipments. The workshop was followed by a site visit where participants witnessed the customs clearance process firsthand.

Regional South Caucasus

CLDP Convenes Intellectual Property Rights Working Group

On December 16, 2023, CLDP facilitated the third meeting of the Caucasus and Eastern Europe Expert Level Working Group on IPR in Chisinau, Moldova. During the meeting, government delegations from Armenia, Georgia, Moldova, and Ukraine discussed the challenges of preventing counterfeit goods in the region. Topics included customs enforcement of IPR, strategies for private sector engagement, and trends in counterfeiting spirits. Discussions were guided by experts from CBP, React Anti-Counterfeiting Network, and the Alliance Against Counterfeit Spirits. The Working Group contributes to more predictable and efficient protection and enforcement of IPR in the region.

Development of Innovation Ecosystems/Technology Transfer

Armenia

CLDP Hosts Roundtable Meetings on Establishing a Technology Transfer Office

From November 6 - 10, 2023, CLDP supported a team of Armenian academics and intellectual property (IP) professionals as they promoted a plan to establish the Armenian Technology Transfer Foundation (ATTF), an independent and not-for-profit foundation that will provide invention and IP management and technology transfer services to clients of public sector research institutions. Promotional events included individual and group meetings with relevant stakeholders in the Government of Armenia, public sector research institutions, and the private sector. The week culminated with two roundtable meetings on November 9 and 10 that reviewed the strategic design and vision for ATTF and gathered input from assembled stakeholders, including potential users and beneficiaries.

CLDP Leads Dialog on Developing a Centralized Technology Transfer Office

On June 4, 2024, CLDP held a meeting to discuss a CLDP strategic plan to develop a centralized, not-for-profit technology transfer office in Armenia. The meeting included professionals from academia, law, and business who were specifically selected for their potential to serve as an initial advisory body for the office. This meeting with potential advisors is a critical step in the formation of the office, as it will require support from a wide range of stakeholders to be sustainable.

Central Asia

CLDP Conducts Technology Transfer Workshops

From May 23 - 31, 2024, CLDP conducted workshops in Tajikistan, Uzbekistan, and the Kyrgyz Republic regarding technology transfer invention evaluation for technology transfer offices (TTOs) and university staff to learn how to select academic inventions worthy of patent and commercialization efforts. CLDP has worked with these Central Asian governments and local universities since 2022 to develop centralized TTOs in each country. The TTOs advise academics on how to patent and commercialize inventions based on their research.

Sri Lanka

CLDP Conducts U.S. Technology Transfer Consultations

From December 7 - 15, 2023, CLDP conducted U.S. technology transfer consultations in Washington, D.C., Ithaca, New York, and Ann Arbor, Michigan. CLDP brought delegates from the Ministry of Finance, Ministry of Education, University Grants Commission, and select Sri Lankan universities to gain insight on the innovation and entrepreneurship ecosystem in the United States, thereby build their own. The consultations included meetings with USPTO experts and technology transfer and commercialization stakeholders at both Cornell University and the University of Michigan.

CLDP Concludes Technology Transfer Portfolio

From April 22 - 26, 2024, as the finale to its technology transfer and intellectual property portfolio, CLDP hosted a series of exchanges on technology transfer in Colombo, Sri Lanka. The sessions included programming for World Intellectual Property Day to secure the high-level support necessary to continue building Sri Lanka's innovation and entrepreneurship ecosystem. The sessions also built off of the recent U.S. consultations completed by Sri Lanka TTOs and focused on negotiation simulations, commercialization consultations, and strengthening the TTOs.

Tajikistan

CLDP Conducts Intellectual Property and Technology Transfer Webinar

On November 14, 2023, CLDP, utilizing expertise from Cornell and Boston Universities, conducted an IP and technology transfer webinar for Tajik government officials who are attempting to establish a viable technology transfer office in Tajikistan. The webinar presented best practices from the World Intellectual Property Organization for the drafting of an IP policy and the development of a technology transfer office that will guide universities in managing innovations from academic research and protect IP for both Tajik and U.S. companies.

CLDP Conducts Technology Transfer Workshop

On November 30 - December 1, 2023, CLDP conducted a workshop as part of a project to establish a central technology transfer office in Tajikistan. The workshop covered IP policy, the technology transfer ecosystem, and the role of the private sector in the technology transfer ecosystem, among other topics. In addition, participants showcased their inventions and obtained feedback from CLDP on how to protect their IP rights and commercialize their inventions.

Uzbekistan

CLDP Conducts Technology Transfer Workshop

On December 4 - 5, 2023, CLDP conducted a workshop as part of a project to establish a central technology transfer office in Uzbekistan. The workshop covered IP policy, the framework of the technology transfer ecosystem, and the role of the private sector in the technology transfer ecosystem, among others. In addition, participants showcased their inventions and obtained feedback from CLDP on how to protect their IP rights and commercialize their inventions.

2) *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 (<https://www.stopfakes.gov/welcome>). 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 latest 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. The toolkits are available at <https://www.stopfakes.gov/IPR-Toolkits>.

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 at <https://www.stopfakes.gov/IPR-Toolkits>.

U.S. Government (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 IP terminology, directs their clients to the correct U.S. Government IP experts, and helps to guide them on how to respond to IP 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 and are available at <https://www.stopfakes.gov/IPR-Toolkits>.

STOPfakes at 2024 Consumer Electronics Show

The STOPfakes team provided in-person IP education and direct outreach to over 3500 attendees during the 2024 Consumer Electronics Show in Las Vegas, Nevada. The STOPfakes engagement included 3 USG interagency STOPfakes partners, including the United States Patent and Trademark Office (USPTO), the Department of State, and Customs and Border Protection (CBP). The Office of the Intellectual Property Enforcement Coordinator (IPEC) participated as well.

STOPfakes at the 2024 SelectUSA Investment Summit

The STOPfakes team provided in-person IP education and direct outreach as part of the U.S. Government pavilion at the 2024 SelectUSA Investment Summit in National Harbor, Maryland. The STOPfakes engagement at SelectUSA included interagency partners from CBP, FBI, USPTO, and IPEC.

OSIP Outreach

STOPfakes Roadshows

The [STOPfakes Roadshows](#) deliver critically important information about IP 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' IP interests:

- The USPTO provides information about how to protect patents and trademarks, resources for SMEs and entrepreneurs, assistance in foreign markets and basics on enforcement of IP rights;
- The U.S. Copyright Office discusses the importance of copyright protection to creators and businesses;

- 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 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; and
- ITA 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 IP rights.

During FY 2024, OSIP coordinated five domestic STOPfakes Roadshows – three in-person programs in San Jose, California, Miami, Florida, and Jackson, Mississippi, and two virtual road shows in Iowa and South Dakota. During the California Roadshow, the STOPfakes team also spoke about the importance of intellectual property rights and protection at a “Brand Owner Day” program and a San Francisco Brand owner roundtable event.

STOPfakes Webinars

During FY 2024, OSIP continued to offer a variety of online webinars to various audiences. These webinars were co-hosted by STOPfakes and featured 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.

Global Diversity ExporTech

In May 2024, OSIP participated in the Global Diversity ExporTech U.S. Commercial Service and National Alliance for Black Businesses event to educate U.S. SMEs in the beauty and skin care industries on the importance of IP protection and enforcement in foreign markets.

Foreign Service Training (FSI)

In July 2024, OSIP participated in the FSI training for State Department foreign officers. OSIP provided an overview of USG IP resources and experts available to Embassy colleagues throughout the world.

3) ***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 2024, NTIA followed developments in the ninth triennial rulemaking proceeding under 17 U.S.C. § 1201(a)(1)(C), which concluded in October 2024. The rulemaking process allows the Librarian of Congress to determine whether to grant any temporary exemptions to the prohibition on circumvention in 17 U.S.C. § 1201(a)(1). NTIA worked to fulfill its statutory role to engage in consultation with the U.S. Copyright Office during the rulemaking. NTIA reviewed the proposals and additional comments received in the process, and participated in several staff-level meetings with the Copyright Office. At the invitation of the Copyright Office, NTIA also participated in the Office-led public hearings in April 2024 to ask questions to supporters and opponents of the various proposals. NTIA formally shared its views with the Copyright Office through an extensive consultation letter transmitted on September 24, 2024.

4) UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)

The Under Secretary of Commerce for Intellectual Property and Director of the USPTO (“USPTO Director”) 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” and may conduct programs or studies related to intellectual property. 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 2024, 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 Review of Notorious Markets for Counterfeiting and Piracy (Notorious Markets List), 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 and ASEAN 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. The USPTO is also a bureau member of the OECD’s Working Party on Countering Illicit Trade (WP-CIT). In April 2024, the USPTO attended the 12th Plenary Meeting of the OECD Working Party on Countering Illicit Trade as a Bureau member as well as part of the U.S. delegation that included the Department of State, Customs and Border Protection, and the Department of Homeland Security, among others. USPTO representatives participated in a WP-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 as well as countering illicit trade in foreign trade zones.

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

Throughout FY 2024, 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 the 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 the 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 the 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. 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, Virginia, and around the country in cooperation with the USPTO's regional offices and other business units. The OPIA collaborates with the USPTO's IP Attachés, Regional Offices, other USG agencies, and the Federal Judiciary. 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.

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 2024, 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.

The USPTO’s “Go For Real” campaign, a partnership with the National Crime Prevention Council (NCPC), 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 four award-winning PSAs, which together have had over 460,000 TV airings, and an ad value of more than \$72 million. As of July 2024, the “Go For Real” campaign materials have made over 3 billion gross impressions since its debut. Ipsos, a market researcher, conducted a national survey to measure the awareness and effectiveness of the “Go For Real” campaign. The survey found that more than half of teens exposed to the campaign engaged with what they saw where: 26% - Talked with a friend or family member about what they saw; 25% - Learned something new; 21% - Did their own research on the topic after viewing; 14% - Made or will make more informed purchasing decisions as a result; 11% - Shared or posted the message to social media; and 9% - Hit the “like” or “love” button on the post. Additionally, the campaign offers three seasons of “Go For Real TV,” a YouTube series developed by USPTO and the NCPC comprising short videos designed to educate our target market about the dangers of counterfeit goods. The campaign has an active social media presence, with more than 16.8 million social media impressions. Additional assets of the Go for Real campaign include radio PSAs, teaching toolkits for educators, an interactive e-book (the “Dupe Detector Kit”), as well as multiple online games.

USPTO celebrates World Intellectual Property Day (WIPD) each year around 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 “IP and the SDGs: Building our common future with innovation and creativity” with an event on Capitol Hill. The 17 SDGs, which include goals such as affordable and clean energy, climate action, and gender equality, represent a blueprint, for people, peace, prosperity, and our planet. In addition to USPTO and the U.S. Copyright Office, organizations participating in this event included the American Bar Association, American Intellectual Property Law Association, Global Intellectual Property Alliance, International Trademark Association, Intellectual Property Owners Association, Licensing Executive Society, U.S. Chamber of Commerce Global Innovation Policy Center, and United States Intellectual Property Alliance.

Capacity-Building and Training

The USPTO’s Global Intellectual Property Academy (GIPA)

In FY 2024, 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 2024, and USPTO continued to leverage 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 2024, GIPA provided capacity programming to over 3,800 U.S. SMEs, U.S. Government officials, and other U.S. stakeholders. About 28% of GIPA's over 125 programs in FY 2024 targeted the domestic audience of IP rights owners, users, and policymakers. About 71% of these programs targeted foreign officials with IP portfolios, engaging over 3,900 officials from 118 countries and intergovernmental organizations. A complete list of all countries represented at GIPA trainings in FY 2024 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 international 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 IP training for outbound Foreign Service Officers. GIPA continued to engage in interagency training coordination meetings with other USG IP training donors such as the State Department, Department of Justice (DOJ), Customs and Border Protection (CBP), and DOC's CLDP, 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.

USPTO Activities Related to IP Protection and Enforcement

Africa

On October 23, 2023, OPIA's Copyright and Enforcement Teams conducted a virtual program on the "*Digital Distribution of Creative Content*," featuring experts from Netflix, Mdundo and others. The program was offered in English with French translation, and garnered over 100 attendees.

On November 13 - 15, 2023, OPIA's Enforcement Team welcomed approximately 20 government officials from Cameroon, Ghana, Senegal, Cote d'Ivoire, Tanzania, and Nigeria for the second iteration of the highly successful "*Countering Illicit Trade Amid Expanding Trade Infrastructure Investments*" program. The program faculty included participants from USPTO, CBP, DOJ, the Food and Drug Administration (FDA), Homeland Security Investigations (HSI) and the National Intellectual Property Rights Coordination Center (IPR Center).

On April 23 - 24, 2024, OPIA's Enforcement Team hosted 32 Ghanaian judges from the High Court and other trial-level courts at the West Africa Regional Training Center in Accra, Ghana. In addition to the USPTO, program faculty included two federal district court judges and a DOJ Computer Crime & Intellectual Property Section (CCIPS) prosecutor. The program included practical sessions on adjudicating copyright and trademark infringement cases, a highlight on digital piracy, and more general matters that touch on IP, such as evaluating experts, Alternative Dispute Resolution (ADR) and mediation and civil and criminal penalties.

On April 25 - 26, 2024, OPIA's Enforcement Team hosted 27 Ghanaian customs and law enforcement officers at the West Africa Regional Training Center in Accra, Ghana. In addition to the USPTO, program faculty included a CCIPS prosecutor and two officials from CBP. Discussion topics included targeting, recordation, investigative techniques and preparing cases for prosecution.

Eurasia

On March 7, 2024, in coordination with the CLDP, OPIA's Patent Team along with its IP Attaché for Eurasia, conducted an online training on patent issues for the Ukrainian National Office for Intellectual Property and Innovations, with participation of ninety-five Ukrainian IP officials.

On May 21 - 23, 2024, in collaboration with HSI, OPIA's Enforcement Team – together with the IP Attaché for Eurasia – conducted a training on “*Intellectual Property Enforcement at the Border*” for Turkish Customs in Istanbul, Türkiye. The program included participation of over forty Turkish Customs officials from nine different regions of the country. The training program received extensive positive coverage in the Turkish media.

On June 7, 2024, the IP Attaché for Eurasia participated in the 16th Global Intellectual Property Convention, which was held in Istanbul, Türkiye. He spoke on a panel on “*Combating Counterfeiting and Piracy in Global Trade*,” which addressed effective intellectual property enforcement strategies.

On July 16 - 18, 2024, OPIA's Enforcement Team attended the Central Asia Trade and Investment Framework Agreement (TIFA) Intellectual Property Working Group (IPWG) meeting in Almaty, Kazakhstan. The meeting brought together government officials from Kazakhstan, the Kyrgyz Republic, Tajikistan, Turkmenistan, and Uzbekistan. During the event, OPIA's Enforcement Team presented on various approaches to combating counterfeiting on e-commerce platforms and engaged in discussions on key topics such as enhancing training and staff qualifications, improving coordination in IP policy, and raising public awareness about counterfeit goods.

Latin America and Caribbean

On October 4, 2023, the IP Attaché based in Mexico, in conjunction with USPTO's Texas Regional Office, organized a webinar on enforcement for U.S. stakeholders as part of the “*Mexico IP Series, Expanding your Market*.” Three enforcement attorneys with the Mexican Association for the Protection of Intellectual Property (AMPPI) gave presentations on how to enforce IP in Mexico.

Between October 24 - 26, 2023, the Brazil IP Attaché Office, together with CBP, co-hosted a customs enforcement capacity-building workshop “*Fighting Crimes against IP: International Dialogues*” at the Port of Santos. Subsequently, the Attaché Office was informed that as a follow on to the program there were 60 counterfeit searches with 19 positive results, including a very important case involving counterfeit Stanley Cups.

The USPTO's Peru IP Attaché Office continued its series of webinars for members of the Judicial Branch of Peru with a session in October 2023 conducted by USPTO's OPIA Enforcement Team on the topic of statutory damages as implemented in the United States.

From November 14 - 16, 2023, the USPTO's Peru IP Attaché Office supported and sponsored attendance by six participants from Ecuador and Chile to the WIPO Sub Regional Seminar on Enforcement of IP Rights in Asuncion, Paraguay.

The USPTO's Peru IP Attaché Office provided administrative and logistical support for the OPIA Enforcement Team and INTERPOL's co-organized Practical Workshop on IP for Prosecutors in Bogotá, Colombia on December 4-8, 2023. Attendees from the Andean Community included law enforcement from Bolivia.

From January 30 - February 1, 2024, the IP Attaché Office based in Mexico organized, with the OPIA Enforcement Team, a "*Regional Workshop on Investigation and Prosecution of Digital Piracy Crimes*" for 109 government officials from Costa Rica, Dominican Republic, El Salvador, Guatemala, and Honduras, in the city of Tegucigalpa. As a result of this training, the Attorney General's Office indicated it was able to successfully prosecute a major digital piracy case in El Salvador.

On February 7 - 8, 2024, the IP Attaché Office based in Mexico, working with the OPIA Enforcement Team, AmCham Mexico, and the Mexican Association for the Protection of Intellectual Property organized the first in-person training since COVID for 54 government officials of the Mexican Customs' Agency (ANAM) in Mexico City.

In recognition of the National Day Against the Falsification of Medicine (February 10), the USPTO's Peru IP Attaché Office coordinated the remote appearance of an expert from the FDA and participated in person during the day long workshop on the impact of online sales of medicines and the influence of illegal commerce. Held on February 13, 2024, the program was directed to governmental authorities, including police, with over 100 in person and another 99 attendees online.

On February 13, 2024, the IP Attaché Office based in Mexico, in collaboration with OPIA Enforcement and Copyright Teams, as well as the U.S. Copyright Office, organized a copyright program in Mexico City entitled "*Promoting and Sustaining Creativity: Copyright Developments in the Digital Age*" for 91 government officials from Instituto Nacional del Derecho de Autor (INDAUTOR), Instituto Mexicano de la Propiedad Industrial (IMPI), the Supreme Court of Justice, the Specialized IP Court, and ANAM. This program was a follow-up seminar to the 2020 "*Copyright in the Digital Age: Supporting Authors, Artists, and the Creative Industries*" program.

On February 29, 2024, the IP Attaché Office Peru's IP Legal Advisor presented during the 3rd Annual Program on "*Measures for Combatting Illegal Commerce*" hosted by the Universidad de los Hemisferios – Ecuador. This 60-hour, 2-week long curriculum featured a wide audience of the National Police of Ecuador, the Ministry of Interior and other governmental authorities.

On March 6, 2024, the IP Attaché Office based in Mexico co-organized with OPIA and CBP a webinar for government officials of the Dominican Republic on border enforcement of intellectual property rights for 96 officials from the National Office of Copyright (ONDA), the Attorney General's Office (PGR), the General Directorate of Customs (DGA), the Ministry of Foreign Affairs (MIREX), the Dominican Institute of Telecommunications (INDOTEL), the Ministry of Industry, Trade and SMEs (MICM), and ProConsumidor.

On March 8, 2024, the IP Attaché Office based in Mexico organized, with the OPIA Enforcement Team and CBP a webinar on "*The Proper Protocol for Storage and Destruction of IP Violative Merchandise*" for 88 Dominican Republic government officials ONDA, PGR, DGA, MIREX, INDOTEL, MICM, and ProConsumidor.

On March 18, 2024, the IP Attaché and IP Legal Advisor in Peru participated in a two-day workshop for police and customs officials from Quito, Ecuador. Co-sponsored by private industry, HSI and USPTO, the event featured presentations from USG officials on the value and importance of IP as well as the perspective of a brand owner and local legal practitioners.

On April 23, 2024, the IP Attaché Office based in Mexico co-organized with the OPIA Patent Team a webinar on "*IP Protection in the U.S.: Patent and Trade Secrets*" for 14 government officials and private sector associations from Bahamas, Belize, Costa Rica, and Honduras.

From April 29 to May 2, 2024, the IP Attaché based in Mexico, co-organized with the USPTO Attaché Offices in Brazil and Peru and OPIA Enforcement Team, a "*Judicial Colloquium on IP*" in Alexandria, VA and Washington, D.C. for 34 Latin American judges from Argentina, Brazil, Colombia, Chile, Costa Rica, Ecuador, Mexico, Peru, and Uruguay.

During the celebrations of the 45th Anniversary of the Andean Community Court of Justice (TJCA), the IP Attaché gave an overview of recent efforts by the United States to counter digital piracy during the IP-Key two-day seminar on the "*Fight Against Violations of IP Rights in the Andean Community*."

Between May 23, 2024 and June 21, 2024, the IP Attaché in Peru's Office, in conjunction with the Peruvian Ministry of Production's Interagency Commission Against Customs and Intellectual Property Crimes (CLCDCPI), the International Anti-Counterfeiting Coalition (IACC) and the private sector, organized seven training and outreach programs in Peru. These activities were focused on disseminating information about the importance of protecting IPRs along with mechanisms and tips for law enforcement. More than 250 government officials (Customs, Police, IP prosecutors and IP authorities) benefitted from these IP-focused activities all around Peru (Cuzco, Arequipa, Tacna, Puno, Puerto de Ilo, Pucallpa, Puerto Maldonado).

On June 24 - 28, 2024, OPIA's Enforcement Team, in collaboration with the IP Attaché Team based in Mexico City, co-organized the "*Workshop on Border Enforcement of Intellectual Property Rights*" with Mexico's National Customs Agency (ANAM). The workshop was supported by and featured participation from CBP, the American Chamber of Commerce of Mexico (AmCham Mexico), and the Mexican Association for the Protection of Intellectual Property (AMPPI).

During the week of July 15 - 19, 2024 USPTO co-organized with INTERPOL and IP-Key a workshop on “*Combatting Pharmaceutical Crime*,” in Buenos Aires, Argentina for specialized police and prosecutors in the digital crimes’ unit and pharma crimes’ units from 10 countries in the region. The workshop was in preparation for an upcoming operation and focused on open cases and investigations, trends in pharmaceutical crime, online investigation tools and techniques, and how to complete forms for data processing and paperwork required for international cooperation under the mutual law enforcement assistance treaty and other cooperative agreements.

During the week of July 22 - 26, 2024, USPTO co-organized, along with WIPO, IP-Key and JPO, a “*Workshop on Enforcement of Intellectual Property Rights*” for approximately 40 police, prosecutors, judicial police and customs officials from Costa Rica, the Dominican Republic, El Salvador, Guatemala, Honduras, Mexico, and Panama. The workshop was held in San Jose, Costa Rica and focused on highlighting best practices in investigation and prosecution of IP crimes, including digital evidence collection, preservation requests for digital evidence to social media and e-commerce platforms, online investigations, prosecuting Internet piracy and illicit streaming device cases, eliminating gaps in enforcement capabilities and improving coordination among government agencies, and working collaboratively with regional partners.

On August 20 - 21, 2024, the USPTO in cooperation with CBP, co-organized a “*Workshop on Customs’ Enforcement Against IPR Infringing Goods*” in Trinidad and Tobago (T&T). The workshop took place at the T&T Custom’s Academy. Approximately 50 entry-level customs officers participated in the workshop and received training on the importance of intellectual property enforcement at the border, risk-based targeting, IP recordation, seizure, destruction and penalties.

On September 12, 2024, USPTO in coordination with CBP presented on the “*Importance of IP Protection and Enforcement of IP*” at the border for the Peruvian Judiciary during a webinar.

In September 2024, the USPTO conducted a webinar for the Columbian Judiciary presenting on the importance of IP protection and enforcement. CBP presented on the role and responsibility of customs in border enforcement of IP.

On September 23 - 25, 2024, the USPTO moderated a panel session on “*Engaging the Judiciary for Maximum Impact Against IP Crime*” during Interpol’s “*17th International Law Enforcement Intellectual Property Crime Conference*” in Willemstad, Curaçao. The USPTO engaged with several stakeholders, including Alibaba International, Amazon, CBP, FDA’s Office of Criminal Investigations, HSI, Interpol, IP House, and TikTok Shop. Additionally, the USPTO organized and conducted, along with colleagues from CBP, a workshop and practical exercise on “*Detecting and Preventing Illicit Trade in Free Trade Zones*,” discussing common challenges and highlighting best practices and practical responses for policing free zones and combating counterfeiting operations.

South East Asia

Capacity Building and Public Awareness Programs

In March 2024, the IP Attaché for Southeast Asia Office provided support to the USPTO and ASEAN Secretariat co-organized “*ASEAN-USPTO Seminar on the Protection of Geographical Indications*” in Kuala Lumpur, Malaysia. The workshop focused on geographical indications (GIs) and the policy and practical considerations related to GIs, such as due process and transparency, examination of applications, ownership and use, standards of identity, preservation, and disclaimer of common names and generic terms, opportunities for opposition and cancellation, enforcement, and challenges facing producers, growers, and farmers. The workshop was attended by 20 IP officials and policymakers from ASEAN IP Offices.

On March 6, 2024, OPIA's Enforcement Team, supported by the U.S. Embassy in Jakarta, Indonesia, conducted a “*Roundtable on Content Streaming and Anti-Piracy Enforcement*” in collaboration with the Directorate General of Intellectual Property (DGIP) and the IP Enforcement Task Force in Jakarta, Indonesia. The discussions during the event centered on key issues, including the evolving landscape of digital piracy, enforcement strategies and best practices for combating content streaming piracy, government support for creative industries, and effective anti-piracy messaging.

On March 7 - 8, 2024, OPIA's Enforcement Team, with support from the U.S. Embassy in Jakarta, Indonesia, conducted a “*Judicial Dialogue on Trade Secret Protection and Enforcement*” in partnership with the Supreme Court of Indonesia in Jakarta, Indonesia. The dialogue focused on the civil and criminal aspects of trade secret protection and enforcement for the judiciary. It included participation from members of both the Indonesian and U.S. judiciaries, as well as representatives HSI, the Federal Bureau of Investigation (FBI), and DOJ's International Computer Hacking and Intellectual Property advisor (ICHIP).

In April 2024, the IP Attaché for Southeast Asia Office provided support to the USPTO and ASEAN Secretariat co-organized “*ASEAN-USPTO Workshop on Effective Practices in Investigation and Enforcement Against Content Piracy*” in Bangkok, Thailand. The workshop provided an overview and discussion of recent developments in copyright laws, new and evolving approaches to protection and enforcement in the ASEAN region and the United States. This included legislative revisions, administrative and regulatory changes, judicial case decisions, treaty implementation, public awareness campaigns, ADR and mediation services, and litigation practices with a specific focus on content piracy and illicit streaming of content. The workshop was attended by 50 enforcement officials, copyright officials, and prosecutors from each of the 10 ASEAN countries

In June 2024, the IP Attaché for Southeast Asia Office supported the USPTO and ASEAN Secretariat jointly organized “*ASEAN-USPTO Colloquium for the Judiciary on Civil and Criminal IP Case Management*” in Manila, Philippines. The workshop focused on various elements of judicial case management and other IP issues, including transparency in proceedings and decision-making, judicial independence and the rule of law, civil litigation and damages,

achieving deterrence, and more. The Colloquium was attended by 70 judges from ASEAN member states both in person and virtually.

In July 2024, the IP Attaché for Southeast Asia Office, with the Thailand Court of Appeal for Specialized Cases, jointly organized the “*Thai-U.S. Judicial Dialogue on the Management of Civil Intellectual Property Litigation*” in Bangkok, Thailand. The program included discussions between Thai and U.S. judges on various aspects of IP civil litigation, covering topics such as dispute resolution, damage assessment, recent U.S. Supreme Court decisions, and emerging challenges in intellectual property. Approximately 80 Thai judges and court officials attended the program.

On July 30 - August 2, 2024, the USPTO, in partnership with CBP, HSI, FDA’s Office of Criminal Investigations, the ASEAN IP Academy, and the EU Intellectual Property Office, and with the support of the Regional Intellectual Property Attachés for South Asia and Southeast Asia, respectively, held an Indo-Pacific Workshop on Enforcement Against Trade in Counterfeit Goods, in Bangkok, Thailand, attended by 130 government officials and stakeholders from 17 countries in the region. Sessions included discussions about approaches to effective anti-counterfeiting investigations, enforcement, prosecutions, and border enforcement, with a focus on online platforms and e-commerce market and sites.

On September 5, 2024, OPIA’s Enforcement Team conducted a “*Dialogue on Intellectual Property Enforcement*” with Bruneian government officials in Bandar Seri Begawan, Brunei Darussalam. Also in attendance were the IP Attaché in Bangkok, the HSI Regional Attaché, and the HSI/ICHIP Special Agent Advisor. The dialogue featured participation from a range of key Bruneian government bodies, including the Attorney General’s Chambers, the Royal Brunei Customs and Excise Department, the Brunei Darussalam Food Authority, the Drug Administration Section of the Ministry of Health, the Market Surveillance Inspection Division of the Ministry of Health, the Authority for Info-communications Technology Industry, and the Competition and Consumer Affairs Department. The discussions focused on Brunei’s enforcement framework, covering topics such as local enforcement actions, the IPR recordation system, and *ex-officio* authority.

On September 10 - 12, 2024, the USPTO, in partnership with the HSI Special Agent for Asia, based in Bangkok, Thailand, and the ASEAN IP Academy, held a capacity building “*Regional Workshop on Intellectual Property Investigations*,” in Bangkok, Thailand, attended by approximately 40 law enforcement officials from Cambodia, Indonesia, and Thailand. The focus of the workshop was on innovative and effective investigation approaches and techniques against intellectual property crime and violations, including content piracy, counterfeit goods, and related financial crimes.

Engagements with U.S. Stakeholders

The IP Attaché for Southeast Asia worked closely with U.S. stakeholders in protecting and enforcing their IP in countries in the region. In addition to providing guidance on IP law and policy and raising their IP concerns with the respective local governments, the IP Attaché also participated in and provided insights on the following programs:

In November 2023, the IP Attaché participated in the US-ASEAN Business Council (USABC) Ambassador Briefing in Bangkok, Thailand. During the briefing, the IP Attaché provided an overview of Thailand’s IP landscape and local IP protection and enforcement concerns to 30 USABC members.

In April 2024, the IP Attaché met with a delegation from the American Intellectual Property Law Association (AIPLA) in Bangkok, Thailand. The delegation included the President, Former President, and Chair of the AIPLA Far East Committee. The purpose of the meeting was to discuss the IP landscape in Southeast Asia. During the meeting, the IP Attaché provided information on the IP systems of each ASEAN country, including current and proposed changes to IP policy, laws, and regulations, as well as IP enforcement regimes and concerns of the US government and stakeholders. The discussion also covered various other topics, including infrastructure, foreign direct investment (FDI), and the investment climate in Thailand and other parts of Southeast Asia. The briefing was attended by 10 AIPLA delegates.

South Asia

On November 14 - 16, 2023, the IP Counselor for South Asia co-hosted a three-day USPTO-U.S. DOJ “*Seventh Meeting of the IP Crimes Enforcement Network (IPCEN VII)*” in Bangkok, Thailand. The program brought together around seventy key law enforcement and industry officials from more than a dozen Asian nations including India, Bangladesh, Sri Lanka, and the Maldives from South Asia. The program series aims to strengthen international cooperation in fighting large-scale IP crimes. IP Counselor moderated two panel discussions focused on effective IPR criminal enforcement strategies with perspectives from India and Bangladesh.

On January 11, 2024, visiting Assistant U.S. Trade Representative for Innovation and IP, and Director for Innovation and IP, along with the USPTO Senior IP Specialists joined an IP Roundtable hosted by AMCHAM for its members. Their senior leadership from a cross-sectoral mix of participants from sectors such as defence, pharma, health, food & agriculture etc. joined the roundtable. They discussed various IP protection and enforcement issues including lack of patent linkage, need for stronger enforcements with respect to counterfeiting and smuggling, and need for stronger enforcement of patents, and sought USG support for their resolution. The roundtable drew around seventeen participants.

On January 30, 2024, the U.S. IP Counselor spoke on IP protection and enforcement in the context of information technology and personal data protection regimes in India at the session on legal services at the mission-supported Indo American Chamber of Commerce (IACC’s) Conference on “*Strengthening Indo-US Relationship in Amritkal-Aatmanirbhar Bharat.*” The conference drew around one hundred fifty participants.

On March 11, 2024, the U.S. IP Counselor joined the visiting USPTO Director Vidal and other colleagues to participate in the IP Session co-hosted by the U.S.- India Strategic Partnership Forum (USISPF) and the USPTO in New Delhi to discuss various IP protection and enforcement issues including counterfeiting and piracy. Director Vidal delivered remarks; heard from the stakeholders and members of USISPF across an eclectic mix of sectors from pharmaceuticals to agriculture to defense to tech to media and entertainment; and emphasized the importance of

working together to create a stronger IP ecosystem in India. The session drew around thirty-five participants.

On March 11, 2024, the U.S. IP Counselor joined the visiting USPTO Director Vidal and other colleagues from the USPTO and DOJ to participate in the “*Roundtable on Trade Secrets*” that was hosted by the Federation of Indian Chambers of Commerce & Industry (FICCI) with the support of the USPTO. The USG representatives were joined by the Delhi High Court Judge, the Chairman of the Law Commission of India, the Director of India’s Department for Promotion of Industry and Internal Trade (DPIIT), and representatives from the Indian IP Office, like-minded missions (the British High Commission and Danish Embassy), and industry members of FICCI, and academicians. Director Vidal and other participants discussed best practices for enhancing the trade secrets protection and enforcement framework in India. The roundtable drew around forty-five participants.

