EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

OFFICE OF THE
U.S. INTELLECTUAL PROPERTY
ENFORCEMENT COORDINATOR

November 20, 2015

The Honorable Bob Goodlatte
Chairman
Committee on Judiciary
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed is the annual report of the Intellectual Property Enforcement Coordinator (IPEC) under Section 304 of the PRO IP Act of 2008 (15 U.S.C. § 8114). The report focuses on the intellectual property enforcement (and related) activities of the Federal Government during Fiscal Year (FY) 2014.

In particular, the report addresses the implementation of the *2013 Joint Strategic Plan on Intellectual Property Enforcement*. Issued in June 2013, the *2013 Joint Strategic Plan* reaffirmed the Administration's continued efforts to elevate intellectual property enforcement issues across the U.S. Government and internationally. The enclosed report sets out the breadth of activities the U.S. Government is undertaking to ensure the United States remains a global leader in protecting innovation and creativity. More specifically, the report provides a detailed description of the efforts Federal departments and agencies have undertaken in furtherance of the 26 action items called for in the *2013 Joint Strategic Plan.*

While there is more work to be done, the accomplishments identified in this report represent the coordinated efforts of the U.S. Government to protect U.S. intellectual property rights. This work is the product of joint efforts within the Executive Branch as well as partnerships between Federal agencies, State and local governments, private industry, trade associations, civil society, and foreign governments. The report reflects the Administration's continued emphasis on addressing intellectual property infringement that threatens U.S. jobs, our global economic competitiveness, and the health and safety of our citizens.

In the months following the period covered by the report, the Administration has continued to implement the *2013 Joint Strategic Plan* and elevate intellectual property enforcement.

A primary focus of my tenure as the IPEC has been the strategic-planning process for preparing the next 3-year *Joint Strategic Plan on Intellectual Property Enforcement*. As I noted, the current strategic plan was issued in June 2013, and thus we are in the final months of its 3-year period. Our objective is to submit the next 3-year plan to the Congress in spring 2016.

To that end, IPEC – in conjunction with the interagency Intellectual Property Enforcement Advisory Committee (IP Enforcement Committee) and the Senior Intellectual Property Enforcement Advisory Committee (Senior Advisory Committee) – has been actively engaged in that process. As part of the planning process, IPEC issued a Federal Register notice on September 1st (80 FR 52800), in which we invited public comments to assist IPEC and the other departments and agencies in developing the next strategic plan (the comment period ended on October 16th). That same day, I shared the Federal Register notice and encouraged the submission of public comments (https://www.whitehouse.gov/blog/2015/09/01/developing-2016-2019-joint-strategic-plan-intellectual-property-enforcement).

If you or your staff have any questions, please do not hesitate to contact our Office of Legislative Affairs at (202) 395-4790.

Sincerely,



Daniel H. Marti
U.S. Intellectual Property Enforcement Coordinator

Enclosure

Identical Letter Sent to:

The Honorable Hal Rogers
The Honorable Nita Lowey
The Honorable Thad Cochran,
The Honorable Barbara Mikulski
The Honorable Bob Goodlatte
The Honorable John Conyers, Jr.
The Honorable Charles Grassley
The Honorable Patrick Leahy

ANNUAL REPORT FOR FISCAL YEAR 2014
UNDER SECTION 304 OF THE PRO IP ACT OF 2008
(15 U.S.C. § 8114)

INTRODUCTION

In June 2013, the Administration issued the IPEC 2013 Joint Strategic Plan, which reaffirmed the Administration's continued efforts to elevate intellectual property enforcement issues across the U.S. Government and internationally. The 2014 Annual Report sets out the breadth of activities the U.S. Government is undertaking to ensure the United States remains a global leader in protecting innovation and creativity. More specifically, the 2014 Annual Report provides a detailed description of the efforts Federal departments and agencies have undertaken in furtherance of the 26 action items called for in the Administration's 2013 Joint Strategic Plan.

While there is more work to be done, the accomplishments identified in this report represent the coordinated efforts of the U.S. Government to protect U.S. intellectual property rights. This work is the product of joint efforts within the Executive Branch as well as partnerships between Federal agencies, state and local governments, private industry, trade associations, civil society, and foreign governments.

The 2014 Annual Report reflects the Administration's continued emphasis on addressing intellectual property infringement that threatens U.S. jobs, our global economic competitiveness, and the health and safety of our citizens.

Leading By Example

1. Secure the U.S. Government Supply Chain Against Counterfeits

Counterfeiting is a significant challenge that can impair supply chains across the Federal Government, with particularly significant consequences for the Department of Defense (DoD) supply chain, by negatively affecting missions, the reliability of weapon systems, the safety of the warfighter, and the integrity of sensitive data and secure networks.

There have been a number of meaningful interagency efforts to address the threat posed by counterfeit goods entering the U.S. Government supply chain. The risks created for the U.S. Government when acquiring products or services from sellers with inadequate integrity, security, resilience, and quality assurance controls are significant both from a national security and mission assurance perspective as well as from an economic standpoint due to the increased costs to American taxpayers.

The goal is to reduce the risk of counterfeits entering the supply chain; quickly and collectively address those that do enter the supply chain; and strengthen remedies against those who provide counterfeit items to the U.S. Government. To that end, Federal buyers need better

visibility into and understanding of (1) how the products, services, and solutions they buy are developed, integrated and deployed, and (2) the processes, procedures, and practices used to ensure the integrity, security, resilience, and quality of those products and services. This visibility must extend through all companies directly involved in delivery of products, services, and solutions to the government, and through all tiers of the supply chain.

Acquisition and Supply Chain Security

In June 2014, DoD, the General Services Administration (GSA), and the National Aeronautics and Space Administration (NASA) issued a proposed rule – Federal Acquisition Regulation Case 2013-002: *Expanded Reporting of Nonconforming Supplies* – to revise the Federal Acquisition Regulation to expand Government and contractor requirements for reporting of nonconforming goods with the intention of reducing the risk of counterfeit goods entering the Government supply chain. Under the proposed rule, contractors would be required to report cases in which an item is counterfeit, or is suspected of being counterfeit, to the Government-Industry Data Exchange Program at www.gidep.org.

In addition, in 2014 two acquisition final rules were published that address the threat of counterfeit goods entering the supply chain. Those final rules were: (1) Federal Acquisition Regulation Case 2012-032, *Higher-Level Contract Quality Requirements*, and (2) Defense Federal Acquisition Regulation Supplement Case 2012-D055, *Detection and Avoidance of Counterfeit Electronic Parts*. Under FAR Case 2012-032, agencies assess the risk of nonconforming items when determining whether higher-level quality standards should be used by the Government and relied on by contractors. DFARS Case 2012-D055 outlines contractor responsibilities for the use of trusted suppliers; the detecting and avoiding the use or inclusion of counterfeit electronic parts or suspect counterfeit electronic parts; and the reporting of counterfeit electronic parts and suspect counterfeit electronic parts.

In support of providing Federal acquisition professionals with the tools necessary to be vigilant in purchasing safe, legitimate products, the U.S. Immigration and Customs Enforcement (ICE)-led National Intellectual Property Rights Coordination Center (IPR Center) has created a training course to provide Federal Government acquisition professionals with the knowledge and skills needed to combat the threat of counterfeit goods in the Federal workplace. Implementation of this course for ICE personnel began in 2013, and continued in 2014, with eight webinars held and 112 acquisition professionals trained on the use of trusted suppliers. The IPR Center is working to expand the training to additional departments and agencies across the Federal Government.

In addition, ICE continues to provide information to DoD for use in risk assessments regarding microelectronics suppliers, to enhance quality assurance on parts no longer available from the original equipment manufacturer.

Law Enforcement Efforts Directed at Securing the U.S. Government Supply Chain

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

Operation Chain Reaction – an IPR Center-coordinated effort of 16 Federal law enforcement agencies including ICE, Customs and Border Protection (CBP), and DoD's criminal investigative offices – works to target counterfeit items entering the U.S. Government supply chain. Under *Operation Chain Reaction*, U.S. Immigration and Customs Enforcement Homeland Security Investigations (ICE-HSI) initiated 45 criminal investigations in 2014 that resulted in 5 criminal arrests, 15 indictments, and 13 convictions, as well as 146 seizures of currency and counterfeit goods with a Manufacturer's Suggested Retail Price (MSRP) of more than $4.9 million.

In June 2014, a Massachusetts man pleaded guilty to importing thousands of counterfeit integrated circuits from China and Hong Kong and then reselling them to U.S. customers, including contractors supplying them to the U.S. Navy for use in nuclear submarines. The case was investigated by ICE-HSI, the Defense Criminal Investigative Service and the Naval Criminal Investigative Service. This is one of the first convictions for trafficking in counterfeit military goods, following the addition of explicit language in 18 U.S.C. § 2320 regarding counterfeit military goods that was enacted as part of the National Defense Authorization Act for Fiscal Year 2012.

2. Use of Software by the Federal Government

IPEC is working with OMB's Office of Electronic Government (also referred to as the Office of the Federal Chief Information Officer), OMB's Office of Federal Procurement Policy (OFPP), and the interagency Chief Information Officers Council to develop and implement best-practice measures for software acquisition and use. The goals of these measures are to ensure that Federal departments and agencies only use legal software and that they effectively and efficiently manage their software licensing – by procuring the necessary number of licenses of software packages and by not spending more than is necessary for the required software capabilities.

Since the 2013 Joint Strategic Plan was issued, OMB has launched two initiatives that advance the software licensing objectives identified in this action item.

The first of these initiatives was discussed by OMB in Memorandum M-14-03 of November 18, 2013 ("Enhancing the Security of Federal Information and Information Systems"). As OMB explained in this Memorandum, this initiative included the establishment by GSA and the Department of Homeland Security (DHS) of "a government-wide Blanket Purchase Agreement (BPA) under Multiple Award Schedule 70, which Federal, State, local and tribal governments can leverage to deploy a basic set of capabilities to support continuous monitoring of security controls in Federal information systems and environments of operation." In addition to

enhancing the Federal Government's ability to identify and respond to the risk of emerging cyber threats, continuous monitoring also enables agencies to collect better and more timely information about what types of software are being used by agency staff (and by how many agency staff). Such information is critical to informing the agency about its software needs; to identifying any uses by agency staff of software for which the agency has not obtained the necessary license; and to identifying any uses by agency staff of software in excess of the applicable license.

The second of these initiatives is the "Category Management" procurement reform, which was discussed by OMB/OFPP in the Memorandum of December 4, 2014 ("Transforming the Marketplace: Simplifying Federal Procurement to Improve Performance, Drive Innovation, and Increase Savings"). One valuable component of category management is for the Federal Government to develop government-wide contract vehicles that will enable agencies to purchase goods and services that – in the case of IT software – will have the required licensing provisions and be priced to reflect the Government's overall purchasing power.

Transparency and Public Outreach

3. Improve Transparency in Intellectual Property Policymaking and International Negotiations

The Administration continues to take meaningful steps to improve transparency in intellectual property policy making and international negotiations. Providing for a transparent environment not only provides the benefit of ensuring that policymakers have access to a diverse set of views to draw upon as part of the policy development process, but allows for greater accountability of policymakers.

Policy Making

Across the Federal Government, departments and agencies have worked to ensure a transparent and open policy-making environment. Such steps include soliciting public comments about key intellectual property issues such as patent, trademark, copyright and trade secret policies, enforcement of ITC exclusion orders, improving notice-and-takedown processes under the Digital Millennium Copyright Act (DMCA), updating the music licensing system, and implementation of voluntary best practices to address online piracy and counterfeiting.

In 2013 and 2014, IPEC continued its longstanding tradition of an open door policy, meeting with hundreds of stakeholders, large and small, across a broad range of sectors in developing and implementing the Administration's strategy for intellectual property enforcement.

In addition, the U.S. Copyright Office solicited formal public comments and held multiple roundtable discussions open to the general public on a wide range of copyright policy topics, including on proposals for the adjudication of small copyright claims and efforts to upgrade and improve the copyright recordation system.

In January 2013, the Department of Justice (DOJ) and the United States Patent and Trademark Office (USPTO) issued a "Policy Statement on Remedies for Standard-Essential Patents Subject to Voluntary F/RAND Commitments" ("Joint Statement"; http://www.justice.gov/atr/public/guidelines/290994.pdf). The Joint Statement addressed the appropriateness of an exclusion order being issued by the ITC as a remedy for the infringement of a standard-essential patent (SEP) that is subject to a voluntary commitment by the patent holder to make licenses available on terms that are RAND (reasonable and non-discriminatory) or FRAND (fair, reasonable and non-discriminatory). In these circumstances, the Joint Statement explained that exclusionary relief may cause competitive harm by facilitating patent hold-up; therefore, an exclusion order may be inconsistent with the statutory public interest standard. The Joint Statement added that an exclusion order may be an appropriate remedy in some circumstances, such as where an implementer of a standard "refuses to pay what has been determined to be a F/RAND royalty or refuses to engage in a negotiation to determine F/RAND terms" (or constructively refuses "to negotiate, such as by insisting on terms clearly outside the bounds of what could reasonably be considered to be F/RAND terms in an attempt to evade the putative licensee's obligation to fairly compensate the patent holder") or if a potential licensee "is not subject to the jurisdiction of a court that could award damages."

Also, departments and agencies have outlined their views to the public on intellectual property enforcement issues through speeches and their remarks at public events, and they have engaged in discussions with industry and interested groups – on all sides of the issues – to hear their views.

For example, speeches by DOJ officials on intellectual property issues include the presentations by the Antitrust Division on "IP, Antitrust, and Looking Back on the Last Four Years" (February 8, 2013); on "The Art of Persuasion: Competition Advocacy at the Intersection of Antitrust and Intellectual Property" (November 8, 2013); and on "At the Intersection of Antitrust & High Tech: Opportunities for Constructive Engagement" (January 24, 2014). Also, as a follow-up to the issuance of the January 2013 Joint Statement (discussed above), the Antitrust Division made a presentation on "A Year in the Life of the Joint DOJ-PTO Policy Statement on Remedies for F/RAND Encumbered Standard-Essential Patents" (on May 25, 2014). These and other DOJ speeches are available at http://www.justice.gov/atr/speeches-0.

In addition, the Department of Justice continued to encourage standards bodies to adopt clear, pro-competitive intellectual property policies that can facilitate the licensing of standards-essential patents. The Department of Justice coordinated its efforts with other Federal agencies, including the Federal Trade Commission (FTC), the Department of Commerce (including its component agencies such as the USPTO, the National Institute for Standards and Technology (NIST), and the International Trade Administration (ITA)), and U.S. Trade

Representative (USTR), as well as the European Commission. Based on its member status in the International Telecommunication Union (ITU), the U.S. Government submitted text in June 2014 for consideration by the ITU-Telecommunications Advisory Group regarding the conditions under which injunctive and exclusionary relief may be available to owners of patents essential to an ITU-T standard that are encumbered by a commitment to make licenses for these patents available on reasonable and non-discriminatory (RAND) terms.

International Negotiations

The Administration's goal is to promote intellectual property protection and enforcement abroad through engagement with our trading partners. Through such engagement, the Administration advocates for strong intellectual property protection and enforcement in other countries, *inter alia*, for works, trademarks, trade secrets and inventions by U.S. creators, inventors, artists and businesses. During negotiations with foreign counterparts, we explain the importance that we place on protecting and enforcing intellectual property, and we seek agreement on concrete measures that trading partners will adopt to protect intellectual property, including that owned by Americans.

Additionally, the multilateral structure of the World Trade Organization provides opportunities for USTR to lead engagement with trading partners on IPR issues, including through accession negotiations for prospective Members, the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council), and the Dispute Settlement Body. In 2014, the United States sponsored discussions in the TRIPS Council on the positive and mutually-reinforcing relationship between the protection and enforcement of IPR and innovation.

To ensure maximum transparency, 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, hosts stakeholder events at rounds of negotiations, and disseminates trade policy materials such as press releases, factsheets and statements on the USTR website. This dialogue is critical at every stage of the negotiating process, including implementation and enforcement of trade rules. USTR seeks public input in connection with various matters under its purview, including international trade negotiations in which intellectual property protections are under discussion, and the annual Special 301 process, through which the United States identifies countries that fail to adequately protect or enforce intellectual property rights and that create unfair barriers to market access for U.S. businesses that rely on intellectual property. Federal Register Notices seeking public input and comments as part of the annual Special 301 process are available for inspection online and public hearings were held in FY13 and FY14. In addition, USTR briefs members of Congress on these matters.

4. Improve Law Enforcement Communications with Stakeholders

The Administration has made great strides in improving communications between law enforcement and key stakeholders, including content providers, brand-holders, importers, trade associations and members of the public. Such communications are now institutionalized through regular working groups, meetings, and conferences, and representatives from Federal law enforcement agencies routinely engage with stakeholders to listen to stakeholder concerns and share information.

The IPR Center forms the communications hub around which much of the interaction between private sector stakeholders and the law enforcement and regulatory communities takes place. In 2014, the IPR Center added two new partner agencies: the Federal Maritime Commission (FMC) and the United States Postal Service Office of Inspector General (USPS-OIG). The IPR Center now includes representatives from 19 key Federal agencies, as well as Canada, Mexico, INTERPOL and Europol. IPR Center partners serve as a single point of contact for stakeholders to report IP theft and to receive information on how to improve IP protection. The IPR Center also de-conflicts and coordinates IP investigations, improves interdiction efforts, and provides training to domestic and international law enforcement. In FYs 2013 and 2014, the IPR Center, through *Operation Jaint Venture*, reached out to 16,519 people in 346 outreach and training events (in FY2013) and to 19,824 people in 290 outreach and training events (in FY2014).

The IPR Center relies on public-private partnerships to maximize its effectiveness. In October 2011, the IPR Center entered into a multi-year partnership with the National Cyber-Forensics and Training Alliance (NCFTA) to provide comprehensive and actionable intelligence on individuals or groups involved in the distribution of counterfeit merchandise. NCFTA uses cyber forensic tools and methodologies to develop intelligence on investigative targets in support of criminal and/or civil investigations regarding the sale of counterfeit merchandise. In FY2014, ICE Special Agents embedded at NCFTA provided case support that resulted in 58 arrests, 45 indictments, 32 convictions, and seizures totaling more than $89 million, as well as the initiation of 167 HSI IP and other trade fraud cases.

In November 2013, the IPR Center participated in the European Office for Harmonization in the Internal Market's (OHIM) Health and Safety Conference in Alicante, Spain. The purpose of the event was to raise awareness and build knowledge and to discuss efficient ways to tackle the illicit trade of counterfeit goods in both the private and public sectors. The event focused on cross border and inter-agency cooperation.

In April 2014, the U.S. Chamber of Commerce hosted its Second Annual IP Champions Event in Washington, D.C. At this event, then-IPR Center Director Lev Kubiak participated in a panel to discuss public-private cooperation and best practices for effective IP enforcement.

In May 2014, ICE Acting Director Thomas S. Winkowski provided keynote remarks for the International Anti-Counterfeiting Coalition Conference in Hong Kong. Acting Director Winkowski

highlighted ICE's goals for turning private partnerships and outreach into actionable enforcement opportunities and results.

In June 2014, the IPR Center participated in the Underwriters Laboratories Brand Protection Conference in Los Angeles, California. The IPR Center provided a presentation entitled, "Effective Enforcement Strategies – Working with the U.S. National IPR Coordination Center," that included an overview of best practices and strategies for combatting IP crime for the private sector.

CBP also emphasizes and maintains frequent interaction with private sector stakeholders. CBP's multi-faceted communication with IPR stakeholders includes daily interaction with industry regarding enforcement activities as well as formal meetings involving both trade facilitation and enforcement efforts. CBP's stakeholder engagement includes:

- Twice monthly meetings with the IPR Working Group of its Federal advisory committee, and quarterly meetings with the full committee;
- Daily interaction with stakeholders affected by IPR enforcement in ports, and nationally through our industry sector aligned Centers of Excellence and Expertise (CEE), and IPR focused headquarters and IPR Center staffs; and
- Participation in industry meetings and speaking engagements.

CBP recognizes that right holders have important expertise to share with Federal authorities. To increase CEE and port expertise regarding their products, rights holders conducted 143 training sessions for CBP personnel at 83 ports.