On March 15 - 17, 2024, the USPTO South Asia Office hosted a 3-day “*South Asia Judicial Conclave on Intellectual Property Rights*” in New Delhi in collaboration with the Delhi Judicial Academy and DOJ with the support of the High Court of Delhi. On March 15th, the visiting USPTO Director Vidal joined the High Court of Delhi Acting Chief Justice, the U.S. Ambassador to India, the U.S. IP Counselor, and other colleagues from the USPTO and DOJ to welcome around 100 lead Judges from across the South Asia region and the United States to the inaugural program of the unprecedented 3-day “*South Asia Judicial Conclave on IPR.*” The Conclave discussed many IP enforcement issues including “Enforcing IP in New Digital Ecosystems,” “Cross Border IP Enforcement and Criminal Remedies,” “Addressing Digital Piracy and Online Counterfeiting,” and trade secrets and standard essential patents (SEP) enforcement, among others. From the U.S. side, a District Judge from the U.S. District Court for the Eastern District of New York, Senior District Judge from the U.S. District for the Middle District of Florida, Magistrate Judge from the U.S. District Court for the Northern District of Florida, OPIA Attorney Advisor, DOJ ICHIP Attorney Advisor, Special Agents from HSI, and representatives from the National IPR Coordination Center delivered remarks or presentations at the Judicial Conclave. The Judicial Conclave drew over four hundred participants.

On March 19, 2024, the U.S. IP Counselor spoke at a Seminar on “*Piracy-Cybercrime Nexus: Risks to Users and Challenges in Disrupting the Criminal Ecosystem*” in Mumbai. The Seminar launching an empirical research study on the linkages between malware and movie piracy websites was organized by Alliance for Creativity and Entertainment (ACE), and Indian School of Business (ISB) in collaboration with the USPTO at the U.S. Consulate, Mumbai. ACE specifically commissioned the ISB study to socialize the very real risks associated with the piracy/malware nexus to both consumers and the government. The study investigated the link between digital piracy and cyber threats, with a focus on malware. The IP Counselor delivered a welcome address. Principal Secretary to Maharashtra Chief Minister, who in his previous role, led the Maharashtra IP Crime Unit, delivered a keynote address. The Seminar drew over fifty participants.

On April 10, 2024, the U.S. IP Counselor participated in a global enforcement meeting with the Motion Picture Association (MPA), its member companies, and its global enforcement arm ACE that drew over fifty attendees. The discussion centered on key initiatives of the IP Attaché

Program, the general need for a national solution for IP crime enforcement, recent events and training in the region, and working on ways to include industry in future programming for decision makers.

In April 2024, the U.S. IP Counselor participated in the USPTO-FDA's program on "*Combating Counterfeit Pharmaceuticals*" organized for Pakistan judges, customs officials and drug regulators.

On April 30, 2024, the U.S. IP Counselor held an interactive session with twenty newly appointed judges at the Lahore High Court. The IP Counselor emphasized the need to bridge disparities between Pakistan's IP laws and international standards. The judges expressed a keen interest in learning about U.S. and international legislation concerning trade secrets, digital piracy, and artificial intelligence.

On May 21, 2024, the U.S. IP Counselor joined an "*IP Attaché Roundtable*" on various trademark protection and enforcement issues including the online environment at the Annual INTA Meeting in Atlanta. The Roundtable drew fifty participants.

In June 2024, the U.S. IP Counselor addressed South Asian government officials and judiciary on the importance of Alternate Dispute Resolution (ADR) for IP matters during a South Asian regional program hosted by CLDP in Kathmandu, Nepal.

On July 13, 2024, the Senior IP Specialist spoke on "*IP and Anti-counterfeiting from the perspective of U.S. – India Bilateral Relationship*" at the Diplomatic Simulation on "*Global Counterfeit Trade: High Cost of Cheap Goods*" organized by the Public Diplomacy Department of the U.S. Embassy, New Delhi. The Public Diplomacy Officer delivered opening remarks. The program drew around thirty participants.

On July 23, 2024, the Senior IP Specialist spoke at a panel on "*Unified Front: How Public-Private Partnerships are Strengthening the Battle Against Counterfeiting*" at the Asia Security Conference on Anti-Counterfeiting, Trademark & Brand Protection organized by the Asias Security Group and PHD Chamber of Commerce and Industry in New Delhi from July 23-24, 2024. Representatives from like-minded missions (UK, France, Denmark, and Japan) and industry joined the panel. The program drew over ninety-five attendees.

Middle East/North Africa

In October 2023, OPIA's Enforcement Team conducted a two-day IPR Administrative Enforcement workshop held in Dubai. The program hosted approximately 33 officials from various Emirati Department of Economic Developments who can exercise administrative authority against counterfeit goods, including representatives from Emirati Customs. The program leveraged expertise from HSI, CBP, North Carolina District Attorney, Michigan State University, and a Federal Magistrate Court Judge. The program included several Emirati speakers and facilitated a positive exchange of best practices.

In January 2024, OPIA’s Enforcement Team conducted a three-day “*IPR Border Enforcement Workshop*” in Tangier, Morocco. The program hosted 27 customs officials, 14 Commercial Court Judges and 2 Office Marocain de la Propriété Industrielle et Commerciale (OMPIC) representatives. The program leveraged expertise from across the USG, including three speakers from CBP’s Intellectual Property Enforcement, Fines Penalties and Forfeiture and New York Operations. The program also included speakers from HSI and DOJ. The speakers utilized a number of case studies in their discussions, which facilitated substantial exchange with the officials. Moreover, the program provided a rare opportunity for judges and customs officials to hear from one another and understand one another’s processes. On the last day of the program, the group visited TANGER-MED, one of the largest ports in North Africa.

In February 2024, OPIA’s Enforcement Team conducted a three-day “*IPR Enforcement Workshop*” in Tunis, Tunisia. The program hosted approximately 40 Tunisian government officials from Ministry of Trade, INNORPI (IP Office), Customs, and the Ministry of Justice. This workshop was a first of its kind for Tunisians as an enforcement workshop had not been conducted at this scale. The program provided a forum for the enforcement officials to interact with one another and explore opportunities of joint coordination. The program also benefited from U.S. expertise, which included representatives from CBP, HSI, DOJ, the Federal Judiciary, and Michigan State University.

In April 2024, OPIA’s Enforcement Team conducted a three-day “*IPR Enforcement Workshop*” for Algerian officials held in Paris, France. The program was co-organized with French Patent and Trademark Office (INPI). The program hosted 28 Algerian government officials from Instituto Nacional de Propiedad Industrial (INAPI), Ministry of Commerce, Ministry of Justice, and Office National de Diffusion Artistique (ONDA). The workshop sought to facilitate dialogue and interaction between the various government ministries and increase coordination on IP Enforcement matters. The program leveraged support from French trademark experts, French Customs, and UNIFAB and focused on U.S. best practices as provided by representatives from DOJ, CBP, HSI, the Federal Judiciary, and Michigan State University.

In July 2024, the MENA Team hosted a 15-person delegation from the Saudi Trademark, Patent and Copyright Grievance Committees. The Enforcement Team organized a day-long session on Copyright Enforcement and then coordinated meetings for the group with DOJ, the U.S. Copyright Office and the Federal Judicial Center.

East Asia

U.S. Embassy Beijing personnel attended the “*Parallel Session of International Cooperation in Protecting IPR and Fighting Against IPR Infringement and Counterfeiting (CIIE IP Forum)*” in Shanghai in November 2023. The forum was hosted by the People’s Republic of China (PRC) Ministry of Commerce (MOFCOM) and the State Administration for Market Regulation (SAMR). The forum touched on a number of topics centered around the progress and challenges of the PRC’s IP enforcement regime. Panelists and speakers highlighted the common challenges in IP enforcement that government and the private sector face globally, and the growing role of AI as a tool in IP enforcement.

On August 5 - 6, 2024, the IP Counselor gave a keynote speech and hosted a panel on *“International Collaboration & Exchange on Criminal IP Enforcement”* during the Quality Brands Protection Committee (QBPC) Criminal IP Enforcement Forum in Changzhou, China. Over 200 people attended the forum, including officials from local public security, procuratorial and judicial departments of 17 provinces and municipalities, China Association of Enterprises with Foreign Investment (CAEFI), IP Key China, INTERPOL, USPTO, Revenue Solicitors Office of Ireland, EUROPOL, officials from foreign embassies and consulates, scholars, and representatives from rights holders and trade associations, including QBPC. The forum included keynote and expert addresses and panel discussions on *“New Trends, Challenges and Explorations in Criminal IP Enforcement,” “Digital Economy and IP Protection,” “New Hotspots and New Characteristics of IP Litigation, Criminal Incidental Civil Litigation,”* and *“International Collaboration & Exchange on Criminal IP Enforcement.”*

The IP Attaché in Shanghai continued commercial diplomacy and outreach efforts with local and provincial governments in Eastern and Central China in FY 2024. In September 2024, the Shanghai IP Attaché traveled to Changsha to support Ambassador Burns’ industry roundtable with AmCham Central China and U.S.-China Business Council (USCBC) members, before moving on the Wuhan to speak at SAMR’s annual national conference on fair competition. SAMR’S annual conference on fair competition (NFCCC) was held this year in Wuhan, Hubei, on September 10-11. The Attaché spoke at SAMR’s invitation on trade secrets during the session on unfair competition. While many of the speakers at the conference argued that there is a need to create a “balance” between fostering innovation and preventing IP “abuse,” the Attaché in her remarks framed IP as pro-competition because IP fosters innovation that drives new entrants to the market. Her outreach to Hubei provincial IP officials and judges in September 2024 was the first meeting to take place between the two sides in several years. She also continued to build on meetings with counterparts in Shanghai, culminating with three substantive meetings with top Shanghai officials in April to coincide with a USPTO visit to discuss priority and topline issues.

USPTO Shanghai aided in capacity building and in promoting public awareness on IP. The IP Attaché recently spoke on trade secrets, including issues of importance in the bilateral relationship, at China’s annual conference on fair competition. For World IP Day, the IP Attaché worked with the Consul General to generate a social media post around this year’s theme. The Attaché also participated, once again, in a major U.S. e-commerce platform’s World IP Day event by speaking to the platform’s sellers on the dos and don’ts of registering IP. USPTO Shanghai also 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.

The IP Counselor in Beijing and the IP Attaché in Shanghai supported USPTO Director Vidal during her successful visits to Beijing and Shanghai, China in April 2024 where she met with government officials to advocate for stronger IP protection and enforcement.

Oceania

From February 28 to April 24, 2024, the USPTO Enforcement Team conducted an eight-week *“Brand Protection and Product Identification Workshop Webinar Series”* in partnership with the Oceania Customs Organization. The series focused on various product categories, including

apparel and footwear, electronics and personal care products, sports apparel and luxury goods, food and beverage, automotive parts, lighters, lubricants, sports equipment, pharmaceuticals, medical devices, healthcare, cosmetics and skincare, agrichemicals, and pet food.

On August 26 - 29, 2024, the USPTO, in partnership with the Oceania Customs Organization, with the support of the Attorney General Alliance, National Association of Attorneys General, and the participation of the CBP, HSI, Consumer Product Safety Commission, U.S. Federal Trade Commission, and the FDA's Office of Criminal Investigations, held a "*Pacific Colloquium on Consumer Protection, Border Security, and Enforcement Against Trade in Counterfeit Goods*" in Los Angeles, California, attended by approximately 50 government officials and stakeholders from a number of Pacific island nations and territories, including Australia, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Fiji, Guam, Kiribati, Nauru, Niue, Papua New Guinea, Samoa, Solomon Islands, Tonga, and Tuvalu. Session discussions focused on the interplay between trademark protection, anti-counterfeiting enforcement, and consumer health and safety, particularly in the border enforcement context.

DEPARTMENT OF DEFENSE

DEPARTMENT OF DEFENSE

“The Defense Criminal Investigative Service (DCIS), the law enforcement arm of the 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 mission and betrays the public’s trust. This investigation demonstrates DCIS’ ongoing commitment to working with its law enforcement partners to hold individuals who defraud the DoD accountable.”³

– Bryan D. Denny, Special Agent in Charge of the DCIS
Western Field Office

Department of Defense Appendix for FY 2024 Annual Report

This appendix discusses the FY 2024 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 develop a high-performing Defense acquisition workforce through talent management, acquisition training, online resources, and organization support to deliver effective, affordable warfighting capabilities.

Capitalizing on the latest technology amid a rapidly evolving and challenging geopolitical environment is central to the future of U.S. national and economic security and its ability to maintain technological superiority by acquiring and sustaining advanced warfighting systems. Intellectual Property (IP) in DoD acquisitions is critical for ensuring return on technology investment, promoting technical innovation, and enhancing competition, supportability, technical research, and affordability.

Guided by its “FY 2021-2026 Intellectual Property Strategic Plan,” DAU continued to develop training resources for the DoD acquisition workforce on this pivotal topic and explore strategic partnerships with DoD and federal agencies, industry, academic institutions and non-profit organizations. FY 2024 training initiatives focused on three themes:

- (1) The intersection of IP and other topical areas significant to sustainment and acquisition of weapon systems;
- (2) Enhancing DAU’s training portfolio on emerging technologies and national security issues; and
- (3) Engaging with federal agencies and industry partners to improve the acquisition process, including licensing of proprietary IP.

³ DOJ press release, “Man Pleads Guilty to Selling \$3.5M in Counterfeit and Deficient Electronics for Use in Military Systems” (March 28, 2024) at <https://www.justice.gov/opa/pr/man-pleads-guilty-selling-35m-counterfeit-and-deficient-electronics-use-military-systems>.

Key highlights of DAU's FY 2024 training initiatives include:

Developed and deployed numerous Online Modules, Credentials and Videos

- ACQ 0710-0740 and ACQ 0760-ACQ 0770 Foundational IP and licensing rights modules; Software Engineering (SWE) 2050 microlearning module
- ACQ 3200, Foreign Investment and National Security
 - Content Highlights
 - Adversarial foreign capital practices to gain technology information and market share focusing on China and Russia;
 - China's anticompetitive practices using foreign company licenses to acquire IP;
 - China's manipulation of the supply chain via a take-and-replace strategy;
 - Foreign actors' effort to gain access through investments in companies to gain control over critical infrastructure; and,
 - Chinese government's cyber espionage campaigns to steal IP from U.S. companies (e.g., oil and energy, steel and aviation industries).
- CLCL 018 Product Support Data Requirements Credential
- Business Innovation Research (SBIR) and Negotiation on-demand topical videos
- Continued development of 6 critical IP topical videos (e.g., IP and Supply Chain, IP and AI)

IP Webinars and Workshops

- 16 Intellectual Property and Data Rights (IPDR) webinars, including a five-part web series discussing requirements and best practices for securing IP for weapon system sustainment from the product support manager's perspective

Representative Workshops:

- DBS Forum, Software Acquisitions: The Basics – Data Rights and License Agreements
 - Let's Talk Data Rights: Leveraging Reverse Engineering to Address Intellectual Property Rights
 - Let's Talk Data Rights: Four-Dimensional Intellectual Property 'Mapping'
 - Developing an IP Strategy, Sustainment Series with Asst. Secretary of Defense for Product Support
 - Intellectual Property Considerations for Performance Based Logistics (PBL), Sustainment Series
 - Leveraging Reverse Engineering to Address IP issues
 - Acquiring Artificial Intelligence (AI)-Enabled Technology
 - Leveraging Technology Transfer for Future Acquisitions
- 12 Intellectual Property and Data Rights (IPDR) Workshops

Representative Workshops/Courses:

- Detroit Arsenal Acquisition Day
- DoD Other Transaction (OT) Monthly Cross Talk Event
- OSD IP Cadre Government and industry Forum
- National Contract Management Association (NCMA) Nexus Event

- OSD Intellectual Property Cadre and DAU OT Workshop
- LOG 465 Government-Industry IP and Data Rights Fundamentals

Collaborative Partnerships

To enhance the development of IP curricula and training initiatives for the DoD acquisition workforce, DAU continued to engage in mission assistance activities across the Department and explore partnerships with DoD and other federal agencies, associations and non-profit organizations, and industry.

Office of Assistant Secretary of Defense (OASD), Science & Technology (S&T)/Technology Innovation Industrial Base (TIIB)/Technology Transfer, Transition, and Commercial Partnerships (T3CP)

T3CP is the Office of Primary Responsibility (OPR) for adoption and implementation of iEdison department-wide, as the exclusive software reporting platform for unclassified extramural research subject inventions under Executive Order 14104 “Federal Research and Development in Support of Domestic Manufacturing and United States Jobs” by December 2025.

In December 2024, the DoD and USPTO formalized a partnership in a Memorandum of Understanding (MOU) to increase communication, cooperation, and coordination in mutual benefit of both Parties in the interest of the United States’ national security and protection of the federal government’s intellectual property and assets.

OSD R&E S&T Program Protection (PP) is performing a study to identify risk for aggregating technology information within iEdison. Results of this study will help the DoD to further reduce any concerns with iEdison by providing insight and mitigations on subject invention report aggregation.

The DoD’s partnership intermediary, TechLink, provides web-based training <https://web.archive.org/web/20200803085631/https://dodt2trainingworkshop.com/>, annual Technology Transfer University (T2U) Training (virtual), and Capstone (in-person) in Bozeman, Montana. TechLink will work with the Laboratory Quality Enhancement Program-Technology Transfer (LQEP-T2) Professional Development Working Group (PDWG), Defense Acquisition University (DAU), the Federal Laboratory Consortium (FLC), and the U.S. Patent and Trademark Office (USPTO) to design a one-hour web-based training for Scientists and Engineers (S&Es), which will be available on-demand for all the DoD T2 workforce.

**DEPARTMENT OF HEALTH AND HUMAN
SERVICES**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

“...[T]he FDA will continue to engage and collaborate with other government agencies to ensure information sharing, data driven strategies, and coordinated efforts to interdict illicit products offered for import...The FDA is proud to be part of the joint National Operational Strategy that will launch in this fiscal year. We will provide surveillance and monitoring of unapproved drug supply chains.”⁴

– Robert M. Califf, FDA Commissioner

Department of Health and Human Services Appendix for FY 2024 Annual Report

This appendix discusses the FY 2024 activities of the Department of Health and Human Services, through the Food and Drug Administration.

Food and Drug Administration (FDA)

Drug counterfeiting is a serious threat to public health. Counterfeit drugs or other illegal medical products can raise significant public health concerns. 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 legitimate 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 dispensers. As of November 27, 2023, the DSCSA also requires critical steps to achieve electronic, interoperable tracing of certain prescription drugs at the package level. These

⁴ Remarks by FDA Commissioner Robert Califf to the 2024 Rx and Illicit Drug Summit” (April 1, 2024) at <https://www.fda.gov/news-events/speeches-fda-officials/remarks-fda-commissioner-robert-califf-rx-and-illicit-drug-summit-04012024>.

requirements 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 2024, in response to concerns about industry readiness and to support successful implementation leading to a safer drug supply chain, FDA published two compliance policies establishing a stabilization period of one year (from November 27, 2023 - November 27, 2024) to accommodate additional time that trading partners in the pharmaceutical supply chain may need to adhere to DSCSA requirements for electronic drug tracing at the package level. For more information see: <https://www.fda.gov/news-events/fda-voices/fda-protects-patients-harmful-drugs-through-drug-supply-chain-security-act>.

Amongst other continued stakeholder engagement, in November 2023, FDA conducted a webinar that covered DSCSA implementation and expectations for trading partners to achieve interoperable, electronic tracing of products at the package level and provided clarity on the stabilization period. In March 2024, FDA attended a National Association of Boards of Pharmacy (NABP) state regulator meeting, and in May 2024, FDA attended the NABP Annual Meeting. In addition, FDA participated in a workshop hosted by the Partnership for DSCSA Governance (PDG) in January 2024. The workshop focused on investigations of suspect product and allowed industry members and regulators to work through examples of the authorized trading partner (ATP)-to-ATP and ATP-to-regulator interactions that occur as part of a suspect product investigation, including, where required, the illegitimate product notification and the 3911 filing processes.⁵ Finally, FDA conducted a joint public meeting with the PDG in June 2024. The meeting focused on DSCSA implementation and industry's stabilization efforts. 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 December 2023, FDA issued a final guidance addressing compliance with DSCSA requirements regarding verification schemes. The *Verification Systems under the Drug Supply Chain Security Act for Certain Prescription Drugs* final guidance describes FDA's interpretation of the requirements of section 582 of the FD&C Act regarding verification systems, including systems to support the verification (as defined in section 581(28) of the FD&C Act) of the product identifier, and provides recommendations for robust verification systems for the determination, quarantine, and investigation of suspect products, as well as the quarantine, notification, and disposition of illegitimate products.

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

⁵ For more information on FDA's 3911 filing process, please see <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/notify-fda-illegitimate-products>.

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.

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.

Improving Public Health in East Africa by Targeting the Distribution of Illicit Medicines

In June 2024, the FDA (represented by the Office of Criminal Investigations (OCI)) partnered with the Pharmacy and Poisons Board of Kenya and National Drug Authority of Uganda for Economic Co-operation and Development, the United Nations International Narcotics Control Board, Universal Postal Union, and the Pharmaceutical Security Institute to execute a first of its kind multilateral effort intended to improve public health in East Africa by combatting the distribution of illicit medicines.

During [Operation African Star](#), joint enforcement teams examined shipments of human medicines, biologic products, and dietary supplements during enforcement operations carried out in Nairobi, Kenya, and Kampala and Entebbe, Uganda. Violative shipments included medicines which had been stored and shipped outside of approved conditions; prescription medicines lacking valid prescriptions and misdeclared to avoid detection; and purported dietary supplements known to contain undeclared active pharmaceutical ingredients and/or imported in violation of domestic regulations.

The participants also received training regarding emerging threats to public health and safety, such as psychotropic, precursor, and related chemicals. They also received training from representatives from the governments of Kenya and Uganda regarding how violative shipments are identified and addressed via their respective regulatory and legal frameworks. The U.S. Department of State updated the country pages on travel.state.gov for Kenya and Uganda to incorporate findings from the operation. Planning is ongoing regarding additional follow-on activities.

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

Illegal Opioids and Stimulants Online and Warning Letters Issued

The drug overdose crisis is an immense public health issue, and addressing it is one of FDA's highest priorities. While the Biden-Harris Administration has made historic progress in reducing the number of overdose deaths across the country, tragically, nearly 107,000 reported fatal overdoses occurred in 2023, primarily driven by synthetic opioids like illicit fentanyl. The online marketing of illegal 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.

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 non-medically, 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.

In FY 2024, FDA issued warning letters to the operators of three websites illegally offering for sale one or more or a combination of unapproved and misbranded opioids and/or stimulants to U.S. consumers in violation of the FD&C Act. The warning letters can be found at:

<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters>.

FDA and the Reagan-Udall Foundation for the FDA-Convened Fifth Online Controlled Substances Summit

The two-day Summit, held in July 2024, focused on identifying innovative solutions to reduce the online availability of controlled substances. The public session on the first day featured FDA leadership and other experts discussing the impact and evolution of online purchases of controlled substances. The closed working session on the second day included social media, internet, tech, and controlled substances experts engaging in intensive planning and evaluation to identify immediately implementable actions as well as long-term strategies aimed at disrupting the trajectory of the current crisis.

FDA Warned Companies Selling Illegal Products Promoted for Energy that Contain Undeclared Pharmaceutical Ingredients

In December 2023, FDA issued warning letters to [Amazon.com, Inc.](#) and to [Hua Da Trading, Inc.](#) for introducing into interstate commerce products promoted for energy enhancement and confirmed by FDA lab analyses to contain the undisclosed pharmaceutical ingredients sildenafil or tadalafil. Sildenafil and tadalafil are the active ingredients in the FDA-approved prescription drugs Viagra and Cialis, respectively, used to treat erectile dysfunction. As prescription drugs, sildenafil and tadalafil can be used safely only at the direction and under the supervision of a licensed health care professional. These undeclared ingredients may interact with nitrates found in some prescription drugs, such as nitroglycerin, and may lower blood pressure to dangerous levels. People with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.

FDA Warned Companies Selling Illegal Unapproved Semaglutide and Tirzepatide Products

In February 2024, FDA issued warning letters to two firms, [US Chem Labs](#) and [Synthetix Inc.](#) doing business as Helix Chemical Supply (or Helix Chemical Supply), for introducing into interstate commerce unapproved and misbranded semaglutide and tirzepatide products. The firms claimed that their products were for research and not for human use; however, the firms marketed their products for conditions such as Alzheimer’s disease, weight loss, reducing the risk of stroke, heart attack, and heart disease. In addition, US Chem Labs also offered for sale an unapproved product called “Thymalin,” for adults and children, for various conditions such as immunosuppression after chemotherapy in cancer patients.

Additionally, in FY 2024, FDA issued five warning letters to the operators of websites offering for sale one or more or a combination of unapproved and misbranded GLP-1 products to U.S. consumers in violation of the FD&C Act. The warning letters can be found at:

<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters>.

FDA Warned Companies Selling Illegal Topical Analgesic Pain Relief Products

In March 2024, FDA issued six warning letters to OTC drug manufacturers for introducing into interstate commerce unapproved topical analgesic pain relief products marketed for use before, during, or after certain cosmetic procedures, such as microdermabrasion, laser hair removal, tattooing and piercing. Several of these products were also labeled to contain higher than allowable concentrations of active ingredients, such as lidocaine, or other ingredients that do not conform with the conditions of marketing in the external analgesics OTC monographs. Furthermore, there is a lack of evidence demonstrating these products are safe for their labeled uses. The firms warned include [TKTX Company](#), [SeeNext Venture, Ltd.](#), [Indelicare, DBA Inkeeze](#), [Tattoo Numbing Cream Co.](#), [Painless Tattoo Cream Co.](#), and [Dermal Source](#).

FDA Warned Companies Selling Unlawful Inhalant Products Marketed to Promote Alertness and Energy

Between February and April 2024, FDA issued six warning letters to firms selling illegal ammonia inhalant products marketed to promote alertness and boost energy as a caffeine alternative. These novel products are unapproved and misbranded drugs and have not been demonstrated to be safe or effective for promoting alertness and boosting energy. The warning letters can be found at: <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters>. In 2023, [FDA previously warned consumers](#) not to purchase or use inhalants that contain ammonia.

FDA Warned Consumers Not to Purchase or Use Tianeptine Products Due to Serious Risks

In February 2024, FDA issued a [warning](#) to consumers not to purchase or use tianeptine products. Tianeptine is not approved by the FDA for any use. Despite that, some companies are marketing and selling unlawful products containing tianeptine to consumers. They are also making potentially dangerous and unproven claims that tianeptine can improve brain function and treat anxiety, depression, pain, opioid use disorder, and other conditions. In the United States, reports of serious adverse events involving tianeptine are increasing. Poison control center cases involving tianeptine exposure have increased nationwide, from 11 total cases between 2000 and 2013 to 151 cases in 2020 alone.

FDA Warned Against Purchasing or Using Chemical Peel Skin Products Without Professional Supervision and Issued Warning Letters to Companies Selling Unlawful Chemical Peel Products

In July 2024, FDA warned consumers not to purchase or use certain chemical peel skin products without appropriate professional supervision due to the risk of serious skin injuries. The agency has not approved any chemical peel products, and consumers were warned that they should only consider using chemical peel products under the supervision of a dermatologist or licensed and trained practitioner. The consumer warning was accompanied by six warning letters to sellers of unapproved chemical peel products. The companies warned were [Amazon.com, Inc.](#), [Isis.Gold](#), [Matte Beauty](#), [Repair Skincare](#), [Skin Beauty Solutions](#), and [Walmart, Inc.](#)

FDA Warned Against Purchasing or Using Products Containing Undeclared Muscle Relaxants, Antihistamines, Corticosteroids, Proton Pump Inhibitors, and/or Nonsteroidal Anti-Inflammatory Drugs

In August 2024, FDA issued warning letters to [Everymarket Inc.](#), [MexHealth LLC](#), and [SoloVital](#) for their distribution of “Ossos-Sans,” “Vail-Bon Jie Yang Wan,” and/or “Umary.” These unapproved products were found by FDA labs to contain undeclared diclofenac, methocarbamol, dexamethasone, chlorpheniramine, and/or omeprazole. These actions were initiated after the agency received several reports of concerning adverse events associated with these products. FDA continues to receive a large volume of adverse event reports, including heart attack and death, associated with the use of Umary products. The warning letters were followed by an [FDA warning](#) to consumers in September 2024 not to purchase or use Umary products because of their potential to cause harm.

Enforcement Actions

The FDA OCI’s Cybercrime Investigations Unit (CcIU) continues to target darknet marketplaces and vendors that manufacture and sell counterfeit or otherwise illicit FDA regulated products, by identifying those responsible, arresting perpetrators, and seizing manufacturing equipment and counterfeit drugs. In FY 2024, CcIU focused resources to counter public health threats, such as the opioid crisis, through enforcement operations such as ***Operation Wild Web***. This Operation is focused on targeting the sale of counterfeit and illicit synthetic drugs, such as fentanyl analogues and benzodiazepines, on the clear and dark web, social media platforms, and encrypted communication applications. Over the last five years, through the end of FY 2024, OCI’s internet investigative efforts, in conjunction with federal government partners, have resulted in 304 arrests, 263 convictions, as well as the seizure of over \$63 million in financial assets, drug counterfeiting paraphernalia, and weapons.

CcIU’s partnership with the FBI’s Joint Criminal Opioid and Darknet Enforcement (JCODE) unit flourished in FY 2024. JCODE is a whole-of-government approach to combating the counterfeit pill epidemic through enforcement actions against dark web perpetrators. In May 2024, OCI along with our federal law enforcement partners, announced the takedown of a major dark web market and the arrest of its administrator. This dark web market, known as Incognito, was in existence since October 2020 and had facilitated the sale of over \$100 million in various forms of narcotics to include counterfeit versions of FDA-regulated products, which pose a significant overdose threat to the American public. This case is a prime example of CcIU’s efforts to disrupt and dismantle the online sale of counterfeit products, including the targeting of the infrastructure which supports the online sale.

CcIU also participates with the National Cyber-Forensics and Training Alliance (NCFTA), the Intellectual Property Rights Coordination Center (IPR Center), the DEA’s Special Operations Division 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 2024, OCI successfully partnered with CBP, the U.S. Patent and Trademark Office (USPTO), U.S. Embassy London, the United Kingdom’s (U.K.) 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 Lascor-Ancord VII**. Initially launched in 2017, **Operation Lascor-Ancord** addresses illicit FDA regulated products being shipped to the United States through the U.K.

Since its inception in 2017, **Operation Lascor-Ancord** has included seven 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 Lascor-Ancord VII**, which was conducted in the U.K. from May 12-18, 2024, examined 943 packages for violative medical products intended for the United States, identified new types of products being transshipped through the U.K. (including semaglutides, cosmetics, and intrauterine devices), and obtained updated intelligence regarding how these products are being distributed.

Throughout FY 2024, OCI hosted meetings 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 that pose 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.

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>.

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

FDA's National Forensic Chemistry Center (NFCC) scientists developed a handheld Counterfeit Detection (CDx) tool to rapidly screen suspect products and packaging, by visualizing differences between suspect and authentic products and providing preliminary findings in the field. The current CDx technology is used at the U.S. International Mail Facilities (IMFs) and other ports of entry to screen suspect incoming packages and 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 completed, 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. NFCC scientists worked with the FDA IT to update the CD5 to connect to the FDA business network. Connection to the business network allows quicker authentic image library updates, as well as easier communication of results between the users and scientists. This capability also enables scientists to evaluate the integration of artificial intelligence (AI) with the CD5 device. As staff are trained on the newly updated CD5, the devices will be re-deployed to our field offices. Nine Consumer Safety Officers (CSOs) were trained by NFCC in FY 2023. In FY 2025, CD5 training will be provided to CSOs at three IMF locations.

In FY 2024, the CD5 was used eight times to screen three products that contained a total of 1,313 tablets. Eight samples were sent to NFCC where findings in the field were confirmed.

Scientific Presence and Field Deployable Tools for Rapid Field Detection of Illegal, Unapproved, and Counterfeit Pharmaceuticals and Tainted Supplements

In October 2020, the FDA, with the Department of Homeland Security (DHS)/CBP and DHS/Immigration and Customs Enforcement (ICE) Commissioners formalized a partnership at IMFs in a Memorandum of Understanding. This agreement increased collaboration to maximize inspection and detection capabilities in order to prevent illegal and harmful products entering the United States through the nation's IMFs. This partnership includes an increase in scientific resources at selected IMFs and sharing of space, technologies, and information, which facilitates mission responsibilities by improving efficiency and reducing duplication of efforts among the agencies. Additionally, the FDA and the CBP partnered in 2022 to conduct joint operations targeting opioids and other unapproved drugs. The first year of this operation included two phases. Phase 1 of this operation included data sharing across FDA and CBP to inform location and product targeting for Phase 2. During Phase 2, the FDA and the CBP partnered at eight IMFs and five Express Courier Hubs (ECH) to identify products of interest.