In addition to these efforts, the law enforcement agencies which support IPR enforcement have numerous other engagements with stakeholders. Some of these public education and outreach efforts are described below:

- Project Trade Watch is ICE-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. ICE and CBP field personnel provide information and red flag indicators of potential import fraud and importer identity theft;

- During 2014, the IPR Center hosted numerous foreign governments with an interest in intellectual property enforcement. Representatives from the customs administrations of Mexico, France, Australia, Pakistan, Sri Lanka, and the People's Republic of China were among the many international delegations hosted by the IPR Center.

- FBI personnel participated in the Underwriters Laboratory Brand Protection Wire & Cable Summit in Melville, NY, which was used to communicate the FBI's mission and program initiatives in IPR enforcement to experts from the manufacturing industry.

- In furtherance of *Operation Engine Newity*, FBI and ICE-HSI personnel met at the IPR Center with representatives from the Alliance of Automobile Manufacturers and the Association of Global Automakers. The meeting was organized by the FBI to initiate liaison contacts with the automotive industry, encourage collaboration, and express interest in receiving investigative lead intelligence. Both associations represent a large number of North American automotive manufacturing companies. Representatives from Honda, Chrysler, Kia, and Nissan also participated in this meeting.

- FBI and ICE-HSI personnel participated in the International Anti-Counterfeiting Coalition (IACC) Annual Spring Conference held in Dallas, Texas, which was attended by over 450 industry representatives including law firms which specialize in brand protection and trademark enforcement. Relevant issues were discussed with industry experts from various disciplines which facilitated open dialogue on a variety of significant issues. Several other roundtable workshops were held by representatives from social media sites, credit card networks, and online marketplaces.

- In 2014, DOJ and the IPR Center co-hosted two meetings of a Counterfeit Microelectronics Working Group to foster direct communication between industry representatives and the prosecutors, law enforcement agents, and other government officials working to combat counterfeit microelectronics in the supply chain. Over 50 representatives from the microelectronics industry and law enforcement attended the April 2014 meeting, and over 80 representatives attended the September 2014 meeting.

- In July 2013 and September 2014, DOJ's Criminal Division hosted the Computer Crime & Intellectual Property Section's (CCIPS') Annual IP Industry and Law Enforcement Meeting in Washington, D.C. These yearly meetings provide representatives from a broad range of industries with an opportunity to communicate directly with the law enforcement agents and prosecutors most responsible for federal criminal enforcement of IP law at the national level. The meetings were attended by high-level DOJ officials, including remarks by the Attorney General, Deputy Attorney General, and Assistant Attorney General. More than 90 individuals attended the meetings, including DOJ, FBI, ICE, CBP, and FDA law enforcement officials and senior representatives from a broad range of industries such as pharmaceuticals, software, luxury goods, electronics, apparel, motion pictures, music, consumer goods, and automobiles.

- In FY2013 and FY2014, DOJ high-level officials and attorneys presented at over 30 domestic and international conferences, symposia, and workshops attended by IP rights holders and law enforcement officials. Recent examples of industry engagement include the September 2014 Partnership for Safe Medicines Interchange in Washington, D.C.; April 2014 ABA's Annual Intellectual Property Law Spring Conference in Washington, D.C.; June 2013 Underwriters Laboratory Brand Protection Workshop in Fort Lauderdale, Florida; and May 2013 International Anti-Counterfeiting Coalition's Spring Conference in Dallas, Texas. Additional private sector outreach activities are described in DOJ's PRO IP Act Reports submitted to the Congress, available at: http://www.justice.gov/dag/iptaskforce/proipact/.

5. Evaluate Enforcement Process of Exclusion Orders Issued by the U.S. International Trade Commission

Since the 2013 Joint Strategic Plan, IPEC has been working with key agencies to strengthen the processes for enforcement of U.S. International Trade Commission (ITC) exclusion orders. A central focus of this effort has been to review existing procedures used by CBP and to explore opportunities to improve upon the effectiveness of directions provided by the ITC in the course of issuing exclusion orders.

On February 23, 2015, ITC announced a pilot program aimed at providing more efficient and effective determinations on the scope of exclusion orders it issues under 19 U.S.C. § 1337. The pilot program directly supports the Administration's efforts aimed at improving how intellectual property rights holders and importers can determine whether imported products are subject to existing ITC exclusion orders. This pilot program is being launched in response to concerns raised by U.S. importers, would-be importers, and intellectual property rights holders in recent years about how to obtain timely, transparent, and binding decisions on whether new and redesigned products are covered by an ITC exclusion order.

The pilot will test an expedited administrative process for modification proceedings and advisory opinion proceedings. Modification proceedings are instituted to determine whether the scope of an existing remedial order should be modified based on changed circumstances of fact or law. The ITC can determine whether a redesigned or new product is covered by an existing exclusion, consent, or cease and desist order and whether the order should provide a "carve-out" for the redesigned or new product. Advisory opinion proceedings result in an advisory opinion from the Commission as to whether importation of a redesigned or new product will violate an existing exclusion, consent, or cease and desist order.

Finally, by encouraging entities to employ the ITC's procedures for seeking such determinations, the pilot program offers timely alternatives to certain aspects of current practice, in that it ensures that scope determinations will be made in an inter parties proceeding, held on the record and, if appropriate, in front of a quasi-judicial fact-finder with the tools available to receive and weigh evidence.

The ITC's pilot program represents a significant milestone to ensure the process and standards utilized during exclusion order enforcement activities are transparent, effective, and efficient.

6. Educate Authors on Fair Use

Effective enforcement is critical to providing meaningful protection of intellectual property rights, but enforcement approaches should not discourage authors from building appropriately on the works of others. Relevant agencies across the U.S. government have stepped up efforts to increase education and awareness in the digital environment. The Administration believes, and the U.S. Copyright Office agrees, that authors and the public would benefit from more guidance on the fair use doctrine. Efforts in this space include activities throughout the Department of Commerce and its component agencies.

The Department of Commerce's Green Paper on *Copyright Policy, Creativity, and Innovation in the Digital Economy* emphasized the importance of fair use as "a fundamental linchpin of the U.S. copyright system," and reiterated the Administration's support for further efforts to educate the public about the doctrine, including through a U.S. Copyright Office-created index of cases as proposed by the 2013 Joint Strategic Plan. As the Green Paper notes, the fair use doctrine is a critical means of balancing "the interests of authors and inventors in the control and exploitation of their writings and discoveries on the one hand, and society's competing interest in the free flow of ideas, information, and commerce on the other hand."

During FY2014, the U.S. Copyright Office compiled an online index of significant fair use judicial decisions, which the Office released in April 2015. The goal of the Copyright Office Fair Use Index is to make the principles and application of fair use more accessible and understandable to the general public by presenting a searchable and user-friendly database of court opinions that may help both lawyers and non-lawyers understand the types of uses courts have previously determined to be fair – or not fair. For each case listed, the index provides a brief summary of the relevant facts, the key question(s) presented, and the court's holding. Users will be able to search for cases involving particular subject matter (*e.g.*, music, film, parody), or from specific jurisdictions. The index is available through the Copyright Office website at http://copyright.gov/fair-use/fair-index.html.

In addition to supporting the efforts of the Copyright Office to create this index, the Department of Commerce has collected comments and engaged in public discussions relating to the creation of remixes or mashups – works created through changing and combining existing works to produce something new and creative – an activity in which fair use plays a significant role.

The Global Intellectual Property Academy (GIPA) of the United States Patent and Trademark Office has continued its efforts to educate the U.S. small- to medium-sized businesses and the general public on the importance of copyright protection and enforcement, within the United States and abroad, and in the digital world. Businesses often are unfamiliar with the concept of "fair use" or its application and GIPA has continued to refine its approach to teaching this concept through its "Intellectual Property (IP) Boot Camps" and its participation with the STOPfakes.gov Road Shows of the Commerce Department's International Trade Administration. In 2014, GIPA visited seventeen cities throughout the United States and provided copyright presentations to over 1,400.

7. Raise Public Awareness

Changing public attitudes toward infringing activities remains essential to an effective intellectual property enforcement strategy. Departments and agencies – including DOJ (and the FBI), DHS (and ICE-HSI and CBP), and USPTO – have stepped up their efforts to increase public awareness. Activities include:

- The Department of Justice contributed to a National Crime Prevention Council public awareness campaign to help educate the public about IP crime and its consequences, the initial phases of which were introduced November 29, 2011. Since November 2011, the campaign has garnered more than $80.4 million in donated media, including more than 77,765 total airings on television in 209 nationwide markets and 22,895 airings on radio. In addition, 1,841 digital mall posters have been displayed in 43 nationwide markets, and print support for the campaign continues to be strong, adding another $412,000 in donated media in FY2014.

- CBP proactively issues frequent national and local press releases, and social media notifications to educate the public on counterfeiting. In FY2013 and FY2014, CBP issued 22 and 16 IPR-related press releases, respectively.

- The IPR Center has begun an initiative to raise awareness about the potential impacts that using counterfeit products may have on the U.S. public. In FY2014, the IPR Center issued approximately 70 notifications through press conferences with the private sector, trade community, and IPR Center members. The IPR Center also issued press releases and conducted electronic media outreach regarding the potential danger caused by counterfeit air bags and automotive parts, holiday-related scams, counterfeit software, and counterfeit cosmetics and beauty supplies. These materials have provided consumers with information regarding how to avoid purchasing counterfeit products, signs and indicators that products might be counterfeit, how to report a possible counterfeit item, and the health and safety threats from these products. One such notice warned the public of the dangers associated with counterfeit decorative contact lenses as part of the joint *Operation Double Vision* undertaken among the U.S. Food and Drug Administration, ICE, and CBP through the IPR Center. Through initiatives like this, interagency partners at the IPR Center seek to protect the public's health and safety. Another notice issued to the public as part of *Operation Engine Newity* warned the public against purchasing counterfeit airbags. Through initiatives like these, interagency partners at the IPR Center seek to protect the public's health and safety.

- In addition, the IPR Center also continues to work with the National Association of Theater Owners to display the anti-piracy warning banner before the showing of films.

- In FY2013, the ICE Global Outreach and Training Unit at the IPR Center conducted 346 outreach and training events which 16,519 people attended. In FY2014, the ICE Outreach and Training Section at the IPR Center conducted 290 outreach and training events which 19,824 people attended.

- During FY2013, the FBI initiated significant projects designed to focus on health and safety threats and increase public awareness of the harm and illegality of intellectual property violations.

- The FBI also produces Private Sector Advisories which rely on information provided by industry partners about company-specific threats. These threats are analyzed and reported in intelligence products, which identify trends across the industry. The desired outcome places the FBI in a position to alert companies to potential vulnerabilities, of which they may not have previously been aware. These companies can utilize this information to better secure their IP. Additionally, this information allows the FBI to send useful investigative leads to FBI field offices.

- Personal Care Products: The Personal Care Products initiative is an FBI and ICE-led initiative focused on counterfeit personal care products such as cosmetics, laundry detergent, shampoo, body wash, and razors. During 2013, the FBI established liaison and organized meetings with individual industry partners and trade associations to share intelligence regarding emerging threats and trends. In addition, this relationship will help develop a more comprehensive understanding of the prevalence of counterfeit personal care products across the industry and throughout the United States, particularly with regard to potential threats to the health and safety of consumers. Intelligence notes regarding counterfeit cosmetics and fragrances have been disseminated to field investigators.

- The Department of State (DOS) also provides small grants to embassies to conduct public outreach initiatives on Counterfeit Medicines and Internet Piracy issues.

- During FY2013 and FY2014, DOS devoted over $500,000 and nearly $187,000, respectively, in public diplomacy funds toward its international "Campaign against Counterfeit Medicines, Counterfeit Products and Internet Piracy." State's Intellectual Property Enforcement office provided seed money to support public awareness campaigns developed by U.S. embassies and consulates in 29 countries (in FY2013) and 16 countries (in FY2014) in Africa, Asia, Europe, the Middle East, and Latin America.

- All of the projects involved partnerships with host governments or other public and private sector partners, whose contributions in many cases matched or exceeded that provided by DOS. Reports of completed programs covered by these and earlier grants include:

  Africa

  - In **Kenya,** Embassy Nairobi extended its public awareness campaign on the dangers of counterfeit medicines and consumer products to rural areas through a World Anti-Counterfeit Day workshop and dissemination of IP and anti-counterfeiting study and through an IP in Modern Health Care and Moot Court Competition on IP Law. The event included 12-15 judges, over 100 students, lawyers, academics, and visitors from Tanzanian, Ugandan, and Rwandan law schools.

  - In **Mauritius,** the embassy ran a seminar for 300 post-secondary students on risks of counterfeit software, with widespread media coverage to spread the word.

Asia

- In **China**, the embassy continued Project Hope anti-counterfeit medicine training and outreach with workshops, articles, and blogs to reach journalists, policymakers, health service providers, and over 1.8 million Chinese consumers. Consulate General Guangzhou held anti-piracy movie screenings on south China university campuses to increase understanding and respect for IPR among students 16-24 and decrease online piracy. Consulate General Hong Kong held a contest called "Youth to Youth: Stopping Digital Piracy" where 100 students aged 14-16 participated and another 220 million are likely to see the media that will discourage piracy by showing how ordinary people rely on work in films to make a living.

- In **India**, Embassy New Delhi held anti-piracy film screenings and public service announcements to reach youth with the message that IPR protects creative industries that create jobs and economic opportunities. The embassy also held workshops on protection of cultural heritage through IP, focusing on women and Muslim entrepreneurs.

- In **Indonesia**, Embassy Jakarta held workshops and installed mall signage to reach several million Indonesians about the dangers of counterfeits. It worked with the Indonesia Shopping Center Management Association to promote "counterfeit free malls."

- In the **Philippines**, Embassy Manila held workshops to educate over 1,000 medical and nursing students on the dangers of counterfeit medication, with a press release and social media to amplify the message.

- In **Pakistan**, Embassy Islamabad held a contest to create a mobile app to promote IPR, targeting urban Pakistanis in the 16-40 age group.

Latin America and Caribbean

- In **Paraguay**, Embassy Asuncion placed cartoons on TV and the internet to describe IPR and innovation. The audience included Spanish speaking viewers in Paraguay as well as neighboring countries.

- In **Mexico**, Embassy Mexico City began a subway public-awareness campaign to educate the 5 million daily passengers about the dangers of counterfeit products, with additional coverage by radio and print journalists and in social media.

- In **Jamaica**, Embassy Kingston conducted radio, print, social media and film anti-piracy outreach targeting youth, using Jamaican contributions to the music and film industry to sensitize Jamaicans to the importance of purchasing legal copies.

- In **Chile**, Embassy Santiago expanded of video game IPR awareness for youth. The program had a "train the trainer" component in 2013 and the 2014 funds enabled post to

give Chilean partners ownership for faster expansion to reach one million secondary school students.

Ensuring Efficiency and Coordination

8. Improve National Law Enforcement Efforts to Protect Intellectual Property Rights

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

To improve efficiency, law enforcement is working not only harder, but also smarter, through improved coordination amongst the IP enforcement agencies. For example, CBP has created an operational network among CBP's trade targeting assets to improve communications, coordinate actions, and standardize procedures for more effective tactical trade targeting. This integration will help unify all trade targeting entities to create a common operating picture, de-conflict targets and operations to reduce redundancies; standardize trade targeting policies and procedures; automate processes and leverage technology and train personnel to utilize trade targeting best practices. CBP is also utilizing its "Centers of Excellence and Expertise" (CEEs) to develop expertise in certain industries, such as pharmaceuticals and electronics, to better identify infringement. CBP's Pharmaceutical and Electronics Centers of Excellence and Expertise (CEEs) conducted special IPR enforcement operations targeting counterfeits in these sectors.

- In FY2013 and FY2014, U.S. law enforcement continued to make progress in enforcing IP rights at our borders. In FY2013, the U.S. Department of Homeland Security (ICE and CBP) was responsible for 24,361 seizures of counterfeit goods, an increase of 7 percent, valued at $1.74 billion manufacturer's suggested retail (MSRP), an increase of 38 percent. ICE initiated 1,361 intellectual property investigations, resulting in 693 arrests, 411 indictments, and 465 convictions. FY2013 convictions increased by 39 percent over FY2012.

- In FY2014, DHS, through ICE and CBP, was responsible for 23,136 seizures of counterfeit goods, with MSRP valued at more than $1.22 billion. In FY2014, ICE-HSI initiated 984 intellectual property investigations and had 683 arrests, 454 indictments, and 461 convictions.

- From FY 2013 to FY 2014, the number of counterfeit auto parts seizures increased by more than 83% (from 118 seizures in FY 2013 to 216 in FY 2014), and the MSRP increased 66% (from $4.1 million in FY 2013 to $6.8 million in FY 2014). In addition, in FY 2014, CBP and ICE-HSI interdicted more than 32,000 counterfeit water filtration parts.

The Department of Justice is focused on the most serious cases of IP infringement, and criminals are learning the hard way that infringing IP rights carries serious consequences. Through the Criminal Division's Computer Crime & Intellectual Property Section, the U.S.

Attorneys' Offices, the Civil Division's Consumer Protection Branch, and the National Security Division's Counterespionage Section, DOJ has continued to prioritize and pursue investigations in three priority areas identified by DOJ's IP Task Force, including offenses that involve (1) health and safety, (2) trade secret theft or economic espionage, and (3) large-scale commercial counterfeiting and piracy. Examples of recent, significant prosecutions in these areas include:

- In April 2014, as part of *Operation Chain Reaction*, a former Chief Executive Officer of a battery distributor was found guilty of five counts of wire fraud and one count of conspiracy to defraud the United States by selling to the U.S. Department of Defense more than $2.6 million in counterfeit batteries from China. The case was investigated jointly by ICE-HSI and DCIS, with assistance from DLA and the Defense Contract Audit Agency. Investigators discovered that the distributor sold more than 80,000 batteries and battery assemblies that the U.S. Navy used for emergency back-up power on aircraft carriers, minesweepers and ballistic submarines.

- In August 2014, two New York individuals pleaded guilty in connection with importing children's toys with copyright-infringing images and counterfeit trademarks as well as unsafe lead levels, small parts that presented choking risks, easily-accessible battery compartments, and other potential hazards. (EDNY, CCIPS, ICE-HSI, NYPD, CPB, CPSC)

- In July 2014, a California businessman was sentenced to 15 years in prison for stealing DuPont's manufacturing secrets and selling the information to Chinese-owned companies. In May 2014, a federal jury found the businessman, his company, and his co-conspirator guilty of economic espionage, theft of trade secrets, bankruptcy fraud, tax evasion, and obstruction of justice. (NDCA, NSD, FBI, IRS)

- In 2014, leading members of three different Android mobile device app piracy groups were charged with conspiracy to commit criminal copyright infringement. Seizure orders were executed against these three website domain names for the illegal distribution of copies of copyrighted Android mobile device apps – the first time website domains involving mobile device app marketplaces have been seized. (NDGA, CCIPS, FBI, CCIPS & Cybercrime Lab, OIA)

- In September 2013, a North Carolina man was sentenced to 84 months in prison after pleading guilty to trafficking in counterfeit airbags he purchased from China and resold through eBay. He sold an estimated 7,000 counterfeit airbags online and earned at least $1.7 million in revenue. (WDNC, ICE, DOT-OIG)

- In June 2013, a Maryland resident was sentenced to 87 months in prison for conspiracy to reproduce and distribute copyrighted commercial software programs worth over $5 million. (DMD, FBI, ICE, USPIS)

- In March 2013, a former employee of a New Jersey-based defense contractor was sentenced to 70 months in prison after a jury convicted him of exporting sensitive United States military technology to China, stealing trade secrets, and lying to federal agents. (DNJ, FBI, ICE, CBP)

The IPR Center's Global Outreach and Training Unit works with ICE-HSI field offices to develop relationships with state and local law enforcement. Examples of state and local law enforcement coordination include:

- The Los Angeles Sheriff's Department and New Hampshire State Police have detailed personnel to the IPR Center for 30-day assignments to work with ICE personnel to identify concerns and develop action plans to enhance ICE's engagement with state and local agencies.

- The IPR Center, with the support of ICE-HSI Fresno, hosted IPR training for state and local counterparts in Fresno, California. Only days after the training, ICE-HSI Fresno and several state and local law enforcement agencies, working in conjunction with the Motion Picture Association of America and the Recording Industry Association of America, conducted enforcement actions against a large-scale, pirated DVD/CD manufacturing and distribution operation. This ongoing investigation has resulted in the arrest of multiple subjects and the seizure of more than $1.3 million worth of counterfeit DVD/CDs.

- Through the state and local engagement, the IPR Center trained more than 200 state and local law enforcement officers before the 2013 Super Bowl. The training and joint enforcement efforts of federal, state, and local enforcement operations resulted in the seizure of more than $17 million in counterfeit goods and 168 counterfeit tickets.

- The IPR Center hosted a panel discussion at the International Association of Chiefs of Police 2013 Annual Conference in Philadelphia, Pennsylvania. The panel included representatives from the IPR Center, the National Crime Prevention Council, the Houston Police Department, the Texas Anti-Gang Center, the Mississippi Attorney General's Office, and the New Hampshire State Police. The panel discussed the economic and criminal impact of counterfeiting and piracy, provided information on enforcement resources for state and local entities, and demonstrated ways in which combined enforcement efforts of federal, state, and local law enforcement can combat criminal counterfeiting and piracy.

- In February 2014, the IPR Center and ICE-HSI Nashville hosted IP training for state and local law enforcement officers in Nashville, Tennessee. Following the training, ICE-HSI Nashville, CBP and several state and local law enforcement agencies coordinated with the Motion Picture Association of America to conduct enforcement actions targeting a large scale pirated DVD manufacturing and distribution operation. This investigation resulted in multiple seizures of counterfeit merchandise with an MSRP of over $300,000.

DOJ's Bureau of Justice Assistance (BJA) has provided grants to state and local authorities to increase IP enforcement and coordination with federal officials. Through FY2014, those receiving program grants have seized over $367 million worth of infringing goods and proceeds. Additionally, between from July 1, 2012 and June 30, 2014, grant recipients arrested 2,046 individuals for violation of IP laws, served 496 state and local search warrants in IP cases, and disrupted or dismantled 875 piracy/counterfeiting organizations.

In coordination with the National White Collar Crime Center, DOJ held a total of 15 training events on IP for state and local law enforcement personnel nationally in FY2013, and 31 events in FY2014.

9. Improve IPR Enforcement Efficacy by Leveraging Advanced Technology and Expertise

In September 2012, FDA unveiled a handheld Counterfeit Detection (CD3) device, developed by FDA scientists, which can be used to rapidly screen and detect suspected products and packaging such as in the case of counterfeits. Light of selected wavelengths emitted by the CD3 enables users to visualize differences between suspect products and authentic products and provides preliminary findings in the field in real-time. FDA continues to refine CD3 and expand use by field staff at the port of entry during the admissibility process. FDA also continues to use this technology in FDA laboratories and at international mail facilities. In 2013 and 2014, FDA initiated assessments of the public health value of this new technology in detecting suspect drugs of significant public health concern such as counterfeit anti-malarial drugs, in Laos and Ghana respectively. Efforts to identify counterfeit products (including falsified and substandard medicines) by optimizing and testing the device further were conducted in partnership with the U.S. Government and non-government organizations. Partners have included the London School of Hygiene and Tropical Medicine, the Skoll Global Threats Foundation, the United States Pharmacopeia, the National Institutes of Health, the Centers for Disease Control and Prevention, and the multiagency Presidents Malaria Initiative, led by the U.S. Agency for International Development.

In June 2014, USPTO organized an advanced workshop to combat counterfeit medicines in Sub-Saharan Africa, which brought together drug regulators and law enforcement officials. The workshop included a focus on new detection technologies to combat counterfeits. An official from FDA's Forensic Chemistry Center participated in the training and demonstrated the use of its Counterfeit Detection (CD3) device.

10. Improve Effectiveness of Personnel Stationed Abroad

Given the range of U.S. agencies with policy and/or enforcement personnel working on intellectual property issues in U.S. embassies abroad, coordination within embassies and between embassies and Washington is essential. U.S. embassies in 18 key countries – Brazil, Russia, India, China, Canada, Chile, Colombia, Egypt, Israel, Kuwait, Mexico, Nigeria, Peru, Saudi

Arabia, Spain, Thailand, Turkey and Ukraine – have established IP working groups that bring together all embassy personnel who play a role on IP enforcement and IP policy engagement. Each has developed a country-specific IP work plan that is updated each year. Each embassy IP team provides a progress report at midyear which, under IPEC's leadership, is subject to interagency review. IP teams from each region collaborate with the IP attachés from the BRIC countries, WTO and WIPO.

Specific activities in this space during FY2013-2014 include:

- USPTO continued to post IPR Attachés in high-priority countries including Brazil, Russia, India, China, Thailand and Mexico. Last year, USPTO hired new IP Attachés for Beijing, China; Guangzhou, China; Kuwait City, Kuwait (to cover the Middle East and North Africa) and Geneva, Switzerland. The IPR Attachés continued to play active leadership roles on enforcement-related issues in IPR Working Groups at Post. They also continued to utilize their IP expertise to improve the protection and enforcement of U.S. intellectual property rights overseas.

- USPTO facilitated interactions between IPR Attachés and U.S. stakeholders. In December of 2013, USPTO hosted its IP Attachés for one week of IP Attaché Consultations in Washington DC. During this week, the IP Attachés participated in the U.S. Chamber of Commerce, Global Intellectual Property Center's IP Attaché roundtable event with more than 150 U.S. Chamber members, other stakeholders and member of the public. The Attachés also had separate meetings with a significant number of U.S. stakeholders, five U.S. agencies, four USPTO business units and their country-specific teams at USPTO. They coordinated for the first time with a group of IP Attachés from France, the UK and Korea on IP issues in third countries. In addition, they participated in the first IP Attaché Career Roundtable. In December of 2014, USPTO organized IP attaché consultations in the United States, including one day in San Francisco, one day in San Jose and five days in Washington DC. During these consultations, the IP Attachés participated in a U.S. Chamber of Commerce, Global Intellectual Property Center's IP Attaché roundtable event with more than 150 U.S. Chamber members, other stakeholders and member of the public, as well as a Business Council for International Understanding event with more than 50 senior industry representatives. The Attachés had separate meetings with a significant number of U.S. stakeholders, six U.S. agencies, four USPTO business units and the attachés' country-specific teams at USPTO. USPTO's IP Attaché coordinated with a group of IP Attachés from Australia, Canada, EU, France, Japan, Singapore and the UK on IP issues in third countries. In addition, they participated in an IP Attaché Career Roundtable with approximately 150 USPTO employees and other participants. Intellectual property enforcement issues were a recurrent topic of discussion during the Consultations.

- The State Department, along with USPTO, held its annual IPR course at the USPTO-based Global Intellectual Property Academy (GIPA) for Foreign Service Officers that will have intellectual property as part of their portfolio at an overseas post. The course enables Foreign Service Officers to actively engage their host governments to improve intellectual

property-related legislation and enforcement and raise public awareness about the role of intellectual property rights in building the local, regional, and national economy and about the danger of counterfeits. The State Department's Office of International Intellectual Property Enforcement (IPE) also integrated a session on intellectual property rights into the economic and political tradecraft courses that are offered almost monthly at the Foreign Service Institute (FSI) and improved its website to facilitate more work on IP issues at posts. IPE has also briefed FSI classes on supporting entrepreneurship and commercial advocacy, and has briefed numerous delegations of business persons, government officials, and civil society leaders brought to the U.S. under the International Visitor Leaders Program (IVLP) on the value of protecting intellectual property.

- To increase enforcement cooperation and raise awareness about IP theft, the IPR Center conducted international outreach and training events (78 such events in FY2013, and 71 in FY2014).

- The IPR Center partnered with Europol, which, through its member countries, launched multilateral enforcement actions under *Operation in Our Sites* (IOS) Project Transatlantic. This ongoing operation targets websites and their operators illegally selling counterfeit merchandise, and involves executing coordinated seizures of domestic and foreign-based Internet domains in the United States and Europe. In FY2013, there were three joint phases of IOS Project Transatlantic, resulting in 2 arrests and the seizure of more than $325,000, counterfeit merchandise with an estimated value of $200,000, and 1,283 domain names. In FY2014, the IPR Center, HSI Attaché Hong Kong, Europol and 11 law enforcement agencies from eight countries seized 188 internet domain names as part of Project Transatlantic IV. These seizures brought the total number of domain names seized to 1,537 since the project began in November 2012.

- ICE-HSI investigates IP violations involving the illegal production, smuggling, and distribution of counterfeit merchandise and pirated works. Since the large majority of infringing and dangerous products are produced overseas and either shipped directly to the United States or via a third country, ICE-HSI Special Agents play a significant role in the enforcement of IP violations through their traditional customs authorities and expertise regarding the illicit importation and exportation of merchandise. ICE's long-term goals are to increase overseas IP investigations through collaboration with its foreign law enforcement and customs counterparts, and to work with host nations in interdicting such exports before they reach the United States. ICE-HSI Attachés establish strong working relationships with host country counterparts. These relationships strengthen ICE's capacity to conduct successful domestic, international, and multilateral operations. ICE-HSI attachés are located in 46 countries internationally; they work closely with host government counterparts and participate in IP working groups at post.

FDA's China Office has facilitated meetings and information exchange regarding counterfeit drug operations between China's Food and Drug Administration (CFDA) and FDA's Office of Criminal Investigations (OCI). In 2012, FDA and CFDA created a working group on economically-motivated adulteration (EMA). EMA— the fraudulent substitution of a substance in a product to increase value or reduce production costs for the purposes of economic gain— has played a key role in a number of recent product safety crises in China, and continues to be a key factor in understanding product safety issues in China today. The U.S.-China working group on EMA in medical products now meets on a regular basis, linking Washington-based experts with CFDA's key decision-makers. Through continued engagement in this working group, FDA aims to expand the thinking of Chinese regulators about EMA and to create a common platform to work to address the underlying incentives that prompt some perpetrators to adulterate products to make a quick profit. Additionally, FDA's China Office collaborated with OCI in May 2013. Based on these collaborations, FDA criminal investigators worked to organize a workshop for CFDA investigators on cybercrime and internet investigations. Most recently, to help frame the work our inspectors will do in China and create mechanisms for collaboration on inspections, two Implementing Arrangements were signed in late 2014— one with CFDA and another with China's General Administration of Quality Supervision, Inspection and Quarantine. FDA is able to increase the number of food and drug investigators it places in China. These inspectors will significantly enhance FDA's ability to conduct investigations in Chinese facilities that produce food and drugs for exports to the United States.

11. Coordination of International Capacity Building and Training

The U.S. Government continues to engage in training and capacity building programs to strengthen intellectual property awareness and enforcement internationally.

Department of Commerce Capacity Building and Training

The Commercial Law Development Program (CLDP) works to improve IP enforcement and protection in key countries around the globe. CLDP efforts included trainings, seminars, and meetings to address topics such as customs and border protection, innovation and the role of IP in the economy, technology transfers, judicial training, capacity building for government institutions and IP enforcement systems, copyright and trademark protection, copyright management, public awareness of IP issues, and IP enforcement in the digital sphere. Targeted countries included Georgia, Ukraine, Armenia, Kyrgyzstan, Kazakhstan, Bosnia and Herzegovina, Qatar, Iraq, Algeria, the United Arab Emirates, Tunisia, Pakistan, and Mali.

Notable CLDP training and capacity building programs since the 2013 Joint Strategic Plan include:

- Judicial Training: In June of 2013 CLDP, the Georgian Copyright Association, and the National Intellectual Property Center of Georgia held a workshop for Georgian judges and lawyers on litigation and adjudication of copyright and trademark disputes.

- Border Enforcement: In June of 2014 CLDP organized and hosted the inaugural meeting of the Central Asia Customs Working Group in Afghanistan. Training and presentations focused on interdiction of IPR-infringing goods at borders including U.S. experiences with this issue.

- Protection of IP on the Internet: In September of 2014 CLDP and the State Intellectual Property Service of Ukraine held a workshop to identify legislative and regulatory impediments to achieving necessary IP protection on the Internet in Ukraine. Participants included both public and private sector officials as well as judges, lawyers, and IP rights holders.

Copyright Management: In September of 2013 CLDP held a workshop in Armenia on capacity building and collective copyright management for Armenian government representatives, local businesses, and rights holders. Participants discussed the importance of collective copyright management and impediments to its effective enforcement in Armenia. This included highlighting the important role played by copyright management organizations on behalf of the interests of end-users and the importance of intellectual property for the economy, innovation, creativity, and culture.

U.S. Patent and Trademark Office Capacity Building and Training

Judicial Colloquia

USPTO continued its efforts to build judicial capacity by holding numerous programs both domestically and internationally.

In February 2013, the USPTO Attaché in Thailand spoke at a Seminar on Intellectual Property Infringement on the Internet and Related Laws, organized by the Thai Central Intellectual Property and International Trade Court, held in Bangkok; the Regional Attaché spoke on the subject of online piracy and counterfeiting legislation and U.S. case law. The seminar was attended by more than 200 judges, government attorneys, public prosecutors, and legal practitioners in Thailand, as part of a training and certification program in intellectual property. The USPTO Attaché and a U.S. judge participated in a Roundtable Discussion on Administrative Law and Claims against the Government, organized by the Thai Central Administrative Court, held in Bangkok. This was a judicial roundtable with members of the Thai Central Administrative Court to discuss issues involving administrative law determinations, appellate review of administrative law decisions, claims against the Government, use of expert witnesses in technically-challenging cases, and utilization of judicial mediation in dispute resolution.

In March 2013, the USPTO Attaché in Thailand helped organize a Judicial Education Seminar on Intellectual Property Protection and Enforcement for Lao Civil and Commercial Court Judges, co-organized with the USAID LUNA-Lao Project and held in Vientiane, Lao PDR. There were 60 attendees and included Lao judges from economic courts at all levels, including the Supreme Court, High Court and Vientiane Capital courts, and key regional and provincial courts, as well

as several key officials from the Ministry of Justice, Office of the Supreme People's Public Prosecutor, and the Law Committee of the National Assembly. This was a particularly important workshop, given that Lao PDR acceded to the World Trade Organization in 2013.

In March 2013, USPTO organized with the Association of Southeast Asian Nations (ASEAN) Secretariat an ASEAN-USPTO Advanced Judicial Roundtable on Intellectual Property Issues and Enforcement, held in Bangkok, Thailand. The roundtable included the participation of U.S. judges. Participants included 24 trial and appellate-level judges from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Thailand, and Vietnam. This workshop included discussions of current and cutting-edge issues in intellectual property protection and enforcement, civil litigation and criminal enforcement, and the role of the judge in fact-finding, decision-making, and appellate review of trial court decisions, as well as discussions of research and transparency in judicial decision-making, rule of law, and utilization of judicial mediation, commercial arbitration, and alternative dispute resolution in intellectual property disputes, including a range of IPR disputes involving copyright and trademark infringement, unfair competition claims, patent infringement, and trade secret protection. Discussion also focused on the civil procedure remedies and provisional measures available to litigants, including pre-trial and preliminary injunctive relief, civil search and seizure orders, civil forfeiture of assets, determinations and calculations of monetary damage awards and statutory damages, and increasing regional and international harmonization.

In March 2013, USPTO co-organized an Advanced Seminar on Criminal Prosecution and Adjudication of Intellectual Property Cases with the U.S. Embassy in Bangkok and the Office of the Thai Attorney General. The seminar was held in Bangkok, Thailand. U.S. judges participated in the seminar along with 28 regional and special public prosecutors from the Office of the Attorney General Department of Intellectual Property and International Trade. Discussions focused on current and cutting-edge issues in intellectual property protection and criminal enforcement, the role of the judge in fact-finding, decision-making, and appellate review of trial court decisions, and a range of intellectual property rights crimes, including commercial-scale copyright piracy, trademark counterfeiting, theft of trade secrets, criminal sentencing, and the seizure and forfeiture of assets involved in criminal enterprises. A program on Intellectual Property Law and Bankruptcy Law with the Thai Central Intellectual Property and International Trade Court and the Thai Central Bankruptcy Court included the participation of a U.S. judge and the participation of 120 Thai judges, attorney practitioners, and law students. This seminar included discussions of intellectual property protection and civil litigation, intellectual property issues in bankruptcy cases, the role of the judge in fact-finding, decision-making, and appellate review of trial court decisions, as well as discussions of research and transparency in judicial decision-making, rule of law, and utilization of judicial mediation, commercial arbitration, and alternative dispute resolution in intellectual property disputes.

In March 2013, USPTO organized with the Association of Southeast Asian Nations (ASEAN) Secretariat an ASEAN-USPTO Roundtable for the Asian Judiciary on Intellectual Property Rights Issues and Enforcement, held in Manila, Philippines. The roundtable included the participation of U.S. judges. Participants included 37 trial and appellate-level judges from Brunei Darussalam,

Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam.

In June 2013, USPTO co-organized with the Philippine Judicial Academy and the Intellectual Property Office of the Philippines a Roundtable Discussion on Issues and Concerns Relating to Intellectual Property Rights Enforcement, held in Manila, Philippines. The roundtable included the participation of U.S. judges. The roundtable included discussions on intellectual property enforcement in the Philippines and the United States and best practices in judicial proceedings.

In August 2013, the USPTO Attaché in Brazil participated in the 50th Anniversary Meeting of the Brazilian Intellectual Property Association, speaking on patent litigation trends in the United States to an audience of 600 Brazilian civil and administrative judges. USPTO held a workshop on internet piracy for 29 Mexican judges. The workshop was designed to provide comparative jurisprudence between U.S. and Mexican law, specifically, how each system treats illegal activity in the online context. Discussions facilitated an exchange between U.S. and Mexican judges about intellectual property enforcement issues in the digital environment. USPTO conducted a two day training seminar on copyright law for judges in Lima, Peru. Over 50 judges from six countries attended the seminar.

In September 2014, USPTO conducted a two day judicial program for Colombian judges in conjunction with the Colombian Judicial School and U.S. Embassy in Bogota, Colombia. Over 100 judges attended the program which included presentations by a broad range of Colombian and U.S. experts on topics such as challenges in prosecuting IPR cases, expert testimony, and electronic evidence. The event included participation by key IPR stakeholders such as the Attorney General's IPR office, the National Copyright Office (Dirección Nacional del Derecho de Autor or DNDA), the Patent and Trademark Office (Superintendencia de Comercio or SIC), and the private sector.

Additional International Outreach and Training Activities Led by USPTO Europe

In September 2013, USPTO hosted a visiting delegation from the Turkish National Police and conducted a program on Intellectual Property Enforcement in the U.S. The program included a focus on combating the threat of counterfeit medicines. The investigation of counterfeit trademark and copyright piracy crimes issues was addressed from both domestic and international perspectives. Presentations and discussions with U.S. Customs and Border Protection, the Department of Justice, the New York Police Department and stake-holders were provided.

In September 2014, USPTO hosted a visiting delegation from the Turkish Customs and Trade Service, and conducted a program on Intellectual Property Enforcement in the U.S. The program included a focus on IP enforcement at the border and a visit to the Port of Baltimore to observe port operations. Presentations and discussions with U.S. Customs and Border Protection, the Department of Justice, and stake-holders were provided.

India

In October and November 2013, the USPTO Attaché in India participated in a joint training program with the Motion Picture Association (India) and the Federation of Indian Chambers of Commerce and Industry (FICCI) for Multiplex/Cinema Owners and Employees. This training program had the specific focus of stopping rampant camcorder-recording of movies in the cinemas. The training was conducted in both Delhi and Ahmdabad. The Attaché also participated in a joint capacity building program for Indian Customs officers in October 2014. The program was offered in Faridibad in conjunction with National Academy of Customs Excise & Narcotics (NACEN) and the Federation of Indian Chambers of Commerce and Industry (FICCI).

In July 2014, USPTO provided training at the Global Intellectual Property Academy to police officers from Mumbai, India, with a focus on Internet piracy. The police officers worked with members of the Virginia State Police, the Department of Justice, ICE and industry.

Pakistan and Sri Lanka

In September 2014, USPTO co-organized with the IPR Center a South Asian Regional Border Enforcement Workshop for Sri Lanka and Pakistan. The program included a visit to the IPR Center and discussions on trademark and copyright law, the importance of intellectual property law, pharmaceutical investigations, law enforcement cooperation, border enforcement, risk analysis, custom recordation procedures, rights holders' perspectives and prosecuting intellectual property crime and sentencing. The program featured U.S. government speakers from the USPTO, U.S. Customs Border Protection, the U.S. Department of Justice, Immigration Customs Enforcement, Federal Bureau of Investigation, Homeland Security Investigations, Interpol, the Pharmaceutical Security Institute and the International Intellectual Property Alliance.