The FY 2023 National Operation Strategy (NOS) operational data and results also provided critical information to support the development of FY 2024 NOS targeting. FY 2024 NOS consisted of two operations: *Operation Opioid and Other Drugs* (OOOD) and *US Pacific Territories* (USPT). FY 2024 NOS covered 13 operations across 12 different ports of entry: five IMFs, three land border ports, and four express consignment hubs, which included two dedicated operations focused on imports from US Pacific Territories entering through Honolulu and Los Angeles IMFs. FY 2024 NOS concluded on July 26, 2024. Planning for FY 2025 NOS operations are underway and will be informed in part by data from FY 2024 NOS.

Under the NOS, FDA and CBP examined over 6,600 FDA-regulated products consisting of opioids, controlled substances, and unapproved drugs from FY 2022 through FY 2024. Through these examinations, approximately 802,000 tablets/capsules/pieces consisting of unapproved drugs and controlled substances were refused, destroyed, or referred to CBP for regulatory action.

Satellite Laboratory Program

FDA's NFCC continued expansion of field screening efforts. Field-based scientists were specially trained to use an established set of analytical instruments (toolkit) designed to be a scientifically reliable and efficient approach for rapidly identifying active pharmaceutical ingredients (APIs) in illicit FDA-regulated products (such as counterfeit or otherwise illegal drugs, including opioids, and adulterated purported dietary supplements) at a wide range of API levels with minimal sample preparation. 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.

In FY 2024, the satellite laboratory program expanded the instrument toolkit to include portable gas chromatography with mass spectrometric (GC-MS) detection. There were no separation capabilities in the instrument toolkit prior to the addition of the portable GC-MS. This instrument improved the program's capabilities, increasing the number of APIs confirmed in the field, and reducing the number of samples sent to the traditional laboratory for secondary analysis. In FY 2024, the New York and Los Angeles satellite laboratories were added to the program, with plans to open a Honolulu satellite laboratory in early FY 2025. FDA's NFCC hired and provided extensive training for five permanent chemists to support operations in Cincinnati, Miami, New York, and Los Angeles.

Since inception, FDA's satellite laboratories have examined more than 2,200 products. FDA has taken regulatory action on 1,959 of these products. Over 95% of these potentially dangerous products consisting of over 800,000 lot units were administratively destroyed or refused entry into the United States. In FY 2024 alone, FCC satellite laboratories examined over 1,000 products and FDA has taken regulatory action on over 800 of these products. Over 93% of these potentially dangerous products consisting of nearly over 215,000 lot units were destroyed or refused entry into the United States.

Intelligence National Threat Response- El Paso Illicit Drug (INTREPID) Program

Scientists from the FDA's NFCC are working with scientists from CBP's Laboratories and Scientific Services (LSS) and DEA's Special Testing Laboratory to establish a program to generate chemical attribution information or chemical fingerprints of counterfeit and illicit opioid tablets and other emerging hazardous illicit drugs. The current program called INTREPID (Intelligence National Threat Response-El Paso Illicit Drug) enables laboratories from the three agencies to share and leverage vast technical knowledge and intelligence from three diverse perspectives. INTREPID scientists use their combined expertise and state-of-the-art analytical methods to provide research, scientific support and actionable intelligence on the nature and source of rapidly evolving illicit drug threats. The data derived from INTREPID offers investigators and the intelligence community in-depth analysis of seized materials to provide trafficking linkages and geo-sourcing of illicit drugs and precursor materials. The two current high priority INTREPID projects include analysis and comparison of seized tablets containing fentanyl, and fentanyl powders, and the analysis of xylazine. The first groups of samples of seized tablets (75 samples/200 items) containing fentanyl and fentanyl powders have been received by NFCC from CBP and are in the process of being analyzed. The results generated by NFCC analysis are being shared and combined with the results generated by CBP and the Drug Enforcement Administration (DEA). NFCC, CBP and DEA scientists meet bi-weekly to discuss on going sample analysis, share data on samples analyzed and share information on new emerging illicit drug threats.

Eventually, the INTREPID program will be based at EPIC (El Paso Intelligence Center, Ft. Bliss), where scientists from each of the three agencies will be co-located, eliminating the need to split and ship evidence. Planning for renovation of space and build out of the laboratory at EPIC is in progress.

Collaboration with CBP at 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, and the number detained, as suspected counterfeit pharmaceuticals; products marketed as foods and/or dietary supplements containing undeclared active pharmaceutical ingredients; other unapproved new drugs; or 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), which is part of the recently renamed Office of Inspections and Investigations (OII) (formerly the Office of Regulatory Affairs), is working – in cooperation with the Office of Specialty Laboratories and Enforcement Support (OSLES) in the Office of the Chief Scientist – to extend CDx applications and explore other handheld technologies for identifying additional potentially counterfeit pharmaceuticals as well as FDA-regulated products that contain undeclared APIs.

Additionally, beginning in May 2022, NFCC held four training sessions for OIO field staff and nine OCI Special Agents on a handheld Raman device. In FY 2023, FDA's NFCC 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. In FY 2024, FDA's NFCC provided beginner handheld Raman training to eight OIO CSOs, followed by an operation to provide a real-world application. The handheld Raman is also used by satellite laboratory chemists to complement the CDx for identification of counterfeit or otherwise illicit pharmaceuticals. This tool can screen for potentially misbranded and adulterated drug products, assist investigators in making sampling decisions, and adds a margin of safety for investigators by permitting some identifications to be accomplished on closed containers, reducing or eliminating investigator exposure to the product.

International Capacity Building and Training: FDA Capacity Building and Training

Below are examples of FDA's OCI capacity building and training activities with foreign countries.

In October 2023, OCI provided an "FDA OCI 101" to the Police Services of Northern Ireland (PSNI) in Belfast, Northern Ireland. OCI described the types of investigations OCI conducts and explained OCI resources.

In November 2023, OCI presented at the "U.S.-U.K. Dialogue on Customs Enforcement of Intellectual Property Rights" hosted by the USPTO. This two-day program, which brought together officials involved in customs-related IP enforcement from the U.K. and the United States, focused on trends, challenges, and best practices regarding IP border enforcement.

In December 2023, OCI participated in the biannual meeting of the European Heads of Medicines Agencies (HMA), Working Group of Enforcement Officers (WGEO) meeting and provided a presentation to its members on OCI's criminal investigative mission. The meeting took place in Madrid, Spain. HMA is a network of the leaders of the National Competent Authorities 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 January 2024, OCI provided "Internet Investigations" training virtually to an African Pharma Crimes Working Group at the request of the Department of Justice and the Department of State.

In February 2024, OCI provided "Internet Investigations" training virtually to Peruvian law enforcement at the request of the USPTO.

In February 2024, OCI participated in the Universal Postal Union's Postal Security Group meeting in Bern, Switzerland, and provided training regarding cross-cutting efforts to secure the mail stream.

In February 2024, OCI provided an "FDA OCI 101" at the "13th Annual Pharma Anti-Counterfeit and Serialization 2023 meeting." OCI described the types of investigations OCI conducts along

with OCI resources to numerous U.K. and European pharmaceutical Global Security members and members of U.K. regulatory agencies.

In March 2024, OCI participated in Europol's *Operation Shield IV/V* kick off meeting in Athens, Greece. Operation Shield is the Europol initiative targeting certain medical related products.

In April 2024, OCI participated in the 1st plenary session of the “*Organisation for Economic Co-operation and Development's Working Party on Countering Illicit Trade (OECD-TFCIT)*” in Paris, France. During the meeting, OCI provided an overview of its criminal investigative mission and ongoing multilateral and bilateral enforcement efforts.

In April 2024, OCI participated in an international symposium led by the Uganda Communications Commission, in partnership with the Universal Postal Union. Held in Kampala, Uganda, the symposium focused on enhancing capacities to secure the mail stream. During the symposium, OCI provided training regarding the evolving threat to public health and safety posed by the distribution of illicit medicines.

In April 2024, OCI participated in Europol's *Operation In Our Sites (IOS)* kick off meeting in Alicante, Spain. Operation IOS is the Europol initiative targeting certain medical related products sold online.

In April 2024, OCI, together with the IPR Center participated in a meeting with U.K. offices – the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA), and the City of London's Police Department (CoLP) and its Police Intellectual Property Crime Unit (PIPCU).

In April 2024, OCI attended the “Future of Financial Crimes” presentation by the U.K.'s His Majesty's Revenue and Customs (HMRC), which was provided to members of the London-based Foreign Law Enforcement Community (FLEC).

In April 2024, FDA-OCI, in partnership with the USPTO Global Intellectual Property Academy, hosted a delegation from Pakistan for a “*Combating Counterfeit Pharmaceuticals Program.*” The purpose of the program was to build on the mutual learning and dialogue that took place during prior modules of the Counterfeit Virtual Program in 2021. This in-person delegation consisted of senior members of the Pakistani Drug Regulatory Authority, Customs and the Pakistani judiciary (to include judges with the Intellectual Property Rights Court). The venue included meetings and presentations at the USPTO facility in Alexandria, Virginia, and the FDA's White Oak Campus in Silver Spring, Maryland. Presentations at these locations included the IPR Center, USPTO, FDA-OCI's CcIU and IOP sections and senior leadership and FDA's Center for Drug Evaluation and Research, among others. The delegation then travelled to New York City where they toured an IMF at JFK International Airport and received briefings from CBP as well as members of the Division of Northeast Imports (DNEI) of the Office of Import Operations in ORA. The visit concluded with a round-table discussion and FDA-OCI case study at the FDA District Office in New York.

In April 2024, OCI participated in a panel discussion at the “2024 EMEA Security Conference” in London. OCI described the types of investigations OCI conducts and OCI resources to numerous U.K. and European pharmaceutical global security members and members of the U.K. and European regulatory agencies.

In April/May 2024, OCI participated in the “U.S. CBP Hit-And-Run-Post Task Force Dutch Study.” This study included nine Dutch customs, police, and prosecutorial representatives. OCI provided an “OCI 101” presentation to them and to the U.S. representatives from CBP, HSI, the U.S. Postal Inspection Service (USPIS), and the DEA.

In May 2024, OCI participated in a week-long workshop with law enforcement representatives from Colombia, Peru, Ecuador, Bolivia and Chile on “Internet Investigations” and combating counterfeit pharmaceuticals sold online. This workshop was provided in person in Bogota, Colombia.

In June 2024, OCI participated in a week-long workshop with foreign law enforcement and provided training on “Internet Investigations” at the request of the IPR Center. This workshop was provided in person in Mauritius.

In July 2024, OCI hosted a three-day operational meeting at Europol on transnational criminal investigations and intelligence sharing related to counterfeit medical products. Participants included representatives from Latvia, United Kingdom, Estonia, Lithuania, Spain, Ukraine, Germany, Canada, and Ireland, as well as Europol AP Sustrans, Europol’s group focusing on money laundering crimes.

In September 2024, OCI participated in the “17th International Law Enforcement Intellectual Property Crime Conference” in Willemstad, Curacao. During the event, OCI facilitated a panel discussion on “Implementing Solutions for Cross-Sector Information and Intelligence Sharing.”

In September 2024, OCI participated in the annual meeting of the “Permanent Forum on International Pharmaceutical Crime” hosted by SwissMedic in Zurich, Switzerland. The annual meeting of law enforcement and regulatory personnel from over 20 countries facilitates planning of joint operations to counter global public health threats.

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’s NFCC and the U.K.’s 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. Recently, the ILFCM has increased its focus on products adulterated with DEG/EG (diethylene glycol and ethylene

glycol), the emergence and use of GLP-1 peptide type compounds (e.g., semaglutide) and e-cigarettes and other tobacco products. 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 four senior operations managers, two of which are posted internationally, and consists of approximately 15 full-time IOP Special Agents. The program is also supported by an intelligence research specialist. IOP's priorities include engaging with foreign counterpart agencies and international organizations, responding to U.S. Postal Service IMFs, express consignment carrier facilities (including integrators such as DHL, UPS, and FedEx), air cargo facilities, and sea and land ports. IOP Special Agents routinely conduct joint 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 \$2,500 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 illegal or unsafe articles imported in the IMFs.

FDA developed procedures for the section 801(u) authority and began using this new authority in March 2019. Utilizing this authority, FDA has been able to administratively destroy over 152,000 drug products from FY 2020 through FY 2024 which represents about 63% of all FDA's destructions of drug products not in compliance with U.S. requirements.

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 devices valued at \$2,500 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. The Final Rule for Administrative Destruction was published on May 31, 2024, and became effective on July 1, 2024.

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 the end of fiscal year 2024, **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.

Operation Shield

FDA continues to participate in the annual **Operation Shield**, which is coordinated by Europol. **Operation Shield** is in its fifth iteration and is an initiative targeting certain medical related products.

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 2024 include the following prosecutions:

Large-scale manufacturer sentenced to more than 21 years for trafficking conspiracy involving counterfeit pills pressed with fentanyl. On October 23, 2023, Brandon Albanito was sentenced to 21 years and 10 months in prison for the illegal sale of counterfeit pills pressed with fentanyl that appeared to be oxycodone and other related offenses. Evidence uncovered during the course of the investigation showed that Mr. Albanito was a large-scale manufacturer as evidenced by the commercial grade pill press seized during the execution of a search warrant at his residence and the numerous mail shipments intercepted containing bulk powders, drug precursors, and controlled substances destined for that same address: <https://www.justice.gov/usao-mdfl/pr/cape-coral-man-sentenced-more-21-years-federal-prison-manufacturing-counterfeit-pills>.

Distributor sentenced to more than 17 years for a counterfeit drug trafficking conspiracy.

On December 18, 2023, Kevin Olando Ombisi was sentenced 17.5 years in prison for his role in a conspiracy in to distribute counterfeit pills appearing to be Adderall but containing methamphetamine. Evidence presented in court showed that Mr. Ombisi distributed the products via the Darknet and the encrypted messaging system Wicker in exchange for bitcoin. Final delivery was made via the U.S. Postal Service.

In July 2023, Mr. Ombisi pled guilty to charges filed in a ten-count superseding indictment, including one count of conspiracy to unlawfully distribute controlled substances, three counts of unlawful distribution, one count of attempted distribution, one count of selling counterfeit drugs, one count of conspiracy to commit money laundering, and three counts of mail fraud:

<https://www.justice.gov/usao-wdtn/pr/counterfeit-prescription-drug-distributor-sentenced-federal-prison>.

DEPARTMENT OF HOMELAND SECURITY

Department of Homeland Security

“Individuals who are in a fight for their life against cancer and other deadly diseases and afflictions shouldn’t have to worry about whether they are actually receiving the life-saving medicines that they need to get better. Our special agents work tirelessly, alongside our partners, to track down the criminal organizations and individuals responsible for this abhorrent criminal conduct to hold them accountable and ensure that the public can have trust in the authenticity and efficacy of our nation’s drug supply.”⁷

- Mark Dawson, Special Agent in Charge, Homeland Security Investigations – Houston, Texas

“Protecting the integrity of the supply chain for everyday consumers, government agencies, and our warfighters remains a top priority for Homeland Security Investigations. My office and our partners will continue to work diligently to remove counterfeit products that adversely affect public health and safety from the stream of commerce and hold the offenders accountable.”⁸

- Eddy Wang, Special Agent in Charge, Homeland Security Investigations - Los Angeles, California

“Handheld hair dryers are one of the most commonly and frequently used appliances in our homes, so consumers should be absolutely certain of the product’s quality and reliability. Don’t gamble with your family’s health and safety just to save a buck; buy an authentic hair dryer from a reputable and authorized vendor.”⁹

- Mark Laria, Port Director at the Port of Norfolk-Newport News, Virginia, Customs and Border Protection

Department of Homeland Security Appendix for FY 2024 Annual Report

This appendix discusses the FY 2024 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 (PLCY) 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.

⁷ HSI press release, “Foreign National Charged With Selling Counterfeit Cancer Drugs” (July 29, 2024) at <https://www.dhs.gov/hsi/news/2024/07/29/foreign-national-charged-selling-counterfeit-drugs>.

⁸ DOJ press release, “Leader of Massive Scheme to Traffic in Fraudulent and Counterfeit Cisco Networking Equipment Sentenced to Prison” (May 2, 2024) at <https://www.justice.gov/opa/pr/leader-massive-scheme-traffic-fraudulent-and-counterfeit-cisco-networking-equipment>.

⁹ CBP press release, “Norfolk CBP Officers are Not Blown Away by Counterfeit Hair Dryers Destined to New Jersey” (July 18, 2024) at <https://www.cbp.gov/newsroom/local-media-release/norfolk-cbp-officers-are-not-blown-away-counterfeit-hair-dryers>.

Throughout 2024, PLCY coordinated DHS’s engagement in the USTR-led Special 301 review of global IP regimes, the Notorious Markets List review and actions related to Section 301 concerning intellectual property rights. In 2024, PLCY also joined the Organization for Economic Cooperation and Development (OECD) Working Party on Countering Illicit Trade (WP-CIT) as a Bureau member, participating in the April Plenary meeting of the WPCIT.

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 workshops in key global locations (e.g., Asia, Eastern Europe, and Western Hemisphere) to collaborate on U.S. and international government efforts to bolster enforcement through the sharing of best practices and approaches for detecting and disrupting illicit trade activities.

The Office of Homeland Security Statistics (OHSS) issues the official DHS statistics describing Department-wide IPR seizures, available at <https://ohss.dhs.gov/topics/international-trade/intellectual-property-rights-seizures>.

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

U.S. Customs and Border Protection (CBP)

CBP is the first line of defense against counterfeit and piratical goods entering the U.S. stream of commerce from abroad. CBP maintains a robust intellectual property (IP) enforcement program and deploys substantial resources to interdict IP-violative goods, which can threaten the health and safety of U.S. consumers, as well as the competitiveness of American businesses.

CBP enforces federally registered trademarks and copyrights that are recorded through the e-Recordation program, utilizes automated risk-management systems to analyze and target imported IP infringing goods, and has the legal authority to detain, seize, forfeit, and ultimately destroy forfeited or abandoned IP infringing merchandise entering the United States.

CBP releases statistics on its IP-related seizures in its annual reports and on a dashboard. Information on seizures through FY 2023 is available at <https://www.cbp.gov/trade/priority-issues/ipr/statistics> (the annual reports) and at <https://www.cbp.gov/newsroom/stats/intellectual-property-rights-ipr-seizures> (the dashboard).

Engagement with the Trade Community

CBP engages with stakeholders on a regular basis to educate them on how to work with CBP to protect their IPR at the border. A sample of the Office of Trade’s (OT) engagement with the trade community, including legal associations and academia, in FY 2024 includes the following:

- **USPTO China IP Roadshows**

OT is a regular participant in the USPTO's China IP Roadshow, which is a program that connects stakeholders with cross-border IP enforcement resources. In FY 2024, OT participated in four Roadshow events:

On October 13, 2023, OT participated in a Roadshow in collaboration with the U.S. Commercial Service's San Diego office, the San Diego and Imperial District Export Council, and the Knauss School of Business at the University of San Diego.

On October 30, 2023, OT participated in a Roadshow in Green Bay, Wisconsin. The program was requested by Representative Mike Gallagher (R – Wisconsin), who chaired the House Select Committee on the Chinese Communist Party. OT provided guidance on its e-recording program, the first step for countering infringing imports, among other border enforcement topics.

On March 26, 2024, OT participated in a Roadshow at Malcom X College in Chicago, Illinois, that was attended by Representatives Raja Krishnamoorthi (D – Illinois), ranking member of the House Select Committee on the Chinese Communist Party, and Danny Davis (D – Illinois), as well as speakers from HSI, DOJ, and local businesses.

On September 25, 2024, OT participated in a Roadshow at S.J. Quinney College of Law, University of Utah that was directed to Utah businesses and legal practitioners regarding the protection of IP in the United States and in China. Opening remarks were provided by Kathi Vidal, the Under Secretary of Commerce for Intellectual Property and USPTO Director, and by the Director of U.S. Commercial Service, Utah. The government delegation included attorneys from the USPTO, HSI, and the U.S. Attorney's Office.

- **International Trade Administration (ITA) STOPfakes Roadshow**

OT is a regular participant and primary partner agency with the ITA in the ITA's STOPfakes Roadshows. The OT presentation provided tools to small and medium sized businesses on how to protect their IP against infringing imports, focusing on the benefits of CBP's eRecording program and CBP's administrative enforcement authorities.

On October 24, 2023, OT participated in a multi-agency STOPfakes Roadshow in Portland, Oregon. Other presenters included representatives from the USPTO, the U.S. Copyright Office, ITA, FBI, and private practitioners.

On January 8 - 12, 2024, OT joined the STOPfakes interagency team that staffed an information booth at the annual Consumer Electronics Show in Las Vegas, Nevada. Other team members included the Office of the IP Enforcement Coordinator (IPEC), the USPTO, ITA, and the State Department. OT served as the subject matter expert for border enforcement of IPR and provided resources to inventors, entrepreneurs, and established companies, detailing the ways in which CBP can protect intellectual property

rights. The team interacted with roughly 300 attendees and distributed brochures covering a range of IP topics, including border enforcement and CBP's IPR e-Recordation System.

On March 19, 2024, OT participated in a STOPfakes Roadshow in Jackson, Mississippi. Other presenters included representatives from the USPTO, ITA, and private sector practitioners. The audience included roughly 17 Mississippi-based businesses and organizations seeking assistance with protecting their intellectual property.

On March 21, 2024, OT participated in a STOPfakes Roadshow in Miami, Florida, with agency partners USPTO, ITA, the Export-Import Bank of the United States, and private practitioners. The audience included roughly 15 Florida-based businesses and organizations seeking assistance with protecting their intellectual property.

On April 11, 2024, OT participated in a STOPfakes Roadshow webinar for Iowa businesses. The program had been requested by the Iowa U.S. Commercial Service. OT presented along with an enforcement attorney from the USPTO's Office of Policy and International Affairs, and the program was moderated by ITA's Office of Standards and Intellectual Property. Iowa's Economic Development Authority also attended.

On June 24 - 26, 2024, OT joined the STOPfakes interagency team that staffed a booth in the U.S. Government Pavilion at the Select USA Investment Summit in Maryland. Discussions with conference attendees included IP border enforcement and CBP's IPR e-Recordation program. The team interacted with approximately 250 attendees and distributed brochures covering a range of IP topics, including border enforcement and CBP's IPR e-Recordation System.

On September 10 - 11, 2024, OT joined the STOPfakes interagency team in San Jose and San Francisco, California, to discuss recordation with local businesses. Over 50 local business representatives attended the event, representing the small and medium sized business community in Northern California. Agency partners ITA, USPTO, HSI, and IPEC also participated.

- **Industry Groups and Trade Organizations**

OT often addresses special industry groups and trade organizations to educate them on CBP activities and initiatives in IP border enforcement and to engage them in enhanced partnership with CBP. In FY 2024, OT participated in the following such events:

On October 18, 2023, OT addressed the Motor & Equipment Manufacturers Association (MEMA) IP Subcommittee on opportunities for informed participation in CBP's post-seizure procedures and associated legal authorities and standards.

On December 8, 2023, OT spoke at a meeting of Be Original Americas, a non-profit organization "committed to informing, educating, and influencing manufacturers, artisans, design professionals, and consumers about the economic, ethical, and environmental value of authentic design" (<https://www.beoriginalamericas.com/>). OT has

engaged with Be Original Americas for many years in furtherance of the protection of trademarked designs (including for mid-century modern furniture) from counterfeits.

On December 12, 2023, OT participated in an event sponsored by the Congressional Trademark Caucus (CTC), International Trademark Association (INTA), and U.S. Chamber of Commerce Global Innovation Policy Center (GIPC) entitled “*‘Tis the Season of Counterfeit Awareness, a Holiday Event on Capitol Hill.*” The event highlighted collective U.S. Government intellectual property enforcement efforts, private sector anti-counterfeiting initiatives, and outreach strategies that emphasize the importance of increased education to consumers about the dangers posed by the persistent presence of counterfeit goods. OT sat on a panel with representatives from HSI and USPTO that was moderated by INTA and the GIPC.

On January 22, 2024, OT participated in a meeting with the Automotive Anti-Counterfeiting Council (A2C2) in Detroit, Michigan, to discuss counterfeiting issues facing the automotive sector and CBP’s IPR enforcement at the border. Attendees included representatives of the major automotive manufacturers in North America. The topics discussed included identifying the types of automotive parts that are frequently counterfeited, assessing CBP’s current enforcement efforts in the auto sector, and mutual improvements that the trade and CBP will undertake.

On March 7, 2024, OT spoke on a panel for members of the Intellectual Property Owners Association (IPO), in Washington, District of Columbia. Topics included working with rights holders, disclosure, and authentication of merchandise. OT also provided information on CBP’s IPR e-Recordation System and answered questions from the audience regarding the resources that CBP provides for the protection of intellectual property.

On March 26 - 28, 2024, OT attended and staffed an informational booth at the CBP Trade Facilitation and Cargo Security Summit in Philadelphia, Pennsylvania, entitled “*Regulations and Rulings (RR) at Your Service: Ruling Requests and Recordation of IP.*” OT informed the trade how members could record their trademarks and copyrights with CBP to obtain border protection. The team interacted with roughly 85 attendees and distributed brochures covering a range of IP topics, including border enforcement and CBP’s IPR e-Recordation System.

On April 16, 2024, OT spoke at the Brainlinx Brand Protection Excellence Forum in New York, New York. The event brought together brand protection professionals from Europe, the Americas, trade associations and NGOs. OT presented on CBP’s e-Recordation program, the first step for countering infringing imports, and working with CBP to protect IP rights.

On April 16, 2024, OT was a featured speaker at the GIPC’s Annual Anti-Counterfeiting Event at the U.S. Chamber of Commerce Headquarters in Washington, District of Columbia. OT discussed legal and practical developments in international IP border

enforcement over the past year, focusing specifically on foreign partners' customs agencies that OT had worked bi-laterally with over the previous year.

On April 22 - 25, 2024, OT attended and staffed an information booth at the EarthX Conference in Dallas, Texas. OT served as the subject matter expert for border enforcement of IPR and provided resources to government officials, the private sector, and the general public on how they can protect their IP. The team interacted with attendees and distributed brochures covering a range of IP topics, including border enforcement and CBP's IPR e-Recordation System.

On April 24, 2024, OT participated in a panel on government resources for IP enforcement at the National Cyber-Forensics and Training Alliance (NCFTA) Annual Meeting. NCFTA is an alliance of private industry and law enforcement partners dedicated to information sharing and disrupting cyber-related threats. Over 1,000 participants attended the event.

On April 24, 2024, OT reprised its well-received March 7 panel on CBP's IP Enforcement Regime (discussed above) at the request of the Intellectual Property Owners Association (IPO), addressing over 70 attendees via webinar.

On May 14, 2024, OT spoke at the Trans-Atlantic IPR Working Group (TIPRWG) stakeholders meeting at the U.S. Chamber of Commerce and provided updates on IP border enforcement. USTR, USPTO, and the Commerce Department all provided updates, and stakeholders were able to provide comments. Members from the Directorate General for Trade (DG Trade) of the European Commission were also in attendance and provided updates. On May 15, 2024, USG and DG Trade met again to discuss the updates and stakeholder comments.

On May 14, 2024, OT provided a one-hour webinar to importers, right holders, and other members of the trade community during Miami's International Trade Week. The presentation focused on CBP's IP enforcement regime, and how the trade can work with CBP to protect their IP rights at the border and at U.S. Ports of Entry. Right holders expressed a great deal of interest in the gray market protection portion of the program, and inquired how they could obtain gray market protection with CBP.

On May 15 - 17, 2024, OT attended, spoke at, and staffed an information table at the International Anti-Counterfeiting Coalition's (IACC) Annual meeting, which was attended by well over 600 people in the anti-counterfeiting and brand protection industry. OT spoke on panels entitled "*A View from the Top: Government Leaders on the State of IP Enforcement*," and "*Building Brand Protection Partners Internally and Externally*." OT's remarks discussed the value of border enforcement of intellectual property in combatting dangers to public health, such as counterfeit pharmaceuticals and medical devices, as well as looking to the future of IP enforcement and the impact of emerging technologies, like AI. Co-panelists included law enforcement from Jamaica, Italy, and the UK, a representative from the USPTO, and pharmaceutical industry representatives. OT also participated in a roundtable discussion with USPTO IP attachés (covering EU and

Brazil). Throughout the conference, OT staffed an exhibition booth and served as the subject matter expert for border enforcement of IPR and provided resources to inventors, entrepreneurs, and established companies, detailing the ways in which CBP can protect intellectual property rights.

On May 30, 2024, OT met with the Society of Product Licensors Committed to Excellence (SPLiCE), to discuss working with CBP through the e-Recordation program. SPLiCE represents a community of licensors who share best practices to protect, promote and enhance brand integrity, with 70+ member companies from academia, the business community, private sector, military, and nonprofit sectors. OT was asked to present to SPLiCE members at their annual meeting in September.

On June 11, 2024, OT attended a meeting of the Automotive Anti-Counterfeiting Council (A2C2) at the IPR Center on resources for countering defective airbags and other dangerous automotive components. The meeting was attended by industry representatives and a panel of government agencies, including IPEC, HSI, DOJ, ATF, and NHTSA. OT presented on how stakeholders, including regulatory agencies, could take advantage of CBP's e-recordation program.

On September 10 - 11, 2024, OT led a session at the Society of Product Licensors Committed to Excellence (SPLiCE) Workshop at McDonald's HQ in Chicago, Illinois, on best practices in working with CBP to enforce IPR at the border, as well as an overview of the CBP regulatory border enforcement procedure and how best to respond to requests for information received from CBP. SPLiCE, founded in 2004, represents a community of licensors who share best practices to protect, promote and enhance brand integrity.

On September 18, 2024, OT provided an educational session to the pharmaceutical industry as part of CBP's Pharmaceutical, Health, and Chemicals Center of Excellence and Expertise Roundtable. OT provided an overview of the eRecordation program and how to best work with CBP to enhance enforcement of recorded IP rights.

On September 23 - 24, 2024, OT participated in the USDA America Food & Beverage (AF&B) Conference at World Trade Center Miami, displaying an educational booth on CBP's border enforcement of food and beverage-related IPR. The AF&B is a three-day conference covering the latest in food and beverage trends, such as top rules and tips for importing food products into the U.S. market, food packaging, regulatory advice, as well as future and economic outlooks in the industry.

- **Legal Associations and Academia**

The attorney-advisors in OT's IP Enforcement Branch often engage with legal associations and academia in accepting speaking requests, moderating panels, and otherwise educating the legal industry on CBP's IP enforcement regime. In FY 2024, OT participated in the following events:

On November 4, 2023, OT served as a judge at the George Mason University, Terrorism, Transnational Crime and Corruption Center (TraCCC)'s "*Bring Down Counterfeiting 2023*" Hackathon, along with representatives from the USPTO, U.S. Chamber of Commerce, and the National Crime Prevention Council. Opening remarks were made by the CBP Office of Trade Deputy Executive Assistant Commissioner John Leonard.

On November 11 - 12, 2023, OT participated in the American Conference Institute's Import Compliance and Enforcement Seminar, speaking on panels concerning U.S. International Trade Commission Section 337 Investigations and the IP border enforcement legal regime, and moderating a panel discussing opposing policy positions on retaining CBP's *de minimis* program.

On March 12 - 14, 2024, OT provided the Keynote Address as the Michigan State University Center for Anti-Counterfeiting and Product Protection (A-CAPP) Brand Protection Strategy Summit in East Lansing, Michigan. OT also presented on CBP's IPR recordation resources and staffed a booth in which trademark owners could inquire about CBP's IPR enforcement. Other A-CAPP Summit participants included academic scholars, brand representatives, trademark attorneys, IPEC, DOJ, FDA, and state and local law enforcement.

On March 27, 2024, OT addressed the American Bar Association International Law Section via a virtual webinar as part of a program entitled "*Customs 101: Protecting Your Brand at the Border.*" OT presented on CBP's legal and regulatory IP border enforcement authorities and procedures. Other panelists included a brand owner and a legal practitioner, who discussed their experience working with CBP.

On April 4 - 5, 2024, OT attended and spoke at the Fordham Law Annual IP Law Conference. OT's remarks discussed the value of border enforcement of intellectual property in combatting dangers to public health, such as counterfeit pharmaceuticals and medical devices. The panel included other government leaders representing the USPTO, U.S. Court of Appeals for the Second Circuit, World Intellectual Property Organization, and European Intellectual Property Office.

On June 26, 2024, OT spoke at the New York Intellectual Property Lawyers Association (NYIPLA) Annual Meeting on CBP's IP enforcement efforts and the legal and regulatory regime in which it operates. This was OT's first engagement with the NYIPLA, and the information imparted was well received.

On June 26, 2024, OT spoke on a panel at the American Conference Institute's annual Women in IP Law Conference in Washington, District of Columbia, discussing CBP's overall IP enforcement regime, e-recordation, and best practices for working with CBP to protect IP rights.

On August 21 - 22, 2024, OT moderated a panel at the inaugural Women's IP Forum hosted by IP Watchdog, on developing a comprehensive IP enforcement strategy. Panelists from the USPTO and the private sector joined OT in sharing the viewpoint from their respective fields regarding building and executing strong IP enforcement strategies.