Afghanistan

In September 2014, USPTO conducted a capacity building program on the implementation requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for Afghanistan. The program focused on an explanation of TRIPS requirements and also included an overview of patent, trademark, copyright, trade secret, and enforcement laws. The program featured U.S. government speakers from the USPTO, U.S. Customs Border Protection and the U.S. Department of Justice.

Commonwealth of Independent States and Georgia

In September 2014, USPTO provided a capacity building program in Tbilisi, Georgia, and included Customs officers from Belarus, Moldova, Azerbaijan, Armenia and Georgia. The U.S. delegation included ICE and CBP, as well as USPTO. Industry also participated in the program, providing important information to the participants on counterfeiting. The second capacity building and training program took place in Almaty, Kazakhstan, and included Customs officers

from Kyrgyzstan, Tajikistan, Uzbekistan, and Kazakhstan. USPTO was supported by ICE and CBP. Industry also met with the attendees to share information on counterfeiting.

In September 2014, the USPTO IP Attaché in Russia participated in the State Intellectual Property Service of Ukraine's XXII International Scientific and Practical Conference "Actual Problematic Issues of IP." The attendees included legal professionals, international experts, government officials, and rights holder representatives.

Southeast Asia

In May 2013, a workshop on Effective Practices in Transnational Cooperation in the Border Enforcement of Intellectual Property Rights was held in Bangkok, Thailand, in cooperation with the ASEAN Secretariat. Customs officials from the following countries participated in the program: Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar (Burma), Thailand, Vietnam, China, and India. The discussions focused on regional trends in combatting illicit trade, the importance of public-private cooperation, challenges faced by specific industries, organized crime, and free trade zones. Attendees actively participated, both as presenters and in discussions with the larger group.

In December 2013, USPTO conducted a program titled "IP Protection & Enforcement: IP and Economic Development, Public Health, and Safety" for officials from the Republic of Korea, representing the Intellectual Property Office, the Fair Trade Commission, the Communications Commission, the Food and Drug Administration, and the Ministry of Education, Science, and Technology. The focus of the program was on enforcement, featuring USG speakers from PTO, CCIPS, ICE, CBP, FBI, and the Copyright Office and stake-holders. Discussion topics included U.S. practice concerning criminal IP prosecution, copyright piracy, pharmaceutical counterfeiting, criminal IP-infringement investigation and counterfeit automotive parts.

In May 2014, in Bangkok, Thailand, USPTO conducted – in cooperation with the Association of Southeast Nations (ASEAN) Secretariat – the second program in a series for customs officials from the following countries: Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar (Burma), Thailand, Vietnam, Philippines, Singapore and China. This workshop on Effective Practices in Transnational Cooperation in the Border Enforcement of Intellectual Property Rights focused on a variety of border enforcement topics, including *ex officio* authority for exports, imports, in-transit goods and transshipments, targeting and risk assessment and interdiction and investigation of pirated and counterfeit products. A representative from many of the delegations participated in presentations and case studies on specific issues from their region, leading to robust discussions with the larger group.

In July 2014, in Cambodia, USPTO conducted two back-to-back programs for the Judiciary and Public Prosecutors on IPR Enforcement. The first program, *ASEAN-USPTO Workshop on IP Enforcement for Judges and Public Prosecutors*, was organized in cooperation with the ASEAN Secretariat and had the participation of judges and public prosecutors from Cambodia, Laos, Vietnam, Myanmar, Brunei, Singapore Indonesia, Malaysia and Philippines. The second

program, a *Capacity Building Seminar for the Judiciary and Public Prosecutors on IPR Enforcement*, was organized for Cambodia judges and prosecutors only. Both programs focused on the training and education of public prosecutors and judges to develop greater awareness of the state of the law, best practices in judicial, prosecutorial, case management of IPR cases, and "train the trainer" workshops.

In October 2014, in the Philippines, USPTO conducted the third and fourth in a series of regional workshops on the Special Rules of Procedure for IP Cases and the Implementation of the new Manual of Criminal Investigation for IP Crimes. The workshops took place in Iloilo and Palawan, Philippines, and were co-organized with the IP Office of the Philippines (IPOPHL), the Philippines Department of Justice, and the Supreme Court of the Philippines, ICE-HSI and the USDOJ IP Law Enforcement Coordinator. Each workshop had the participation of approximately 80 local law enforcement criminal investigators and public prosecutors from neighboring islands.

Africa

USPTO has sought to improve IP enforcement in Sub-Saharan Africa through its capacity building and technical assistance programs.

In particular, in June 2014, USPTO worked with INTERPOL's Trafficking in Illicit Goods Program in organizing a joint IP enforcement training in Gaborone, Botswana for 45 police, prosecutors, and customs officials from Botswana, Malawi, Namibia, South Africa, and Zambia. Following this capacity-building program, INTERPOL coordinated enforcement actions, under *Operation Kalahari*, resulting in the seizure of over $1.2 million in counterfeit products. USPTO supported the National Intellectual Property Rights Coordination Center in holding the first-ever IP enforcement training at the US International Law Enforcement Academy in Botswana, Gaborone. Over 35 enforcement officials from Botswana, Ghana, Mauritius, Nigeria, Seychelles and Swaziland participated in the program. In addition to instruction on IP enforcement best practices, a computer lab session was also conducted so participants could learn how to access and use various online IP databases.

China

In April 2013, the acting USPTO Attaché presented at a FCS-sponsored webinar on enforcing IPR in China. These remarks were part of the coordinated outreach to American SMEs exhibiting at the April 2013 China Medical Equipment Fair in Shenzhen, China.

In September 2013, USPTO participated in an INTERPOL conference on Trafficking in Illicit Goods and Counterfeiting Capacity Building Seminar, co-hosted by Interpol and the Chinese Ministry of Public Security. In a four-day seminar (held at the Zhejiang Police College in Hangzhou, China), presenters from the City of London Police, Hong Kong Customs, Dubai Police, and the Chinese Ministry of Public Security among others provided information concerning best practices on criminal IP enforcement in their various jurisdictions. The IP Attaché in Guangzhou

provided a presentation on US and foreign understanding of the Chinese IP enforcement system with a focus on criminal enforcement.

In September 2013, in Nanjing and Qingdao, USPTO provided presentations on how to protect intellectual property in the United States, part of the PTO's outreach and capacity-building initiatives.

In December 2013, USPTO organized the Third Annual China IP conference at George Washington University Law School.

Western Hemisphere

In September 2013, USPTO conducted a two day law enforcement training program in Belo Horizonte, Brazil. Over 150 officers and supervisors were trained, the first program of its kind in the largest city in the most industrialized state in Brazil. The USPTO attaché gave a speech at law enforcement training/seminar sponsored by the "PD Academy" of the government of Chile. About 100 higher level law enforcement officers from different branches of the federal and state governments attended. Other US speakers included DOJ, DHS/ICE, and the State Department. The USPTO sponsored and spoke at two seminars for law enforcement officials to combat counterfeits at the 2016 Olympic Games. The seminars were held in Brasilia and Rio de Janeiro to transfer best practices learned during the 2014 World Cup (country wide) to the local authorities in Rio. U.S. speakers included representatives from DHS/ICE/CBP and the IPR Center. There has been direct follow up with both state and city anti-counterfeiting police units.

In October 2013, USPTO sponsored a copyright awareness and anti-counterfeiting seminar as part of the Rio Film Festival, providing information to film producers about intellectual property both in Brazil and the U.S. Another industry in which IPR in the form of patents plays a crucial role in Brazil is biotechnology. Cooperative efforts are ongoing.

In March and April 2014, the USPTO Attaché in Mexico organized a regional IP capacity building program in conjunction with DOJ and the World Customs Organization for IP officials from Mexico, Costa Rica and Panama that focused on training customs officials and IP authorities on IP risk analysis and coordination techniques at the ports in Panama. In October 2014, the Attaché also organized a regional IP capacity building program for Caribbean IP officials that focused on IP protection and enforcement throughout the region. The diverse group of participants included U.S. and Caribbean judges, IP administrators, customs officials and law enforcement authorities from eight Caribbean countries.

Notorious physical and online markets assist in the proliferation of the commercial sale of counterfeit and pirated goods that undermine U.S. IP-based industries. In order to combat the negative effects of these markets, in July 2014, the USPTO Attaché for Mexico organized the Advanced Workshop on Effective Enforcement against Notorious Markets in Mexico City. The capacity building program included over 100 participants from the public and private sectors

that discussed policy, enforcement and public awareness initiatives to combat notorious markets in the region.

North Africa and the Middle East

In November 2013 and May 2014, USPTO organized workshops for judges and prosecutors under a two-phase project held first in Casablanca, Morocco and then in Alexandria, Virginia. The workshops focused on infringement determinations, case processing, calculating damages, determining conflicts of interest, reducing corruption, investigations, collecting and handling evidence, storage and disposal of seized goods, asset forfeiture and money laundering. Each program was attended by approximately 20 prosecutors and judges.

In March 2014, USPTO hosted an Intellectual Property Rights (IPR) Conference with the participation of Government of Oman (GoO) officials and private sector stakeholders, which succeeded in clarifying roles and responsibilities for the enforcement of IPR in Oman and facilitated discussion between agencies on Oman's current enforcement regime. The conference, co-hosted by the U.S. Embassy in Muscat, Oman and the Oman American Business Council, was applauded both by the GoO representatives who heard concerns directly from rights-holders, and by private sector contacts who left significantly more confident in their understanding of the roles various GoO agencies play in IPR enforcement. The GoO participants and private sector stakeholders together generated a list of recommendations, which were delivered to the Minister of Commerce and Industry for follow-up action.

World Intellectual Property Organization

From July 22-August 2, 2013, WIPO and USPTO organized a Summer School program held at PTO's headquarters in Alexandria, Virginia. The two-week course focused on basic and advanced copyright law topics with a heavy emphasis on digital technologies and the Internet and included discussion of enforcement issues. Over 30 law students and young professionals from Europe, North and South America, and Asia participated in the course. The program's faculty was composed of experts from the USPTO, the United States Copyright Office, the Federal Communications Commission, academia, and the private sector.

International Trade Administration Capacity Building and Training

- ITA's Office of Intellectual Property Rights (OIPR) continued to coordinate the interagency STOPfakes.gov Road Shows, an outreach program to increase awareness of federal Government resources and capabilities for IPR protection. OIPR partners with U.S. Export Assistance Centers (USEACs), USPTO, FBI, the IPR Center and WIPO on the Road Shows. During FY 2013 and FY 2014, the Road Show traveled to 20 U.S. cities to raise public awareness on avoiding IPR pitfalls when exporting to foreign markets. The Road Show also provided opportunities for small and medium-sized enterprises (SMEs) to receive individualized attention from IPR and trade experts through one-on-one consultations.

- As part of the DOC's overall IPR-outreach related activities, ITA's OIPR continued its China Webinar Series. These webinars, conducted by the Office of China and Mongolia, offer U.S. SMEs the opportunity to discuss current IPR issues with attorneys practicing in China. The webinars are designed to assist companies doing business in China by addressing a wide variety of issues related intellectual property protection and enforcement. The China IPR Webinars are available for public access at http://www.stopfakes.gov/china-ipr-webinar.

Department of Homeland Security Capacity Building and Training

- In FY2014, CBP supported U.S. Government sponsored IPR capacity building and training programs, providing instructors for training sessions for foreign customs officials in Kazakhstan, Armenia, Azerbaijan, Belarus, Georgia, Moldova, Kyrgyz Republic, Uzbekistan, Tajikistan, India, Ghana, Morocco, Kuwait, Vietnam, Lao PDR, El Salvador, Hungary, Chile, and Togo.

- The IPR Center works closely with partner agencies, overseas attachés, and U.S. embassies to deliver training and support capacity building through such venues as the interagency International Law Enforcement Academy (ILEA) program; training events delivered by the U.S. Patent and Trademark Office and INTERPOL; and DoS's Bureau of International Narcotics and Law Enforcement Affairs-funded country-specific and regional programs. In FY2013, the IPR Center participated in 21 international trainings in support of these programs and 20 in FY2014.

- ICE-HSI continues to work closely with its law enforcement counterparts, particularly those who received training in IP enforcement. For example:

    - In 2013, utilizing International Narcotics and Law Enforcement Affairs (INL) Asia-Pacific Economic Cooperation funding, the IPR Center, with the assistance of ICE-HSI Manila, sponsored pharmaceutical-focused training events to support capacity-building efforts in the region. The training focused on illicit trade and the transnational organizations that compromise pharmaceutical supply chain systems. On September 18, 2013, ICE-HSI Manila and the Philippine National Bureau of Investigation (NBI), coordinated a joint intellectual property investigation and determined that the pharmaceuticals sold by GOLDEN LING in Cebu, Philippines, were counterfeit pharmaceuticals. In September 2013, Special Agents from ICE-HSI Manila conducted a search warrant operation of GOLDEN LING, in Cebu, Philippines, seizing several types of counterfeit pharmaceuticals and arresting two individuals.

    - In 2014, utilizing DoS Bureau of International Narcotics and Law Enforcement Affairs (INL) funding, the IPR Center collaborated with ICE-HSI Bangkok to assist the Thai government with IP enforcement. ICE-HSI provided two experts to support capacity building and provide training to key personnel under the Thailand National Intellectual Property Rights Centre for Enforcement (NICE) initiative managed by the Thai Ministry of Commerce. The HSI technical advisers presented a seminar for Thai

law enforcement on the topic of IPR fraud detection, enforcement and investigative techniques, and post-seizure analysis. The U.S. advisers shared best practices and advised Thai law enforcement while observing 10 IPR enforcement operations undertaken by the Department of Intellectual Property (DIP) and Economic Crime Suppression Division (ECD). During those operations, Thai officials made 65 seizures and 12 arrests. 11,118 items were seized with a MSRP of more than $2 million. The majority of the products included apparel, luxury purses and jewelry, and a small numbers of health and safety items.

- In May 2014, the IPR Center, with ICE-HSI Buenos Aires, used INL funding to sponsor an IPR enforcement training in Santiago, Chile for approximately 45 Chilean and Paraguayan customs and police officers and prosecutors. The training emphasized health and safety issues related to IP crime; the need for domestic and international cooperation; the role of international organized crime groups in IP crime; and the developing threat of IP crime on the Internet. The hosts announced the results of two enforcement operations by Chile Customs and the Policia de Investigaciones de Chile (PDI) that resulted in seizures of counterfeit merchandise, including over 26,000 pieces of counterfeit makeup kits with carcinogenic ingredients. Subsequent enforcement action by Chile Customs involved the seizure of approximately 9,900 counterfeit soccer jerseys and apparel items, many of which bore the logos of teams participating in the 2014 Brazil World Cup. The estimated MSRP of the seized goods was nearly $350 million.

- From November 1, 2014 through December 13, 2014, two ICE Special Agents were assigned to a temporary assignment at the Attaché Bangkok to serve as Technical Advisors to the Thailand National Intellectual Property Rights Centre for Enforcement (NICE). HSI agents observed, or advised on 10 IPR operations where Thai officials made sixty-five seizures and twelve criminal arrests. The seizures included a total of 11,118 individual items with a Manufacturer's Suggested Retail Price (MSRP) of $2,057,574 US Dollars (67,561,471.08 Thai Baht).

Department of State Capacity Building and Training

Government-to-Government Enforcement Training: The DOS, using foreign assistance anti-crime funds managed by the Bureau of International Narcotics and Law Enforcement Affairs (INL), in collaboration with the Economic Bureau (EB), has a long-standing program to provide capacity-building training and technical assistance to foreign law enforcement partners to combat intellectual property rights crime. The DOS enables U.S. Government law enforcement interagency training teams to prioritize assistance to developing countries in the Middle East, Latin America, Africa and the Asia Pacific that are named in the Special 301 Report as countries of concern and that face human health and safety risks associated with counterfeit medicines as well as growing digital piracy.

As an example of this government-to-government training, in 2013 Embassy Bangkok held a series of workshops for Association of Southeast Asian Nations (ASEAN) judges and prosecutors focused on judicial and prosecutorial management of IPR cases, especially those that involve transnational organized crime. The first workshop was attended by 30 judges, three from each of the ASEAN countries. The program focused on IP protection and enforcement, provided a comparison of U.S. and ASEAN enforcement and judicial systems, an overview and case study discussion on civil litigation, criminal IP prosecution and trials, and utilization of judicial mediation in dispute resolution of IPR cases. The second workshop had the participation of 40 public prosecutors and law enforcement officials from the ASEAN countries. The workshops focused on investigating and prosecuting IPR crimes in the digital environment, approaches for confronting the problem of organized crime, handling electronic evidence, shutting down infringing websites that traffic in counterfeit and piratical goods, and working with private industry to identify infringing goods. The last two days of the program incorporated a DOJ guided IP Criminal Enforcement Network (IPCEN) training that covered advanced concepts including discussions on consumer safety, money laundering, illegal downloading, criminal conspiracies and organized crime.

U.S. Embassies around the world continued to make IPR an integral part of their bilateral policy dialogues with host governments. DOS's diplomatic engagement on IPR is "whole-of-government." Economic Counselors, together with IP attachés when jointly posted, typically lead the engagement with support from other agencies and, when appropriate, with support from Ambassadors and Deputy Chiefs of Mission (DCMs). For example, our Embassies in Turkey, Spain and Ukraine work productively with their host governments on pharmaceutical market access issues, Internet piracy and counterfeit pharmaceuticals.

U.S. Food and Drug Administration Capacity Building and Training

FDA-OCI works closely with our international partners through membership in the Permanent Forum on International Pharmaceutical Crime (PFIPC) as well as the assignment of an international liaison officer to Interpol's Medical Products Counterfeiting and Pharmaceutical Crime Unit (MPCPCU). In 2013, OCI conducted cybercrime training programs for the enforcement arms of the Australian Therapeutic Goods Administration, the China Food and Drug Administration and the European Working Group of Enforcement Officers.

Department of Justice Capacity Building and Training

Issues that arise when intellectual property rights and antitrust law intersect were an important competition advocacy and enforcement priority at the Antitrust Division of the Department of Justice in FYs 2013 and 2014.

The Department of Justice has actively engaged with its foreign counterparts to promote application of competition laws to intellectual property rights that is based on analysis of competitive effects, not domestic or industrial policy goals. For example, in a speech on "International Antitrust Enforcement: Program Made; Work To Be Done" (September 12, 2014) before the 41st Annual Conference on International Antitrust Law and Policy, the Antitrust

Division (Assistant Attorney General Bill Baer) explained that the sound application of antitrust laws is particularly important in matters involving intellectual property rights. This is because economic growth can be hampered when antitrust laws are improperly applied in such cases. The speech counseled that competition enforcers be particularly careful about imposing price controls or prohibiting so-called "excessive pricing": "Using antitrust enforcement to reduce the price firms pay to license technology owned and developed by others is short-sighted. Any short-term gains derived from imposing what are effectively price controls will diminish incentives of existing and potential licensors to compete and innovate over the long term, depriving jurisdictions of the benefits of an innovation-based economy." This and other DOJ speeches are available at http://justice.gov/atr/speeches-0.

The Department of Justice continued its work with international organizations on issues involving the intersection of antitrust and IP. Jointly with the FTC and PTO, the Division engaged with the World Intellectual Property Organization's Intellectual Property and Competition Policy Division on several projects, including surveys directed toward information sharing and promoting procompetitive intellectual property licensing practices in Member States.

With respect to international IP criminal enforcement efforts, DOJ has long recognized that intellectual property crime – including offenses involving copyrights, trademarks and trade secrets, among others – not only has a significant international component but in many cases also has a substantial overlap with other economic crimes, including those related to cyber offenses, money laundering and tax evasion, and smuggling. Because the vast majority of intellectual property and other computer crimes originate in other countries, the Department has made its efforts to strengthen international law enforcement relationships a top priority.