On September 5, 2024, OT spoke on the legal aspects of IP border enforcement at the World Intellectual Property Review North America conference in San Diego, California. The event provided a platform to discuss legislative and regulatory developments impacting IP owners.

On September 30, 2024, OT moderated a panel on working with foreign customs administrations as part of the IP Watchdog Live Conference in Crystal City, Virginia. The conference was attended by business executives, attorneys, and right holders, and included government content on IP enforcement activities and resources available to IP owners. The moderator discussed CBP's IP border enforcement regime compared to that of the European Union, China, and the MENA region, on which the three panelists provided expert perspective.

CBP Internal Training

OT is also entrusted with training CBP personnel stationed at all 328 Ports of Entry on how to recognize IPR violations and take appropriate enforcement action. Such training initiatives in FY 2024 included the following:

- **Basic IP Enforcement Training**

On March 18, 2024, OT conducted a comprehensive Intellectual Property training at the Port of Baltimore. The training covered basic topics in CBP's IPR border enforcement. The training was attended by 10 CBP Officers and Import Specialists.

On September 4, 2024, OT conducted a training session on IP enforcement to Officers and Import Specialists stationed at the Philadelphia Port of Entry, covering fundamental topics in CBP's IPR border enforcement.

- **Advanced IP Enforcement and Restricted Merchandise Training**

On November 14, 2023, OT conducted an advanced virtual training to CBP's Base Metals Center of Excellence and Expertise (CEE). The training included advanced topics in CBP's IPR border enforcement regime and IPR petition processing. The program also included a module on restricted merchandise presented by a representative of the Cargo Security, Carriers, and Restricted Merchandise Branch, as well as a module on penalties assessment by the Penalties and Seizure Branch. Approximately 65 CBP employees attended the training.

On January 11, 2024, OT conducted an advanced virtual joint training to CBP's Electronics Center of Excellence and Expertise. Together, the Intellectual Property

Enforcement Branch and the Cargo Security, Carriers and Restricted Merchandise Branch provided instruction on advanced topics in the enforcement of IP rights, petition adjudication, and enforcement as to restricted merchandise. Approximately 35 CBP employees attended the training.

On January 23, 2024, OT conducted an advanced IPR training to frontline officers and other CBP staff at the cargo facility in Detroit, Michigan. The training included advanced topics in CBP's IPR border enforcement regime and IPR petition processing. The program also included a restricted merchandise module presented by a representative of the Cargo Security, Carriers, and Restricted Merchandise Branch. The audience included roughly 40 CBP frontline officers and other staff.

On January 25, 2024, OT conducted an advanced IPR training at the Field Office in Chicago, Illinois. OT conducted training on advanced topics of IPR and IPR petition processing. The program also included presentations from the Office of Field Operations, which covered targeting and risk assessment, and trainings on restricted merchandise and the Jones Act presented by a representative of the Cargo Security, Carriers, and Restricted Merchandise Branch. The hybrid audience comprised roughly 75 CBP personnel, including frontline officers, import specialists, other field office staff, and the Office of Chief Counsel.

On March 27, 2024, OT conducted an advanced IPR training to frontline officers and other CBP staff at the Port of JFK. The training included advanced topics in CBP's IPR border enforcement regime and IPR petition processing. The program also included a restricted merchandise module presented by a representative of the Cargo Security, Carriers, and Restricted Merchandise Branch and the Penalties and Seizures Branch. The audience included roughly 40 CBP Officers and other staff.

On March 28, 2024, OT conducted an advanced IPR training to frontline officers and other staff at the Port of Newark. The training included advanced topics in CBP's IPR border enforcement regime and IPR petition processing. The program also included a restricted merchandise module presented by a representative of the Cargo Security, Carriers, and Restricted Merchandise Branch and the Penalties and Seizures Branch. The audience included roughly 20 CBP Officers and other staff.

On May 7 - 9, 2024, OT participated in an advanced Border Security and Trade Compliance (BSTC) Division training to the Ports of Ponce and San Juan, Puerto Rico. The attendees were primarily CBP Officers, Import Specialists, and Fines, Penalties, and Forfeiture paralegals. The IP portion of the training focused on how to establish probable cause for seizure, regulations surrounding disclosure, and how to make infringement determinations. Other presenters included attorneys from the Cargo, Carriers, and Restricted Merchandise Branch, the Penalties and Seizures Branch, as well as Office of Field Operations experts on the Jones Act and other maritime enforcement.

On May 7 - 9, 2024, OT presented on IP issues to CBP Import Specialists from the Center of Excellence and Expertise for Apparel, Footwear, and Textiles (AFT) and the

Center for Consumer Products and Mass Merchandising (CPMM) in Charleston, South Carolina. OT also trained CBP Officers at the Port of Charleston on intellectual property enforcement.

On May 14, 2024, OT conducted an advanced IPR training to CBP Officers, Import Specialists, and Fines Penalties & Forfeitures staff at the Port of Anchorage, Alaska. The training included an overview of U.S. IPR border enforcement laws and regulations, use of CBP's internal IPR database, and best practices in processing an IPR case.

On May 16, 2024, OT conducted an IPR training to CBP Officers at the Port of Ketchikan, Alaska. As Ketchikan is primarily a passenger port, the IP portion focused on specialized topics, including the personal use exemption for trademark and copyright violations.

On June 12, 2024, OT provided a webinar for CBP's Electronics Center of Excellence and Expertise. Specifically, the training covered issues related to some recently recorded product configuration marks and trademark doctrines concerning refurbished electronics.

On August 13 - 15, 2024, OT's BSTC Division provided advanced IPR training to CBP Officers, Import Specialists, and Fines Penalties & Forfeitures staff at the Ports of Seattle and Blaine in Washington State. Other presenters included attorney-advisors from the Cargo Security, Carriers, and Restricted Merchandise Branch, and the Penalties and Seizures Branch.

On August 28 - 29, a team of attorney-advisors from OT's BSTC Division provided a two-day advanced "*IP and Restricted Merchandise Enforcement*" training to 30 CBP Officers and Import Specialists at the Port of Sweet Grass, Montana.

On September 10 - 11, 2024, OT provided BSTC Division training to the Ports of San Francisco and Oakland, California. The IP portion focused on probable cause determinations, regulations surrounding disclosure, and making substantive infringement determinations. Other topics included exclusion order enforcement, IPR penalties, and restricted merchandise enforcement.

On September 17, 2024, OT provided Advanced BSTC Division training to the Port of Portland, Washington. The IP portion focused on IP infringement determinations, proper border enforcement procedure, and substantive defenses to infringement. Other topics included IPR penalties, and restricted merchandise enforcement.

- **HSI's Intellectual Property and Trade Enforcement Course (IPTEI)**

On May 1, 2024 and August 20, 2024, OT conducted an IPR training for roughly 40 personnel from HSI, ICE, and CBP. The training covered basic topics in CBP's IPR border enforcement.

International Engagements and Capacity Building Initiatives

OT is responsible for fulfilling requests made by other government agencies for technical legal experts able to provide capacity building to foreign audiences. OT participates in bi-lateral engagements, regional workshops, as well as multi-lateral organization activities centered on border enforcement of intellectual property rights. In FY 2024, CBP participated in the following international engagements and capacity building activities:

- **European Union Agency for Law Enforcement (Europol)**

On October 26–27, 2023, OT participated in the 2023 Europol IP Crime Conference in Lisbon, Portugal. OT spoke on a panel covering the harmful impact of counterfeits on public health and safety. The co-panelists included brand and trade association representatives. The annual conference provides an opportunity for European and U.S. law enforcement and brand representatives to share best practices.

On March 7, 2024, OT attended the debrief of *Operation Shield IV*, in which CBP had participated, in Athens, Greece. The event was attended by all Europol members that were a part of the operation, who presented the final numbers and findings from the operation. *Operation Shield IV*, coordinated by Europol, brought together legal, judicial, customs, medical and anti-doping authorities from 30 countries across three continents come together in a major crackdown that exposed the scale of the falsified medicines trade and the role of organized criminal networks in driving it.

On April 3, 2024, OT participated in *Operation Elektron*, sponsored by Europol, in Malta. The scope of the meeting was to strengthen existing collaboration in counterfeit electronics enforcement between law enforcement and right-holders and to enhance strategic and operational partnerships through shared intelligence, mutual actions, and future support. Representatives from major companies shared their extensive expertise and experience in combatting counterfeit electronics and provided valuable insight, in the context of brand protection. Methodologies and key identifiers used to safeguard and mitigate the risk of their products being counterfeited, were also shared.

- **The International Criminal Police Organization (INTERPOL)**

On September 23, 2024, OT co-hosted a half day workshop in coordination with the USPTO and INTERPOL IP Crime Investigators Academy, immediately prior to the kick-off of the “17th International Law Enforcement Intellectual Property Conference” held in Willemstad, Curacao. The workshop gathered 80 law enforcement and international Foreign-Trae Zone (FTZ) administrators and consisted of instruction followed by interactive case studies on different regulatory models of FTZs around the world.

The International Criminal Police Organization (INTERPOL)

On September 25, 2024, OT sat on a panel moderated by the World Customs Organization’s Manager of IPR, Health and Safety Program, which discussed creative solutions for customs administrations to combat illicit trade through FTZs.

- **World Customs Organization**

From November 21 - 22, 2023, OT virtually participated in the “*20th Meeting of the World Customs Organization’s Counterfeiting and Piracy (“CAP”) Group.*” The agenda included discussing successful international IP operations, such as ***Operation STOP III*** which focused on the small parcel environment. The Committee also discussed the importance of developing IP experts to provide international training, as well as the importance of raising awareness of the negative impacts of counterfeiting and piracy for the general public through the use of social media.

On February 6, 2024, OT provided a webinar to the World Customs Organization (WCO) Americas and Caribbean Region on e-Commerce and IPR. OT presented on IPR enforcement policy, legal and regulatory authorities governing IPR enforcement, and best practices in screening and examining small parcels for IPR violations. Over 150 participants logged into the webinar.

- **Organization for Economic Co-operation and Development (OECD)**

On April 4 - 5, 2024, OT joined the U.S. delegation at the first plenary of the OECD Working Party on Countering Illicit Trade (WPCIT) since the group transitioned from a Level III body (under the OECD’s Public Governance Directorate) to a Level II body (under the OECD’s Trade Committee). OT delivered remarks supporting the Clean FTZ Certification Scheme and acquired a seat on the FTZ Experts Network and the Research/Evidence Regarding Illicit Trade in IP Infringing Goods Experts Group.

In August 2024, OT was named Chair of the OECD Experts Network on FTZs, which held its inaugural meeting on September 19, 2024. The Experts Network is tasked with a number of duties such as providing guidance on implementation of the Certification Scheme, which incorporates the OECD Recommendation on Countering Illicit Trade and Enhancing Transparency in Free Trade Zones and the Code of Conduct.

- **U.S. Patent and Trademark Office Programs**

On October 11, 2023, OT participated in the USPTO’s “*Korea-US Intellectual Property Forum and Patent Cooperation Treaty (PCT) Roundtable*” in Alexandria, Virginia. The Roundtable featured speakers from the Korean IP Office (KIPO), Korea Trade-Investment Promotion Agency (KOTRA), American & Korean IP experts from the private sector, and U.S. Government Officials. OT facilitated a discussion regarding IP enforcement with representatives from the Korean agencies and the private sector.

On October 19, 2023, OT participated in the USPTO Global Intellectual Property Academy’s “*Copyright Seminar for Foreign Government Copyright Officials*” as an expert on a panel entitled “Interagency Work: Copyright Policy, Outreach and Enforcement.” OT discussed copyright protection through the e-Recordation program and how CBP enforces copyrights at the border. Other panelists included representatives of USTR, IPEC, ITA, U.S. Copyright Office and DOJ/CCIPS.

On October 24 - 26, 2023, OT participated in a USPTO Workshop in Santos, Brazil, with the Brazilian Customs Authority and Federal Highway Police entitled “*Fighting*

Intellectual Property Crimes: International Dialogues.” OT presented on numerous topics over the three-day program, including: CBP’s legal and regulatory authorities for IP enforcement, suspension of release and seizure of infringing goods, and the storage, destruction and penalties associated with IP enforcement actions.

On October 25 - 26, 2023, OT participated in a workshop on “*Best Practices in IPR Administrative Enforcement*” sponsored by the USPTO for customs and intellectual property enforcement officials of the United Arab Emirates in Sharjah. OT presented alongside representatives of HSI, DOJ, the federal judiciary, state governments, and academia.

On November 29 - 30, 2023, OT participated in a two-day dialogue with government representatives of the United Kingdom in London regarding customs enforcement of IPR. The dialogue was organized by the USPTO IP Attaché for Europe based in Brussels, Belgium. OT presented on several topics: the U.S. legal framework for IPR enforcement, the IPR e-Recordation System, enforcement of IPR in FTZs, the challenges of enforcement in the small parcel environment, and coordination with partner government agencies. Other presenters included representatives from CBP’s Office of Field Operations who presented on targeting and risk assessment, as well as representatives of major intellectual property rights holders active in the UK. The audience was hybrid and included in-person representatives of the UKIPO and UK Home Office, as well as customs officials who joined virtually.

On January 30 - February 1, 2024, OT participated in a three-day Intellectual Property Rights Border Enforcement Workshop sponsored by USPTO’s Office of Policy and International Affairs, in partnership with the U.S. State Department’s Middle East Partnership Initiative, in Tangier, Morocco. The workshop was attended by government representatives from the United States and Morocco on border enforcement of intellectual property. Subject matter experts on IP border enforcement from each government spoke on their respective IP enforcement regimes and best practices. Attendees included nearly 50 Moroccan Customs officials, judges, prosecutors, and private sector representatives.

On February 7 - 8, 2024, OT participated in a program organized by the USPTO and State Department in Mexico City, Mexico, on “*Border Enforcement of Intellectual Property Rights.*” The program was the first such engagement with Mexican Customs in several years. OT presented for most of the first day on the U.S. legal framework, targeting and risk assessment, and recent developments in U.S. law. As part of the program, Mexican trademark owners were invited to speak on the second day concerning product authentication measures.

On February 12 - 15, 2024, OT participated in two programs in Tunis, Tunisia, organized by the USPTO as part of its Middle East Partnership Initiative program with the Department of State. As part of the first program, “*Roundtable Discussion with Tunisian Industry on the Importance of IPRs,*” OT sat on a panel of U.S. Government experts in intellectual property enforcement. Attendees included nearly 30 members of the local American Chamber of Commerce, as well as Tunisian legal practitioners. The second

program, “*Intellectual Property Rights Enforcement Workshop for Tunisia*” was a three-day program for Tunisian judges, prosecutors, and customs officials. During this program, OT presented on the U.S. legal framework for the border enforcement of intellectual property rights, as well as on CBP’s trademark infringement analysis procedures. OT also co-led a case study on enforcement against counterfeiting. Other U.S. experts on the program included a U.S. District Judge, a retired U.S. Magistrate Judge, an ICHIP Attorney Advisor, CCIPS Senior Counsel, an HSI Special Agent & Program Manager, and the Associate Director of Research at the Center for Anti-Counterfeiting and Product Protection (A-CAPP Center) at Michigan State University.

On March 6, 2024, OT participated in a program organized by the USPTO and State Department focused on engaging with the Dominican Republic’s Customs authority. OT presented on the border enforcement of intellectual property (including U.S. legal authorities, procedures, and targeting and risk assessment) and discussed questions and concerns from Dominican authorities, especially concerning the treatment of detained and seized merchandise. The event was virtually attended by Dominican Customs as well as the Dominican National Office of Intellectual Property (ONAPI).

From April 22 - 25, 2024, OT participated in an IP workshop directed to Algerian Judges and Prosecutors hosted by the USPTO’s Global IP Academy in Paris, France. The program was the third and final installment of a series directed at the Algerian government to develop capacity for the enforcement of intellectual property rights. OT presented on CBP’s e-recording program, as well as on how CBP makes its own infringement determinations, whereas these determinations are instead made by judges in the majority of other countries. Other presentations were provided by HSI, DOJ, USPTO, and the French Patent and Trademark Office, as well as French trade associations.

From April 24 - 26, 2024, OT participated in a two-day Intellectual Property Rights Border Enforcement Workshop organized by the USPTO’s Office of Policy and International Affairs, in Accra, Ghana. OT presented on the U.S. legal framework for the border enforcement of IPR and led a case study on the seizure of counterfeit products. Other experts from the U.S. Government included a prosecutor from CCIPS, the regional HSI attaché, and the Assistant Director of CBP’s Center of Excellence and Expertise (CEE) for Pharmaceuticals, Health and Chemicals. The program was attended by around 30 Ghanaian officials from the Customs, Revenue, and Border Police services.

On May 21 - 23, 2024, OT participated in a three-day program organized by the USPTO in Istanbul, Türkiye, entitled “*Intellectual Property Enforcement at the Border.*” The audience consisted of Turkish customs officials and internal market surveillance authorities. OT experts presented on numerous topics such as the legal and regulatory border enforcement authorities, disposal and destruction of IP infringing goods, challenges in trans-shipment and FTZs, asset forfeiture and penalties. Other USG experts included the USPTO IP Attaché for Eurasia and Special Agents and attachés from HSI.

On June 25 - 27, 2024, OT participated in a “*Workshop on Border Enforcement of Intellectual Property Rights*” in Mexico City organized by the USPTO and the U.S. Embassy in Mexico City. The program focused on training Mexican customs officials and officers on enforcing intellectual property rights at the border. Presenters at the workshop included representatives from CBP, USPTO, the Mexican Institute of Industrial Property, the National Customs Agency of Mexico, the National Copyrights Institute of Mexico, and the Mexican Association for the Protection of Intellectual Property, amongst others. OT presented on the U.S. legal framework for intellectual property enforcement at the border and on U.S. *ex officio* authority at the examination, seizure, and destruction stages of enforcement.

On July 31 - August 1, 2024, OT participated in the “*Indo-Pacific Workshop on Enforcement Against Trade in Counterfeit Goods*” in Bangkok, Thailand. The workshop was organized by the USPTO’s Office of Policy and International Affairs and included representatives from more than 14 ASEAN and South Asian countries, as well as private industry. OT participated in multiple panel discussions covering topics ranging from CBP’s legal and regulatory IPR border enforcement regime to combatting illicit trade in FTZs.

On August 27 - 30, 2024, OT joined the faculty of government and academics addressing government officials from thirteen countries in the Oceania region during the “*Pacific Colloquium on Consumer Protection, Border Security, and Enforcement Against Trade in Counterfeit Goods,*” at the Arizona State University California Center, Los Angeles. OT sat on multiple panels concerning border enforcement of IP.

On September 12, 2024, OT provided an overview of CBP’s IP border enforcement statutory and regulatory regime for members of the Shanghai IP Administration, at USPTO HQ in Alexandria, Virginia.

On September 12, 2024, OT provided a comprehensive webinar to 145 Peruvian judges on the role of customs in interdicting IP infringing merchandise at the border. OT provided an overview of the legal authorities utilized by CBP, infringement determinations under U.S. law, and recommendations on supporting customs IP enforcement actions.

On September 19, 2024, OT provided a webinar to 80 Colombia judges on the role of customs in interdicting IP infringing goods and how the judiciary can support those enforcement actions.

- **Homeland Security Investigations Programs**

On June 4–June 7, 2024, together with the IPR Center, OT hosted the “*African Regional Workshop on Counterfeit Pharmaceuticals*” in Mauritius. Representatives from CBP, DOJ, FDA, and pharmaceutical companies attended. The workshop was aimed at investigators, prosecutors, and customs officials from Mauritius, Kenya, South Africa, and Tanzania and focused on IPR enforcement in the protection of public health, as well as the economic and social well-being of developing nations. The workshop strengthened

collaborative relationships and provided information that could be used to deter, detect, and respond to harmful drugs entering and moving through the global supply chain. The workshop included case-studies, investigative techniques, and best practices of interdiction, investigation, and prosecution. During the training, Mauritian officials discovered an IPR violative shipment that entered the country. Mauritius Customs, along with CBP and HSI, carried out an on-the-spot operation, which resulted in seizures of counterfeit pharmaceuticals and health supplements.

On August 27 - 29, 2024, OT participated in the IP and financial investigations program “*Intellectual Property Investigations: The Intersection of Illicit Trade and Finance*,” in Bangkok, Thailand. This IPR enforcement training program provided specialized instruction on IPR violations, including interdictions and investigations, with additional training on the use of financial and fraud investigative techniques. The program focused on the impact of IP infringement on public safety and its role in facilitating illicit trade and finance, while strengthening the capabilities of the participating agencies to address these violations and forfeit illicit proceeds. Participants included Thai officials from customs, national law enforcement, IP and health regulatory agencies, financial crimes enforcement authorities, and Transnational Criminal Investigative Units (TCIUs).

- **Commercial Law Development Program (CLDP) Events**

On December 16, 2023, OT participated in CLDP’s “*Caucasus and Eastern Europe Expert Level Working Group on Intellectual Property Rights*” in Chisinau, Moldova. This was the third meeting for the working group. The program was attended by government officials from the Republic of Armenia, Georgia, the Republic of Moldova, and Ukraine, as well as representatives from DOJ, CLDP, REACT – The Anti-Counterfeiting Network, and the Alliance Against Counterfeit Spirits (AACS). The meeting focused on shared challenges in identifying and targeting counterfeit goods at the border. Participants discussed best practices for customs’ enforcement of intellectual property rights, effective strategies in private sector management of intellectual property rights, and regional challenges in counterfeiting of goods in key sectors. OT presented on best practices for Intellectual Property Enforcement at the border. Other presentations were provided by CLDP, REACT, and AACS.

On December 18 - 20, 2023, OT participated in CLDP’s “*Intellectual Property Enforcement Workshop*” in Chisinau, Moldova. This three-day capacity building workshop included government officials from the Republic of Armenia, Georgia, the Republic of Moldova, and Ukraine, as well as representatives from DOJ, CLDP, REACT – The Anti-Counterfeiting Network, and the Alliance Against Counterfeit Spirits (AACS), as well as several individual brand owners. The workshop aimed to build the capacity of customs officers and other relevant stakeholders on brand protection and identification of genuine and counterfeit goods of specific brands. OT presented on the “*U.S. Legal Framework for the Border Enforcement of Intellectual Property Rights*” and presented several case studies demonstrating CBP’s enforcement mechanisms. OT also moderated a panel discussion on international best practices and challenges in IP enforcement and participated in a panel on engaging the private sector.

On January 30 - February 1, 2024, OT participated in two programs in Baku, Azerbaijan, organized by CLDP and the American Chamber of Commerce in Azerbaijan. The first program was the “*Intellectual Property Best Practices Conference for Public and Private Sector.*” OT presented on best practices for intellectual property enforcement at the border and moderated a panel of IP experts from the United States and Georgia. The second program was the “*Workshop on IP for Lawyers and Law Students.*” During this program, OT presented on the U.S. legal framework for the border enforcement of intellectual property rights at the border, as well as on successful engagement with right holders. OT also moderated and participated in panels on enforcement topics. Participants for the first program included several representatives from the Azerbaijan IP Agency as well as nearly 70 members of the local AMCHAM. Participants for the workshop included around 75 legal practitioners and law students from Azerbaijan.

From July 16 - 18, 2024, OT participated in a meeting of the Central Asia Regional Expert Level Working Group on Intellectual Property Rights under the U.S. - Central Asia Trade and Investment Framework Agreement (TIFA) in Almaty, Kazakhstan. TIFAs are led by the Office of the U.S. Trade Representative 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 includes government officials from the Republic of Kazakhstan, the Kyrgyz Republic, the Republic of Tajikistan, Turkmenistan, and the Republic of Uzbekistan. This was the sixth meeting of the IP Expert Level Working Group (which first met in 2019), and the third meeting in which OT has participated.

- **U.S. Department of Justice Programs**

On March 12 - 13, 2024, OT participated in a program in Tbilisi, Georgia, organized by the DOJ/ICHIP Attorney-Advisor for Central, Southern, and Eastern Europe. The program focused on enforcement against counterfeit alcohol products and included representatives from the governments of Türkiye, Georgia, Armenia, and Kazakhstan. The OT attorney-advisor presented on border enforcement of intellectual property rights, including risk assessment, examination, seizure, forfeiture, and the administrative process for relief. Other presenters included the DOJ, HSI, and private sector representatives. In total, the audience was comprised of roughly 50 people.

On May 7 - 9, 2024, OT participated in the “*Workshop on the Danger and Risks of Counterfeit Pharmaceuticals*” program presented by the DOJ/ICHIP in Bogotá, Colombia, and sponsored by the IPR Center. In addition to DHS, the event featured panelists including attorneys from the ICHIP network; an HSI attaché based in Bogotá; a prosecutor and a forensic computer scientist from the DOJ/CCIPS; an FDA Office of Criminal Investigations (OCI) Special Agent; and private industry representatives. This three-day program brought together prosecutors, law enforcement, and customs officials representing the Andean region (Colombia, Peru, Ecuador, Chile, and Bolivia) to discuss investigative and prosecutorial methods for disrupting and destroying the markets and supply chains for dangerous counterfeit pharmaceuticals and medical devices, with an eye toward effective criminal investigations and prosecutions. OT presented on CBP’s

targeting and examination laws, procedures, components; IP enforcement; and the IPR e-recordation database. The event concluded with a law enforcement case study.

On May 14 - 16, 2024, OT participated in a Department of Justice ICHIP and OPDAT program on “*Protecting the Government Supply Chain: Combatting Counterfeiting and Corruption*” in Varna, Bulgaria. The program was attended by around 40 representatives from the governments of Ukraine, Bulgaria, Romania, and Moldova. OT presented on the “*U.S. Legal Framework for the Border Protection of Intellectual Property Rights*” and helped lead discussions among the participants on case studies involving corruption and counterfeiting.

- **CBP’s Office of International Affairs**

On December 21, 2023, OT provided a comprehensive virtual training on border enforcement of IPR to Vietnamese customs officials in coordination with the CBP attaché stationed in Bangkok. Topics included the U.S. legal framework for border enforcement of IP, CBP’s IPR e-Recordation System, risk assessment, and enforcement techniques and procedures. The program was coordinated by the CBP attaché covering the Mekong region, and the audience included roughly 30 Vietnamese government officials.

From April 15 - 19, 2024, OT participated in a CBP-led Customs workshop in Nairobi, Kenya. CBP’s Office of International Affairs’ East Africa Regional Team hosted a regional trade workshop for Eastern and Southern African Partners. The workshop provided an overview of CBP’s trade and customs processes, which featured presentations from CBP subject matter experts on the following topics: Intellectual Property Rights; the Development of Regional Standards for Authorized Economic Operator; the Africa Growth and Opportunity Act (AGOA); e-Commerce; and customs clearance processes. Participants included representatives from Kenya, Tanzania, Madagascar, Malawi, and Mozambique.

On April 29, 2024, OT provided a comprehensive virtual IP enforcement training to Spain’s Guardia Civil Officers. The presentation was part of a two-week program organized by CBP’s Office of International Affairs, taking place in Barcelona, Spain. OT presented on the legal, regulatory, and operational aspects of CBP’s IP enforcement regime, highlighting the aspects that differ from those of the European Union.

On August 20 - 22, 2024, OT provided a two-day training to customs officials, police, prosecutors and judicial authorities of Trinidad and Tobago.

- **Other International Engagements**

On April 25 - 26, 2024, OT participated in a two-day Geographical Indicators (GI) workshop organized by the Tequila Regulatory Council. OT participated in two panels and spoke on GIs as certification marks and how to register those in the United States. OT also spoke about CBP’s recordation system in general. Other experts included private sector attorneys and an attorney from the USPTO.

From June 5 - 7, 2024, OT participated in the “*U.S.-Argentina Innovation and Creativity for Economic Development (ICED) Forum*” in Buenos Aires, Argentina and also participated in an IP roundtable with members of the Argentinian pharmaceutical industry. The USPTO, USTR, ITA, and CBP made presentations and interventions, with CBP presenting on an “*Overview and Updates to the U.S.’s Border Enforcement of IP.*” The Argentinian representatives came from various agencies such as the Instituto Nacional de la Propiedad Industrial (INPI), Ministry of Foreign Affairs (MFA), Coast Guard, Federal Police, the Secretariat of Innovation, Science, and Technology, and the National Seed Institute (INASE), and presented updates on treaty discussions, the intellectual property office, customs and enforcement, agriculture, and GIs.

On August 2, 2024, OT, in collaboration with the USPTO and the CBP attaché in Bangkok, Thailand, gave opening remarks at the “*14th ASEAN Network of IP Enforcement Experts*” (ANIEE) meeting in Bangkok, Thailand. The ANIEE is made up of representatives from ASEAN Member States (AMS) involved in IP rights enforcement. The objective is to ensure that the AMS maintain a regional action plan on IP rights enforcement in line with the ASEAN IPR Action Plan 2016-2025.

On August 20 - 22, 2024, OT provided a comprehensive two-day workshop to customs officials from Trinidad and Tobago at the city of Port of Spain. The workshop was organized in coordination with the USPTO and featured introductory sessions on IP border enforcement such as international standards, U.S. legal and regulatory regime, identifying illicit goods, and engagement with the public.

Interagency Collaboration

OT collaborates with other federal agencies to further the mission of protecting the country from importations of IP infringing goods. Examples of such collaborative efforts in FY 2024 include:

- **U.S. Patent and Trademark Office Programs**

On October 3, 2023, OT participated in a panel on supply chain security specifically in relation to IP enforcement at the USPTO’s *Roundtable on Future Strategies in Anticounterfeiting and Antipiracy*. The Roundtable discussed topics raised in the public responses that USPTO received in response to its May 25, 2023 [Federal Register Notice](#) on “Future Strategies in Anticounterfeiting and Antipiracy” (88 FR 33872), in which USPTO requested “information on current anticounterfeiting and antipiracy strategies that have proven effective, as well as ideas for future strategies.”

On July 11, 2024, OT provided an overview of CBP’s IP enforcement regime to USPTO’s undergraduate student interns. The students learned about how CBP makes infringement determinations and examined samples of counterfeit and genuine merchandise. A CBP officer also participated virtually and provided the officer’s perspective on IP enforcement at U.S. ports of entry. Both OT and CBP’s Office of Field Operations (OFO) provided guidance on pursuing careers at CBP. Approximately 23 students attended the program.

On August 16 - 17, 2024, OT presented an educational booth at the USPTO's Invention-Con 2024, entitled "*The Place of Inventors, Makers, and Entrepreneurs.*" The annual event provides educational seminars and resources to innovators of all ages. Other government partners with booths in the pavilion included the U.S. Copyright Office, the U.S. Census, and the USPTO together with the National Crime Prevention Council. HSI also staffed the booth to discuss criminal enforcement of IPR.

- **Homeland Security Investigations Programs**

On May 3, 2024, OT provided virtual training to HSI agents and CBP Officers on how to conduct a search in CBP's Intellectual Property Rights Internal Search (IPRiS) database. USPTO also participated in the training and demonstrated how to conduct searches in its new Trademark Search database. HSI hosted the training program.

On August 29, 2024, OT hosted a virtual training directed to attorneys at the USPTO, HSI agents, and CBP Officers, on how to conduct a search in CBP's IPRiS database. USPTO also participated in the training and demonstrated how to conduct searches in its new Trademark Search database.

- **State Department Programs**

On July 24, 2024, OT provided training to a group of foreign service officers as part of a broader IP enforcement training program through the State Department. OT's presentation focused on CBP's role in international engagement and capacity building for IP rights, as well as CBP's IP enforcement regime. The presentation took place at Dulles Airport and was followed by a tour of IP enforcement at the airport.

- **Department of Justice Programs**

On March 7, 2024, OT provided training to a group of DOJ CCIPS attorneys, focusing on CBP's intellectual property rights border enforcement authorities and procedures. The presentation took place at DOJ/CCIPS Headquarters and was attended by around 25 CCIPS attorneys.

- **State and Judicial Programs**

On April 10, 2024, OT participated in an e-cigarette enforcement roundtable organized by the National Association of Attorneys General. The discussion focused on sharing best practices and success stories in combatting the e-cigarette epidemic in the youth population. OT provided guidance on ensuring that restricted gray market products, notably flavored pods, do not make their way into the United States. OT also provided general information regarding CBP's IPR enforcement process.

On April 24, 2024, OT provided a briefing to the Chief Administrative Law Judge of the U.S. International Trade Commission regarding CBP's border measures. The briefing covered topics such as ex officio authority, de minimis, gray market goods, and the responsibilities assigned to competent authorities.

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

On May 26, 2021, CBP and the U.S. Chamber of Commerce (Chamber) signed a memorandum of understanding (MOU) that highlights 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 show how both entities contribute to the MOU effort. The MOU was renewed for five years in August 2023.

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 public about the dangers of counterfeit goods. During the 2023 holiday season, CBP and the Chamber once again participated in the “Shop Smart” Campaign. This campaign included representatives from CBP and the Chamber collaborating to speak with news stations across the country on how counterfeit goods are a problem for consumers. The campaign highlighted the higher demand for consumer goods during the holiday season and the importance of buying genuine products. The holiday campaign consisted of a satellite media tour with leadership from CBP and the Chamber, an audio news release from CBP leadership, a social media blitz, and a joint press release. The campaign had over 84 million impressions.