DOJ has collaborated with other U.S. agencies and foreign law enforcement counterparts to address international intellectual property crime through a combination of joint criminal enforcement operations, case referrals for foreign investigations and prosecutions, training and technical assistance programs for foreign law enforcement, judiciary, and legislators, and engagement in bilateral and multi-lateral working groups that address trademark counterfeiting and copyright piracy.

DOJ's front line in addressing international IP crime is the IP Law Enforcement Coordinator program (IPLEC), which places experienced prosecutors in high-impact regions to enhance individual countries' capacity to investigate and prosecute IP crimes and to develop regional networks to more effectively deter and detect IP crimes. The IPLECs, currently placed in Bangkok, Thailand and Bucharest, Romania accomplish these goals by developing contacts in the region with appropriate IP law enforcement officials and assisting in the regional and bilateral training of prosecutors and investigators in the area of IP crimes. Additionally, the IPLECs foster improved communication between and among the law enforcement officials in their respective regions to increase the disruption of the organized criminal groups that specialize in the transshipment of counterfeit goods or the use of the internet to sell pirated works. Finally, the IPLECs provide assistance to increase the accessibility of courts for victims of

IP crime, while also developing the courts' familiarity with high tech crimes and evidentiary issues.

U.S. Copyright Office Capacity Building and Training

The U.S. Copyright Office has continued to provide outreach and education on copyright issues for members of the public and foreign visitors. In FY2013 and FY2014, Copyright Office staff participated in a number of conferences and meetings in the United States and abroad to discuss current copyright issues and inform the public about the activities of the Copyright Office.

In FY2013, one highlight of the Office's outreach work was its collaboration with the U.S. Patent and Trademark Office (USPTO) and the World Intellectual Property Organization (WIPO) on the two-week "WIPO Copyright Summer School" held at the USPTO Global IP Academy and at the Copyright Office in late July-early August 2013 (also discussed above). The third day of the Summer School was hosted by the Copyright Office and covered registration practice, fair use and fair dealing, limitations and exceptions to copyright, and the ongoing congressional copyright review process.

In FY2014, the Copyright Office continued to host smaller groups of international visitors at its offices to discuss and exchange information on the U.S. copyright system and important international copyright issues, including visitors from Botswana, China, Georgia, Germany, Japan, Korea, Mexico, Philippines, Singapore, Thailand, and the United Arab Emirates. In May 2014, the Copyright Office hosted its biannual joint international training program for foreign officials with WIPO. The week-long program was entitled "International Symposium on Contemporary Issues in Collective Copyright Management for Developing Countries and Countries with Economies in Transition." The program brought together senior-level copyright officials and collective management specialists from fourteen countries to hear from more than fifty government, private industry, and civil society experts on a range of emerging issues in copyright law and policy with regard to collective management, including efficient licensing mechanisms in the global digital environment, mass digitization, enforcement challenges, and the importance of transparency, accountability and good governance.

12. Consider Alternative Forums for Enforcement of Rights

IP right holders and others have expressed frustration that the current Federal court litigation framework for pursuing civil enforcement of the intellectual property rights is time consuming and relatively expensive, and have expressed an interest in exploring other cost-effective means of pursuing infringement claims that have relatively small value.

U.S. Copyright Office

On September 30, 2013, the Copyright Office issued a report on "Copyright Small Claims," detailing its findings following a two-year study of copyright small claims, which the Office had conducted in response to a request from the House Judiciary Committee. To aid in its review of the issues, the Copyright Office published three notices of inquiry calling for written comments and held four days of public roundtable discussions (in which USPTO participated). In addition to the information received through public comment and the roundtable discussions, the Copyright Office analyzed a number of issues including the possibility of leveraging the approach used for small claims courts within state and local judicial systems.

The Copyright Office's report on Copyright Small Claims is available at http://www.copyright.gov/docs/smallclaims/usco-smallcopyrightclaims.pdf. The report documents the significant costs and other challenges of litigating copyright claims of a relatively low economic value and recommends establishing a voluntary, streamlined system of adjudication as an alternative to federal court. The report highlights the fact that the cost of Federal court litigation to pursue a small copyright claim ($350,000 for a case with less than $1 million at stake) may sometimes be disproportionate to what certain individuals can invest in a lawsuit, and to what a copyright claimant often can recover in a relatively modest infringement matter. Thus, for some copyright owners (particularly individual authors), the Copyright Office concluded that, due to considerations of relative cost and complexity, Federal court litigation may not always provide the optimal means for the enforcement of rights in small claims scenarios.

To address this disparity and improve the availability of enforcement mechanisms for small copyright claims, the Copyright Office report recommends that the Congress create a centralized small claims tribunal within the Copyright Office that would administer proceedings through online and teleconferencing facilities without the requirement of personal appearances. Its focus would be on infringement cases valued at no more than $30,000 in damages. Those notified of a claim against them would need to consent before the matter could proceed in the alternative forum, and would be able to present relevant defenses, such as fair use. The tribunal's decisions would be binding only with respect to the parties and claims at issue and would have no precedential effect. The Copyright Office's small-claims proposal was one of the topics discussed at a congressional hearing on "Copyright Remedies" before the House Subcommittee on the Courts, Intellectual Property, and the Internet on July 24, 2014 (the Subcommittee's report on the hearing is No. 113-107).

USPTO

USPTO has continued its work exploring patent small claims in the United States. In a Federal Register Notice issued on December 18, 2012, the USPTO solicited comments as to whether the United States should develop a small-claims proceeding for patent enforcement. Among the information solicited was whether there is a need for or interest in a small-claims proceeding and, if there is such a need or interest, what should be the features of the proceeding. USPTO

received comments from over twenty public comments. The commenters expressed a variety of positions, and their comments did not reveal a clear position regarding a need or desire for a patent small-claims proceeding or what should be the features of such a proceeding. The current discussions in the Congress relating to patent reform involve related issues and concepts and this discussion may help to identify whether any further consideration of a patent small claims proceeding is warranted.

Enforcing Our Rights Abroad

13. Enhance Foreign Law Enforcement Cooperation

A key priority in the Administration's Joint Strategic Plan is to strengthen intellectual property protection through partnerships with foreign law enforcement. Innovative ideas can travel around the globe in an instant. In a global economy, to protect intellectual property once it is misappropriated, the United States needs strong partnerships with foreign counterparts to collaborate on investigations, share investigative leads, and seize infringing products as they cross international borders.

U.S. law enforcement's relationships with foreign counterparts paid significant dividends in 2013. The United States participated in INTERPOL-led *Operation Pangea VI*, which was organized to target the advertisement, sale, and supply of counterfeit and illicit medicines and medical devices that threaten worldwide public health and safety. Unregulated websites that provide counterfeit pharmaceuticals are a growing global phenomenon in the area of IP theft.

Operation Pangea VI was conducted from June 18–25, 2013, and was supported in Lyon, France, by the ICE-led IPR Center. Internationally, *Operation Pangeo VI* included participation from 99 countries resulting in 213 arrests, 13,763 domain names taken down, and inspection of 534,562 packages, of which 41,954 were seized containing 10,192,274 pills with an estimated value of more than $36 million. The U.S. portion of the operation, managed by the IPR Center, resulted in 700 seizures and 626 detentions, including seizure of more than 1.3 million units (tablets, capsules, inhalers, vials, and bags of powder) with a value of more than $11 million. ICE-HSI field offices attempted seven controlled deliveries. Five arrests were made based on controlled deliveries resulting from enforcement operations at international mail facilities in Chicago, New York, and Los Angeles.

In 2014, CBP, ICE-HSI, and FDA participated in *Operation Pangea VII*, led by INTERPOL, which is the largest global Internet-based operation focusing on illicit websites selling fake or counterfeit medicines. *Operation Pangea* engages police, customs and national regulatory authorities to target websites supplying counterfeit and illicit medicines, and to increase awareness of the serious health risks connected to purchasing medicines online. As part of this operation, 113 countries participated. These international efforts resulted in 434 arrests worldwide; the seizure of 9.6 million medicines valued at more than $32 million; the removal of 22,807 advertisements for illicit pharmaceuticals via social media platforms; the shutdown of 11,863

websites; and the inspection of approximately 618,191 packages by customs and regulatory authorities (35,206 of which were seized).

In addition, the IPR Center through ICE-HSI also partnered with Europol, which leveraged its member countries to launch multilateral enforcement actions under IOS *Project TransAtlantic*. This operation targeted websites and their operators illegally selling counterfeit merchandise and executed coordinated seizures of domestic and foreign-based Internet domains in the United States and Europe. In 2013, there were three joint phases of IOS *Project TransAtlantic*, resulting in 2 arrests and the seizure of more than $325,000, counterfeit merchandise with an estimated value of $200,000, and 1,283 domain names. In FY2014, as part of *Project TransAtlantic IV*, the IPR Center, the ICE-HSI Attaché Hong Kong, Europol and 11 law enforcement agencies from eight countries seized 188 domain names.

Cooperation with our Asian law enforcement counterparts to address infringement is critical, and U.S. law enforcement marked a significant milestone in 2013: U.S. Customs and Border Protection and China Customs performed the first ever joint IPR enforcement operation between the two agencies. The month-long operation resulted in 1,735 seized shipments, which removed more than 243,000 counterfeit consumer electronic products from entering commerce. This is an important advancement in U.S.-China law enforcement cooperation.

DOJ has continued to engage with China through the bilateral IP Criminal Enforcement Working Group (IPCEWG) of the Joint Liaison Group (JLG). The JLG is designed to strengthen law enforcement cooperation between the United States and China across a range of issues, including intellectual property. In November 2013 and December 2014, DOJ attorneys—as well as DOS, FBI, and DHS representatives—participated in the JLG Annual Meetings that were held, respectively, in Washington, D.C. and Beijing.

FDA's Office of Criminal Investigations (FDA-OCI) assigned its first special agent overseas through assignment at Europol, The Hague, Netherlands. This assignment will help FDA protect the public health of the United States by enabling the real-time coordination with European law enforcement on criminal investigations involving the distribution and manufacture of counterfeit and adulterated pharmaceuticals, medical devices, cosmetics, and tobacco and food products. Further, FDA-OCI's liaison officer to Europol will help facilitate requests for information from our European partners as well as coordinate our efforts at combating transnational organized criminal networks that place profits over public health. In early 2014, FDA-OCI sent an investigator on a temporary duty to India and the agency is continuing to explore the possibilities of deploying additional investigators in other strategic locations around the globe such as China, Singapore, Canada and Panama.

FDA-OCI also works closely with our international partners through membership in the Permanent Forum on International Pharmaceutical Crime (pfipc.org) as well as the assignment of an international liaison officer to Interpol's Medical Products Counterfeiting and Pharmaceutical Crime Unit (MPCPCU). In December 2014, FDA-OCI entered into a Letter of

Intent with the French National Gendarmerie on combatting counterfeit drugs which was formally presented at the French Embassy during an event on December 2, 2014.

Other important developments in enhancing cooperation with foreign law enforcement include:

- CBP continues to support U.S. Government sponsored IPR training sessions, providing instructors for recent sessions for foreign customs officials in El Salvador, Peru, Thailand and Kyrgyzstan;

- In FY2013, the IPR Center, through *Operation Joint Venture*, was able to reach 16,519 people by conducting 346 outreach and training events; this training included 2,931 foreign government and industry personnel. In FY2014, the IPR Center, through *Operation Joint Venture*, was able to reach 19,824 people by conducting 290 outreach and training events; this training included approximately 3,839 foreign government and industry personnel;

- On December 2, 2013, the IPR Center, ICE, and 10 foreign law enforcement agencies criminally seized or administratively shut down 706 domain names that had been set up to trick potential customers into buying counterfeit products during the busy holiday shopping season;

- In November 2012, and again in June 2013, law enforcement agencies from Belgium, Denmark, France, Romania, and the United Kingdom joined forces with HSI to take down 182 domain names selling counterfeit goods;

- In FY2013, ICE at the IPR Center as well as ICE-HSI Attaché Toronto and the Toronto Police Service (TPS) coordinated an operation focusing on counterfeit health and safety products in Canada, with emphasis on pharmaceuticals, automotive parts, and electronics. IPR Center assistance was provided under the project Partners against Counterfeiting Everywhere (PACE). PACE is a coordinated ICE-HSI and TPS investigation targeting individuals and entities involved in the illegal importation of counterfeit health and safety products in Canada;

- In FY2013, the IPR Center provided IPR training in Mexico City for participants from Mexico and other Central American countries. A separate joint ICE–Mexican SAT pharmaceutical training was held in August 2013. Mexico also participated in enforcement efforts as part of *Operation Team Player*;

- During FY2014, as part of a coordinated investigation, China's Ministry of Public Security and the Guangdong/Guangzhou Economic Crime Investigation Department, conducted enforcement operations in Guangzhou, China targeting a criminal organization involved in the manufacture, sales and smuggling of counterfeit airbags to the United States, Thailand, and Russia. This enforcement action resulted in multiple arrests in the United States and China, multiple seizures, and the disruption of a criminal organization. These airbags were

tested by the auto manufacturers/brand holders, who found the items were substandard and posed a significant public health and safety risk;

- In late 2014, the Department of State provided funding to ICE-HSI Bangkok for two temporary duty (TDY) Special Agents with IPR backgrounds to work at the Thai Ministry of Commerce for 30-45 days focusing on best practices, intelligence driven investigations, and laws and regulations that the United States uses to enforce its IPR laws. ICE-HSI TDY agents observed or provided information regarding ten IP operations undertaken by the Department of Intellectual Property and Economics Crime Suppression Division. During those operations, Thai officials made 65 seizures and 12 criminal arrests. The seizures included a total of 11,118 items with a MSRP of more than $2 million;

- Since 2012, ICE-HSI Brasilia has partnered with the Brazilian Federal Highway Police, Brazilian Federal Police, Brazilian Customs, Brazil's Food and Drug Administration, and Brazil's National Forum against Piracy to combat criminal organizations exploiting pathways in the tri-border area and seaports to facilitate illegal smuggling and counterfeiting activities. This initiative, known as *Operation Eye Patch/OTEFIS*, combines collaborative outreach and training with actual operational activities throughout Brazil each year. ICE-HSI Brasilia, Brazilian Customs, and Brazilian Federal Police have been sharing information which, after data analysis and targeted inspections, has resulted in several interdictions of illegally imported counterfeit goods at several major sea ports in Brazil. As a result of these efforts, Brazilian authorities, in coordination with ICE-HSI Brasilia, have seized over $14 million in counterfeit toys, clothes, electronics and other illegally imported merchandise; and

- In April and May 2014, ICE-HSI Rome, CBP and Italian Customs participated in an enforcement operation targeting IPR merchandise. CBP conducted approximately 320 seizures of counterfeit merchandise valued at more than $14.4 million. Also during this operation, Italian customs officials detained approximately 63,000 bottles of counterfeit designer fragrances (valued at more than $3 million) that were destined for the United States.

14. Strengthen Intellectual Property Enforcement through International Organizations

The U.S. Government continues to improve enforcement of intellectual property through a number of international organizations. A summary of key accomplishments include:

- CBP and DOS continue to support the further development and deployment of the World Customs Organization's (WCO) Cargo Targeting System (CTS) which was successfully piloted in 2013. The CTS has the potential to enhance targeting to assist in identifying counterfeit products. It allows foreign customs administrations to receive electronic cargo manifest data to identify high-risk shipments at import, export and transshipment across the full

range of customs threats, including trade in counterfeit products. The CTS has potential to enhance cooperation between the United States and foreign partners through targeting efforts to identify and interdict counterfeit product. Attachés at the WCO continue to train and support customs administrations in CTS operation.

- In 2013, as part of CBP's participation in APEC, CBP led an enforcement operation targeting consumer electronics in the postal and express carrier environments. Participating APEC economies were Chinese, Taipei, Hong Kong, Japan, South Korea, Malaysia, Mexico, New Zealand, Singapore, Thailand, Vietnam and the United States. The operation resulted in 656 seizures totaling more than 1.4 million articles.

- In September 2013, CBP and French Customs' Fake Medicines Observatory jointly seized approximately 100,000 counterfeit and prohibited pharmaceuticals as part of *Operation Pharmacy*. This joint action fell on the heels of *Operation Core Systems*, CBP's coordinated effort with French Customs that resulted in seizure of 480 shipments of counterfeit electronic components.

- The IPR Center through ICE-HSI has continued to expand its partnerships with international organizations, and in FY2013 and FY2014 partnered with Europol on an operation known as *Project Transatlantic*, a subset of *Operation in Our Sites*. The IPR Center also continued to collaborate with INTERPOL on *Operation Pangea*: an annual global enforcement effort aimed at disrupting the organized crime networks behind the illicit online sale of counterfeit or adulterated drugs. The IPR Center participates in the following WCO groups:

    - The Enforcement Committee: ICE-HSI's Executive Associate Director chaired the Enforcement Committee in March 2014. The Enforcement Committee focuses on commercial fraud including IPR crimes, trade transparency, cybercrimes, smuggling, and transnational organized crime.

    - The Working Group on Revenue Compliance and Fraud (WGRCF): This working group has the mandate to address revenue risks ranging from traditional commercial fraud activities and revenue leakage through smuggling of highly taxed goods and trade based money laundering. This working group was formerly known as the Commercial Fraud Working Group.

    - The Counterfeiting and Piracy Group: Operates as a subset of the Permanent Technical Committee. Its role is to enhance cooperation between customs administrations and governmental and non-governmental (private sector) organizations in the field of trade facilitation.

- The IPR Center worked with the International Trademark Association (INTA) to advance global intellectual property enforcement efforts. In FY2013, the IPR Center provided presentations on the foundations of IP enforcement and transshipment of counterfeit goods at INTA's Anti-Counterfeiting Conference in Istanbul, Turkey. Additionally, the IPR

Center presented at INTA's 2013 Winter Leadership Board meeting and 2013 Annual Conference. In FY2014, the IPR Center provided presentations regarding the foundations of IP enforcement and transshipment of counterfeit goods at the INTA Anti-Counterfeiting Conference in Hong Kong.

- The IPR Center coordinated with the International Anti-Counterfeiting Coalition (IACC) to provide training to state and local law enforcement as well as foreign law enforcement. This training brought together brand holders and investigators to address the counterfeiting issue and to provide strategies for strengthening IP enforcement efforts. In FY2013, the IPR Center participated in 10 IACC trainings. In FY2014, the IPR Center participated in 10 state and local IACC trainings and one international training event in Willemstad, Curacao. In addition, in May 2014, the IPR Center provided presentations and speakers for the IACC Spring Conference in Hong Kong.

- In 2013 and 2014, the Department of State continued its efforts to promote respect for IPR through international organizations and in other multilateral forums. Where relevant, DOS representatives requested that U.S. international development and trade agency partners actively educate their program recipients about the importance of intellectual property to support business development, entrepreneurship, and innovation. These Agencies' efforts contributed to an increased focus on the role of intellectual property and development by the U.N. International Trade Centre (UNITC) and the U.N. Conference on Trade and Development (UNCTAD). For example, UNITC's Ethical Fashion Initiative matches artisans and micro-entrepreneurs in developing countries with representatives at high-end fashion brands that benefit from trademark protection and sell at a premium. This allows those artisans and micro-entrepreneurs to earn a higher wage.

- DOS also contributed to U.S. Government efforts to advance intellectual property goals in APEC, ASEAN, TPP and TTIP negotiations and the G-7. In APEC and ASEAN, DOS used government-to-government law enforcement training funds to contribute to efforts to improve intellectual property systems in the region, to foster economic growth, and to encourage harmonization of IP systems. This training included a five-day APEC training workshop in Mexico on counterfeit pharmaceuticals in August 2013 and a report on the trade secrets regimes of APEC economies completed in August 2014.

World Intellectual Property Organization

The USPTO served as the US Representative at the Eighth and Ninth Sessions of the World Intellectual Property Organization's (WIPO) Advisory Committee on Enforcement (ACE), the principal multilateral forum on international intellectual property enforcement issues. The US delegation worked proactively with other member countries to ensure that future work of the ACE would reflect the enforcement mandate of the committee. Through successful US engagement, the Secretariat adopted the theme of "preventive actions, measures or successful experiences to complement ongoing enforcement measures with a view to reducing the size of the market for pirated or counterfeited goods." At the Ninth Session, the US advanced the issue

of alternative dispute resolution of intellectual property cases, by sharing its national experience in this area. In addition, the US participated in a WIPO/ACE exhibition on national IPR initiatives, and showcased the public awareness campaigns developed by the Department of Justice's Bureau of Justice Assistance and the National Crime Prevention Council.

On June 26, 2012, the United States signed the Audiovisual Performances Treaty (otherwise known as the "Beijing Treaty"), which is the first substantive multilateral copyright treaty since the 1996 WIPO Copyright Treaty and WIPO Performances and Phonograms Treaty. Once the Beijing Treaty enters into force, it will fill a gap in the international copyright system and make it easier for American actors to be compensated for their performances. The United States also signed the Treaty for the Visually Impaired (also known as the Marrakesh Treaty) on October 1, 2013, in Geneva. This treaty will facilitate access to published works for persons who are blind, visually impaired, or otherwise print disabled.

Since signing the Audiovisual Performances Treaty and the Treaty for the Visually Impaired, the Administration has worked to advance ratification of both treaties. Such efforts during 2013 and 2014 included preparation of implementation packages for both the Beijing and Marrakesh Treaties, Congressional briefings, and technical assistance.

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

The U.S. Government uses a range of trade policy tools to promote strong intellectual property rights protection and enforcement, including the annual Special 301 review of intellectual property protection and certain market access practices in foreign countries, trade agreement negotiation, monitoring and enforcement of those agreements, participation in work at the World Trade Organization Council on Trade-Related Intellectual Property Rights, and high-level engagement in multilateral and bilateral meetings.

Given the international competitiveness of U.S. innovative and creative industries, the United States considers strong and effective protection and enforcement of IP rights as critical to U.S. economic growth and American jobs. Nearly 40 million American jobs are reported to be directly or indirectly attributable to "IP-intensive" industries. These jobs pay higher wages to their workers, and these industries drive approximately 60 percent of U.S. merchandise exports and a large share of services exports. Innovation and creativity are key export strengths for the United States. To help ensure that American innovators and creators face a level playing field around the world, the U.S. Government uses all the tools at its disposal to promote effective intellectual property rights (IPR) protection and enforcement by its trading partners.

During 2013 and 2014, and in addition to the Administration's work on the Trans-Pacific Partnership (TPP) and the Transatlantic Trade and Investment Partnership (T-TIP), trade-related initiatives that advanced IPR protection included the following.

Ongoing Trade Agreement Implementation and Enforcement

In 2013 and 2014, the United States continued to engage with FTA partners (e.g., Korea, Colombia, and Panama) to ensure that FTA obligations, including those related to IPR, 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 of intellectual property by our trading partners. USTR actively employs the Special 301 process to identify and address key IPR challenges for American businesses engaged in trade. The Special 301 process also has been used to document and encourage continued progress in countries that undertook important legislative and enforcement reforms following engagement under Special 301. 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. In May 2013 and April 2014, USTR issued Special 301 reports, fulfilling USTR's Congressional mandate to report on intellectual property protection and enforcement laws, policies and practices of U.S. trading partners.

In the Special 301 report released in May 2013, USTR placed Barbados, Bulgaria, and Trinidad & Tobago on the Special 301 Watch List, lowered Canada and Israel from the Special 301 Priority Watch List to the Watch List, and removed Brunei Darussalam from the Watch List. The 2013 Special 301 Report praised positive steps by eleven countries to address issues cited in previous Special 301 Reports. In addition to listing the trading partners with inadequate or ineffective protection of intellectual property rights, the Special 301 Report also identified trends in global intellectual property protection and threats posed by new and emerging methods of piracy and counterfeiting.

Further, in the May 2013 report, USTR designated Ukraine as a Priority Foreign Country (PFC), the first PFC designation in seven years. This identification resulted in the initiation of an investigation under section 301 of the Trade Act of 1974. The investigation addressed specific problems in Ukraine's IPR regime with respect to government use of pirated software, piracy over the Internet, and non-transparent and unfair administration and operation of copyright collecting societies. In September 2013, USTR held a public hearing on the issues under investigation. Over the course of the investigation, which concluded in March 2014, USTR determined that while IPR problems persisted, no adverse actions would be taken against Ukraine because of the political situation in Ukraine at that time. See Notice of Determination in Section 301 Investigation of Ukraine, 79 FR 14326 (March 13, 2014). The 2014 Special 301 Report reiterated the severe deficiencies in Ukraine's IPR protection and enforcement.

In its Special 301 report issued on April 30, 2014, USTR also highlighted growing concerns with respect to the environment for IPR protection and enforcement in India and other markets. USTR listed India on the Priority Watch List, and, in addition, called for renewed and intensive

engagement with the Government of India as elections concluded and new counterparts took office. In light of the election in India, USTR decided to look to an Out-of-Cycle Review (OCR) focused on India in the fall of 2014 to evaluate ongoing engagement on issues of concern with respect to India's environment for intellectual property protection and enforcement. USTR also expressed ongoing, serious concerns about the protection and enforcement of trade secrets with respect to China, and emerging concerns in other markets. USTR removed Italy and the Philippines from the Watch List in recognition of their IPR-related accomplishments, and as an indication of support for their commitment to continued progress. The Report highlighted music licensing and cable broadcasting concerns throughout the Caribbean that adversely affect U.S. copyright holders, including creators of original pay television programming, songwriters, and other independent artists, and USTR announced that it would conduct Out-of-Cycle reviews to promote engagement and progress on IPR challenges identified in the 2014 reviews of India, Kuwait, Paraguay and Spain.

Notorious Markets List

The publication of the Notorious Markets List by USTR helps motivate appropriate action on the part of owners and operators in the private sector as well as governments to reduce piracy and counterfeiting. The Notorious Markets review was initiated September 20, 2013 through the publication in the Federal Register of a request for comments from the public. On February 2014, USTR issued a Special 301 Out-of-Cycle Review of Notorious Markets to shine a spotlight on marketplaces that facilitate and sustain global piracy and counterfeiting. Several websites identified in the Notorious Markets List in the past (e.g., Baidu, Taobao and Sogou) have begun to work with rights holders to address counterfeiting and piracy. Several markets have also ceased operations, such as Gougou, btjunkie, Consolesource, and modchip.ca.

U.S.-China Joint Commission on Commerce and Trade and the U.S.-China Strategic and Economic Dialogue

The United States also addresses IPR issues in China through results-oriented bilateral dialogues such as the U.S.-China Joint Commission on Commerce and Trade (JCCT) and the Strategic and Economic Dialogue (S&ED), as well as by pursuing concrete IPR outcomes through high-level engagement. Areas of progress include:

- pushing back on "indigenous innovation" policies to ensure that foreign-owned IP rights are protected in the same manner as Chinese IP rights and that companies are free to base technology transfer decisions on business and market considerations;

- commitments to prioritize enforcement against trade secrets misappropriation, and to undertake reviews of existing laws and regulations protecting trade secrets;

- commitments to combat the illegal manufacture, distribution, and export of counterfeit and substandard active pharmaceutical ingredients (APIs) and APIs used for counterfeit and substandard products;

- revision of a patent examination standard that was being used to invalidate existing pharmaceutical patents and deny applications for new ones;

- ensuring the Chinese government and SOEs use only licensed software;

- clarifying rules to improve enforcement against online piracy; and

- ensuring that high-level Chinese government attention is given to intellectual property enforcement issues.

During the 25th meeting of the JCCT in Chicago, Illinois (December 16-18, 2014), China and the U.S. reached agreement on a number of IP-related issues, including, in the enforcement area, strengthening Sino-U.S. law enforcement cooperation simultaneously through both the JCCT and the Joint Liaison Group (JLG); promoting sustained judicial exchange and cooperation between U.S. and Chinese jurists; and increasing on-line enforcement against trademark counterfeiting and copyright piracy. The United States secured China's commitments to take significant steps on IP and innovation, as China recognized the need to strengthen procedures and remedies against the misappropriation of trade secrets; to enforce requirements on state-owned enterprises to purchase legitimate software; and to take effective legislative and other measures to fight counterfeiting and piracy, particularly on the Internet. China also confirmed that it would provide patent protection for pharmaceutical inventions in line with international norms.

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

The multilateral structure of the WTO provides opportunities for USTR to lead engagement with trading partners on IPR issues, including through accession negotiations for prospective Members, the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council), and the Dispute Settlement Body.

The United States, for example, along with the European Union, Singapore and Switzerland, lead a TRIPS Council initiative on the role of intellectual property in attracting investment in innovation, including in R&D-intensive small-and-medium-sized enterprises. As part of this initiative, a range of diverse WTO Members exchanged national experiences and best practices regarding their efforts to promote enabling environments for innovation financing. The United States shared information on the role of investors, including banks, stock markets, venture capital, and angel investors, in the innovation life cycle, including early research and development as well as later-stage manufacturing and commercialization. This analysis showed how IP protection can mitigate the financial risk associated with innovation, and can enhance

the reward profile of R&D investment, including economic as well as social benefits. The United States and other WTO delegations shared their extensive research demonstrating the catalytic significance of IP incentivizing innovation through attracting financing.

In 2014, the United States also co-sponsored several related agenda items in the TRIPS Council. In June 2014, the United States and Taiwan co-sponsored a TRIPS Council agenda item on IPR and innovation focused on innovation incubators. This discussion in the TRIPS Council stressed the importance of incubators, including their work with respect to IPR, as part of the enabling environment for innovation. WTO countries exchanged best practices and success stories regarding their national experiences with facilities and groups such as incubators and accelerators, which provide critical support to start-ups and other new innovative entities to assist in the early stages of development.

In February 2014, the United States sponsored a TRIPS Council agenda item on university technology partnerships. Discussions focused on the extent to which universities around the world are engines for innovation and technology transfer. Numerous WTO Members underscored the critical role that IPR plays in helping to support the types of university technology partnerships that translate basic research into goods and services that benefit consumers and society at large.

World Trade Organization Accession

Those Governments, which are 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 intellectual property regimes, as well as to advance trade and enhance the investment climate for innovative and creative industries. With strong support from the United States, Yemen became the WTO's 160th Member in December 2013. USTR also worked on IPR matters to advance WTO accession negotiations with Afghanistan, Kazakhstan, and the Bahamas (among others).

Multilateral Organizations

Although the WTO is the principal forum for addressing trade-related aspects of intellectual property, the United States advances these issues in other multilateral fora, including the Organization for Economic Cooperation and Development (OECD), World Intellectual Property Organization (WIPO), Asia-Pacific Economic Cooperation forum (APEC) and various bodies of the United Nations.

Additional Areas of IPR Engagement through Trade Policy

The United States has raised concerns surrounding the environment for innovation in India over the past several years. Following the 2014 Special 301 Report, USTR conducted an Out-of-Cycle Review to evaluate the level of meaningful and constructive bilateral engagement on IP between the United States and India, particularly following national elections in India. USTR has

worked closely with the IPR interagency to promote robust engagement on IP with India and has intensified its engagement on IPR issues identified as priorities by U.S. stakeholders.

Furthermore, USTR has engaged closely with the Philippines and Taiwan as they took steps to bolster IP protection. The Philippines enacted long-awaited amendments to its Intellectual Property Code, including strong enforcement provisions, and took significant actions to address piracy over the Internet. USTR also coordinated with Taiwan on its strengthening of its Trade Secret Act. The new act includes increased deterrent penalties and enhanced penalties to deter cross-border theft. Finally, USTR worked with Israel to advance implementation of the commitments Israel made to update its pharmaceutical laws in a Memorandum of Understanding in 2010.

16. Combat Foreign-Based and Foreign-Controlled Websites That Infringe American Intellectual Property Rights

Online infringement takes many forms, including foreign criminal organizations that establish websites advertising infringing goods and pirated works to U.S. customers. Combating such infringement poses challenges, because it can be difficult to identify the foreign individuals who are operating the websites and distributing the counterfeit, piratical and otherwise infringing products.

Recognizing the challenges, FDA's Office of Criminal Investigations (OCI) formed a new Cybercrimes Investigation Unit (CcIU) in March 2013, to address rogue online pharmacies that distribute unapproved or counterfeit pharmaceuticals or medical devices by means of the Internet. CcIU is a special team of highly trained investigators within the Office of Criminal Investigations (OCI). This unit protects public health by working with other domestic and international law enforcement and regulatory agencies to disrupt and dismantle online networks that illegally sell counterfeit or adulterated medicines, medical devices, cosmetics, and tobacco and food products. The CcIU agents follow the cyber-trail of these sophisticated criminals and often go undercover to infiltrate the illicit criminal network.

Not all infringing sites sell pharmaceuticals. Some distribute counterfeit merchandise, apparel, and pirated software. DHS combats such infringement through *Operation in Our Sites*. As background, the Illicit Cyber Commerce Program (ICC) is an ongoing ICE-HSI initiative targeting entities that sell counterfeit products through the internet. The ICC program consists of a well-known operation dubbed *Operation in Our Sites*, which was initiated as a method to disrupt these rogue websites. By seizing the domain names, ICE-HSI disrupts the sale of counterfeit and pirated items by eliminating the point-of-sale access to consumers for the criminals who are profiting from this illegal activity. As of December 31, 2013, 2,550 domain names had been seized, of which 1,760 were forfeited to the Federal Government. Of the seized sites, 686 sold counterfeit pharmaceuticals. In FY2014, ICE-HSI seized a total of 460 domain names and arrested one individual.

ICC's strategy is focused on developing investigations that identify targets, assets, and financial schemes used in operating the infringing websites domestically and internationally. ICC provides support to ICE-HSI field offices to proactively target websites discovered in their IP investigations. These investigations are initiated and developed by ICE-HSI field offices through IPR Center leads, seizures at ports of entry, informants, consumer complaints, industry leads, and other investigative techniques.

The IPR Center ICE-HSI personnel assigned to the NCFTA leverage the resources and analytical tools of the NCFTA to identify suspect internet domains and affiliated networks in support of criminal investigations or potential civil enforcement action.

In addition, the IPR Center, through ICE-HSI, also partnered with Europol, which leveraged its member countries to launch multilateral enforcement actions under IOS *Project Transotlantic*. This operation targeted websites and their operators illegally selling counterfeit merchandise, and involved the execution of coordinated seizures of domestic and foreign-based Internet domains in the United States and Europe. In 2013, there were three joint phases of IOS *Project Transatlantic*, resulting in 2 arrests and the seizure of more than $325,000, counterfeit merchandise with an estimated value of $200,000, and 1,283 domain names. In FY2014, as part of *Project Transatlantic IV*, the IPR Center, the ICE-HSI Attaché Hong Kong, Europol and 11 law enforcement agencies from eight countries seized 188 domain names.

17. Protect Intellectual Property at ICANN

NTIA, in active collaboration with the USPTO, IPEC, and other Federal agencies, continued to advance the effective implementation by ICANN of the new gTLD safeguard advice developed by ICANN's Governmental Advisory Committee (GAC), as a complement to earlier amendments proposed by the GAC to the Registrar Accreditation Agreements that address the concerns of trademark and other rights holders. Of the 1,930 new gTLD applications received for 1,430 unique strings, 734 have been delegated; 604 are currently moving through the program; 543 applications were withdrawn; and 49 applications will not proceed/not approved. As new gTLDs are in various stages of becoming operational, NTIA, IPEC, and other interagency colleagues will focus attention during the upcoming year on the effectiveness of the new rights protection mechanisms created to protect Intellectual Property, such as the Trademark Clearinghouse and Trademark Claims Service and the Uniform Rapid Suspension System. IPEC believes these actions represent positive steps that will support rights holders with the new gTLDs and will continue to work within the interagency and through the GAC process to continue to support intellectual property rights through ICANN.

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

IPR protection and enforcement are critical to the success of U.S. businesses, including SMEs, and to the U.S. economy as a whole. The U.S. Chamber of Commerce estimates that IP-intensive industries employ more than 55.7 million Americans, and the Small Business

Administration has estimated that SMEs account for 65 percent of net new jobs annually. The theft of IP from SMEs, in particular, is a serious matter, as it stifles innovation, slows economic growth, and weakens the competitiveness of U.S. employers, threatening American jobs. Intellectual property theft has an adverse impact on innovation, commercialization of new products, and overall economic success. SMEs are particularly vulnerable because they are at a distinct disadvantage in that they often lack the resources to secure adequate protection of their IPR in foreign markets and confront its resulting theft.

Intellectual property is a top priority with the U.S. Department of Commerce. DOC is committed to ensuring that intellectual property remains a viable driver of innovation and that our IP-intensive industries can compete effectively in the international market place. U.S. Department of Commerce bureaus, namely the U.S. Patent and Trademark Office (USPTO) and the International Trade Administration (ITA) work alongside the Intellectual Property Enforcement Coordinator and other U.S. agencies involved in intellectual property rights enforcement to help businesses secure and enforce intellectual property rights at home and abroad.

- ITA's Office of Intellectual Property Rights administers STOPfakes.gov on behalf of the U.S. Government. STOPfakes.gov serves as a one-stop shop for U.S. Government tools and resources on intellectual property rights (IPR). The federal agencies behind STOPfakes.gov have developed a number of resources to educate and assist businesses, including SMEs, as well as consumers, government officials, and the general public. In addition to providing information and access to these interagency resources, ITA's Office of Intellectual Property Rights also answers hundreds of IPR-related inquiries every year from businesses and individuals.

- ITA partners with U.S. Export Assistance Centers (USEAC), the USPTO, FBI, the IPR Center, and WIPO on the STOPfakes Road Show initiative. Since its inception, Road Shows have been held in dozens of cities to raise business community awareness about working with law enforcement and avoiding pitfalls when exporting to foreign markets. The road shows also provided opportunities for participants to receive individualized attention from IPR and trade experts.

- As part of the DOC's overall IPR-outreach related activities, ITA continued its highly successful China IP Webinar Series. These webinars, conducted by the Office of China and Mongolia, are designed to assist U.S. companies doing business in China by addressing a wide a variety of issues related to intellectual property protection and enforcement. The entire webinar series is available free of charge on STOPfakes.gov (at http://www.stopfakes.gov/china-ipr-webinar).

- ITA also partners with the European Commission's Directorate-General for the Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) to jointly administer the Transatlantic IPR Portal, which is housed on the STOPfakes.gov website. The portal provides resources for SMEs on both sides of the Atlantic interested in exporting to either the United States or the European Union as well as for those entrepreneurs who

require assistance for counterfeiting and infringement encountered in third-country markets like China and India. In addition, information about protection and enforcement of intellectual property rights in both the US and the EU are highlighted on the portal. In light of the Transatlantic Trade and Investment Partnership negotiations and the tremendous interest and opportunities generated as a result, ITA and DG GROW will continue to highlight the portal in its respective stakeholder outreach and roadshows.

USPTO's GIPA retains its strong commitment to supporting U.S. veteran entrepreneurs, conducting workshops at several programs for entrepreneurs and small businesses focusing on protection and enforcement in 2014, including programs for disabled U.S. veteran entrepreneurs and women veteran entrepreneurs.

Throughout the year, the USPTO-Beijing Office frequently talked to U.S. companies to share information on China's IPR protection and enforcement mechanisms and to discuss their concerns about protection of IPR in China; most of these companies were SMEs. Many companies were "new to China" and desired to better understand steps they could take to protect their IP here. Many other were involved in current IPR disputes in China, and were looking to better understand their enforcement options. By regularly meeting with companies, USPTO-Beijing was able to position the companies to best protect and enforcement their IPR here.

The Department of State increased the level of detail in the intellectual property section of the Investment Climate Statement (ICS) updated annually by all embassies. The ICS is publicly available on the DOS website, is incorporated into DOC's Country Commercial Guides, and provides useful information to SMEs before they invest in or export to a country, or if their IP has been infringed.

19. Examine Labor Conditions Associated with Infringing Goods

IPEC has coordinated with the Department of State, the Department of Labor, CBP, and ICE-HSI to review existing data sets to identify and provide preliminary indicators of the overlap between labor conditions and the production of infringing goods. Additionally, IPEC has coordinated with the same organizations to gather more data related to this issue. In support of these efforts, ICE-HSI has developed a preliminary plan for implementation. As part of this plan, ICE-HSI has identified a single point of contact (SPOC) for forced labor matters, as well as a public email address for reporting possible violations. These steps will lead to increased scrutiny on the linkages between IP violations and forced labor used in the production of items which violate IP laws. This SPOC works with ICE-HSI attachés to develop information and investigative leads for future attention. The SPOC has begun developing information sharing mechanisms and cooperation between the domestic ICE-HSI personnel involved in investigating forced labor and IP violations and ICE-HSI's personnel assigned overseas. ICE-HSI has begun to increase interaction with the Department of State, the Department of Labor, and CBP as well as non-governmental organizations and other interested private sector parties to leverage the expertise and data holdings of these agencies regarding overseas forced labor. This

collaborative approach to enhanced enforcement work and the mitigation of labor exploitation began in early FY2014, and has been growing steadily since that time.