In April 2024, the Chamber published a blog written by the OT Executive Assistant Commissioner for World IP Day on April 26, 2024. The blog was focused on the lack of sustainability inherent to counterfeit goods as the World IP Day theme for 2024 was “*IP and the Sustainable Development Goals – Building our common future with innovation and creativity.*” The blog post is available at: <https://www.uschamber.com/intellectual-property/counterfeits-undermine-sustainable-development-lets-work-to-stop-them>.

In addition, CBP and the Chamber once again worked together to raise awareness during the back-to-school period through the “Shop Smart” campaign. These campaign efforts consisted of a radio spot, joint press release, and joint blogpost for a total of over 21.5 million impressions.

- CBP IPR Statistics Data Sharing –
CBP provides intellectual property rights seizure statistics on a quarterly basis to the Chamber.
- Training –
CBP and the Chamber have agreed to provide bi-directional training to each of their relevant personnel/members. As part of educating Chamber members on CBP initiatives and programs, CBP began conducting the CBP Speaker Series. To date, in FY 2024, CBP has presented to the Chamber on the 21st Century Customs Framework (21CCF), the Donations Acceptance Program, and the Fines, Penalties, and Forfeitures detention and seizures processes and procedures.

In August 2024, CBP hosted Chamber members for port tours at the Los Angeles Airport cargo facilities as well as a de minimis briefing and a roundtable with CBP and Chamber leadership.

- **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 to better target and seize imports of counterfeit and pirated goods and other IPR violative merchandise.

Currently the pilot includes industry partners such as Apple, Pfizer, Merck, and Johnson & Johnson. By working with each of these companies CBP has been able to have an improved posture toward IPR enforcement for their respective commodity groups by gaining data and information on suspected illicit trade.

Other Engagements

CBP's multi-faceted communication with IP stakeholders includes daily interaction with industry regarding enforcement activities, formal meetings involving both trade facilitation and enforcement efforts, and participation in numerous national trade events.

CBP's stakeholder engagement includes:

- Regular conference calls with the IPR working group of the Commercial Customs Operations Advisory Committee (COAC) and quarterly public meetings with COAC members culminated in the submission of nine recommendations from the COAC IPR working group at the June 2024 public COAC meeting. These nine recommendations were focused in two key areas: enhancements to the current trade seminars mailbox and expansions to automation for stakeholder communication on the detention and seizure process.
- Daily interaction with stakeholders for CBP's IPR enforcement efforts at the ports of entry, and nationally through CBP's ten industry-aligned Centers of Excellence and Expertise, the IPR-focused staff at headquarters, and the IPR Center in the Washington, District of Columbia metro area.
- Participation in national and local trade events, industry meetings, speaking engagements, and industry-specific rightsholder roundtables.
- In FY 2024, OT held 18 bilateral meetings with IPR recordation holders concerning enforcement of their IP, where they heard concerns specific to the brand and provided guidance as to how to enhance border enforcement of their IP utilizing CBP programs and resources.

- In FY 2024, OT held 5 bilateral meetings with industry associations to discuss IP enforcement issues facing their industry. Such associations included, for example, the International Safety Equipment Association, Essential Minerals Association, and Be Original Americas. These bilateral meetings allow industry to provide feedback to CBP and seek suggestions on how to best serve their membership in protecting their IP at the border.
- The Office of Trade holds monthly Priority Trade Issues IPR meetings with the IPR Coordinators in the CBP field. During these meetings, speakers from throughout CBP share their findings on recent enforcement efforts. Other speakers are also brought in from different areas of CBP to discuss their contributions to IPR-related issues.

Educating the Public

Changing public attitudes toward infringing activities remains essential to an effective intellectual property enforcement strategy. CBP’s activities during FY 2024 included:

- CBP proactively and frequently issues national and local press releases, and social media notifications to educate the public on counterfeiting and alert the media to significant seizures.
- The “*Truth Behind Counterfeits*” public awareness campaign is designed to educate consumers, through social media posts and engagement, about the many negative impacts associated with the purchase of counterfeits. The campaign and its “*Fake Goods, Real Dangers*” messages highlight that purchasing these illegitimate goods damages the 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 five platforms (Instagram, Facebook, X, Snapchat, and YouTube). Additionally, CBP continued to leverage its existing social media presence with monthly posts on CBP X and Facebook accounts.
- CBP continued to expand the “*Truth Behind Counterfeits*” efforts with road shows located at major U.S. airports to amplify the messages of the public awareness campaign. These events gave CBP IPR personnel the opportunity to have one-on-one conversations with the public about the harms connected to purchasing counterfeit goods. In FY 2024, CBP held events at five airports in Philadelphia, Houston, Dallas, Los Angeles, and New York. These five events gave CBP personnel the opportunity to have in depth conversations with approximately 1,400 people.

CBP Product ID Guide Webinars

In FY 2024, as of August 9, 2024, the CBP Office of Trade hosted 12 Product ID Guide webinars, reaching over approximately 1,000 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.

HSI-led National Intellectual Property Rights Coordination Center (IPR Center)

Predatory and illegal IP trade practices affect every aspect of our lives. The HSI-led National Intellectual Property Rights Coordination Center (IPR Center) leads the U.S. Government's response to stop global IP theft and enforce trade laws.

Comprised of federal agencies and industry experts, the IPR Center develops initiatives, coordinates enforcement actions, and shares information related to IP theft. It also stops predatory, illegal trade practices that threaten the public's health and safety, the U.S. economy, and national security.

The IPR Center's Intellectual Property Unit oversees national programs and operations related to intellectual property, manages ongoing national IP initiatives, and tracks and reports on investigations related to intellectual property. The IPR Center's Government Supply Chain Investigations Unit performs a similar role, with a specific focus on purchases made by the U.S. Government.

Intellectual Property Unit (IPU)

Law Enforcement 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 2024, 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, targeting inbound counterfeit pharmaceuticals. Based on the FY 2023 efforts, the same model was replicated in FY 2024, and is further expanding into additional international mail facilities and courier hubs across the United States. This will ultimately lead to increased incidents of seizure and enhanced criminal investigations concerning illicit pharmaceuticals.

In FY 2024, ***Operation Apothecary*** conducted two advanced pharmaceutical applied workshops in Mauritius and Türkiye. These workshops incorporated regional countries in Sub-Saharan Africa and Europe to work collaboratively on combating illicit medications in the regions, which

ultimately are destined for introduction into the local and regional economies as well as the United States. Included in the advanced workshops were law enforcement, customs officials, tax authorities, and prosecutors, to bring together a pool of resources and expertise to disrupt and dismantle transnational criminal organizations.

E-Commerce and 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 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 (<https://www.iprcenter.gov/file-repository/ice-hsi-e-commerce-strategic-plan.pdf/view>). 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 while utilizing various e-commerce outlets including open-net websites, the dark web, point-to-point sales platforms, social media, and a variety of payment processors and shipping methods.

In FY 2024, **Operation IOS**, in partnership with the National Cyber Forensic Training Alliance (NCFTA), developed a training curriculum for law enforcement to further advance efforts in combating digital piracy. In June 2024, the first training event commenced for 20 HSI special agents. IPR Center partners from NCFTA, Motion Picture Association Alliance for Creativity and Entertainment, Recording Industry Association of America, U.S. Department of Justice (DOJ) Computer Crime and Intellectual Property Section (CCIPS), Western District of Pennsylvania Assistant U.S. Attorney's Office, and HSI Pittsburgh provided instructional blocks.

In FY 2024, **Operation IOS** partnered with the DOJ CCIPS and International Computer Hacking and Intellectual Property (ICHIP) Section to develop the Western Hemisphere Digital Piracy Working Group. This group is comprised of law enforcement, prosecutors, and judges from Argentina, Panama, Brazil, Columbia, Costa Rica, Dominican Republic, Romania, and Bulgaria. Two training and outreach events have been conducted in collaboration with the NCFTA in Pittsburgh, PA, and London, England.

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 September 2024, the IPR Center launched a new public awareness automotive safety campaign, “**Put the Brakes on Fakes**,” to highlight the severe risks associated with counterfeit automotive parts. The primary goal is to educate consumers about the life-threatening dangers posed by counterfeit parts, which can result in serious injuries or fatalities during accidents. This multi-phase initiative, part of *OEN*, includes a compelling public service announcement and engaging educational content delivered through digital platforms (YouTube, Twitter/X and LinkedIn).

In September 2024, the IPR Center supported HSI Raleigh’s investigation of a United Kingdom (U.K.)-based counterfeit airbag supplier to the United States. HSI made a referral to U.K. law enforcement and also joined – in an operation led by the Police Intellectual Property Crime Unit (PIPCU) of the City of London Police (CoLP) – in the execution of search warrants in or near London, England as part of an international bi-lateral investigation combating illicit trade. The warrants resulted in the arrest of three individuals, seizure of approximately 500 suspected counterfeit airbags (approximately \$400k MSRP), approximately £140,000 in bulk currency (approximately \$186k), and evidence linking suspects to the smuggling of counterfeit airbags from the U.K. to the United States. (The CoLP press release – “Three arrested over sale of dangerous counterfeit car airbags” (September 23, 2024) – is at [https://www.cityoflondon.police.uk/news/city-of-london/news/2024/september/three-arrested-over-sale-of-dangerous-counterfeit-car-airbags/.](https://www.cityoflondon.police.uk/news/city-of-london/news/2024/september/three-arrested-over-sale-of-dangerous-counterfeit-car-airbags/))

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 May 2024, IPR Center personnel traveled to Los Angeles, California to support HSI Los Angeles arrest and search warrants involving the use of counterfeit electronics in a warranty and return fraud scheme, that defrauded both manufacturers and retailers. As a result of the

enforcement operation, five subjects were arrested, hundreds of suspected counterfeit electronics products were seized along with approximately \$168,000 in bulk cash.

In June 2024, IPR Center personnel traveled to Chicago, Illinois to support HSI Chicago in a search and seizure warrant involving a business trafficking counterfeit electronics. The suspect business purchased damaged electronic devices wholesale, then utilized counterfeit parts and packaging to recondition the devices, which were then sold as new. The business utilized multiple methods of sale to include a website, business-to-business contracts, and multiple e-commerce platforms with sales in excess of \$45 million. The operation resulted in the seizure of approximately 103,000 counterfeit items with an approximate value of \$20 million and approximately \$400,000 in monetary assets.

Operation Body Armor

Operation Body Armor combines the expertise of HSI, CBP, and the Food and Drug Administration-Office of Criminal Investigations (FDA-OCI) to combat the sale of counterfeit personal healthcare and beauty products. It was initiated in January 2015 by the IPR Center in partnership with industry and other entities associated with the healthcare and beauty product community.

In FY 2024, the IPR Center collaborated with the NCFTA to create a counterfeit healthcare and beauty product working group. NCFTA members will bring resources, expertise, and investigative leads to the working group to share information and expand on investigative efforts to combat counterfeit beauty products. It is expected that these efforts will result in more comprehensive investigations.

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 work 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 2024 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.

In January 2024, IPRC personnel traveled to Alicante, Spain, in support of a European Anti-Fraud Office (OLAF), European Union Intellectual Property Office (EUIPO) sponsored event, “*Sport week: Customs against Fakes*,” regarding the trafficking of counterfeit sports merchandise involving high profile sporting events. The training and outreach program involved OLAF, EUIPO, Europol components, and private industry. The training focused on identifying counterfeit sports merchandise and conducting IP enforcement involving large sporting events in

anticipation of the 2024 EUEFA European Championship in Germany and the 2024 Olympics in France.

In February 2024, during pre-Super Bowl week, the IPR Center supported HSI Las Vegas through **OTP**. As part of the operation, HSI Las Vegas conducted enforcement operations that resulted in approximately 4,600 counterfeit items seized. Further, the IPR Center participated in media events highlighting the threat of counterfeit goods and HSI's efforts to counter those threats. The media events led to positive publicity with local, national, and international outlets. In addition to support and media engagement, the IPR Center also hosted an international delegation of European law enforcement officials to demonstrate how HSI plans for large scale enforcement operations which target counterfeit goods at sporting events. This foreign delegation was learning from HSI and the IPR Center in preparation for the upcoming 2024 Paris Olympics. In September 2024, IPR Center personnel traveled to Sao Paulo, Brazil, to conduct advanced training for Brazilian authorities in best practices for IPR enforcement for sporting events and the sporting merchandise sector as a whole. The training included representatives from the U.S. DOJ ICHIP, Brazilian law enforcement and prosecutors, and industry.

In September 2024, IPR Center personnel traveled to Roanoke, VA to support HSI Harrisonburg arrest and search warrants involving a business trafficking in counterfeit sporting goods through a storefront, website, and multiple e-commerce platforms. As a result of the operation, one subject was arrested and over 5,200 counterfeit items were seized.

Engaging with Stakeholders

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

In January 2024, the IPR Center hosted IPRC Learning Series, a virtual follow up to the May 2023 Annual Summit Series, which focused on inter-industry collaboration, protecting trade secrets, and how to effectively build, present, and prosecute cases. The webinar discussed case evaluation categories and special factors considered in the evaluation process. Designed to help rights holders and brand protection specialists produce impactful investigative referrals to law enforcement, the event attracted 91 participants representing private sector and U.S. Government agencies involved in IP protection.

Operation Joint Venture and Project Trade Watch

Through the IPR Center's Outreach and Capacity Building Section, HSI coordinates with the public and private sectors to combat IP infringement through its **Operation Joint Venture (OJV)** initiative. This IPR Center-led outreach initiative is designed to increase information sharing with public and private sectors to combat the illegal importation and distribution of counterfeit, substandard, and tainted goods, as well as the evasion of duties. The initiative is aimed at fostering investigations into commercial fraud, including activities that threaten public health and safety and violate IP rights. Through **OJV**, the IPR Center engages with rightsholders, manufacturers, importers, customs brokers, freight forwarders, bonded facilities, carriers, and

others to discuss the IPR Center's priorities of protecting public health and safety, the economy, and the U.S. Government's supply chain. Through outreach and public engagement, the IPR Center raises the public's awareness of the dangers of commercial fraud violations (such as those involving IP) and serves as a public point of contact for investigative leads. The IPR Center's audience includes a broad spectrum of industries and government agencies, including but not limited to the pharmaceutical, entertainment, wearing apparel, sports, electronic, and automobile industries, as well as customs bonded entities, importers, and law enforcement officials.

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

Government Supply Chain Investigations Unit (GSCIU)

Law Enforcement Operations

In June 2023, amid growing concerns over the infiltration of counterfeit and substandard goods into the U.S. Government supply chain, HSI established the Government Supply Chain Investigations Unit (GSCIU) within the Global Trade Investigations Division (GTI). This new unit was designated to operate from within the IPR Center.

The GSCIU assumed oversight of ***Operation Chain Reaction (OCR)***, an HSI-led task force that proactively targets counterfeit goods, specifically microelectronics, entering the supply chains of the Department of Defense and other U.S. Government agencies. ***OCR*** combines the expertise of numerous federal agencies, and was conceived in 2011 to address the significant national security, health, and safety threats posed by counterfeit electronics being introduced to the Department of Defense weapons-track supply chain. Prior to the GSCIU assuming oversight, ***OCR*** had operated within the Intellectual Property Unit (IPU).

OCR remains a vital program within the IPR Center, and the GSCUI – as a dedicated government supply chain unit – facilitates a comprehensive supply chain risk management system across the federal government. This effort broadens the focus from microelectronics alone and now includes additional areas of priority focus such as ballistic equipment, small-arm weapons and weapon components, pharmaceuticals, and medical devices. These are but a few examples of additional counterfeit or substandard products already introduced into the government supply chain gravely impacting the national security and military readiness of the United States.

Like the IPU, the GSCIU leverages key public and private partnerships, with each entity contributing varying expertise and authority. The GSCIU is modernizing infrastructure and processes, and is integrating and analyzing interagency data sources to identify and combat threats to our federal supply chain.

Operation Gung Ho

Operation Gung Ho (OGH) is dedicated to the identification and interdiction of counterfeit and non-compliant weapon components from entering the U.S. supply chain. Many of these counterfeit and non-compliant components are associated with small-arm weapons systems, ammunition, body armor, ballistic helmets, and optical sights, among others. **OGH** safeguards crucial supply streams essential to the security of the United States, and protects end users – such as members of our military, federal law enforcement officials, and state and local first responders – from the threats posed by counterfeit and non-compliant components. **OGH** personnel collaborate closely with rights holders, vendors, the U.S. military, and law enforcement entities to protect those who safeguard our nation.

As an example of this approach, in January 2024, **OGH** personnel hosted an information booth at a prominent industry trade show attended by approximately 60,000 visitors from private and public sector entities. During the event, special agents from **OGH** engaged with vendors from private industry and procurement officials from various government entities. These contacts were instrumental in bolstering the program’s proactive and collaborative efforts to secure the government supply chain, ensuring that the warfighter has reliable weapons systems, firearms, and ammunition on the battlefield. Furthermore, these engagements reinforced the program’s commitment to providing American law enforcement officers with the assurance that their equipment will function effectively when needed most.

In 2024, **OGH** has achieved significant progress through multiple investigative cases uncovering instances where American law enforcement agencies and military branches inadvertently purchased counterfeit or non-compliant ballistic personal protective equipment (PPE). These cases highlight the critical importance of ensuring the authenticity and compliance of PPE used by frontline personnel. By identifying and addressing these issues, **OGH** plays a vital role in enhancing the safety and effectiveness of American soldiers, law enforcement officers, and first responders in the performance of their duties. This proactive approach not only protects lives but also reinforces the integrity of the supply chain essential for national security efforts.

Operation Genuine Valor

Operation Genuine Valor (OGV) is one of the cornerstone operations of the GSCIU. **OGV** is dedicated to safeguarding the health and safety of U.S. Veterans. In line with the critical mission of the GSCIU, **OGV** is expanding its reach and partnering with personnel from the Defense Health Agency (DHA), the State Department (DOS), and the Bureau of Prisons (BOP). All of these agencies make substantial purchases of pharmaceuticals, medical devices, and supplies through federal contracts. The GSCIU and its partners stand ready to ensure that these life-sustaining materials are genuine and perform as expected. **OGV** fulfills this mission using strategic enforcement operations, interdiction efforts, and complex investigations.

In FY 2024, **OGV** engaged over 1,000 stakeholders from private and public sectors during key events outreach and training events. Notable engagements included the Veterans Health Administration (VHA) Logistics Conference and critical briefings to VA’s National Acquisition Center, which is pivotal to those overseeing pharmaceutical procurement. During these events

and through the review of data collected by the National Center for Patient Safety, the GSCIU and VA OIG personnel identified the need for a real-time reporting tool to enhance reporting capabilities of frontline personnel. To address this need, **OGV** developed and launched an internal reporting website and mobile application for VA employees which streamlines the reporting of suspicious activities related to counterfeit medical products.

Since its inception in June 2023, **OGV** has received reports of concern and generated numerous actionable leads that have been distributed to field offices throughout the United States. **OGV** is collaborating closely with VA contracting officers to preemptively address threats to supply chain integrity. These proactive measures underscore the IPR Center commitment to safeguarding veterans' health and ensuring the reliability of medical supplies.

In addition, **OGV** has fortified key partnerships with agencies such as CBP, DOJ, and international entities like the World Health Organization (WHO) and the United Kingdom's Veterinary Medicines Directorate (VMD). Participating in global initiatives, such as the Working Group of Enforcement Officers (WGEO) of the European Union, demonstrates the **OGV** commitment to international collaboration and intelligence sharing.

Operation Roll Back

Operation Roll Back (ORB) takes a resolute stance against vulnerabilities in the government supply chain through proactive measures. By leveraging data received from e-commerce platforms, **ORB** identifies third-party vendors who have been found to engage in counterfeiting and other intellectual property rights violations before those entities can harm the U.S. Government's procurement efforts.

Central to **ORB's** success is its robust interagency coordination and partnership. This approach exemplifies **ORB's** commitment to securing supply chains and safeguarding national security. In one recent example, a collaborative effort between HSI and the Government Services Administration Office of the Inspector General IG (GSA OIG) was initiated following the development of criminal intelligence from within the GSCIU. This investigation led to the identification of more than a dozen companies with a substantial history of suspicions of Trade Agreement Act (TAA) violations.

ORB's public-private partnerships ensure that bad actors impacting both private citizens and government entities are identified and investigated thoroughly. This proactive stance underscores the dedication of **ORB** to maintaining the integrity of government procurement and protecting critical national interests.

Operation Chain Reaction

As the legacy operation with the GSCIU, **Operation Chain Reaction (OCR)** is the bedrock of the GSCIU and is charged with safeguarding national security through vigilance and proactive measures. Since inception, **OCR** has stood at the forefront of the effort to safeguard the integrity of the DoD supply chain. This initiative represents a robust response to the pervasive threat posed by counterfeit parts infiltrating critical military infrastructure; such infiltration not only

undermines operational readiness but also poses a direct risk to the lives of our service members. Recognizing the complexity and severity of this challenge, **OCR** was meticulously crafted to combat these threats effectively.

International criminal organizations employ sophisticated tactics to introduce counterfeit goods into U.S. Government supply chains. **OCR** stands as a bulwark against these tactics, harnessing the unparalleled expertise of the GSCIU, the expertise of the GSCIU task force members, an extensive network of data sources, and the development of analytical tools to combat this pervasive threat.

OCR is not merely a defensive strategy; it is a proactive operation that reinforces the resilience of our national defense. By fortifying the DoD supply chain against counterfeit infiltration, **OCR** upholds the integrity of vital military operations and safeguard the trust placed in us by the American people. As an example of this effort, in 2024, **OCR** and their partners initiated a pilot program with the Defense Criminal Investigative Service (DCIS) and the Defense Logistics Agency (DLA) to identify, interdict, and further investigate “bad actor” entities who seek to sell counterfeit or substandard commodities to DLA. Leveraging newly developed tools and processes, **OCR** can illuminate the criminal network used to move counterfeits from offshore facilities through U.S. ports and into sensitive supply stores. While in its infancy, this pilot project has developed relevant information that will aid in the interdiction of suspect goods – thereby fulfilling the primary goal of the operation, which is to protect U.S. national security and the military readiness of U.S. warfighters and their allies.

As threats evolve, **OCR** evolves with them. In FY 2024, **OCR** and the GSCIU remain committed to advancing its capabilities, refining strategies, and strengthening partnerships to ensure that our nation’s defense remains unyielding in the face of emerging challenges. Data scientists within the IPR Center and AI professionals at HSI’s Innovation Lab are developing tools that will allow **OCR** to ingest large data sets that are used to direct **OCR** resources and efforts now, and into the future.

Like all operations within the IPR Center, **OCR** constantly seeks to expand the connectivity between government investigative and enforcement efforts with the needs and expertise of rightsholders. Efforts in FY 2024 were no different. **OCR** hosted and participated in outreach, training, and industry conversations on a near-monthly basis. Partnerships with OEMs like Cisco, Hewlett Packard, Seagate Technology, and Samsung, to name just a few, have enhanced the knowledge base of **OCR** special agents through the exchange of up-to-date and relevant information. **OCR** responsiveness to pertinent bad actor data remains an important focus of these expanding relationships, as does the importance of protecting the intellectual property of the OEMs.

The public/private partnership discussed above helps to achieve success like that found in the identification, interdiction, investigation, and successful prosecution of Onur Aksoy and the PRO NETWORK suite of companies. More information is available at: <https://www.justice.gov/usao-nj/pr/ceo-dozens-companies-sentenced-78-months-prison-massive-scheme-traffic-fraudulent-and>

This HSI-led investigation was supported by **OCR** and required extensive assistance from private sector companies like Cisco. The PRO NETWORK investigation is a model for future efforts and has been incorporated into outreach and training materials that will reach investigative and business professionals at home and internationally.

Engagements

In FY 2024, the GSCIU continued to expand operations and its influence with industry and other government agencies. The GSCIU contributed to this mission by raising awareness, by capacity building, and by conducting outreach and training. Examples of this include:

- Initiated 57 recurring inter-agency collaborative meetings to develop shared government supply chain investigative resources and discuss government supply chain issues.
- Briefed 17 new public and private partners and liaised with four brand protection entities to expand the government supply chain collaborative network and provide government supply chain training.
- Teamed up with the Veterans Health Administration to expand government medical supply chain investigative data resources and reporting tools.
- Hosted members of the Global and National Security Institute at the University of South Florida (GNSI USF) to explore the development of research-based counterfeit detection methods and validation systems to improve the security posture of the U.S. Government supply chain.
- Engaged with the National Institute of Justice (NIJ) to discuss the reporting and tracking of compliance testing for Ballistic Resistant Body Armor with specific regard to the identification of sub-standard or out-of-certification products.
- Presented at the Heads of Medicines Agency (HMA), Working Group of Enforcement Officers (WGEO) in Belgium on the topic of counterfeit pharmaceuticals in the supply chain.
- Presented at the “17th International Law Enforcement Intellectual Property Crime Conference in Curacao” on the topic of combating Transnational Organized Crime throughout the supply chain.

IPR Center - Other Engagements

DHS law enforcement agencies which support IP enforcement had numerous other engagements with stakeholders during FY 2024. 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 2024, the IPR Center continued the quarterly 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 in order 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.

In FY 2024, the IPR Center responded to media requests to bring more public awareness to the dangers of buying counterfeits, including counterfeits of weight loss and diabetes medications. One notable engagement was the interview of the IPR Center director and a national program manager (NPM) for the June 2024 Vanity Fair article on “Why Counterfeit Ozempic Is a Global-Growth Industry.” The article highlighted the efforts of the IPR Center and included quotes by the IPR Center director and the NPM. “We’re going to work with our international law enforcement partners and try to make the biggest impact we can,” said (former) IPR Center Director James Mancuso. (<https://www.vanityfair.com/news/story/counterfeit-ozempic-global-growth-industry>)

Throughout FY 2024, HSI – through its leadership at the IPR Center – collaborated with industry and other government agencies to present training and foster communication.

Examples of this IPR Center collaboration include its:

- Hosting of representatives from the International Olympic Committee and U.S. Olympic Committee to discuss counterfeit goods and digital piracy issues ahead of the 2024 Olympics and 2028 Olympics.
- Engagement with the Automotive Anti-Counterfeiting Council (A2C2) and the Automotive Aftermarket Suppliers Association (AASA) to provide a case study related training, addressing counterfeit automobile parts.
- Collaboration with the DOJ CCIPS and USPTO to provide training on various IP enforcement topics.
- Liaison with CBP’s OT on numerous virtual training opportunities in combating commercial fraud and intellectual property rights enforcement.

In addition,

- In April 2024, IPR Center personnel met with Pfizer’s executive leadership in their Global Security division. During the two days of meetings, Pfizer regional directors learned about IPR Center programs and discussed ongoing counterfeit medical products investigative matters. Presentations during the meeting highlighted the existing public/private working relationship between Pfizer, Chamber of Commerce, and the IPR Center. Specific focus was placed on how the information received from Pfizer is being used for training with foreign law enforcement and lead development in furtherance of criminal investigations. This interaction was able to produce additional lead development and future interaction on additional training.
- IPR Center personnel assigned to NCFTA leveraged 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. In FY 2024, under the auspices of *Operation IOS*, the NCFTA assisted the IPR Center and HSI agents with facilitating the seizures of 371 domains. (The NCFTA is an alliance of private industry and law enforcement partners dedicated to information sharing and disrupting cyber-related threats.)
- Also in FY 2024, the IPR Center received over 27,678 leads. Of those received leads, the NCFTA indexed and conducted research on 21,029 of them. 124 of those leads were

referred to HSI field offices for investigation and 273 leads were deconflicted with law enforcement and the private industry.

Cooperating with Foreign Law Enforcement

As discussed above, DHS law enforcement agencies regularly cooperate with other Federal and foreign law enforcement agencies. Below are 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 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 2024, the IPR Center hosted foreign government officials with an interest in IP enforcement, including representatives from The Gambia, Ukraine, and Europol. The IPR Center also engaged with foreign counterparts in meetings and various outreach and training efforts throughout the world. Among these were representatives from Algeria, Argentina, Bangladesh, Botswana, Brazil, Bulgaria, Chile, Colombia, Costa Rica, Ghana, Hungary, India, Indonesia, Ivory Coast, Kazakhstan, Kenya, Kosovo, Lao People's Democratic Republic, Malaysia, Maldives, Malta, Mauritius, Mongolia, Morocco, Panama, Philippines, Tanzania, Thailand, Ukraine, the Seychelles, South Africa, Republic of South Korea, Sri Lanka, Tunisia, Türkiye, Ukraine, the United Arab Emirates, Uzbekistan, and Vietnam.

Capacity Building and Training

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

Domestic Capacity Building and Training

The IPR Center works closely with partner U.S. Government agencies, as well as state and local agencies, to deliver training and support domestic investigative and enforcement capacity building throughout the United States. In FY 2024, 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. The course strengthens ties between agencies, initiating new avenues for collaboration. 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 May and August 2024, the IPR Center provided the IPTEI training to HSI and CBP personnel. The course included presentations from HSI, CBP, and industry experts in the areas of commercial fraud and IP enforcement. Methodology modules, discussions, and case studies offered additional information to participants that can be applied in real-life scenarios.

The IPR Center also coordinates and hosts virtual training to partner agencies on the use of USPTO's trademark search and CBP's Intellectual Property Rights Search (IPRS) systems in support of IP enforcement and investigative efforts. In April 2024, the IPR Center hosted a virtual training on how to conduct searches in the IPRS and trademark search system online sites. The training was presented by subject matter experts from the USPTO Trademarks Customer Outreach, and CBP OT, Intellectual Property Enforcement Branch. This training was attended by 97 HSI and CBP participants and included personnel currently assigned to a commercial fraud, IP, or global trade investigations group, or those who anticipate an assignment in this area.

In June 2024, the IPR Center, in collaboration with the NCFETA, developed and hosted HSI's first Digital Piracy Investigations Training Course. Twenty HSI special agents were taught investigative techniques to dismantle online piracy groups. Topics of instruction included case studies, the use of open-source intelligence resources, source code analysis, de-obfuscation techniques, cryptocurrency tracing, and other financial investigative techniques. At the end of the training, agents were able to apply what they learned during a practical exercise utilizing a mock digital piracy website.

In FY 2024, the IPR Center (CBP and HSI) initiated long-term training and outreach effort in collaboration with the Alliance for Safe Online Pharmacies (ASOP Global) to develop training products for the IPR Center and its partners to utilize in raising awareness and increase enforcement efforts to combat counterfeit pharmaceuticals and medical devices in the U.S. economy and government supply chain.

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 – complements the U.S. Transnational and High-Tech Crime Global Law Enforcement Network (GLEN) in developing and delivering training and technical assistance for foreign partners in the investigative, prosecutorial, judicial, and customs and border enforcement areas. The initiative strengthens the enforcement capacity of these foreign partners for IP and computer crimes involving transnational organizations.

Through this initiative, and in conjunction with HSI attaché offices, the IPR Center 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 such as smuggling and money laundering. The training programs are interactive workshops led by subject matter experts and focus particularly on counterfeit health and safety 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 industries may face in a particular region and to highlight the necessity of government and industry cooperation.

In FY 2024, and to further protect U.S. national and economic security from transnational organized crime threats, the IPR Center expanded its support of the GLEN through the deployment of two HSI special agent on temporary duty assignment as ICHIP advisors to enhance the ongoing work of the IPR Center and the existing ICHIP network. An HSI ICHIP advisor is deployed to Bangkok, Thailand, for a second year with an area of responsibility of Southeast and South Asia. Another HSI ICHIP advisor is deployed to Athens, Greece for the first time, with an area of responsibility of Eastern Europe and Central Asia. Both HSI ICHIP advisors hold regional responsibilities to build capacity for foreign law enforcement counterparts, including investigators, police, prosecutors, policy officials, and lawmakers. This capacity building work is accomplished through practical technical training and case-based mentoring, which is focused on how to effectively interdict, investigate, and prosecute IP crime and related cybercrime. This training and mentoring delivers the technical skills and resources that the countries need in order to be able to interdict and investigate IP crimes and obtain and preserve evidence for use at trial.

In FY 2024, the IPR Center and its HSI ICHIPs participated in 47 international training and outreach events. 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 its international program:

- USPTO-hosted IPR Workshop: Best Practices Concerning IPR Administrative Enforcement: Sharjah, United Arab Emirates

On October 25 - 26, 2023, the IPR Center participated in a USPTO-hosted IPR workshop entitled “*Best Practices Concerning IPR Administrative Enforcement*” in Sharjah, United Arab Emirates. The IPR workshop was attended by Department of Economic Development (DED) personnel from six different Emirates as well as Ministry of Economy representatives. Representatives from USPTO, HSI IPR Center, CBP OT, a U.S. Magistrate Judge (Ret.), a North Carolina Secretary of State special prosecutor, and a professor from Michigan State University presented in the training.

- USPTO-hosted Subregional Seminar on the Enforcement of IP Rights: Asuncion, Paraguay

On November 15, 2023, HSI Phoenix presented a case study to South & Central American countries demonstrating HSI’s enforcement strategies as they relate to IPR investigations.