Securing the Supply Chain

20. Expand Information-Sharing By DHS to Identify Counterfeit Goods at the Border

Since the 2013 Joint Strategic Plan, DHS (ICE-HSI and CBP) has continued to further leverage information-sharing efforts with the private sector in an effort to combat increasingly sophisticated counterfeit and pirated goods.

The CBP's Center of Excellence and Expertise (CEE) has been heavily involved in the development and implementation of the trade intelligence concept, a CBP effort to establish formal linkages with the private sector to develop actionable intelligence. As part of these efforts, the CEE engages in continual dialogue, information sharing, and trend analysis (*e.g.*, with the pharmaceutical industry) in order to safeguard the American public from counterfeit, substandard, or illegal products.

The IPR Center continues to support efforts to provide DHS law enforcement officials with explicit legal authority to share samples of suspected IP-violating merchandise with rights holders, including providing technical expertise to members of Congress and legislative staff as requested.

CBP is drafting a regulatory package to address this issue of expanding the agency's authority to share with affected companies' information concerning circumvention devices.

In addition, during FY2014, the IPR Center's *Operation Chain Reaction* task force began coordinating with rights holders to determine if microelectronics detained at the port of entry were authentic parts. On several occasions, the rights holders provided information indicating that the parts were not only counterfeit, but were military grade. This coordination has led to additional on-site training for CBP Officers at express consignment facilities as well as increased information sharing with industry representatives.

21. Increase Focus on Counterfeits Shipped Through International Mail and Express Carriers

CBP, ICE-HSI, FDA, and USPIS continued to conduct *Operation Safeguard* in FY2013 and FY2014. Operation Safeguard activities are conducted monthly at International Mail Facilities and Express Consignment Centers throughout the United States. Each onsite examination period lasts several days and entails the inspection of hundreds of parcels containing pharmaceuticals and designer drugs. In FY2014, *Operation Safeguard* documented shipments of 4,056

pharmaceuticals (33% more than in FY2013) containing 324 DEA scheduled substances where 11% where determined to be illicit goods. *Operation Safeguard* continued in FY 2015.

ICE-HSI *Operation Apothecary* addresses, analyzes, and attacks potential vulnerabilities in the entry process that might allow for the Internet-facilitated smuggling of commercial quantities of counterfeit, unapproved, and/or adulterated drugs through international mail facilities, express courier hubs, and land borders. In FY2013, *Operation Apothecary* resulted in 47 new cases, 63 arrests, 53 indictments, and 42 convictions, as well as the seizure of more than $6.5 million in counterfeit items. In FY2014, *Operation Apothecary* resulted in 33 new cases, 32 arrests, 36 indictments, and 33 convictions, as well as 739 seizures of counterfeit items with a potential retail value of approximately $1.4 million.

FDA's Division of Import Operations (DIO) is an active partner and supporter of CBP's *Operation Safeguard*. This multi-agency initiative targets illicit imports of prescription drugs. Once a month, CBP and FDA target a specific international mail or express courier facility and, for three days, conduct extensive examinations and seizures of illicit prescription drug shipments.

As part of FDA's Import Operation Strategy, FDA personnel assigned to import operations work daily with CBP personnel at international mail facilities and ports of entry. FDA Investigators determine admissibility of FDA regulated products. All parcels reviewed which contain pharmaceuticals, regardless of detention status, are documented and processed. FDA collects daily data from all 9 international mail facilities regarding the seizure or detention of all suspected counterfeit pharmaceuticals and tainted dietary supplements. This data is shared within FDA and CBP. FDA also shares technology with CBP. For example, FDA and CBP personnel collaborate to utilize FDA's handheld Counterfeit Detector v3 (CD3) and Ion Mobility Spectrum (IMS) to identify counterfeit pharmaceuticals and dietary supplements tainted with Sibutramine at international mail facilities. FDA-DIO is currently working to expand the use of both the CD3 and the ISM to include other active pharmaceutical ingredients.

During FY2014, FDA's Division of Imports Operations, in coordination with OCI and CBP, started a series of operations to target counterfeit tobacco products being imported through the international mail facilities and express carriers. These operations have resulted in the identification of several parties involved in the importation of counterfeit cigarettes.

22. Facilitate Voluntary Initiatives to Reduce Online Intellectual Property Infringement and Illegal Internet Pharmacies

Private sector stakeholders play a critical role in combatting online intellectual property infringement and illegal Internet pharmacies. Content owners need to work with Internet Service Providers (ISP's) to educate the public about infringement. In addition, search engines, Internet registrars, online advertising networks, payment processors, and package delivery companies each provide services that facilitate legitimate online commerce. The Administration's goal has been to educate the public (including members of the Internet eco-

system) about the existence of illegal online activity; to encourage the public to choose legal, rather than infringing content; and to encourage responsible stakeholders to adopt policies to avoid unwittingly assisting in the distribution of infringing merchandise, pirated works, and counterfeit pharmaceuticals (and to do so in a manner consistent with principles of due process, free speech, competition and privacy).

With IPEC's support, five private sector voluntary initiatives are in place to reduce intellectual property infringement in the digital environment:

- The Center for Safe Internet Pharmacies (CSIP) brings together search engines, Internet registrars, and credit card companies with the goal of withdrawing payment services from fake online pharmacies, refusing to advertise fake online pharmacies, and de-registering domain names associated with fake online pharmacies.
- To address copyright infringement, the Center for Copyright Information created a process where Internet Service Provider (ISP) subscribers are notified, through a series of alerts, when illegal movie or music content is being downloaded on the subscriber's ISP account.
- To address financing of infringing products, several major credit card companies and payment processors adopted best practices for terminating payment services to websites that intentionally sell infringing content.
- In July 2013, leading ad networks came together to establish a set of best practices to address online intellectual property infringement by reducing the flow of ad revenue to operators of sites engaged in significant counterfeiting and piracy. The guidelines will help ad networks establish a set of self-regulating best practices to address known infringing sites in their respective ad networks.
- Further, the trade associations representing online advertisers and advertising agencies adopted a leadership pledge to commit to take affirmative steps to avoid placing ads on websites dedicated to infringing activity.

In conjunction with the release of the 2013 Joint Strategic Plan on Intellectual Property Enforcement, the U.S. Patent and Trademark Office issued a Federal Register Notice on June 20, 2013, seeking input from all interested parties on the processes, data metrics, and methodologies that could be used to assess the effectiveness of private sector efforts to reduce online infringement through the development and implementation of cooperative, voluntary initiatives. USPTO received 21 comments from industry associations, private parties and other stakeholders. Relevant issues raised include: the definition of "effectiveness"; the types of data that would be particularly useful for measuring the effectiveness of voluntary initiatives that are aimed at reducing infringement (and, if relevant data is not available, ways through which such data could be obtained); the existence of particular impediments to measuring effectiveness; mechanisms employed to assist in measuring the effectiveness; and the existence of data regarding efficacy of particular practices, processes or methodologies.

In conjunction with the information developed through the public comments, USPTO has conducted a series of meetings with the parties to the individual voluntary initiatives addressing safe internet pharmacies, the copyright alert system and payment processors to discuss experiences and results, and is currently evaluating the input received in the course of these discussions.

Going forward, USPTO will continue to facilitate the evaluation of the effectiveness of these private sector voluntary initiatives by also engaging members of the leading ad networks, and the trade associations representing online advertisers and advertising agencies, in discussions on their best practices aimed at reducing the flow of ad revenue to operators of sites engaged in significant counterfeiting and piracy.

23. Combat the Proliferation of Counterfeit Pharmaceuticals and Medical Devices

Counterfeit pharmaceuticals and medical devices pose serious health and safety hazards to the public. Consumers must have confidence that the pharmaceuticals and medical devices that they purchase are safe and effective for treating the conditions for which such products were approved. Counterfeit products, bearing the logo of the branded manufacturer but containing none of the health and safety assurances that the legitimate manufacturer has promised to uphold, are illegal and dangerous.

The Administration is committed to addressing this problem through a combination of public education and outreach, domestic enforcement, border interdiction, improved targeting, and coordination with foreign law enforcement counterparts. To facilitate the identification of counterfeits at the border, CBP has created a Pharmaceuticals Center of Excellent and Expertise (CEE), which works closely with the private sector to expand CBP's knowledge base about the pharmaceutical industry, and to improve targeting for counterfeits and unapproved drugs. Drug manufacturers and other industry partners have provided CBP with materials on identifying counterfeit pharmaceuticals which have been used to train port personnel. To further expand relationships, the CEE hosted a meeting with industry partners in August 2013. The meeting was the first of an on-going dialogue which will provide CBP with in-depth information on industry trends and concerns.

In addition, the CEE established relationships with the security divisions of the larger pharmaceutical firms (divisions that often operate separately from the trade compliance units that CBP usually interacts with). The security personnel in these firms have provided training materials and presentations, and sent information they have uncovered from their own private investigations. This information has allowed the CEE to refine its targeting efforts, and helps identify trends, countries of interest, and even individual shippers.

The IPR Center plays a critical role in coordinating criminal investigations of counterfeit pharmaceutical trafficking organizations. *Operation Guardian* is the IPR Center's public health and safety initiative, and *Operation Apothecary* is a subset of *Operation Guardion*. *Operation*

Apothecary 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 FY2013, *Operation Apothecary* resulted in 47 new cases, 63 arrests, 53 indictments, and 42 convictions, as well as the seizure of more than $6.5 million in counterfeit items. In FY2014, *Operation Apothecary* resulted in 33 new cases, 32 arrests, 36 indictments, and 33 convictions, as well as 739 seizures of counterfeit items with a potential retail value of approximately $1.4 million.

Other important efforts by the U.S. Government to curb the prevalence of counterfeit pharmaceuticals and medical devices include the following.

Operation Pangea, now in its seventh year, is a coordinated global effort led by INTERPOL as a means of further reducing the advertisement, sale, and supply of counterfeit, unapproved, and substandard medicines and medical devices. Unregulated websites providing counterfeit pharmaceuticals are a significant and growing global problem both from a public health and safety standpoint, as well as from an intellectual property protection standpoint.

- *Operation Pangea VII* was conducted in FY2014 and was supported by the IPR Center. One hundred thirteen countries participated, resulting in 434 arrests worldwide, the seizure of 9.6 million medicines valued at more than $32 million, the removal of 22,807 advertisements for illicit pharmaceuticals via social media platforms, the shutdown of 11,863 websites, and the inspection by customs and regulatory authorities of 618,191 packages (of which 35,206 were seized).

The illicit sale of counterfeit medicines, devices and equipment is a growing concern for both industrialized and developing nations. Increasing access to the Internet along with new methods for manufacturing and distributing counterfeit medicines have created new challenges in safeguarding the pharmaceutical supply chain. Recognizing that a multi-faceted approach is necessary to combat the proliferation of counterfeit medicines, the USPTO incorporates the issue of counterfeit medicines into many of its training and capacity building programs. In FY2014, the issue of counterfeit medicines was integrated into USPTO programs where the audience included regulatory officials, investigators, prosecutors and judges, as well as law enforcement, customs and border officials.

- USPTO participated as a speaker in a two day regional program hosted by CLDP on The Prevention of Counterfeit Products in Rabat, Morocco. The program included speakers from the IP and customs offices of Morocco, Tunisia, Mauritania, Libya, and Algeria as well as speakers from French Customs, the WTO and the National Institute for Industrial Property (INPI).

- USPTO participated in a Health and Wellness Expo at the 2nd Annual Food Safety Conference organized by Embassy Manama, in Bahrain. Approximately 3,000 people attended the Food Safety Conference, including food and health professionals, as well

as members of the general public. USPTO spoke on the topic of combating counterfeit pharmaceutical drugs, participated in a panel on the topic of counterfeit and fake foods and engaged with policy makers from the Ministry of Health to discuss strategies to confront the issue of counterfeit medicines in Bahrain.

- USPTO organized an advanced program on combating counterfeit medicines in Sub-Saharan Africa, which brought together drug regulators and law enforcement officials from Angola, Botswana, Mozambique, Namibia, Tanzania, and South Africa. The program highlighted the use of innovation to fight fake drugs, and introduced the participants to several counterfeit medicines detection technologies.

Efforts to Protect the Integrity of the Public Health Supply Chain

Drug counterfeiting and adulteration have caused serious threats to public health. Counterfeit drugs raise significant public health concerns because their safety and effectiveness is unknown. In the United States, a relatively comprehensive system of laws, regulations, and enforcement by Federal and state authorities has kept drug counterfeiting incidents relatively rare, and the U.S. Food and Drug Administration (FDA) works to ensure that Americans can have a high degree of confidence in the drugs that they obtain through legal channels. FDA has made it a priority to investigate reports of counterfeit products and works with U.S. drug supply chain stakeholders to improve our ability to prevent, detect, and respond to threats of counterfeit and substandard drugs. FDA also educates consumers and the health care community about the risks of, and minimizing exposure to, counterfeit and substandard drug products through recalls, public awareness campaigns, and other steps. Additionally, FDA reaches beyond U.S. borders and works with our foreign counterparts to identify global supply chain vulnerabilities as well as identify and implement realistic solutions, nationally and internationally.

New Statutes and Regulation

In July 2012, President Obama signed into law Public Law 112-144 (The Food and Drug Administration Safety and Innovation Act; FDASIA), which incorporates several of the IPR enforcement recommendations contained in the March 2011 Administration White Paper. FDASIA provided for enhanced penalties for trafficking in counterfeit drugs, and it directs USSC to review and amend, if appropriate, its guidelines and policy statements related to counterfeit drugs. In 2013, FDA advocated for higher penalties for adulterated and counterfeit drugs before the USSC which became effective on November 1, 2013. Further, FDASIA authorized FDA, upon issuance of regulations, to destroy, without the opportunity to export, counterfeit, misbranded or adulterated drugs imported to the United States that are valued at $2,500 or less. FDA issued a proposed rule for this provision on May 6, 2014. The Act also allows FDA, upon issuance of guidance or regulation, to require that commercial importers, manufacturers, and wholesale distributors notify FDA if a drug has been counterfeited or stolen. There is a similar provision related to notification of illegitimate product under the Drug Supply Chain Security Act, and FDA issued draft guidance on June 11, 2014, to set out the process for making such notifications; this process will serve as the foundation for the FDASIA requirement. FDA is

actively engaged in developing the statutorily-required regulations and guidance necessary to implement this important new law, and has established FDASIA-TRACK, a webpage dedicated to providing the public with information detailing FDA's progress on implementation.

FDASIA also provided authority that deems adulterated any drug that is manufactured in an establishment that delays, limits, denies or refuses to permit entry or inspection. On October 22, 2014, FDA issued final guidance with examples of the types of conduct that FDA considers to be in violation of this provision. In addition, FDA issued both a proposed and, on May 29, 2014, a final rule implementing the FDASIA provision that extends to drugs FDA's current statutory authority to administratively detain, for a reasonable period of time, devices and tobacco products that an FDA investigator has reason to believe is adulterated or misbranded.

On July 12, 2013, FDA held a Public Meeting on the drug supply chain provisions found in Title VII of FDASIA. Title VII gives FDA new authorities to address the challenges posed by an increasingly global drug supply chain. The purpose of the meeting was to provide an overview of Title VII, discuss how FDA plans to implement it and hear public comment about those provisions that specifically address imported drugs and importers. These provisions authorize FDA to require that importers submit information demonstrating that their drug complies with applicable requirements of the Federal Food, Drug and Cosmetic Act before their products can enter the United States. Working together with stakeholders, FDA will continue its strategic implementation of FDASIA Title VII by prioritizing its efforts based on the maximum benefit to the public health.

The Drug Quality and Security Act (DQSA), was signed into law by President Obama on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States by 2023. DSCSA aims to facilitate the exchange of information to verify product legitimacy, enhance detection and notification of an illegitimate product, and facilitate product recalls. Drug manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) will be called on to work in cooperation with the FDA to develop the new system over the next 9 years.
The law requires the FDA to establish in standards, issue guidance documents, and develop a pilot program(s), in addition to other efforts, to support effective implementation and compliance. In 2014, the FDA issued a draft guidance establishing standards for the interoperable exchange of transaction information for trading partners. Four additional draft and final guidance regarding wholesale drug distributor and third-party logistics provider annual reporting requirements, preemption, identification of suspect products and notification, and compliance policy.

FDA's Division of Imports Operations (DIO) is actively working with CDER, OPRM, and other FDA components as well as CBP and USPS to develop policy, rules and operational procedures to implement Section 708 of Title VII of FDASIA. Section 708 gives FDA the authority to destroy adulterated, misbranded, or counterfeit drugs offered for import. Implementation of this authority will provide an additional deterrent for purveyors of non-permitted and counterfeit

pharmaceuticals by permanently removing offending articles from the stream of commerce. For copies of the guidances and more information about DSCSA implementation see: http://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/

Secure Supply Chain Pilot Program (SSCPP)

The Secure Supply Chain Pilot Program (SSCPP) is a voluntary program initiated in February of 2014 to assist the FDA in its efforts to prevent the importation of adulterated, misbranded, or unapproved drugs. The goal of the program is to enable the FDA to evaluate resource savings that will allow the agency to focus imports surveillance resources on preventing the entry of high-risk drugs that are the most likely to compromise the quality and safety of the U.S. drug supply. Firms who are selected to participate receive expedited entry. At this time, 13 firms have been selected to participate. During these next two years, the FDA will evaluate the program's effectiveness at enhancing imported drug compliance with FDA regulations and the security of the drug supply chain. If the FDA determines the program to be effective, a more permanent program may be established and possibly extended to additional participating companies. Additional information on the pilot can be found at: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm365626.htm

Stakeholder Engagement

Asia Pacific Economic Cooperation (APEC) Roadmap for Global Medicol Product Quality and Supply Choin Integrity

Under the FDA's leadership, in 2013 the Asia Pacific Economic Cooperation (APEC) commenced a five-year plan drawing subject matter experts (SMEs) from industry and leading regulatory authorities from around the world to develop a roadmap for global medical product quality and supply chain integrity. FDA leads the project, which includes gap assessments, development of guidelines for best practices, training materials, and assessment tools across APEC economies to ensure that good quality medical products are available to the U.S. Ten work streams comprised of SMEs focused on supply chain-related matters covering every transactional node from raw material sourcing through finished dosage form manufacturing to pharmacy practices have been established to look holistically at the movement of medical products and in international commerce. Thus far, five workshops have been held, including three training programs covering product security, good distribution practices, and establishment of a national single point of contact system for reporting of suspicious products.

Intergovernmental Forum on Substandard, Spurious, Falsified, Falsely-labeled, and Counterfeit (SSFFC) Products

In 2014, the FDA and Department of State established an "Intergovernmental Forum on SSFFC" (IFoS). The purpose of the IFoS is to provide a forum for U.S. government agencies to share information about activities, initiatives, and outreach related to SSFFC medical products. This will enable the FDA and other USG agencies to leverage internal and outreach resources,

partner on initiatives, minimize duplication of efforts, and align U.S. government positions. Among other things, the IFoS will share information about efforts and initiative related to SSFFC medical products, keep members apprised of international efforts, and plan for external engagement beyond the U.S. government agencies.

Countering the Problem of Falsified and Substandard Drugs - Institute of Medicine (IOM)

To address information gaps related to this global public health threat, FDA commissioned and released in early 2013 the Institute of Medicine's report, "Countering the Problem of Falsified and Substandard Drugs." This report confirmed that falsified and substandard medicines are an international public health threat requiring international cooperation. FDA is implementing a number of the report's recommendations, and will pursue further efforts in a multifaceted manner, in partnership with a wide range of stakeholders including international and domestic government and nongovernment organizations. In early 2014, FDA collaborated with the Center for Strategic and International Studies and the IOM to disseminate the findings to major donor and medical product procurement organizations. The meeting resulted in greater collaboration among major organizations to share information and address weaknesses in regulatory capacity.