- DOJ OPDAT and ICHIP Hong Kong-hosted Intellectual Property Crimes Enforcement Network (IPCEN) VII: Bangkok, Thailand

On November 14 - 16, 2023 the IPR Center's HSI ICHIP Bangkok supported the DOJ OPDAT and ICHIP Hong Kong hosted IPCEN VII program in Bangkok, Thailand. The support included participation on panels highlighting IP enforcement case studies and U.S. Government resources available for protecting IP rights. This multi-national conference included foreign partners from Bangladesh, India, Indonesia, Republic of Korea, Lao People's Democratic Republic, Malaysia, Maldives, Mongolia, Philippines, Sri Lanka, Thailand, and Vietnam.

- USPTO-hosted Morocco Intellectual Property Rights Border Enforcement Workshop: Tangier, Morocco

On January 30 - February 1, 2024, the IPR Center participated in an IPR Border Enforcement Workshop in Tangier, Morocco. This event was hosted by the USPTO through the Middle East Partnership Initiative. HSI IPR Center, CBP, and DOJ CCIPS personnel were invited to present and participate in the workshop. The workshop also included presentations by Morocco Customs. Participants included judicial, customs, intellectual property office, and ministry officials.

- USPTO-hosted Intellectual Property Rights Workshop for Tunisian Officials: Tunis, Tunisia

On February 13 - 15, 2024, the USPTO, through the Middle East Partnership Initiative, conducted an IPR Border Enforcement Workshop in Tunis, Tunisia. HSI IPR Center, CBP, and DOJ CCIPS personnel were invited to present and participate in the workshop. The U.S. Embassy Economic Counselor participated in the workshop as well. Participants included judicial, customs, intellectual property office, and ministry officials.

- DOJ ICHIP Hong Kong and USPTO-hosted Strengthening IPR Enforcement and Prosecution in India Workshop: New Delhi, India

On March 18, 2024, the DOJ ICHIP Hong Kong, along with the IPR Center and USPTO, held a workshop on digital piracy, counterfeit pharmaceuticals, theft of trade secrets, and working with the private sector, with the support of INTA for Indian Prosecutors, Customs Officials, and Advocates. A federal judge also presented during the program.

- DOJ ICHIP Hong Kong and USPTO-hosted Strengthening IPR Enforcement and Prosecution in India Workshop: Mumbai, India

On March 20, 2024, the DOJ ICHIP Hong Kong – along with the IPR Center and USPTO (and with the support of the International Trademark Association (INTA) and the Alliance for Creativity and Entertainment (ACE)) – held a workshop on digital piracy, counterfeit pharmaceuticals, theft of trade secrets, and working with the private sector. The workshop was for Indian Prosecutors, Cybercrime Investigators, Customs Officers, IP Officials, and Advocates. A federal judge also presented.

- HSI New Delhi hosted 2024 Cross Border Investigations Workshop: Mumbai, India

On March 21, 2024, HSI New Delhi held a smuggling conference (with case studies on counterfeit pharmaceuticals and counterfeit luxury goods, and discussions on best practices in combating IPR crime) for investigators from Indian Customs and other Indian law enforcement. The IPR Center, DOJ ICHIP Hong Kong, and a federal judge spoke at the event.

- DOJ ICHIP Sao Paolo- hosted Latin America Digital Piracy Working Group: London, United Kingdom

In April 2024, representatives from the IPR Center supported a DOJ ICHIP Sao Paolo-hosted Digital Piracy Working Group program in London, United Kingdom. The program was attended by representatives from Argentina, Panama, Brazil, Columbia, Costa Rica, Dominican Republic, Romania, and Bulgaria. Private industry representatives from the Motion Picture Association (MPA), Entertainment Software Association (ESA), International Federation of the Phonographic Industry (IFPI) and others were in attendance and participated in presentations. National program managers provided presentations, participated in panels, and moderated discussion panels. In addition, former IPR Center Director James Mancuso provided the keynote address. Foreign government presentations were given by the EU Intellectual Property Office (EUIPO), the United Kingdom Intellectual Property Office (UK IPO), the Police Intellectual Property Crime Unit (PIPCU) of the City of London Police (CoLP), and others.

- DOJ ICHIP Romania-hosted Criminal IP Enforcement Program – Eastern Europe: ILEA Budapest, Hungary

On April 8–12, 2024, at the ILEA in Budapest, Hungary, the IPR Center presented at a program entitled “*Scams, Hacks, and Streaming: The Foundations of Cyber-Enabled Crime*” hosted by DOJ ICHIPs Bucharest and Zagreb. Attendees included law enforcement officers, investigators, and prosecutors from Bulgaria, Hungary, Moldova, Romania, and Ukraine. This program built the participants’ knowledge about the functionality and structure of the internet and computing. Attendees gained a better understanding of the reliability of electronic evidence and actively discussed investigations related to computer hacking, trade secrets violations, business email compromises, and digital piracy.

- CLDP-hosted IP Protection Workshop: Pristina, Kosovo

On April 16 - 18, 2024, representatives from the IPR Center, Department of Justice, UK Intellectual Property Office, Universal Music Group (UMG), and other intellectual property experts, joined CLDP in Pristina, Kosovo, to provide training on combatting digital piracy and counterfeiting to customs officials, police investigators, prosecutors, judges, and private consulting firms. The HSI Attaché from Athens also attended. The topics included why governments should prioritize fighting piracy and counterfeiting, inter-ministerial approaches and initiatives, global trends, and private sector perspectives and challenges. A panel discussion on inter-ministerial cooperation on intellectual property enforcement included perspectives from the DOJ ICHIP Bucharest and special agent advisors, and UK IPO. The training also included

interactive exercises for the participants to engage in discussions regarding appropriate interdictions, investigations, and enforcement operations related to IP crimes.

- USPTO/DOJ IPR Enforcement Judicial Workshop: Ulaanbaatar, Mongolia

On April 22 - 26, 2024, in Ulaanbaatar, Mongolia, the DOJ ICHIP Hong Kong, HSI ICHIP Bangkok, USPTO, and the Economic Section of Embassy Ulaanbaatar partnered to deliver four IP enforcement workshops for Mongolian judges, prosecutors, police, customs officers, and IP officials. U.S. expert presenters included a Northern District of California District Judge, Eastern District of New York Magistrate, an attorney from DOJ's Office of International Affairs (OIA), and assistant attachés for HSI Beijing and Guangzhou. A prosecutor from Korea's Supreme Prosecutors Office also presented on Korea's approach to combatting IP crime, as part of the ICHIP's joint capacity building efforts with the Republic of Korea (ROK) in the region. The workshops addressed calculating damages and loss amounts, forfeiture, and asset seizure in IPR cases, formal international cooperation, the importance of electronic evidence, and theft of trade secrets.

- USPTO IPR Enforcement Program for Algeria: Paris, France

On April 23 - 25, 2024, the IPR Center supported USPTO-sponsored IP training for Algerian officials responsible for the enforcement of patent, trademark, and/or copyright policies.

- USPTO West Africa Regional IP Enforcement Training Program: Accra, Ghana

On April 23 - 25, 2024, the IPR Center and HSI Dakar supported a USPTO-hosted West Africa Regional IP Enforcement Training program. The program took place at the Regional Training Center in Accra and included law enforcement and customs officials from Ghana.

- USPTO Effective Practices in Investigation and Enforcement Against Content Piracy: Bangkok, Thailand

On April 23 - 25, 2024, the DOJ ICHIP Hong Kong and HSI ICHIP Bangkok spoke on best practices in investigating digital piracy cases at a workshop for ASEAN countries on copyright organized by the USPTO.

- DOJ ICHIP São Paulo Multilateral Counterfeit Pharma Workshop: Bogota, Colombia

On May 7 - 9, 2024, in Bogota, Colombia, the IPR Center supported the DOJ ICHIPs São Paulo and Internet Fraud and Public Health (IFPH)-hosted program on counterfeit pharmaceuticals for prosecutors, investigators, customs, and health officials from Colombia, Peru, Ecuador, Chile, and Bolivia. The program focused on common issues specific to the Andean region and featured workshops on best practices for conducting undercover investigations, and for collecting and preserving digital evidence (particularly from social media), and mock trial exercises. Through collaboration with the pharmaceutical industry and the IPR Center, the program culminated in robust discussions of real case leads developed in advance of the program. The DOJ ICHIPs and

HSI agents provided case-based mentoring to participants, effectively bridging the gap between theoretical lectures and practical application.

- IP Enforcement and Customs Interdiction Workshop: Ho Chi Minh City, Vietnam

On May 13 - 17, 2024, the DOJ ICHIP Hong Kong and HSI ICHIP Bangkok spoke to Vietnam Customs officials about IPR smuggling and counterfeit goods, at a workshop on smuggling organized by HSI Vietnam.

- DOJ ICHIP Bucharest hosted Combatting Counterfeiting and Corruption: Black Sea Regional Workshop: Varna, Bulgaria

On May 14 - 16, 2024, in Varna, Bulgaria, the HSI ICHIP Athens supported the DOJ Bucharest's Central Europe Anti-Corruption (CEAC) RLA IP enforcement and corruption program for police, prosecutors, and customs officials from Bulgaria, Moldova, Romania, and Ukraine. The program focused on investigative and prosecutorial methods for combatting intellectual property crimes connected with the government supply chain and facilitated through corruption.

- USPTO IP Enforcement at the Border: Istanbul, Türkiye

On May 21 - 23, 2024, the HSI ICHIP Athens and HSI Istanbul supported a USPTO-hosted workshop on "*Intellectual Property Enforcement at the Border*" that was attended by judicial and enforcement officials from the Government of Türkiye.

- Asia-Pacific Cybercrime Capacity Building Hub Training: Seoul, Korea

On May 27 - 31, 2024, the DOJ ICHIP Hong Kong and HSI ICHIP Bangkok taught at cybercrime workshop organized by Republic of Korea through its Asia-Pacific Cybercrime Capacity Building Hub. The audience consisted of prosecutors, police, and other government officials from the Philippines, Bhutan, and Solomon Islands.

- INTERPOL Global Meeting on Digital Piracy: Lyon, France

On May 29 - 31, 2024, the IPR Center participated in the INTERPOL Global Meeting on Digital Piracy. This meeting was attended by the acting IPR Center director, who provided opening remarks regarding digital piracy and the IPR Center's efforts in this area. The event was also supported by HSI ICHIP Athens. The event was attended by over 200 officials from the government and industry/private sectors.

- African Regional Workshop on Counterfeit Pharmaceuticals - Plaine Magnien, Mauritius

On June 4 - 7, 2024, the IPR Center and HSI Pretoria co-hosted the African Regional Workshop on Counterfeit Pharmaceuticals for investigators, prosecutors, and customs officials from Mauritius, Kenya, the Seychelles, South Africa, and Tanzania. The applied trade enforcement

workshop was held at the Integrated Customs Clearance Centre (ICCC) in Plaine Magnien, Mauritius. It also included an applied trade enforcement practical exercise at the DHL Mail Facility, hosted by the Mauritius Revenue Authority (MRA). The workshop was supported by instructors from HSI New York, CBP's National Targeting Center, FDA-OCI, and DOJ's Office of Overseas Prosecutorial Development, Assistance, and Training (OPDAT) and the Computer Crime and Intellectual Property Section (CCIPS). Presentations were also provided by international representatives from the MRA and the South Africa National Prosecuting Authority. Industry representatives from the U.S. Chamber of Commerce, Pfizer, MSD South Africa (Merck), and Johnson & Johnson also supported the program, outlining their enforcement efforts and collaboration with law enforcement to combat counterfeit pharmaceuticals and global illicit trade.

The workshop provided participants with an increased understanding of the threats, impacts, and enforcement challenges in the intellectual property environment, specifically related to the increasing risks that counterfeit pharmaceuticals pose to health and safety, and the economy. The workshop also strengthened the collaborative relationships – across agencies, countries, and industry sectors – that are necessary to effectively deter, detect, and respond to harmful illicit drugs entering and moving through the global supply chain. The workshop demonstrated the importance of a whole-of-government approach to IP enforcement and highlighted successes of the U.S. IP enforcement framework. The workshop topics, case-studies, and applied exercises addressed emerging threats, investigative techniques, resources, and best practices for interdiction, investigation, and prosecution of counterfeit pharmaceutical crimes, thereby strengthening the ability of foreign enforcement authorities to disrupt transnational criminal networks that traffic in counterfeit pharmaceuticals.

This HSI-led international capacity-building training workshop was funded by the Department of State's Bureau of International Narcotics and Law Enforcement Affairs (INL).

- DOJ ICHIP Bucharest, UNODC, WHO Pharma Program: Tashkent, Uzbekistan

On June 18 - 20, 2024, in Tashkent, Uzbekistan, the HSI ICHIP Athens supported DOJ ICHIP Bucharest, the United Nations Office on Drugs and Crime (UNODC), and the WHO workshop for participants from Kazakhstan, Uzbekistan, and Kyrgyzstan. The program provided law enforcement and prosecutors with necessary tools and methods to successfully investigate and prosecute crimes involving counterfeit pharmaceuticals and other falsified medical products.

- Meeting with Rightsholders and INTERPOL- Singapore

On July 9 - July 11, 2024, the HSI ICHIP Bangkok, HSI Singapore, and the IPR Center met in Singapore with various rightsholders, industry representatives, and INTERPOL. They discussed IPR and illicit trade concerns, customs and law enforcement challenges and successes, and areas for mutual collaboration and coordination in Southeast Asia. The following organizations participated in the meetings: Alliance for Creativity and Entertainment (ACE), Apple, International Federation of the Phonographic Industry (IFPI), Johnson & Johnson, Merck Sharp & Dohme (MSD), Pfizer, and Proctor & Gamble.

- ASIA Security Conference & Exhibition - New Delhi, India

On July 23 - 24, 2024, the HSI ICHIP Bangkok spoke at the ASIA Security Conference & Exhibition in New Delhi, India. The event brought together brand owners, regulators, law enforcement agencies, government policymakers, and security solution providers to address the challenges to online brand protection and cross-border product security that are posed by counterfeit trafficking, product smuggling, and diversion. Speakers shared best practices in halting these illicit trade activities, enabling leaders in government, civil society, and the private sector to work together in addressing both the root causes and negative effects of this global issue.

- Indo-Pacific Workshop on Enforcement Against Trade in Counterfeit Goods – Bangkok, Thailand

On July 30 - August 1, 2024, USPTO, the HSI ICHIP Bangkok, and the Association of Southeast Asian Nations (ASEAN) Secretariat held the “*Indo-Pacific Workshop on Enforcement Against Trade in Counterfeit Goods*” in Bangkok, Thailand. Speakers shared their expertise, insights, and observations on the challenges posed by counterfeit goods in the marketplace, and especially online. The program focused on enforcement methods and challenges for investigative and regulatory agencies, including those from customs, postal, and public health agencies. Participants included members from ASEAN and South Asian countries.

- ILEA Bangkok IPR Course: Session 9 – ILEA Bangkok, Thailand

On August 19 - 23, 2024, the HSI ICHIP Bangkok – in conjunction with the IPR Center, HSI Dharan, and HSI Long Beach – conducted the “*Intellectual Property Rights Course: Session 9*” at the International Law Enforcement Academy in Bangkok, Thailand (ILEA Bangkok). This course provides participants with an understanding of current investigative and interdiction methodologies used to protect and regulate IPR. Additionally, participants learned how partnership with industry representatives can aid in the interdiction, identification, and seizure of infringing goods, along with best practices in prosecuting individuals who violate IPR regulations and the related criminal statutes.

- African Judges Dialogue Forum – Marrakech, Morocco

On August 26 - 28, 2024, the HSI ICHIP Athens – along with HSI, CBP, FBI, and DOJ/OPDAT – supported HSI Casablanca and the International Organization for Migration, African Regional Migration Program (IOM/ARMP) at the first international meeting of the African Judges Dialogue Forum in Marrakech, Morocco. The participants included high level judges and prosecutors from Morocco, Mauritania, Mozambique, Senegal, Ivory Coast, Togo, and the Republic of Central Africa. Subject matter experts from the region and the U.S. Government provided experiences and perspectives on challenges, vulnerabilities, and cross-border crimes associated with migration, with the focus on protecting children. Topics included human trafficking, child exploitation, trafficking in counterfeit goods, darknet weapons smuggling, and evidence sharing. Presenters focused on how transnational criminal organizations utilize various types of criminal activities and the importance of international collaboration to combat these

threats. HSI Acting Assistant Director for International Operations provided opening remarks, and the U.S. Consul General in Casablanca provided closing remarks.

- Pacific Colloquium on Consumer Protection, Border Security, and Enforcement Against Trade in Counterfeit Goods – Los Angeles, California

On August 27 - 29, 2024, USPTO held a three-day program entitled the “*Pacific Colloquium on Consumer Protection, Border Security, and Enforcement Against Trade in Counterfeit Goods*” in Los Angeles, California. The event brought together various government and customs officials from the Pacific Islands region, along with U.S. Government officials and state Attorneys General Offices, for a discussion of the interplay between consumer protection, border security, and enforcement against trade in counterfeit and illicit goods. The HSI ICHIP Bangkok and IPR Center personnel presented at the training event.

- IPR Investigations: The Intersection of Illicit Trade and Finance – Bangkok, Thailand

On August 27, 2024, the HSI ICHIP Bangkok, in partnership with HSI Bangkok and in support of interagency cooperation with CBP, held three separate one-day training events to separate audiences that consisted of IP officials, customs agencies, law enforcement, and prosecutors. The IPR Enforcement training program provided specialized instruction on IPR violations, including interdictions and investigations, with additional training on the use of financial and fraud investigative techniques. The program focused on the impact of IP infringement on public safety and its role in facilitating illicit trade and finance, and it strengthened the capabilities of the participating agencies to address IPR violations.

- Workshop for IP Investigations in the Sports Sector – Sao Paulo, Brazil

On September 3, 2024, the IPR Center and HSI Brasilia participated in a law enforcement training for Brazilian authorities regarding anti-counterfeiting best practices in the sports merchandise sector.

- Brunei-U.S. Dialogue on IP Enforcement– Bandar Seri Begawan, Brunei

On September 5, 2024, the HSI ICHIP Bangkok and HSI Singapore participated in roundtable discussions between the USPTO and the Government of Brunei. The roundtable discussed activities in IP and illicit trade enforcement through civil, administrative, and criminal enforcement actions and included a dialogue on local enforcement actions, IPR recordation systems, and ex officio authority. Multiple agencies from the Government of Brunei were represented, including officials from customs, law enforcement, and food and drug regulatory agencies.

- ASEAN Regional Workshop on IP Investigations – Bangkok, Thailand

On September 10 - 12, 2024, HSI ICHIP Bangkok – in partnership with HSI Bangkok, the IPR Center, USPTO and ASEAN – hosted a three-day IPR Investigative Workshop. The workshop brought together subject matter experts from various U.S. agencies, including HSI, USPTO,

CBP, and FDA. These experts provided specialized instruction on IPR investigations, with a focus on e-commerce, digital technology, cyber investigative techniques, and handling electronic evidence. The program emphasized the growing impact of intellectual property infringement, particularly through the sale of counterfeit goods online and the use of cyber-enabled technologies. The workshop enhanced the investigative capabilities of the participating agencies in addressing these violations. Participants included officials from Thailand, Indonesia, and Cambodia.

- Illicit Trade and Counterfeit Pharmaceutical Regional Enforcement Workshop– Istanbul, Türkiye

On September 10 - 13, 2024, HSI Istanbul and the IPR Center co-hosted the Illicit Trade and “*Counterfeit Pharmaceutical Regional Enforcement Workshop: Central Asia*” in Istanbul, Türkiye. This workshop included law enforcement, customs, and judiciary officials from the Republics of Kazakhstan and Uzbekistan. The HSI ICHIP Athens, the U.S. Chamber of Commerce, and the Organization for Economic Cooperation and Development (OECD) also supported the program.

This workshop provided participants with an increased understanding of the health threats, economic impacts, and enforcement challenges posed by counterfeit pharmaceuticals. Workshop topics and case-studies addressed investigative techniques, resources, and best practices for criminal investigations and prosecutions of counterfeit pharmaceutical crimes to equip attendees with the tools necessary to disrupt transnational criminal networks involved in these illicit activities. The workshop also demonstrated the intersection of illicit trade and financial crimes, in order to enhance investigative techniques in combatting illicit trade in pharmaceuticals. Through this engagement, HSI strengthened collaborative relationships – across agencies, countries, and industry sectors – that are necessary to effectively deter, detect, and respond to harmful illicit pharmaceuticals entering and moving through the global supply chain.

Industry representatives from Pfizer, Merck Sharp & Dohme, and Johnson & Johnson also attended, and they presented information on their collaborative enforcement efforts with law enforcement to combat counterfeit pharmaceuticals and global illicit trade. The workshop also included a rights holder networking fair, which provided participants with an opportunity to engage directly with pharmaceutical industry representatives. The fair also provided participants with a hands-on experience with legitimate and counterfeit pharmaceutical product packaging, as well as authentication methods and best practices used by the pharmaceutical industry.

DEPARTMENT OF JUSTICE

DEPARTMENT OF JUSTICE

“The defendants conspired to operate an online streaming service that unlawfully reproduced and distributed thousands of copyrighted television programs for their own personal gain. This case is another example of our steadfast commitment to combat intellectual property theft and to hold accountable those who violate intellectual property rights laws.”¹⁰

– Jason M. Frierson, U.S. Attorney for the District of Nevada

“The defendant sold counterfeit and deficient fan assemblies for use in military systems to increase his profit. Criminals who cheat the U.S. military by selling deficient or counterfeit goods put our national security at risk. This case demonstrates the Justice Department’s commitment to protecting the military supply chain and Americans’ security.”¹¹

– Nicole M. Argentieri, Principal Deputy Assistant Attorney General, DOJ Criminal Division

“The defendants stand accused of stealing valuable proprietary technology from a U.S. electric car manufacturer and using it to set up a rival business overseas. This blatant theft of advanced trade secrets relating to battery components and assembly blunts America’s technological edge, and the Justice Department will hold accountable those who would try to cheat our country of its economic potential and threaten our national security.”¹²

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

Department of Justice Appendix for FY 2024 Annual Report

This appendix for the Department of Justice (DOJ or the Department) discusses the Department’s activities during FY 2024 relating to intellectual property (IP) protection and enforcement. In addition, the Federal Bureau of Investigation (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.

¹⁰ DOJ press release, “Five Men Convicted for Operating Major Illegal Streaming Service” (June 20, 2024) at <https://www.justice.gov/opa/pr/five-men-convicted-operating-major-illegal-streaming-service>.

¹¹ DOJ press release, “Man Pleads Guilty to Selling \$3.5M in Counterfeit and Deficient Electronics for Use in Military Systems” (March 28, 2024) at <https://www.justice.gov/opa/pr/man-pleads-guilty-selling-35m-counterfeit-and-deficient-electronics-use-military-systems>.

¹² DOJ press release, “Owners of China-Based Company Charged with Conspiracy to Send Trade Secrets Belonging to Leading U.S.-Based Electric Vehicle Company: Defendants Allegedly Conspired to Send Millions of Dollars-Worth of Trade Secrets to Undercover Law Enforcement Officers Posing as Potential Customers” (March 19, 2024) at <https://www.justice.gov/opa/pr/owners-china-based-company-charged-conspiracy-send-trade-secrets-belonging-leading-us-based>.

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 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>.

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 2024.

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

Florida Man Sentenced to One Year and One Day in Federal Prison for Providing Illegal Access to Digital Streaming Services. On May 2, 2024, the Department of Justice announced that Franklin Valverde Jr. of Melbourne, Florida was sentenced to one year and one day to be followed by a three-year term of court-ordered supervision. Valverde was also ordered to pay \$22,639.27 in restitution, plus a fine of \$250,000. The sentence follows Valverde’s plea to charges of providing illegal access to digital streaming services. The conviction is believed to be the first in the nation under the “Protecting Lawful Streaming Act” (PLSA) that went into effect in 2021. Evidence presented to the court showed that Valverde made hundreds of thousands of dollars illegally selling access codes to individuals that allowed them to view the entire video libraries of Dish Network and Sling TV. Valverde is now retired from the Air Force but was stationed at Shaw Air Force Base in Sumter when he began his involvement in the scheme to illegally sell the access codes. According to evidence presented before the court, Valverde sold access codes to individuals, typically for \$10 per month. The codes allowed the customers to illegally access all the copyrighted content of Dish Network and Sling TV, including pay-per-view sporting events, movies, and television programs. Valverde also provided websites and apps to his customers so that they could view the copyrighted materials. (DSC, FBI)

<https://www.justice.gov/usao-sc/pr/florida-man-sentenced-one-year-and-one-day-federal-prison-providing-illegal-access>

Five Men Convicted for Operating Major Illegal Streaming Service. On June 18, 2024, a federal jury in Las Vegas returned guilty verdicts against five men for their roles in running one of the largest unauthorized streaming services in the United States, which generated millions of dollars in subscription revenue while causing substantial harm to television program copyright owners. According to court documents and evidence presented at trial, beginning as early as 2007, Kristopher Dallmann, Douglas Courson, Felipe Garcia, Jared Jaurequi, and Peter Huber operated an online, subscription-based streaming service known as Jetflixs. The Jetflixs group used sophisticated computer scripts and software to scour pirate websites for illegal copies of

television episodes, which they then downloaded and hosted on Jetflix servers. The group reproduced hundreds of thousands of copyrighted television episodes without authorization, amassing a catalog larger than the combined catalogues of Netflix, Hulu, Vudu, and Amazon Prime. Dallmann and his co-conspirators made millions of dollars streaming and distributing this catalogue of stolen content to tens of thousands of paid subscribers.

The jury convicted Dallmann, Courson, Garcia, Jaurequi, and Huber of conspiracy to commit criminal copyright infringement. The jury also convicted Dallmann of two counts of money laundering by concealment and three counts of misdemeanor criminal copyright infringement. Courson, Garcia, Jaurequi, and Huber each face a maximum penalty of five years in prison, and Dallmann faces a maximum penalty of 48 years in prison. Sentencing is set for the first week of February 2025. A federal district court judge will determine any sentence after considering the U.S. Sentencing Guidelines and other statutory factors. (DNV, CCIPS, FBI)

<https://www.justice.gov/opa/pr/five-men-convicted-operating-major-illegal-streaming-service>

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

California Resident Steve H.S. Kim Sentenced for Selling \$3.5M In Counterfeit And Substandard Electronics For Use In Military Systems. On July 17, 2024, a California man was sentenced to three years and six months in prison for a scheme to defraud the Department of Defense's (DoD) Defense Logistics Agency (DLA) by selling over \$3.5 million worth of fan assemblies to the DLA that were either counterfeit or that he misrepresented were new when in fact they were used or surplus. According to court documents, Steve H.S. Kim, of Alameda County, controlled Company A, which sold fan assemblies to the DLA that were either counterfeit or were used or surplus fan assemblies that Kim claimed were new. To trick the DLA into accepting the fan assemblies, Kim created counterfeit labels—some of which used Company B's registered trademarks—that he attached to the fan assemblies he sold to the DLA. When the DLA questioned Kim about the origin of the fan assemblies, Kim concealed his scheme by giving the DLA fake tracing documents that he created and often signed using a false identity. Some of these counterfeit fans were installed or intended to be installed with electrical components on a nuclear submarine, a laser system on an aircraft, and a surface-to-air missile system. (NDCA, CCIPS, Fraud, DCIS, NCIS, HSI, Army CID)

<https://www.justice.gov/usao-ndca/pr/california-resident-steve-hs-kim-sentenced-selling-35m-counterfeit-and-substandard>

Jury Convicts Two for Conspiring to Traffic Counterfeit Levi's. On August 2, 2024, a federal jury convicted Marin Morales-Espinoza and Francisco Alvarado-Ramirez of conspiracy to traffic counterfeit Levi's jeans labels, tags, rivets and buttons to make counterfeit Levi's jeans. Morales paid people to smuggle counterfeit Levi's pieces and parts into the United States from Mexico at the Calexico Port of Entry. Another co-conspirator paid Morales to drive the pieces to his home in Los Angeles. That co-conspirator brought the pieces to Alvarado at his factory in the Garment District to make the counterfeit Levi's jeans. Tens of thousands of counterfeit Levi's tags, buttons and rivets were seized at the Port of Entry. Over 2,000 completed counterfeit Levi's jeans were seized from Alvarado's factory. These fake Levi's were sold at local swap meets by other co-

conspirators. The Senior Director of Global Brand Protection for Levi Strauss & Co. testified that none of the co-conspirators worked for Levi's. He walked the jury through the seized merchandise to explain how they were not genuine Levi's products. The defendants are scheduled to be sentenced November 1, 2024. (SDCA, HSI)

<https://www.justice.gov/usao-sdca/pr/jury-convicts-two-conspiring-traffic-counterfeit-levis>

Ontario Importer Sentenced to Imprisonment for Trafficking in Over \$4 Million Dollars in Counterfeit Merchandise. On December 11, 2024, Wasseem Ramjaun, of Vaughan, Ontario, was sentenced to two years imprisonment and ordered to pay \$4.8 million dollars in restitution based on his guilty plea to trafficking in counterfeit goods. Ramjaun operated various importing and exporting businesses in Canada. From approximately October 2016 to August 1, 2017, Ramjaun agreed to provide an individual with authentic Yeti, Vera Bradley, and Lacoste merchandise. However, Ramjaun was not authorized to use the trademarks of these companies. As a result, Ramjaun contacted a manufacturers in China and Peru and ordered various merchandise bearing the trademarks of Yeti, Vera Bradley, and Lacoste that appeared identical to genuine merchandise. For example, to make sure the bags appeared authentic, Ramjaun provided the manufacturer with photographs and tags of authentic Vera Bradley bags. Ramjaun then imported the counterfeit Vera Bradley bags into the United States through a port of entry in Western District of New York. To conceal the fact that the bags were fraudulent, Ramjaun provided United States Customs and Border Protection with a fraudulent manufacturing agreement. \$4.8 million dollars was the total loss associated with Ramjaun's conduct. (WDNY, HSI)

<https://www.justice.gov/usao-wdny/pr/ontario-importer-going-prison-two-years-trafficking-48-million-dollars-counterfeit>

TRAFFICKING IN COUNTERFEIT PHARMACEUTICALS

Foreign National Charged for Selling Counterfeit Cancer Drugs. On July 25, 2024, a federal grand jury in Houston, Texas returned an indictment charging an Indian national with selling and shipping tens of thousands of dollars' worth of counterfeit oncology pharmaceuticals into the United States. According to court documents, Sanjay Kumar, of Bihar, India, and his co-conspirators allegedly arranged for the sale and shipment of fake, counterfeit versions of oncology pharmaceuticals—including Keytruda—to individuals in the United States. Genuine Keytruda is a cancer immunotherapy that is approved in the United States for 19 different indications, including to treat certain types of melanoma, lung cancer, head and neck cancer, Hodgkin lymphoma, gastric cancer, cervical cancer, and breast cancer. Merck Sharp & Dohme LLC, formerly known as Merck Sharp & Dohme Corp., has the exclusive right to authorize the manufacture of Keytruda for introduction into interstate commerce. Kumar was arrested on June 26 in Houston after traveling to the United States to conduct further negotiations aimed at expanding his business selling fake Keytruda in the U.S. market. Kumar is charged with one count of conspiracy to traffic in counterfeit drugs and four counts of trafficking in counterfeit drugs. If convicted, he faces a maximum penalty of 20 years in prison on each count. (SDTX, CCIPS, HSI, FDA)

TRADE SECRET THEFT (18 U.S.C. § 1832)

Siemens Energy, Inc. Pleads Guilty to Stealing Confidential Competitor Information In \$104M Resolution After Former Corporate Executive and Others Were Sentenced. On September 30, 2024, Siemens Energy, Inc. (Siemens), pleaded guilty and has agreed to pay \$104 million to resolve the Justice Department’s criminal investigation into violations related to the misappropriation of confidential competitor information. Additionally, Siemens has agreed to a three-year term of organizational probation. Siemens is a U.S.-based subsidiary of a Germany-based global manufacturing conglomerate, Siemens Energy AG (SMNEY), whose technology is responsible for one sixth of electricity production worldwide.

According to court documents, in 2019, Dominion Energy, Inc. (Dominion), a utility company based in Richmond that provides electricity to four million customers in Virginia, North Carolina, and South Carolina, sought to build a “Peaker” combustion turbine power plant in the greater Richmond metropolitan area. Peaker power plants are specifically designed to add electricity generation capacity to alleviate high grid load and improve electric grid resiliency. The electricity infrastructure project had projected cost of upwards of \$500 million. To build the power plant, Dominion opened a competitive, closed bid process soliciting requests for proposals from qualified companies. Three companies bid for the work: General Electric Company (GE), Mitsubishi Heavy Industries, Ltd. (MHI), and Siemens. All companies executed non-disclosure agreements restricting the disclosure of confidential information provided to Dominion during the bid.

After GE and MHI submitted their closed bids to Dominion in May 2019, Account Manager, Michael P. Hillen of Siemens coordinated with a Dominion insider, Director of Generation System Planning Theodore S. Fasca, who used his sensitive position to improperly obtain GE and MHI confidential information. Hillen and Fasca funneled the pilfered GE and MHI bid information through private email accounts, including Hillen’s wife’s Hotmail email address, before sending the confidential information to Hillen’s Siemens email address. Hillen then disseminated the confidential information to Siemens Account Manager Mehran Sharifi, who analyzed the confidential bid information with other employees.

Realizing that Siemens had a less competitive bid than GE by some metrics, Sharifi recommended to Siemens Executive Vice President and Head of Sales for North America, John Gibson, that Siemens resubmit a lowered bid to undercut GE’s bid price. Gibson, Sharifi, Hillen, and Fasca all knew the GE and MHI bid information was improperly obtained and that Siemens should not have had access to this information. Gibson strategically disseminated the confidential information to other Siemens senior executives, to leaders within Siemens’ business intelligence unit, and to representatives of Siemens’ then-parent company in Germany. Gibson’s dissemination of the information was calculated to provide Siemens with a competitive advantage in the bid for the Dominion project, improve Siemens’ business intelligence, and provide Siemens with a competitive advantage in future bids, all to the detriment of GE and MHI. After learning of GE’s and MHI’s bids for the Dominion project, Gibson authorized and obtained approvals within Siemens, including from the Chief Executive Officer for Power

Generation and representatives of Siemens' then-parent company in Germany, to resubmit a lower bid for the Dominion project, undercutting GE's bid. Siemens won the bid with Dominion. Even after submitting the lowered bid, Siemens continued misappropriating GE and MHI confidential information on numerous occasions throughout June 2019.

The company's plea comes after Gibson, Hillen, Fasca, and Sharifi entered guilty pleas for their roles in the criminal misconduct. Gibson pled guilty to conspiracy to convert trade secrets and was sentenced to three years and seven months in prison. Hillen and Fasca each pled guilty to conspiracy to commit wire fraud and were sentenced to three years and one month in prison. (EDVA)

<https://www.justice.gov/usao-edva/pr/siemens-energy-inc-pleads-guilty-stealing-confidential-competitor-information-104m>

ALTERNATIVE CHARGES IN CASES INVOLVING INTELLECTUAL PROPERTY

ACCESS DEVICE FRAUD (18 U.S.C. § 1029)

Plymouth Man Indicted for His Role in International Conspiracy to Traffic Counterfeit

Computer Network Devices. On September 25, 2024, a federal grand jury returned an indictment against a Plymouth, Minnesota man for engaging in an international counterfeit access device fraud scheme. According to court documents, Benjamin Paley, who co-owned and operated GEN8 Services, Inc., an information technology business based in Plymouth, and his co-conspirators Wade Huber and David Rosenblatt, engaged in an international counterfeiting scheme spanning Minnesota, North Carolina, and Ukraine, among other locations, to use and traffic in counterfeit access devices.

According to court documents, Brocade Communications Systems, Inc., a global technology company headquartered in San Jose, California, manufactured and sold computer networking products, including equipment commonly known in the technology sector as a "Brocade switch." Brocade switches are networking hardware that allow multiple devices to connect to a computer network. Switches are used to maintain computer networks across a wide variety of industries and sectors, including businesses, universities, hospitals, and government agencies. To use a Brocade switch, customers are required to purchase a license and pay a licensing fee to Brocade, which range between \$1,400 to over \$100,000. Counterfeiters use programs that create counterfeit software license keys to "crack the code" and generate illegitimate license key strings that are indistinguishable from Brocade's legitimate licensing tools. Counterfeit license keys are illicitly sold on the black market for a fraction of the price of a legitimate license transaction.

According to court documents, from 2014 through April 2022, Paley, Huber, Rosenblatt, and others used and trafficked in counterfeit license keys obtained with the intent to defraud Brocade and others to make money for themselves by fraudulently selling license keys at a heavily discounted rate. As part of the scheme, Rosenblatt and Huber routinely communicated with and obtained information from clients and prospective customers who wanted to purchase switches and license keys. Paley used that information to procure counterfeit license keys that enabled additional ports or functionality on the switches to be accessible to their clients.

In total, Paley possessed and sold at least 3,637 counterfeit license keys for switches at amounts substantially below the market rate for legitimate license key sales, resulting in millions of dollars in financial losses to Brocade. Paley is charged with one count of conspiracy to commit access device fraud and three counts of access device fraud. On November 30, 2023, and January 5, 2024, Huber and Rosenblatt, respectively, pleaded guilty to one count each of conspiracy to commit access device fraud. (DMN, CCIPS, FBI)

<https://www.justice.gov/usao-mn/pr/plymouth-man-indicted-his-role-international-conspiracy-traffic-counterfeit-computer>

WIRE FRAUD (18 U.S.C. § 1343)

Three Individuals Sentenced for Massive \$88M Business Telephone System Software License Piracy Scheme. Three individuals have been sentenced for participating in an international scheme involving the sale of tens of thousands of pirated business telephone system software licenses with a retail value of over \$88 million. On July 25, 2024, Raymond Bradley “Brad” Pearce, of Tuttle, Oklahoma, a computer system administrator, was sentenced to four years in prison and ordered to forfeit \$4 million. In June, Dusti O. Pearce, also of Tuttle, was sentenced to one year and a day in prison and ordered to forfeit \$4 million. In July, Jason M. Hines, of Caldwell, New Jersey, was sentenced to one year and six months in prison and an additional 18 months of home confinement, and ordered to forfeit \$2 million. In addition, the three defendants have agreed to pay restitution—specifically, \$17 million for Brad Pearce, \$10 million for Dusti Pearce, and more than \$5 million for Hines.

According to court documents, Brad and Dusti Pearce conspired with Hines to commit wire fraud in a scheme that involved generating and then selling unauthorized Avaya Direct International (ADI) software licenses. The ADI software licenses were used to unlock features and functionalities of a popular telephone system product called “IP Office” used by thousands of companies around the world. The ADI software licensing system has since been decommissioned. Avaya Holdings Corporation, a multinational business communications company headquartered in California, sold IP Office to many midsize and small businesses in the United States and abroad. To unlock features and functionalities of IP Office, such as voicemail or telephones, customers had to purchase software licenses generated by Avaya from an authorized Avaya distributor or reseller. Avaya used software license keys to control access to Avaya’s copyright-protected software and to ensure that only customers who paid for the software could use it. Moreover, Avaya required that each software license on an IP Office system be associated with a proprietary memory card with a unique serial number that the end user had to keep in its possession to use the licenses.

Brad Pearce, a long-time customer service employee at Avaya, used his system administrator privileges to generate tens of thousands of ADI software license keys that he sold to Hines and other customers, who in turn sold them to resellers and end users around the world. The retail value of each Avaya software license ranged from under \$100 to thousands of dollars. Brad Pearce also employed his system administrator privileges to hijack the accounts of former Avaya employees to generate additional ADI software license keys. Pearce concealed the fraud scheme

for many years by using these privileges to alter information about the accounts, which helped hide his creation of unauthorized license keys. Dusti Pearce handled accounting for the illegal business.

Hines operated Direct Business Services International (DBSI), formerly known as Dedicated Business Systems International, a New Jersey-based business communications systems provider and a de-authorized Avaya reseller. He bought ADI software license keys from Brad and Dusti Pearce and then sold them to resellers and end users around the world for significantly below the wholesale price. Hines was by far the Pearces' largest customer and significantly influenced how the scheme operated. Hines was one of the biggest users of the ADI license system in the world. Altogether, the Pearces and Hines reaped millions of dollars from the scheme. To hide the nature and source of the money, the Pearces funneled their illegal gains through a PayPal account created under a false name to multiple bank accounts, and then transferred the money to investment and bank accounts. They also purchased large quantities of gold bullion and other valuable items. In July 2023, Hines pleaded guilty to conspiracy to commit wire fraud. In September 2023, the Pearces also pleaded guilty to conspiracy to commit wire fraud. (WDOK, CCIPS, FBI)

<https://www.justice.gov/opa/pr/three-individuals-sentenced-massive-88m-business-telephone-system-software-license-piracy>

TITLE 21 NARCOTICS VIOLATIONS

Large-Scale Counterfeit Pill Manufacturer Indicted on Drug Offenses and Pandemic Loan Fraud. On August 14, 2024, a Cambridge, Massachusetts man was indicted by a federal grand jury in connection with an ongoing investigation into counterfeit pills containing fentanyl and methamphetamine. It is alleged that the defendant is responsible for the manufacturing over 200 kilograms of counterfeit pills. Schuyler Oppenheimer, a/k/a "SK," a/k/a "Michael Sylvain," has been charged with possession of 500 grams and more of a mixture and substance containing a detectable amount of methamphetamine and two counts of wire fraud. The defendant was arrested and charged by criminal complaint on July 18, 2024.

According to court documents, Oppenheimer is alleged to be technically skilled in the chemical processes used in the synthesis of fentanyl, the compounding of controlled substances for distribution and the manufacturing of counterfeit pills. As alleged, recipes, pill press molds used in the manufacturing process, documents and invoices demonstrating that Oppenheimer purchased numerous pill presses and parts for pill presses from online vendors were seized. It also alleged that multiple packages shipped from China to Oppenheimer, and various associates of Oppenheimer, that contained pill press parts were also seized. It is alleged that since 2019, Oppenheimer obtained over 200 kilograms of these filler powders. According to the recipes recovered during the investigation, when manufactured into counterfeit pills, 200 kilograms of filler powder equates to millions of counterfeit pills containing fentanyl and methamphetamine. Oppenheimer is alleged to have communicated directly with an illegal chemical supplier based in China. Oppenheimer allegedly inquired about the availability of controlled substances and fentanyl precursor chemicals and sought to purchase kilogram quantities of these substances. Fentanyl precursor chemicals are substances that can be used to synthesize raw fentanyl in a

laboratory setting. It is alleged that Oppenheimer sought to synthesize his own fentanyl through the importation of these fentanyl precursor chemicals into the United States. Lastly, Oppenheimer is alleged to have obtained over \$40,000 through two fraudulent Paycheck Protection Program loan applications that were submitted in April 2021 over the internet. Oppenheimer is also alleged to have submitted false statements concerning his income through self-employment for the 2019 tax years and provided false tax return documents substantiating that income. During the execution of a search warrant on Parker Street in Cambridge on July 18, 2024, over five kilograms of suspected counterfeit Adderall pills containing methamphetamine and a loaded firearm were recovered. Based on prior felony convictions, Oppenheimer is prohibited from possessing firearms. (DMA, FBI, DEA, HSI, CBP, Massachusetts State Police)

<https://www.justice.gov/usao-ma/pr/large-scale-counterfeit-pill-manufacturer-indicted-drug-offenses-and-pandemic-loan-fraud>

Supplier Sentenced for Selling Counterfeit M30 Pills. On August 19, 2024, Dairon Jissan Rodriguez-Escalante, a legal permanent resident from Cuba living in Maricopa, Arizona was sentenced to 33 months in prison, followed by three years of supervised release. Rodriguez-Escalante pleaded guilty to Possession with the Intent to Distribute Fentanyl on March 27, 2024. In 2021, Rodriguez-Escalante was identified through social media as a source of supply of counterfeit M30 pills containing fentanyl for other individuals who sent narcotics through the mail. In October and November 2021, Rodriguez-Escalante sold over 650 grams of blue M30 pills containing fentanyl to U.S. Postal Inspection Service and Drug Enforcement Administration agents on two separate occasions. (DAZ, USPIS, DEA, Peoria Police Department, Mesa Police Department Forensic Laboratory)

<https://www.justice.gov/usao-az/pr/supplier-sentenced-selling-counterfeit-m30-pills>

Lynn Man Sentenced to Over 12 Years in Prison for Counterfeit Pill Trafficking Conspiracy. On August 1, 2024, a Lynn, Massachusetts man was sentenced in federal court in Boston for his role in a North Shore-based drug trafficking organization (DTO) that distributed tens of thousands of counterfeit prescription pills containing fentanyl and methamphetamine.

Lawrence Nagle Sr. (Nagle Sr.) was sentenced to 151 months in prison to be followed by five years of supervised release. In April 2024, Nagle pleaded guilty to one count of conspiracy to distribute and to possess with intent to distribute controlled substances.

Nagle Sr.'s two sons, Christopher Nagle and Lawrence Michael Nagle, were allegedly identified as leaders of a DTO distributing various controlled substances throughout the North Shore region of Massachusetts. 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.

Lawrence Michael Nagle allegedly distributed controlled substances to a small network of individuals who would then redistribute the drugs to other traffickers.

The investigation revealed that Nagle Sr. was a member of the DTO, allegedly distributing controlled substances on his sons' behalf and storing substantial quantities of controlled substances at his residence. On Oct. 25, 2024, investigators searched Nagle Sr.'s residence and recovered 5.9 kilograms of fentanyl, including tens of thousands counterfeit oxycodone pills containing fentanyl; 1.3 kilograms of methamphetamine, including several thousand counterfeit Adderall pills containing methamphetamine; and one kilogram of cocaine. Christopher Nagle was sentenced to 139 months imprisonment (see below). Lawrence Michael Nagle has pleaded not guilty and is pending trial. (DMA, DEA, Massachusetts State Police, ATF, OCDETF)

<https://www.justice.gov/usao-ma/pr/lynn-man-sentenced-over-12-years-prison-counterfeit-pill-trafficking-conspiracy>

Co-Conspirators Sentenced for Drug Trafficking Conspiracy. On August 13, 2024, Christopher Nagle, of Revere, Massachusetts and Isaac Clayton of Lynn, Massachusetts were sentenced. Christopher Nagle was sentenced to 139 months in prison and five years of supervised release. Clayton was sentenced to two months in prison to be followed by three years of supervised release, with the first six months to be served in home confinement. In February 2024, Clayton pleaded guilty to one count of conspiring to distribute and to possess with intent to distribute controlled substances. In April 2024, Christopher Nagle pleaded guilty to one count of conspiring to distribute and to possess with intent to distribute controlled substances and one count of possession with intent to distribute more than 500 grams of methamphetamine.

According to court documents, the DTO distributed counterfeit oxycodone pills containing fentanyl and counterfeit Adderall pills containing methamphetamine, among other things, to various individuals in the Lynn area.

Christopher Nagle, and allegedly his brother Lawrence Michael Nagle, were identified 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.

A search of Christopher Nagle's apartment recovered more than 74,000 counterfeit Adderall pills containing methamphetamine, weighing more than 24 kilograms.

As part of the conspiracy, Clayton stored various controlled substances including marijuana, cocaine, cocaine base (crack cocaine) and counterfeit oxycodone pills containing fentanyl at his apartment on behalf of the DTO. A search of his apartment in October 2022 resulted in the seizure of various quantities of marijuana, cocaine base and fentanyl, as well as three loaded firearms, additional rounds of ammunition, \$2,640 in drug proceeds and materials used to package and distribute controlled substances. (DMA, DEA, Massachusetts State Police, ATF, OCDETF)

<https://www.justice.gov/usao-ma/pr/co-conspirators-sentenced-drug-trafficking-conspiracy>

Lynn Man Sentenced to More than Two Years in Prison for Conspiracy to Traffic Counterfeit Pills Containing Fentanyl. On September 16, 2024, a Lynn, Massachusetts man was sentenced in federal court in Boston for his role in a North Shore-based drug trafficking organization (DTO) that manufactured and distributed tens of thousands of counterfeit prescription pills containing narcotics. Edward Ortiz, was sentenced to 28 months in prison and three years of supervised release. On June 17, 2024, Ortiz pleaded guilty to conspiracy to distribute and possess with intent to distribute controlled substances. Ortiz was among 23 individuals charged in October 2022 in connection with a wide-ranging conspiracy to traffic counterfeit prescription pills. The defendants were subsequently indicted along with two additional alleged co-conspirators in December 2022. According to court documents, the DTO distributed counterfeit oxycodone pills containing fentanyl and counterfeit Adderall pills containing methamphetamine, among other things, to various individuals in the Lynn area. During the investigation, investigators seized from Ortiz approximately 1,000 counterfeit oxycodone pills containing fentanyl that Ortiz had just obtained from one of the co-conspirators in this matter. (DMA, DEA, Massachusetts State Police, ATF, OCDETF)

<https://www.justice.gov/usao-ma/pr/lynn-man-sentenced-more-two-years-prison-conspiracy-traffic-counterfeit-pills-containing>

Seven Charged after Federal Investigation Disrupts Massive Counterfeit Pill Manufacturing Operation. On September 18, 2024, a federal grand jury in Bridgeport returned an indictment charging the following seven individuals with offenses related to the large-scale manufacture and trafficking of counterfeit pills containing synthetic opioids and other substances: Kelldon Hinton, of New Haven, Connecticut; Heshima Harris, of New Haven, Connecticut; Emanuel Payton, of New Haven, Connecticut; Marvin Ogman, of West Haven, Connecticut; Shawn Stephens, of West Haven, Connecticut; Arnaldo Echevarria, of Waterbury, Connecticut; and Cheryle Tyson, of West Haven, Connecticut.

As alleged in court documents and statements made in court, this matter stems from an investigation led by the DEA New Haven’s Tactical Diversion Squad and the U.S. Postal Inspection Service targeting the manufacture and distribution of counterfeit oxycodone, Xanax, and Adderall tablets containing methamphetamine, protonitazene, dimethylpentylone, xylazine, and other substances. Protonitazene is a Schedule I synthetic opioid that is three times more potent than fentanyl.

In June 2023, law enforcement received information that Kelldon Hinton was using a pill press to manufacture large quantities of counterfeit pills containing controlled substances. Through the use of physical and electronic surveillance, the seizure and searches of parcels sent through the U.S. Mail and commercial delivery services, undercover purchases of counterfeit pills, trash pulls, and other investigative methods, investigators determined that Hinton, with the assistance of his co-conspirators, was purchasing protonitazene, dimethylpentylone, xylazine, other substances, and pill press parts from China and elsewhere, using tableting machines (“pill presses”) to manufacture counterfeit pills in a garage he rented in East Haven, marketing and selling the pills on the dark web, and mailing pills to customers around the United States. In text messages, Hinton referred to the rented garage as his “lab.” Between February 2023 and February 2024, Hinton shipped more than 1,300 packages through the U.S. Mail. Hinton also

distributed the counterfeit pills to associates in Connecticut, who sold them to their own customers.

On September 5, 2024, Hinton, Harris, Payton, Stephens, and Echevarria were arrested on federal criminal complaints. On that date, investigators conducted court-authorized searches of several locations, including the garage located on Tyler Street Extension in East Haven, which yielded several hundred thousand pills, two large pill presses, and pill manufacturing equipment. One of the pill presses seized was capable of producing 100,000 pills per hour. It is further alleged that, as the investigation continued, Ogman communicated with Tyson and shared with her news reports of the search and court information of the arrests. He also continued to distribute pills produced by Hinton, and law enforcement is currently investigating a drug overdose death that occurred recently in Connecticut. Pills recovered from the scene appear to match those produced by the Hinton organization, and a preliminary search of the victim's cellphone text messages revealed that Ogman supplied pills to the victim. The indictment added Ogman and Tyson as defendants, and was returned on September 18. Ogman and Tyson were arrested on September 19. The indictment charges each of the seven defendants with conspiracy to manufacture, distribute and to possess with intent to distribute methamphetamine and protonitazene. On this charge, based on the quantities of controlled substances attributed to each defendant, Hinton faces a mandatory minimum term of imprisonment of 10 years and a maximum term of imprisonment of life, and the other six defendants each face a maximum term of imprisonment of 20 years. The indictment also charges Hinton with one count of possession with intent to distribute 500 grams or more of methamphetamine and a quantity of protonitazene, which carries a mandatory minimum term of imprisonment of 10 years and maximum term of imprisonment of life, and Echevarria with one count of possession with intent to distribute protonitazene, which carries a maximum term of imprisonment of 20 years. (DCONN, DEA, USPIS, HSI, CBP, FBI, USMS, East Haven Police Department)

<https://www.justice.gov/usao-ct/pr/seven-charged-after-federal-investigation-disrupts-massive-counterfeit-pill>

Eighteen Defendants Charged In Scheme To Manufacture And Distribute Millions Of Deadly Counterfeit Pharmaceuticals Through Fake Online Pharmacies. On September 30, 2024, charges were unsealed against Francisco Alberto Lopez Reyes, a/k/a “Frank,” and 17 other defendants located in the United States, Dominican Republic, and India for their involvement in a scheme to advertise, sell, manufacture, and ship millions of deadly pills disguised as legitimate pharmaceuticals. These counterfeit pills were purchased by tens of thousands of victims from fake online pharmacies run by Lopez Reyes and his co-conspirators. At least nine of those victims later died of narcotics poisoning. Federal authorities have seized nine website domains used by the defendants and their co-conspirators to sell counterfeit pills, four of which are named in the Indictment.

According to the allegations contained in the Indictment, for at least the last two and a half years, a network of individuals located in the United States, the Dominican Republic, India, and elsewhere have exploited Americans' reliance on online pharmacies by advertising, selling, manufacturing, and shipping through the mail millions of unregulated counterfeit prescription pills to tens of thousands of victims. Instead of prescription drugs at a bargain, what customers

actually received were phony pills made of fentanyl, para-fluorofentanyl—an analogue of fentanyl—and methamphetamine. Shaped, dyed, and stamped to be indistinguishable from actual prescription medication, these tablets were in fact manufactured by the defendants in industrial-scale milling facilities, or pill mills, located in the basements of several residential buildings in, among other places, Manhattan and the Bronx, New York.

As part of this scheme, the defendants shipped counterfeit pharmaceuticals to victims across the United States and around the world, including in all 50 U.S. states, Washington, D.C., the U.S. Virgin Islands, Puerto Rico, Germany, and Slovenia. The victims of this criminal enterprise range in age from at least 23 to 77 years old. They include veterans, doctors, lawyers, musicians, artists, politicians, economists, restaurant managers, personal trainers, dancers, former schoolteachers, administrative executives, and first responders, among others. Between in or about August 2023 and in or about June 2024, at least nine victims—all of whom purchased counterfeit prescription pills from the defendants—died of narcotics poisoning. One victim, Victim-1, a 45-year-old woman, was a veteran who had served for 12 years in the U.S. Army National Guard. Victim-1 believed she was purchasing 30-milligram oxycodone, also known as “M30s,” from the defendants’ online pharmacy, but the pills were, in fact, made of fentanyl and para-fluorofentanyl. After receiving the pills, Victim-1 conducted research to attempt to learn whether the pills were genuine, but, because the defendants made the pills look real, Victim-1 was unable to tell the difference. Five days after receiving counterfeit oxycodone pills advertised, sold, manufactured, and shipped by the defendants, Victim-1 died from acute fentanyl intoxication. Lopez Reyes led the enterprise, orchestrating and controlling every facet of the scheme from the Dominican Republic. (SDNY, DEA, HSI, NYPD, New York State Police, USPIS, IRS, Kings County District Attorney’s Office, the New York City Border Enforcement Security Task Force Contraband Group, OCDETF, New York Strike Force)

<https://www.justice.gov/usao-sdny/pr/us-attorney-announces-charges-against-18-defendants-scheme-manufacture-and-distribute>

DEPARTMENT OF STATE

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“My message today is simple: There is no better place in the world to invest than the United States and no better time to do it than right now – world-class universities, tech hubs, manufacturing centers that incubate ideas and incubate talent; a culture of innovation and entrepreneurship that’s second to none, encouraging people to take big risks and to solve big challenges; a transparent, independent legal system with the strongest intellectual protection—property protections in the world, ensuring that successful invention won’t be ripped off as soon as it becomes profitable; a workforce whose skill, productivity, and commitment are second to none.”

* * *

“When we raise labor standards, when we raise environmental standards, when we take steps to protect intellectual property and create a level playing field, we’re not just supporting U.S. companies and workers. We’re helping every country, every business, every worker that seeks a fair, sustainable, and competitive market. Encouraging more of these mutually beneficial investments is a top priority for the Department of State.”¹³

- Anthony J. Blinken, Secretary of State

Strong intellectual property rights regimes establish secure legal frameworks for investment in – and commercialization of – innovation and creativity. This enables firms, including innovative start-ups, to navigate the perilous process of transforming a creative work into a commercially viable product and to successfully compete in the global marketplace. Those IP frameworks simultaneously safeguard the public interest and create an environment in which innovation and creativity can generate growth and prosperity.

“A strong system of IP rights assures inventors, industrial designers, and creative artists that their ideas will be protected and that they can receive payment for the use of their creations. Moreover, it attracts additional investment into the creative industries. After all, who wants to invest in innovations without assurance that their investment will be protected? Strong IP protection therefore creates value and jobs that extend well beyond the traditional boundaries of the creative sector. The drivers, managers, caterers, venue hosts, and so many more, are all employed throughout the creative economy. Rising tides lift all boats.”¹⁴

- Ramin Toloui, Assistant Secretary, Bureau of Economic and Business Affairs

Department of State Appendix for FY 2024 Annual Report

In FY 2024, 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

¹³ “Secretary Antony J. Blinken At the 2024 SelectUSA Investment Summit” (June 25, 2024) at <https://www.state.gov/secretary-antony-j-blinken-at-the-2024-selectusa-investment-summit/>.

¹⁴ “Assistant Secretary Ramin Toloui’s Keynote Remarks on IP Protection at the Africa Creative Market” (November 6, 2023) at <https://ng.usembassy.gov/assistant-secretary-ramin-tolouis-keynote-remarks-on-intellectual-property-protection-at-the-africa-creative-market/>.

dialogues and in multilateral fora; collaborates with bilateral, interagency, and private sector partners on capacity building; monitors the state of IP protections and enforcement around the world to better address problem areas; and educates public and official audiences on the value of IP both to generate economic growth and to improve people's quality of life. Aligned with the Biden-Harris Administration's foreign policy for the middle class, better IP protection and enforcement abroad allows U.S. companies, including small to medium enterprises, to conduct business around the world with greater confidence.

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

Department of State economic sections at embassies also liaise with local and global representatives of creative industries, manufacturers, and others about IP issues and advocate for U.S. rightsholders. Department of State officials working on IP issues overseas collaborate with and support many agencies, including the U.S. Patent and Trademark Office (USPTO) IP Attachés, while the Department of State Bureau for International Narcotics and Law Enforcement Affairs (INL) 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.

Throughout the fiscal year, the Department of State continued crucial bilateral dialogues, created and participated in a broad range of IP-related events and activities, discussed IP issues with interagency partners, and advanced 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 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 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 2024.

Argentina: In June, U.S. and Argentine officials met in Buenos Aires for the eighth Forum on Innovation and Creativity for Economic Development (ICED Forum). Eleven Argentine agencies participated in the two-day meeting. The USTR-led delegation from the United States found opportunities for constructive dialogue on key IPR treaties, increased enforcement action against counterfeit goods, technology transfer from publicly funded research, and market access for products using common names. This meeting advanced Mission Argentina’s goal to promote a prosperous, sustainable economy in Argentina.

China: U.S. Embassy Beijing personnel attended the “*Parallel Session of International Cooperation in Protecting IPR and Fighting Against IPR Infringement and Counterfeiting*” (CIIE IP Forum) in Shanghai in November, 2023. The forum was hosted by the People’s Republic of China (PRC) Ministry of Commerce (MOFCOM) and the State Administration for Market Regulation (SAMR). The forum touched on a number of topics centered around the progress and challenges of the PRC’s IP enforcement regime. Panelists and speakers highlighted the common challenges in IP enforcement that government and the private sector face globally, and the growing role of AI as a tool in IP enforcement. Embassy Beijing’s USPTO IP Attaché spoke at the event, where he highlighted the importance of U.S.-PRC cooperation on IP matters and underscored that cooperation includes both engagement on tough issues and taking action. On November 14, 2023 the Embassy Beijing IP Counselor and Economic IP officer presented at AmCham China’s Healthcare Industry IP Protection Workshop in Beijing. The IP Counselor discussed the IP challenges and opportunities in China’s healthcare sector and IP resources for companies. The workshop was attended by over 20 healthcare companies and provided a forum for expert presentations and discussions on IP issues, protections, and best practices. Other presenters covered topics such as counterfeiting, patent linkage, patent term extension, and risk management of medical patents.

Ghana, Kenya, Nigeria: The U.S. Department of State hosted eight participants from Ghana, Kenya, and Nigeria through an International Visitor Leadership Program (IVLP) to promote creative industry growth and support more robust intellectual property protection and enforcement in Africa. Participants traveled to Washington, D.C. to meet with U.S. policymakers and industry associations; Los Angeles to meet with industry leaders and professional guilds; and Atlanta to meet with production studios and local government.

Ghana, Kenya, Nigeria, Cote d’Ivoire: As a follow-up to the Africa Leaders Summit, IPE worked with the U.S. Embassies in Ghana, Kenya, Nigeria, and Cote d’Ivoire to host roundtables in each country focused on fostering growth in their creative industries by improving IP protection and enforcement frameworks. Each Round Table fostered a dialogue focused on the

business environment/ecosystem of the creative industries in each country. These successful discussions gave artists, creatives, government officials, lawmakers and other stakeholders an opportunity to express their concerns about the current situation specific to each country and to explore ways to improve the ecosystem, increase public awareness, and advocate for changes where needed.

Egypt: IPE partnered with USPTO to host a roundtable discussion with creative industry private sector representatives and Egyptian government officials to discuss the creative industry landscape and the intellectual property environment that provides support, protection, and enforcement for creators. Several meetings with key government officials and other sector stakeholders and innovators emphasized our mutual interest in promoting intellectual property rights and enforcement, economic growth, and partnership in Egypt.

Pakistan: In coordination with Mission Pakistan, USPTO led a training for IPO Pakistan on September 9 - 10, 2024, on how to handle well-known and non-traditional marks, strategies for maintaining high examination quality standards, and examination mechanisms under the Madrid Protocol.

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 "*IP and the Sustainable Development Goals (SDGs): Building our common future with innovation and creativity.*" IPE, in collaboration with the Office of Economic Policy Analysis and Public Diplomacy (EPPD), awarded funding to four posts: Malawi, Botswana, Suriname, and Ecuador. The funding supported their World IP Day programming efforts featuring workshops, panel discussions, breakout sessions, seminars, exhibitions, photography & art competitions, and brochures & booklets highlighting IP through the lens of the 17 SDGs which can be used into the future. Each program brought together IP experts from local government, creative industries, academics, local IP experts, members of the public, and mission personnel. 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, the IPE Director's World IP Day video message was posted on the Department's public website and made available to posts for their social media use. 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 17-day countdown campaign on social media, posting content to generate excitement and interest for the April 26th events.

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

Argentina: On World IP Day, U.S. Embassy Buenos Aires, USPTO Rio de Janeiro, and Austral University held a hybrid seminar: "*Intellectual Property as a Tool for Innovation and*

Development.” Around 180 people from both public and private sectors attended the seminar. The USPTO Regional Advisor provided examples of how patents, trademarks, and copyright protections have been used to further the United Nations (UN) SDGs, and a program chair from Austral University gave a presentation on technology transfer for development.

Kuwait: In celebration of World IP Day, the Ministry of Commerce and Industry and the Copyright Office of the National Library of Kuwait hosted a panel discussion on the importance of intellectual property rights (IPR) protections. Speakers hailed from multiple government institutions and academia while the audience consisted of mostly Kuwaitis. Multiple speakers pointed out the link between strong IPR protections and economic growth as Kuwait seeks to diversify from an oil-based economy to a knowledge-based economy. The head of the Patent and Intellectual Property Rights Office at Kuwait University characterized a robust IPR regime as a necessary condition. “When intellectual property rights are upheld, innovators, entrepreneurs, and creators are incentivized to invest their time, resources, and talents into developing new products, technologies, and artistic works,” she told the audience. The head of the GCC Intellectual Property Training Center (IPTC) concurred adding that “protecting intellectual property and copyrights in Kuwait can have a profoundly positive impact on the economy by fostering innovation, incentivizing investment, and nurturing a conducive environment for creativity.”

Ecuador: Embassy Quito co-hosted a World IP Day event April 29 with the Quito Chamber of Commerce (CCQ) focused on the 2024 theme of innovation and the UN SDGs. Ecuador’s IP agency (SENADI) helped kick off the event and a DHS representative also offered remarks. Two Ecuadorian businesses discussed how their organizations contribute to SDGs, including inclusive education and producing with sustainable methods. A panel of experts representing a business chamber, an IP association, and a law firm provided concrete examples of how IP relates to the UN SDGs. They underscored the importance of the government providing security and legal stability as a foundation for fair competition. The experts detailed how “protected ideas” can translate to equitable economic growth. Panelists also outlined the challenges in Ecuador’s IP landscape, including a low culture of understanding and respect for IP (one notorious example includes illegally streamed sports content), the lack of state-provided financing and scholarship in the field, and laws that fail to protect specific IP rights.

Japan: On April 25 the Motion Picture Association (MPA) and the Japan and International Motion Picture Copyright Association Inc. (JIMCA) held a movie screening event with U.S. Embassy support to commemorate World IP Day and its theme of “IP and SDGs.” Japan’s Minister of the Environment kicked off the event by noting that the movie industry had a comparatively small carbon footprint compared to traditional manufacturing and heavy industry. The Minister, who completed a graduate program in film directing from the American Film Institute and previously worked as a film director, drew on his personal experience to underscore the importance of intellectual property protection and enforcement saying “the impact movies have on society is a thousand times greater than any other industrial product and significantly impacts the well-being of people . . . I hope that ideas about intellectual property movies and the SDGs will spread widely that the world will come together to solve international problems.”

China: On April 24, U.S. Embassy Beijing and the Cornell China Center hosted a World IP Day panel discussion in Beijing entitled “*IP and the Sustainable Development Goals (SDG): Celebrating Innovative, Creative, and Enterprising Changemakers Around the World.*” The event, organized by the Department of State and USPTO, featured panelists from a PRC-based tech company, a Hong Kong-based IP firm, and a PRC Supreme People’s Court (SPC)-appointed attorney. The USPTO Attaché served as moderator during the interactive session in which panelists and over 70 audience members shared insights on the importance of IP protection, especially for start-up enterprises, and discussed the necessity of registering trademarks and how to protect trade secrets, copyrights and patents for software products. The panelists also discussed strategies for early-stage IP protection and the use of official government websites and AI tools for patent and trademark searches. The World IP Day panel discussion received very positive feedback from participants, and many remarked that it provided a unique and much-needed opportunity to receive information about how individual rightsholders can protect their IP.

Jordan: The U.S. Embassy hosted a workshop with the Government of Jordan (GOJ) in recognition of World IP Day, where policymakers agreed to develop a new National IPR Strategy, specifically targeting IPTV piracy. The event brought together GOJ policymakers, IPR holders, and representatives from various regulatory agencies, including the Media Commission and the Telecommunication Regulatory Commission. The workshop featured panel discussions, case studies, and breakout sessions, all aimed at fostering public-private dialogue and achieving practical solutions. This initiative aligns with the UN SDGs by promoting innovation and protecting intellectual property, which are essential for sustainable economic growth. Stakeholder-led dialogues enhanced traditional training methods to address complex issues like IPTV piracy.

Pakistan: Mission Pakistan participated in two World IP Day events this year. The Intellectual Property Organization of Pakistan (IPO) and the Islamabad Chamber of Commerce and Industry organized a seminar in Islamabad on April 26. The event, attended by Pakistan's Commerce Minister, business executives, and scholars, focused on the theme of the UN’s SDGs. During the seminar, the USPTO emphasized the crucial role of IPR in fostering innovation, driving economic growth, and achieving the SDGs. Other speakers echoed these points, emphasizing the need for a robust innovation ecosystem to address Pakistan’s economic challenges. On May 2, the IP Attaché also participated in a roundtable discussion at Karachi’s Lincoln Corner, alongside IP lawyers, United Nations Development Programme (UNDP) personnel, a university researcher, startup entrepreneurs, and an IPO official. The panel explored strategies for raising IPR awareness, streamlining patent processes, and fostering collaboration to drive sustainable development in Pakistan. In a separate series of meetings with legal stakeholders, the IP Attaché emphasized the need to bridge disparities between Pakistan's IP laws and international standards. Twenty newly appointed judges in the Lahore High Court expressed interest in learning about U.S. and international legislation concerning trade secrets, digital piracy, and artificial intelligence. These events underscored the necessity of collaborative efforts across sectors to nurture innovation and effectively address IP-related challenges.

Angola: American Spaces at U.S. Embassy Luanda hosted the third annual Intellectual Property Rights Conference in September 2024, supported by the Government of the Republic of Angola (GRA), and capping off steady Embassy programming that has empowered creators and businesses with the knowledge and skills to protect their IP. Over 1,200 participants convened virtually and in-person to analyze the crucial role of IPR in driving economic growth and cultural development, addressing challenges and opportunities in the digital economy, and advocating for stronger integration of IPR education within Angola's academic institutions. Participants from civil society, businesses, higher education institutions, and creators noted significant barriers to integration into the global economy caused by Angola's lack of accession to the Madrid Protocol, the Rome Convention, the Berne Convention, and the Marrakesh Treaty. All parties supported increasing understanding of IPR in Angola to cultivate a globally minded business environment, aligning with GRA goals of promoting cultural exports and increasing tourism.

Botswana: At the 2024 commemoration of World IP Day on April 26, the Ambassador delivered keynote remarks championing innovation, and U.S.-Botswana cooperation, as the key for advancing economic diversification and job creation. The event – on “*IP and the SDGs: Building Our Common Future with Innovation and Creativity*” – was joined by representatives from the South African Development Community (SADC), the Companies and Intellectual Property Authority (CIPA) of Botswana, and other stakeholders, and it featured local artists, innovators, and students. CIPA's acting Registrar General presented an overview of Botswana's IP ambitions and thanked the United States for its continued partnership. He welcomed continued cooperation on IP-protection capacity building for law enforcement and judicial system infrastructure.

The annual event, supported with funding from the Bureau of Economic and Business Affairs, continues strong U.S.-Botswana cooperation on IP issues, and reaffirms the Botswana Government's goal to transition Botswana from a minerals-led economy to a knowledge-based economy, through the adoption of reforms that make Botswana products and services more competitive on the global market. E-commerce is high on the agenda for both SADC and the African Union (AU) due to its prominence in the African Continental Free Trade Area (AfCFTA). Working with Botswana, the Mission SADC, and the Botswana Government, stakeholders focused the day's events on the five SDGs that are considered to be most relevant to Botswana: (SDG1) No poverty; (SDG2) Zero hunger; (SDG7) Affordable and clean energy; (SDG9) industry innovation and infrastructure; and (SDG13) Climate action. An Art Competition and an Innovation Competition showcased ideas of Botswana's creators on how to solve local problems linked to the identified SDGs.

Malawi: Embassy Lilongwe, in collaboration with the Copyright Society of Malawi (COSOMA), organized a 2024 World IP Day event on April 25 that convened presenters and panelists from government and the private sector to discuss IPR in Malawi. Discussions revealed gaps in IPR awareness and limited opportunities for creatives to profit from their work. The event aimed to demonstrate how Malawi can leverage IP to achieve the UN's SDGs. The program also targeted youth in IP discussions through an ongoing public diplomacy-funded entrepreneurship workshop. The World IP Day activities were supported in part by funds from the Bureau of Economic and Business Affairs.

Peru: The USPTO’s office of the Regional IP Attaché for the Andean Community and Chile collaborated with Embassy Lima’s Public Diplomacy Section (PDAS) to highlight the ways in which the activities of the IP Attaché advanced the UN’s SDGs in Peru. The USPTO’s World IP Day social media campaign featured the seventeen SDGs and tied the events and topics of the work of the IP Attaché to a variety of the goals. In the realm of Good Health and Well-being (SDG 3), the office highlighted the public health risks of counterfeit medicines during a seminar organized by the Ministry of Health on the national day against counterfeit medicines. For Quality Education (SDG 4), participation in a comic drawing workshop at the Lima Museum of Art provided insights into copyright protection and the importance of safeguarding intellectual creations. To further Gender Equality (SDG 5), talks were given to the American Chamber of Commerce in Peru on USPTO’s programs supporting women in IP and promoting inclusive innovation for underrepresented communities. Additionally, the USPTO Legal Advisor for the Andean Community and Chile, a founding member of “Women in IP – Peru,” continues to advocate for gender equality by uniting IP women from various sectors and countries. In support of Industry, Innovation, and Infrastructure (SDG 9), the “Innovation + IP Forum” was hosted for members of the American Chamber of Commerce in Peru, addressing the innovation process, its link to intellectual property, and its role in strengthening brands and protecting competitive advantage. Finally, to promote Peace, Justice, and Strong Institutions (SDG 16), a webinar with the Peruvian Judiciary explored the implications of AI on patent law, fostering a deeper understanding of this emerging field.

In addition to work with Embassy Lima’s Public Diplomacy Section, the IP Attaché collaborated with the Foreign Commercial Service (FCS) of Embassy Lima as well as colleagues in Embassy Santiago to participate in the SDG World IP Day campaign utilizing the events the IP Attaché’s office conducted in accordance with the mission of these partners. And on April 26, 2024, the IP Attaché and IP Legal Advisor attended the day’s event entitled “*Intellectual Property and the Sustainable Development Goals*” hosted by the National Institute for the Defense of Competition and Protection of Intellectual Property (Indecopi).

Suriname: In April 2024, Embassy Paramaribo officials and the USPTO Regional IP Attaché met with government counterparts, including the Minister of Economic Affairs, to discuss the importance of forming a robust IP framework ahead of Suriname’s oil and gas boom. The delegation also met the director of a local art gallery which showcases indigenous artwork, to understand what issues indigenous communities face in terms of protecting their crafts and cultural intellectual property. This coincided with World IP Day. For the occasion, Post hosted an IP roundtable at Suriname’s Anton de Kom University. Students and practitioners learned how IP regulations are applied in the United States and brainstormed ways this could be applied in Suriname. The Regional Attaché’s office is now holding preliminary meetings with Suriname’s Bureau of Intellectual Property to discuss Suriname’s inclusion in the USPTO’s Accelerated Patent Grant Program. The arrangement allows for expedited grants of Surinamese patents to U.S. patent holders.

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) Working Party on Countering Illicit Trade, the World Intellectual Property Organization (WIPO), 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 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 TRIPS 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 TRIPS 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.

Other activities that the Department of State participated in during FY 2024 include the following:

OECD Working Party on Countering Illicit Trade

IPE leads the U.S. delegation to the OECD Working Party on Countering Illicit Trade (WP-CIT). In April 2024, 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. The United States discussed its whole-of-government approach to countering illicit trade and highlighted the importance of supply chain security and resiliency. 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 nearly 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 that describes current IP laws and enforcement progress. These ICS Reports also

form a chapter of the Department of Commerce's (DOC'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 DOC to further align the Statements and Guides to ensure a more complete view of the country's IPR situation tolerance.

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 Notorious Markets List. 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 the protection and infringement of trademarks, copyrights, patents, and trade secrets.

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

The U.S. GLEN consists of DOJ ICHIPs, Global Cyber Forensic Advisors (GCFAs), and long-term agent mentors (<https://www.justice.gov/criminal/criminal-opdat/global-cyber-and-intellectual-property-crimes>). 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 Salem, Tanzania; Bangkok, Thailand; and Kuala Lumpur, Malaysia. In addition, three ICHIPs are deployed out of Washington, DC. Two of the U.S.-based ICHIPs are global subject matter experts, one specializing in Dark Web and Cryptocurrency and the other in Internet Fraud and Public Health. The third U.S.-based ICHIP covers South Asia.

The GLEN is a partnership between INL and DOJ's Computer Crime and Intellectual Property Section (CCIPS) and the Office of Overseas Prosecutorial Development, Assistance and Training (OPDAT). INL and DOJ also 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.

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.

- INL-Funded GLEN ICHIP's Digital Piracy Working Group (DPWG) is a pivotal platform led by the GLEN ICHIP based in Sao Paulo, Brazil, that unites prosecution, law enforcement, and forensic partners across multiple countries in the Western Hemisphere (Argentina, Brazil, Costa Rica, Dominican Republic, Panama, and Peru). Established in early 2023, the DPWG facilitates cooperation as well as the timely exchange of information, strategies, and best practices. While focused on digital piracy, this collaborative effort has also had tremendous impact in combatting various forms of cybercrime, including counterfeiting, phishing scams, and identity theft. Crediting the DPWG, members reported substantial gains in knowledge and felt better equipped for real-world scenarios, with many successfully applying their skills in subsequent investigations and takedowns. As a direct result of their membership in the DPWG, Argentine Federal Police pursued an innovative piracy case against the videogame industry by connecting with federal Argentinean prosecutors and HSI, using the tools learned during the DPWG meetings. Likewise, a Costa Rican investigator (and DPWG member) initiated an international investigation into counterfeiting and smuggling of soccer jerseys and paraphernalia into Costa Rica, and led a simultaneous seizure of 16 storage facilities and stores containing counterfeit versions of clothing and sports apparel (including items from Nike and Kappa) valued at more than \$3.6 million USD.

- In December 2023, Romania adopted a National Intellectual Property Strategy and Action Plan, after several years of close collaboration between the Bucharest-based GLEN ICHIP and an interagency group of Romanian officials. Following two unsuccessful attempts in 2012 and 2022, the adoption of the National IP Strategy and Action Plan is a significant step. The ICHIP directly contributed to the adoption of the Strategy through continuous support, including numerous meetings with key stakeholders and the provision of various guidance documents and models to the Romanian government. The ICHIP continues to collaborate closely with members of Romania’s IP Working Group to implement the IP Action Plan through ICHIP-led capacity-building programs for police and prosecutors handling intellectual property crimes.
- In March 2024, following 2.5 years of continuous engagement by GLEN ICHIP Hong Kong (in collaboration with HSI Vietnam, MPA’s Alliance for Creativity and Entertainment (ACE), and the English Premier League), Vietnam charged the operator of BestBuyIPTV, a Vietnam-based illegal IPTV subscription service, with criminal copyright infringement. Listed for several years as a “Notorious Market” by the U.S. Trade Representative (USTR), BestBuyIPTV unlawfully provided pirated sports, films, and TV series to consumers in Vietnam and around the world – about 10,000 channels from 38 countries and 19,000 video-on-demand titles. The operator of the service pleaded guilty, was sentenced to 30 months in jail (suspended), and was ordered to pay about a \$4,000 USD fine, forfeit \$24,000 USD in proceeds, and pay an additional \$12,000 USD in restitution. This first ever conviction for digital piracy in Vietnam is the landmark result of years of advocacy and trainings by ICHIP Hong Kong, HSI Vietnam, and the private sector.

In August 2024, Hanoi Police shut down Fmovies and related piracy sites. Like BestBuyIPTV, USTR had listed Fmovies as a “Notorious Market” for several years, describing it as “reportedly one of the most popular websites in the world for streaming pirated copies of popular movies and television shows directly to computer desktops, mobile phones, or through IPTV apps on illicit streaming devices. It reportedly received 119 million site visits globally from 9.2 million unique visitors in August 2023.” (USTR’s 2023 Notorious Markets List (January 2024), p. 25, at https://ustr.gov/sites/default/files/2023_Review_of_Notorious_Markets_for_Counterfeiting_and_Piracy_Notorious_Markets_List_final.pdf).

- As a result, in part, of INL and GLEN ICHIP engagement, USTR removed the Dominican Republic from its Special 301 Watch List this year “for making significant progress on addressing concerns with intellectual property (IP) enforcement and transparency” (see USTR’s 2024 Special 301 report (April 2024), p. 10, at <https://ustr.gov/sites/default/files/2024%20Special%20301%20Report.pdf>). INL worked extensively with the Dominican Republic government through diplomatic engagement as well as DOJ and GLEN ICHIP-led capacity building initiatives. As USTR explained, the Dominican Republic “increased enforcement actions against counterfeit medicines” and “increased enforcement actions and interagency cooperation on combating signal piracy, improved resource allocation for agencies, made publicly available enforcement-related

statistics, increased the number of specialized IP prosecutors, and worked with various U.S. agencies to receive training and technical assistance.”

In addition, in FY 2024, IPE continued to coordinate with other U.S. agencies on the IP training programs that several U.S. agencies conduct overseas, which have the goal of improving IP protection and enforcement in other countries. 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 in improving IP protection and enforcement, and started the process of developing coordinated training plans that will seek to maximize the impact of the U.S.-provided training.

Strengthening Intellectual Property Rights Protections in Academic Institutions

In May, IPE hosted more than 40 research and development center professionals from 21 countries for a three-day workshop on protecting intellectual property during international scientific collaborations. Remarks were provided by the Principal Deputy Assistant Secretary for the State Department’s Bureau of Economic and Business Affairs, and by the Principal Deputy Director for Science, Society, and Policy at the White House Office of Science and Technology Policy. University professionals from the United States and abroad discussed challenges and opportunities in safeguarding their institutions’ IP, and developed new ideas on ways to improve policies and address gaps in protection. This engagement achieved key goals of raising awareness, developing peer-led information-sharing networks, and encouraging a distributed sense of responsibility among research and development stakeholders.

International Visitor Leadership Program (IVLP)

Representatives from IPE met with eight groups of International Visitor Leadership Program (IVLP) visitors and discussed the role the office plays in engaging with foreign governments and the private sector to promote intellectual property protection and enforcement frameworks. Themes for the IVLP programs included Intellectual Property and the Creative Economy, Women and Entrepreneurship, Research Security and IPR, Research and Investigation for Journalists, and IP and Development.

Internal Education Activities

The Department of State is committed to educating its employees about IP issues. In July 2024, IPE partnered with USPTO’s Global IP Academy (GIPA), the IPR Center, CBP, and the Foreign Service Institute (FSI) 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 FSI'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. FSI also offers a one-hour distance learning course entitled "Intellectual Property: Special 301 Report." This course covers the process used to create the Congressionally-mandated annual review of IP protection and enforcement among U.S. trading partners around the world, known as the Special 301 Report. The course reviews the inter-agency process used to compile the Special 301 Report, and the role of the Department of State in contributing to, promoting, and defending the report to host country governments.

DEPARTMENT OF THE TREASURY

DEPARTMENT OF THE TREASURY

Department of the Treasury Appendix for FY 2024 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 retained the sole authority to approve any regulations concerning copyright and trademark enforcement at the border and worked closely on these promulgations with DHS and its components. On October 30, 2024, the Secretary of the Treasury delegated these remaining Customs revenue functions to DHS.¹⁵

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

¹⁵ See Treasury Order 100-20, "Delegation of Customs revenue functions to Homeland Security," at <https://home.treasury.gov/about/general-information/orders-and-directives/treasury-order-100-20>.

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

“The trade in counterfeit and pirated goods harms workers, consumers, and small businesses, and ultimately hurts the U.S. economy. Robust enforcement to combat trade in these goods is important to growing our economy from the middle out and the bottom up.”¹⁶

– Ambassador Katherine Tai, U.S. Trade Representative

Office of the U.S. Trade Representative Appendix for FY 2024 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 adequate and effective protection and enforcement of IP rights as critical to U.S. economic growth and American jobs. Innovation and creativity are key export strengths for the United States. Combatting unfair IP trade policies can 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.

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

¹⁶ USTR press release, “USTR Releases 2023 Review of Notorious Markets for Counterfeiting and Piracy” (January 30, 2024), at <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2024/january/ustr-releases-2023-review-notorious-markets-counterfeiting-and-piracy>.

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 9, 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.¹⁷

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

¹⁷ 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>.

Ongoing Trade Agreement Implementation and Enforcement

In FY 2024, the United States continued to engage with Free Trade Agreement (FTA) partners (including Australia, Bahrain, Chile, Peru, Colombia, Costa Rica, Dominican Republic, Guatemala, 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 2024 Special 301 Report in April 2024. (The 2024 Report is at <https://ustr.gov/sites/default/files/2024%20Special%20301%20Report.pdf>, and the related press release is at <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2024/april/ustr-releases-2024-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”¹⁸ 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, foster American innovation and creativity, and increase economic security for American workers and families.

¹⁸ In certain countries, preferences or policies on “indigenous IP” or “indigenous innovation” refer to a top-down, state-directed approach to technology development, which can include explicit market share targets that are to be filled by producers using domestically owned or developed IP.

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 2023 Notorious Markets List was issued in January 2024. (The NML is at https://ustr.gov/sites/default/files/2023_Review_of_Notorious_Markets_for_Counterfeiting_and_Piracy_Notorious_Markets_List_final.pdf, and the related press release is at <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2024/january/ustr-releases-2023-review-notorious-markets-counterfeiting-and-piracy>.) The 2023 NML includes an Issue Focus section that examines the potential health and safety risks posed by counterfeit goods.

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 and the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council).

In FY 2024, the United States advanced its IP and Innovation agenda in the TRIPS Council by focusing on intellectual property awareness. The United States is working with WTO Members – including Australia, Canada, Chile, Chinese Taipei, the European Union, Japan, Singapore, South Korea, Switzerland, New Zealand, the United Kingdom, and Hong Kong, China – to examine how IP awareness promotes 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 2024, 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 the APEC Intellectual Property Experts Group (IPEG), the United States continued to lead an initiative on illicit streaming, which involved the joint publication with APEC in 2021 of the *Report on Results of Survey Questionnaire on Domestic Treatment of Illicit Streaming Devices (ISDs) by APEC Economies* (<https://www.apec.org/publications/2021/03/apec-report-on-domestic-treatment-of-isds>) and discussions on effective practices for enforcement against illicit streaming.

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 October 2023, the Caribbean Community (CARICOM) and the United States held the ninth meeting of the Trade and Investment Council under the United States-CARICOM TIFA. During this meeting, both sides discussed the importance of intellectual property protection and enforcement in CARICOM member states. The United States emphasized the importance of addressing signal piracy, as well as joining and fully implementing the WIPO Internet Treaties. On the sidelines of this meeting, the United States also held bilateral talks with Barbados and Trinidad and Tobago to discuss concerns raised in the Special 301 Report.

In November 2023, the twelfth meeting of the United States and Ukraine Trade and Investment Council was held to discuss Ukraine's ongoing efforts to develop a strong IP environment despite Russia's full-scale invasion in 2022.

In December 2023, the United States and Vietnam held a TIFA Intellectual Property Working Group meeting to discuss issues such as IP enforcement.

In January 2024, at the fourteenth Ministerial-level meeting of the United States-India Trade Policy Forum (TPF), India highlighted reforms focusing on streamlining the Indian patent

system. Additional IP Working Group meetings under the TPF took place in September and December 2023 and in May and August 2024.

In April 2024, the United States and Ecuador held the fifth meeting of the United States-Ecuador Trade and Investment Council, where the United States raised concerns related to online piracy and customs enforcement.

In May 2024, the United States-Iraq TIFA meeting included engagement on updates to Iraq's IP laws and improvements in IP enforcement.

In June 2024, on the margins of the fourth meeting of the Trade and Investment Council under the United States-Argentina TIFA, the United States and Argentina held the eighth Innovation and Creativity for Economic Development (ICED) Forum to discuss IP issues.

Also in June 2024, the United States and the Philippines held a technical meeting to discuss IP issues raised under the United States-Philippines TIFA, followed by a TIFA meeting in July.

In July 2024, 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.

Also in July 2024, the United States-Saudi Arabia TIFA was held, to discuss private-public engagement on IP issues, including counterfeit trademark enforcement; updates on Saudi Arabia's planned accession to several IP treaties; and efforts to establish a system of collective rights management.

In September 2024, 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.

Also in September 2024, the United States-Nepal TIFA meeting included discussions of recent updates on draft IP legislation in Nepal, ongoing work on capacity building in IP policy and regulations, and the need for improvements to Nepal's administration and examination of trademarks.

Throughout the course of FY 2024, 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, and to support the Dominican Republic's efforts to address concerns raised under the Special 301 Report. As a result of these efforts, the Dominican Republic was removed from the Watch List in the 2024 Special 301 Report.

Other IP-related engagements include meetings with Bangladesh in April 2024, Egypt in June 2024, the Maldives in July 2024, and Vietnam and Thailand in September 2024.

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. 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.

UNITED STATES COPYRIGHT OFFICE

U.S. COPYRIGHT OFFICE

U.S. Copyright Office Appendix for FY 2024 Annual Report

This appendix summarizes some of the key enforcement-related activities taken by the United States Copyright Office during Fiscal Year 2024.

Overview

The U.S. Copyright Office continued to work on important public initiatives during FY 2024. As part of the Library of Congress since 1870, and recognized by Congress as a separate department of the Library since 1897, the Copyright Office registers copyright claims, records information about copyright ownership, provides information to the public, and assists Congress and other parts of the government on a wide range of copyright issues.

During FY 2024, the Office marked the two-year anniversary of the new Copyright Claims Board (CCB), continued with its initiative on copyright and artificial intelligence (AI), completed policy studies, conducted rulemakings to implement provisions of the Copyright Act, and continued work to modernize IT 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 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 in June 2022. By the close of FY 2024, 976 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 the close of FY 2024, the CCB had issued twenty-three final determinations. 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.
- Easy online access: 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.

Additional summary information on the first twenty-one months of CCB activities is posted at <https://ccb.gov/CCB-Statistics-and-FAQs.pdf>. For more information on the CCB, visit <https://www.ccb.gov/>.

Initiative on Copyright and Artificial Intelligence

In early 2023, the Office publicly launched 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. The Office issued a notice of inquiry about copyright and the use of generative-AI on August 30, 2023. This notice built on work done in 2023 which included public webinars and listening sessions and registration guidance that clarified that applicants must disclose the inclusion of more than *de minimis* AI-generated content in works submitted for registration. Over 10,000 comments were submitted in this docket, including commenters from every U.S. state and sixty-six other countries.

On July 31, 2024, the Copyright Office released Part 1 of its Report on the legal and policy issues related to copyright and artificial intelligence (AI), addressing the topic of digital replicas. *Part One: Digital Replicas* responds to the proliferation of videos, images, or audio recordings that have been digitally created or manipulated to realistically but falsely depict an individual. Given the gaps in existing legal protections, the Office recommends that Congress enact a new federal law that protects all individuals from the knowing distribution of unauthorized digital

replicas. The Copyright Office recognizes that Congress continues to consider these important issues as well and remains available to provide technical assistance on proposed legislation.

Forthcoming parts of the Office's Report will address the copyrightability of materials created in whole or in part by generative AI, the legal implications of training AI models on copyright-protected works, licensing considerations, and the allocation of potential liability for AI-generated outputs that may infringe copyright.

For more information on the Copyright Office's AI initiative, visit www.copyright.gov/ai.

Reports and Studies

During FY 2024, the Office worked on several 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.

Joint Study on Non-Fungible Tokens and Intellectual Property

On March 12, 2024, the Copyright Office and the U.S. Patent and Trademark Office (USPTO) issued a joint report on *Non-Fungible Tokens and Intellectual Property*. Work on this report commenced in June 2022 based on a letter from Senators Patrick Leahy and Thom Tillis. 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 Copyright Office held public roundtables on copyright and NFTs on January 31, 2023.

In the report, the Offices concluded that current applications of NFT technology do not require changes to intellectual property laws. Furthermore, both Offices determined that incorporating NFTs into their registration and recordation practices is not necessary or advisable at this time. The Offices acknowledged commenters' views that NFTs may enable artists to secure remuneration for downstream resales of their works; aid trademark owners in expanding their brand appeal; or play a supportive role in the management, transfer, or licensing of intellectual property rights. They also recognized widespread concern that NFT buyers and sellers do not know what IP rights are implicated in the creation, marketing, and transfer of NFTs and that NFTs may be used to facilitate copyright or trademark infringement. The Offices determined, however, that existing statutory enforcement mechanisms are sufficient to address the IP-infringement concerns, and that product transparency and consumer education more appropriately address those concerns that fall outside the realm of intellectual property laws.

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>.

The Resilience of Creativity: An Examination of the COVID-19 Impact on Copyright-Reliant Industries and Their Subsequent Recovery

On May 23, 2024, the Office released a special report prepared by the Office of the Chief Economist examining the impact and subsequent recovery from the COVID-19 pandemic in terms of employment, revenues, and creative outputs in copyright-reliant industries. The report revealed that copyright-reliant industries experienced a substantial downturn resulting from the COVID-19 pandemic, but the effect was decidedly smaller than that on the broader U.S. economy, and copyright-reliant industries, as a whole, recovered from the pandemic-induced downturn substantially quicker than the broader U.S. economy. Moreover, the report found that the pandemic impact on employees was substantially larger than the impact on copyright-reliant firms (which is consistent with the experience of non-copyright reliant industries), and that the pandemic effects were significantly varied among industries.

This report can be found at <https://www.copyright.gov/economic-research/resilience-of-creativity/>.

The Geography of Copyright Registrations

On September 11, 2024, the Office released a report prepared by the Office of the Chief Economist examining the geographic distribution of copyright claims registered by individuals and organizations within the United States. This report examined the patterns in copyright registration across the country to better understand where and how the copyright system is used. The report revealed that the majority of copyright registrations originate from a handful of large metropolitan areas, that certain geographic areas specialize in different types of creative works, and that certain geographic areas emerge more prominently when controlling for population.

This report can be found at <https://www.copyright.gov/economic-research/geography/>.

Rulemakings

The Copyright Office has the statutory responsibility to implement many provisions of the Copyright Act via rulemaking. During FY 2024, 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: Active Proceedings and Evidence — Smaller Claims Procedures

The Office issued a final rule regarding certain CCB procedures on January 16, 2024. In connection with rulemaking connected to the implementation of the CASE Act, the Office published a final rule in May 2022 establishing a streamlined procedure for smaller claims, in which total damages sought do not exceed \$5,000 (exclusive of attorneys' fees and costs). Concurrent with the May 2022 final rule, the Office sought further comment regarding the smaller claims process to assess whether the updated regulation struck "the proper balance between streamlining the smaller claims process and providing sufficient procedural protections to all parties." The final rule issued on January 16, 2024; it addresses several rules and

regulations identified by commenters, and clarifies or addresses modification of certain procedural rules as appropriate.

The final rule can be found at <https://www.copyright.gov/rulemaking/case-act-implementation/active-proceedings/>.

Termination Rights, Royalty Distributions, Ownership Transfers, Disputes, and the Music Modernization Act

The Office issued a notice of proposed rulemaking on October 25, 2022, and a supplemental notice of proposed rulemaking on September 26, 2023, regarding the administration of the statutory mechanical blanket license and related provisions of the Music Modernization Act of 2018. On July 9, 2024, the Office published a final rule confirming that the derivative works exception to termination rights under the Copyright Act does not apply to the statutory blanket mechanical license. The final rule also addressed other matters relevant to identifying the proper payee to whom the mechanical licensing collective must distribute royalties. The Office adopted regulations addressing the mechanical licensing collective's distribution of matched historical royalties and administration of ownership transfers, other royalty payee changes, and related disputes. While the final rule retains many elements from the supplemental notice of proposed rulemaking, it also adopts a number of changes in response to public comments.

The final rule can be found at <https://www.copyright.gov/rulemaking/mma-termination/#>.

Group Registration of Updates to a News Website

On July 22, 2024, the Copyright Office created a new group registration option, known as Group Registration for Updates to a News Website (or GRNW), to allow news publishers to register frequently updated news websites as collective works with a deposit composed of identifying material representing sufficient portions of the works included over one month, rather than the complete contents of the website. In early January, 2024, the Office issued a notice of proposed rulemaking about this proposal and, after consideration, was able to both finalize the rule (in July 2024) and complete necessary technical amendments to the new form so that it could go into effect on the date the rule was issued.

The final rule can be found at <https://www.copyright.gov/rulemaking/newswebsite/>.

Section 1201 Triennial Rulemaking

In October 2024, the Copyright Office initiated the ninth triennial rulemaking proceeding under the Digital Millennium Copyright Act (DMCA), section 1201 of Title 17 of the United States Code, which provides that the Librarian of Congress, upon the recommendation of the Register of Copyrights, may adopt temporary exemptions to the section 1201 prohibition against circumvention of technological measures that control access to copyrighted works.

The ultimate goal of the triennial rulemaking proceeding is to determine whether there are particular classes of works as to which users are, or are likely to be in the next three years,

adversely affected in their ability to make non-infringing uses due to the prohibition on circumventing access controls. When such classes are identified, the Librarian promulgates regulations exempting the classes from the prohibition for the succeeding three-year period.

For the ninth triennial proceeding, the Office received 37 petitions seeking renewal of exemptions adopted in prior rulemakings, as well as 11 petitions seeking new exemptions or expansion of existing exemptions. The Office organized the petitions for expanded or new exemptions into seven classes. After multiple rounds of written comments, three days of public hearings and additional meetings, the Register recommended granting proposed exemptions, in whole or in part, in three of the seven classes, as well as renewing all existing exemptions for which petitions were filed. The Librarian of Congress adopted the Register's recommendations in full, and the final rule was published on October 28, 2024.

More information related to the ninth triennial 1201 rulemaking, including the final rule, is available at <https://www.copyright.gov/1201/2024/>.

Fair Use Index

The Copyright Office hosts and maintains the Fair Use Index on its website; it originated a decade ago in coordination with the Intellectual Property Enforcement Coordinator. 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 FY2024, the Index saw nearly 286,000 visits and over 51,500 resource downloads. 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 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 2024, the Office participated in the annual Special 301 review facilitated by USTR (including the Notorious Markets List 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 the updated webpage at <https://copyright.gov/continuous-development/>.

Public Outreach

The Copyright Office implements a full program of outreach and communications activities to educate the public regarding copyright protections, and to provide updates about 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 2024, Copyright Office staff fielded over 225,000 public inquiries on copyright topics ranging in complexity, after launching a new best-in-class multimodal contact center to manage demand for information in FY23. The Office provided thought leadership and educational outreach by speaking about copyright to a variety of audiences at 209 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 February 2024, the Office hosted a public program to celebrate the fiftieth anniversary of hip-hop, addressing how hip-hop has influenced creators worldwide and about the Office resources available on sampling, interpolation, and beat stores. A recording of the program is available online at <https://www.copyright.gov/events/black-history-month-hip-hop-2024/>. The Office also hosted webinars related to copyright public records searches and to copyright basics. A recording of the August 2024 public records search webinar is available online at <https://www.copyright.gov/events/level-up/>. A recording of the March 2024 Copyright Essentials

webinar is available at <https://www.copyright.gov/events/copyright-myths-explained/>. By popular demand, the Office hosted an updated “*Copyright Essentials: Myths Explained*” webinar in September 2024. Combined, these webinars reached an audience of 1,280 attendees. While the majority of these attendees were located in New York and California in both sessions, audience members joined these events internationally to learn basic information about copyright law and the Copyright Office’s function. A recording of the September 2024 “*Copyright Essentials*” webinar is available at <https://www.copyright.gov/events/copyright-myths-explained-sept-2024/>.