FDA/WHO Global Surveillance and Monitoring System for Substandard, Spurious, Falsely-Labeled, Falsified, Counterfeit (SSFFC) Medicol Products

Since 2010, FDA has supported the World Health Organization to establish the WHO Global Surveillance and Monitoring System for SSFFC Medical Products. The purpose of this project is to determine: 1) the scale of the issue; 2) the geographic extent; 3) the medicines affected; 4) the harm caused; 5) the value of the market; and 6) supply chain vulnerabilities. Work on this project will continue as a means to share information on a global scale regarding counterfeit medical products. As of October 2014, 80 Member States have been trained in the system in 8 workshops; 230 regulatory personnel have been trained, along with 18 large procurement agencies. Over 500 suspect products were reported occurring in 62 countries. Over half (54%) of reported incidents of medical products were on the WHO Essential Medicines List; and 50 reports referred to WHO prequalified medicines. Of all reports, 10% involved serious adverse reactions. WHO has issued 8 international drug alerts based on incident reports.

Consumer Education

Know Your Source

To address the risks from the growing network of rogue wholesale drug distributors selling potentially unsafe medicines in the U.S., in September 2014, FDA launched the "Know Your Source" campaign. The campaign aims to educate health care practitioners about safe buying practices for medicines and the possible public health risks to patients. Specifically, the FDA's Know Your Source website provides tips for health care professionals to buy medicines safely

and resources that allow health care professionals to verify whether a specific wholesale drug distributor is licensed in a state.

Outreach to Doctors

In the past few years, FDA has become aware of certain medical practices that purchased potentially counterfeit medicines and unapproved injectable cancer medicines from foreign or unlicensed suppliers. In response to these risky purchases, FDA, among other things, issued letters to numerous medical practices across the nation requesting them to cease using, and retain and secure all remaining drug products and informing them of the risks that they posed to their patients. The letters were then posted on FDA's website.

During FY2013, FDA engaged in targeted educational outreach to healthcare provider organizations and convened a workshop in July 2013 with stakeholders to identify avenues to reduce the threat of counterfeit and unapproved drugs in clinical settings.

Counterfeit/Unapproved Public Health Alerts Drug

In April 2012, FDA informed the health care community and the public that a cancer medicine had been determined to be counterfeit. Specifically, a counterfeit version of Roche's Altuzan 400mg/16m. (Bevacizumab), originating from a foreign source and purchased by U.S. medical practices, contained no active ingredient. In February 2013, FDA informed the healthcare community that two lot numbers were determined to be counterfeit versions of Roche's Altuzan 400mg/16ml (bevacizumab). FDA issues letters to medical practices that may have purchased and administered unapproved cancer medicine that potentially included the counterfeit versions of Altuzan.

In April 2013, FDA informed the healthcare community and the public of fraudulent versions of Botox that were being sold to U.S. medical practices. The outer carton was counterfeit, while the vial inside is labeled as a foreign version of Botox, which is not FDA-approved for sale in the United States. These products were sold by unlicensed suppliers who are not part of the legitimate U.S. supply chain. FDA issued letters to medical practices that may have purchased the fraudulent Botox or other unapproved prescription medications.

Enforcement Actions

In addition to ICE's Homeland Security Investigations, FDA also has a leadership role in combating counterfeit pharmaceuticals and medical devices.

International Internet Week of Action

From May 13-20, 2014, FDA contributed to the success of efforts under INTERPOL's *Operatian Pangea* initiative, an operation that involved more than 100 countries. As part of *Operation Pangea VII*, authorities from participating countries detained or seized 19,618 packages which

contained medicines purportedly from Australia, the United Kingdom (UK), New Zealand and Canada. These packages actually contained unapproved or suspected counterfeit drugs from other countries, such as India, China, Singapore, Taiwan, Mexico, Lao PDR, Malaysia, as well as Australia, New Zealand and the UK.

In support of the Operation, FDA and the CBP inspected packages at the mail facilities in Los Angeles, New York and Chicago, and detained or seized 583 packages. Preliminary findings show that certain drug products from abroad, such as insulin, estrogen, bimatoprost, human chorionic gonadotropin, tramadol, tadalafil and sildenafil citrate were on their way to U.S. consumers. FDA also notified Internet service providers, domain name registrars and related organizations that 1,975 websites were selling products in violation of U.S. law.

Significant illustrative enforcement actions include:

Two Turkish Nationals Indicted for Smuggling Counterfeit Cancer Drug

On January 16, 2014, FDA's Office of Criminal Investigations in coordination with the United States Attorney's Office for the Eastern District of Missouri announced that Ozkan Semizoglu and Sabahaddin Akman, both from Turkey, had been charged with obtaining unapproved, misbranded, adulterated and counterfeit cancer treatment prescription drugs from Turkey and other foreign countries and smuggling the drugs into the United States, including three shipments sent from Turkey to Chesterfield, Missouri.

The arrests of Semizoglu and Akman stemmed from the arrest and conviction Richard J. Taylor of Warwickshire, England, who was sentenced on July 11, 2013 to 18 months of imprisonment and a fine of $800,000 for distributing adulterated prescription drugs used for cancer treatment to multiple physicians in the United States. As part of Taylor's plea agreement, Taylor admitted that he and others imported Altuzan, an intravenous cancer treatment drug marketed in Turkey that contains the same active ingredient as the drug marketed in the United States as Avastin® into the United States. On May 10, 2011, Taylor was notified that "we had an unfortunate experience" after an oncology nurse of a U.S. doctor reported that two patients had "immediate bad reactions" during infusions of Altuzan. One of these patients, "who has been on Avastin for a while started to shake in the middle of being transfused and had to be disconnected from treatment." The nurse advised that she had been administering Avastin for years and never had a patient reaction like this before. Ultimately, the U.S. Food and Drug Administration seized packages marked "Altuzan" from several of Taylor's customers in the United States and tested the substances, determining that Taylor's customers had received counterfeit versions of Altuzan that did not contain any of the active drug ingredient bevacizumab that is found in legitimate versions of Altuzan and Avastin®. Semizoglu and Akman both subsequently pleaded guilty to violations of the Federal Food, Drug and Cosmetic Act. Semizoglu was sentenced to 27 months in prison on October 28, 2014 and Akman was sentenced to 30 months imprisonment and a $150,000 fine on January 23, 2015.
http://www.fda.gov/ICECI/CriminalInvestigations/ucm383001.htm
http://www.fda.gov/ICECI/CriminalInvestigations/ucm360652.htm

Two Officers of Long Island Based Company Indicted for Sale of $17 Million Worth of Misbranded Prescription Drugs Including Counterfeit Cancer Drugs

On April 30, 2014, a 73-count indictment was unsealed in Central Islip, NY, charging William Scully and Shahrad Rodi Lameh – President and Vice President, respectively, of Pharmalogical, Inc., d/b/a Medical Device King in Great Neck, New York. As alleged in the indictment, the defendants operated the illegal schemes since March, 2009, which involved the sale of a counterfeit cancer treatment medication. The counterfeit medication was sold to an oncology practice in Iowa. The defendants also sold other drugs and devices including, Mirena brand intrauterine birth control implant devices ("IUDs") manufactured in Finland that were not approved by the United States Food and Drug Administration for use in the United States. The unapproved IUDs were sold throughout the country to women's clinics and health care providers. The defendants also sold a variety of other unapproved prescription drugs during the course of the scheme and grossed over $17 million. On October 16, 2014, Lameh pleaded guilty to conspiracy to commit wire fraud, and conspiracy to defraud the FDA by distributing misbranded drugs. This matter was investigated by FDA's Office of Criminal Investigations. http://www.fda.gov/iceci/criminalinvestigations/ucm397100.htm

Data-Driven Government

24. Conduct Comprehensive Review of Domestic Laws to Determine Needed Legislative Changes to Improve Enforcement

The Department of Commerce's Green Paper on *Copyright Policy, Creativity, and Innovation in the Digital Economy*, issued in July 2013, provided a comprehensive overview of the current state of copyright law in the digital environment, including a review of all existing tools for online copyright enforcement and a discussion of potential new ones. The paper highlighted a number of areas in which work is already underway to continue updating copyright law for the digital age, either through the U.S. Copyright Office or in the Congress, and also identified topics on which the Department proposed to undertake further public discussion and analysis. That work has been ongoing and includes a multi-stakeholder dialogue involving copyright owners, internet service providers and consumer advocates who have formulated a statement of good, bad and situational practices for participants in the Digital Millennium Copyright Act's notice and takedown system. It also includes soliciting and receiving public comments and conducting roundtables around the country examining issues including the appropriate calibration of statutory damages in the contexts of individual file sharers and of secondary liability for large-scale infringement, the role of fair use in the context of the creation of remixes or mashups, and the application of the first sale doctrine to digital transmissions.

25. Assess the Economic Impact of Intellectual Property-Intensive Industries

The USPTO continues its collaborative efforts with the U.S. Census Bureau to create new data products describing the business dynamics of innovative firms along with a technical note discussing the methodology used to develop a set of innovation indicators. These indicators are designed to capture (1) the degree of technological novelty associated with a firm's patents; (2) the impact on downstream inventions and innovations; and (3) the broader impacts on the economy such as job creation. An important output of this collaboration has been the production of datasets linking USPTO patent data to Census Bureau data on workers and firms. The datasets will eventually be made accessible through the Census Bureau Regional Data Centers. Other outputs of this collaboration include datasets containing disambiguated identifiers for inventors and patent assignees.

With the Office of Patent Legal Administration and the Office of Patent Quality Assurance, the Office of Chief Economist conducted a joint study investigating the relationship between patent examination characteristics and subsequent patent litigation and *inter partes* review proceedings. The report is available on the Office of Chief Economist's Publications webpage (*Patent Litigation and USPTO Trials: Implications for Patent Examination Quality*, at http://www.uspto.gov/about-us/organizational-offices/office-policy-and-international-affairs/office-chief-economist-5).

26. Monitor U.S. Government Resources Spent on Intellectual Property Enforcement

Several agencies devote resources toward intellectual property enforcement. As the 2013 Joint Strategic Plan explained, IPEC has collected resource-related information from these agencies, through data collections issued by the Office of Management and Budget. These data collections, known as a Budget Data Requests (BDRs), were issued for four successive years, starting in the spring of 2010, for resource-related information covering fiscal years (FYs) 2009, 2010, 2011, and 2012.

In addition, IPEC has reviewed the separate reporting by agencies regarding their IP-enforcement activities. This reporting includes the 2013 Joint Strategic Plan as well as this annual report (which covers the agencies' activities during FYs 2013 and 2014); the annual reports that are issued by DHS on the seizures by CBP and ICE/HSI of imports that infringe trademarks, copyrights and patents (i.e., the "Intellectual Property Rights Seizure Statistics"); the annual reports that the Justice Department submits to the Congress pursuant to Section 404(a) of the PRO IP Act, 42 U.S.C. § 3713d (which, by statute, include a "summary of the efforts, activities, and resources the Department of Justice has allocated to the enforcement, investigation, and prosecution of intellectual property crimes"); the annual reports that the FBI submits to the Congress pursuant to Section 404(c) of the PRO IP Act (which, by statute, include a "Bureau-wide assessment of the staff, financial resources, and other resources (such as time, technology, and training) devoted to the enforcement, investigation, and prosecution of

intellectual property crimes, including the number of investigators, prosecutors, and forensic specialists dedicated to investigating and prosecuting intellectual property crimes"); the annual "Special 301" reports that USTR issues, pursuant to Section 182 of the Trade Act of 1974, as amended (19 U.S.C. § 2242); and other agency reporting on IP matters.

Based on IPEC's review of the agencies' responses to the BDRs, and of the agencies' reporting on their IP-enforcement activities, we believe that the BDRs were helpful – in the immediate years following the enactment of the PRO-IP Act – in focusing agencies' attention on the resources that they devote to IP-enforcement. We have also considered whether the continuation of the BDR-reporting would be an efficient and effective use of the agencies' IP-enforcement resources, taking into account the agencies' competing resource-needs. In light of the increased attention that agencies have devoted to IP-enforcement in recent years, as well as the separate reporting that agencies have done (and will continue to do) regarding their IP-enforcement activities, we believe that a further continuation of the BDRs is not warranted at this time. This is an issue that IPEC will consider further as it develops the next three year Joint Strategic Plan, which will be issued in 2016.

Performance Data

I. Intellectual Property Related Seizures (DHS ICE and CBP seizures)

- In FY2013, the number of IPR seizures increased nearly 7% to 24,361 from 22,848 in FY2012 with a MSRP of $1.74 billion. This was an increase of the MSRP by 38% from FY2012.

- In FY2014, the number of IPR seizures decreased nearly 5% to 23,140 from 24,361 in FY2013. The manufacturer's suggested retail price (MSRP) of the goods had they been genuine decreased 30% to $1.23 billion.

    - DHS's IPR seizure statistics represent the 3rd highest level since DHS started publicly reporting IPR seizure statistics in 2003. The number of IPR seizures in FY2014 reflect a 5% decrease from FY2013, due mainly to a significant decrease in the number of wearing apparel and accessories seizures (7,922 in FY2014 compared to 9,894 in FY2013). However, the statistics reveal increases in seizures of consumer electronics, pharmaceuticals, and watches and jewelry.

A. Seizures of Consumer Safety and Critical Technology Products

- In FY2013, the top three categories of Consumer Safety and Security seizures by value were Pharmaceuticals/Personal Care, Consumer Electronics/Parts, and Critical Technology Components. The total number of seizures in these categories is 2,979 with a MSRP of $117,501,438.

- In FY2014, the top three categories of Consumer Safety and Security seizures by value were Pharmaceuticals/Personal Care, Consumer Electronics/Parts, and Batteries. The total number of seizures in these categories is 3,023 with a MSRP of $99,557,736.

B. Seizures across Shipping Environments

- In FY2013, the majority of intellectual property seizures occurred in the international mail and express carrier shipping environments. Representing 81% of all intellectual property seizures for FY2013, a total of 11,196 seizures occurred in the express carrier shipping environment and 8,558 seizures occurred in the international mail shipping environment.

- In FY2014, 86% of all seizures occurred in the express carrier shipping and international mail environments. There were 12,623 seizures in the express carrier shipping environment and 7,300 seizures occurred in the international mail shipping environment.

C. Seizures of Circumvention Devices

- In FY2013, CBP seized 20 circumvention devices, a technology that works to bypass technological measures intended to protect copyrighted works such as videogame software and DVDs in for violation of the Digital Millennium Copyright Act.

- In FY2014, 144 shipments of circumvention devices were seized by CBP.

D. Seizures Pursuant to on ITC Exclusion Order Enforcement

- In FY2013, CBP carried out 35 enforcement actions against IPR infringing imports covered by an ITC exclusion order.

- In FY2014, CBP carried out 44 enforcement actions against infringing imports covered by an ITC exclusion order.

II. Law Enforcement Investigations and Prosecutions

A. FBI

- At the end of FY2014, the FBI had 357 pending IPR investigations with the following areas of focus:

    - 102 investigations of theft of trade secrets
    - 44 investigations of copyright infringement related to software
    - 82 investigations of other copyright infringement
    - 42 investigations of trademark infringement
    - 10 investigations of copyright infringement related to signal theft
    - 8 investigations of counterfeit aircraft parts
    - 14 investigations of counterfeit electrical parts
    - 8 investigations of counterfeit automotive parts
    - 44 investigations of counterfeit health products
    - 3 investigations of other counterfeit health and safety products

- The following is a summary of statistics for IPR investigations for FY2014:

    - 71 new investigations initiated
    - 68 arrests
    - 52 information/indictments
    - 52 convictions
    - Seizures totaling $378,851
    - Forfeitures totaling $2,391,401
    - Restitution totaling $145,045

B. ICE-HSI

- In FY2013, ICE-HSI initiated 1,361 intellectual property investigations and had 693 arrests, 411 indictments and 465 convictions.

- In FY2014, ICE-HSI initiated 984 intellectual property investigations and had 683 arrests, 454 indictments, and 461 convictions.

C. National Intellectual Property Rights Coordination Center (IPR Center)

- In FY2013, the IPR Center vetted 8,539 investigative leads and de-conflicted 1,505 investigative targets with partner agencies or industry. While performing these de-conflictions, the IPR Center identified 111 "blue on blue" situations where two or more entities were investigating the same target. In FY2014, 12,988 investigative leads were vetted and 1,999 were de-conflicted with the help of partner agencies or industry. Similar to FY2014 IPR Center identified 142 "blue on blue" situations.

FY2014

- In late 2011, the IPR Center and the NCFTA established a multi-year partnership aimed at developing comprehensive and actionable intelligence on individuals or groups involved in intellectual property infringement. As a result of this collaboration ICE-HSI Agents have been able to effectuate a number of enforcement activities targeting the distribution of counterfeit merchandise. Specifically, in FY2013, HSI agents imbedded at the NCFTA provided case support resulting in 60 arrests, 70 indictments, 41 convictions and 1,172 seizure incidents totaling more than $20.6 million in MSRP, as well as the initiation of 94 HSI fraud cases. In FY2014, HSI agents imbedded at the NCFTA provided case support resulting in 58 arrests, 45 indictments, 32 convictions and seizures totaling more than $89 million in MSRP, as well as the support of 167 HSI fraud cases.

D. DOJ Prosecutions

- Charges:
    - In FY2013, DOJ received 334 intellectual property referrals, and as a result, 163 cases were charged involving 213 defendants.
    - In FY2014, DOJ received 256 intellectual property referrals, and as a result, 142 cases were charged involving 200 defendants.

- Sentencing:

  - In FY2013, courts sentenced 205 intellectual property defendants. 96 received no prison term, 35 received sentences of 1-12 months in prison, 29 received sentences of 13-24 months in prison, 21 received sentences of 25-36 months in prison, 19 received sentences of 37-60 months and 5 received sentences of more than 60 months in prison.

  - In FY2014, courts sentenced 184 intellectual property defendants. 92 received no prison term, 30 received sentences of 1-12 months in prison, 30 received sentences of 13-24 months in prison, 14 received sentences of 25-36 months in prison, 13 received sentences of 37-60 months and 5 received sentences of more than 60 months in prison

The chart below depicts FY2014 statistics for criminal IP cases based on type of charge.[1]

Charge	Cases Charged	Percentage
Trademark *Trafficking in counterfeit goods, 18 U.S.C. § 2320*	91	59.9%
Copyright *Criminal copyright infringement, 17 U.S.C. §506 & 18 U.S.C. § 2319* *Counterfeit labels, 18 U.S.C. § 2318* *DMCA, 17 U.S.C. § 1201*	44	29.6%
Economic Espionage Act *Theft of trade secrets, 18 U.S.C. § 1831* *Economic espionage, 18 U.S.C. § 1832*	14	9.9%
Signal Piracy *Unauthorized reception of coble service, 47 U.S.C. § 553* *Unauthorized publication or use of communications, 47 U.S.C. § 605*	1	0.7%
Total	**150**	**100%**

1. The Executive Office for United States Attorneys compiled the statistics for number of cases charged broken down by IP statute. These statistics may not reflect cases where only a conspiracy to violate one of these offenses was charged, and there may be double-counting of cases where more than one statute was charged in the same case. For more detailed information on the DOJ and FBI's overall efforts to combat intellectual property crime, see the respective PRO IP Act Reports submitted to Congress. The reports are available at http://www.justice.gov/dag/iptaskforce/proipact/.

III. Major Enforcement Activities

A. *Operation Team Player*: The IPR Center's *Operation Team Player* targets the sale and trafficking of counterfeit sports merchandise, apparel and tickets, a multi-million dollar criminal industry. The trafficking of these items is extremely lucrative and becomes more profitable in markets involving successful and popular teams. The culmination of the sports season involving the playoffs and finals games are events that stimulate the sale of counterfeit items. ICE-HSI Special Agents and CBP Officers worked with sports leagues and law enforcement agencies throughout the Nation to identify shipments of counterfeit sports merchandise being imported to the United States or being sold by vendors. As a result of this collaboration, in 2014 more than 397,140 items of counterfeit sports memorabilia worth $37.8 million was seized and 76 individuals were arrested by law enforcement.

B. *Operation Chain Reaction*: *Operation Chain Reaction* is a combined effort of 16 federal law enforcement agencies including CBP and ICE-HSI to target counterfeit items entering the supply chains of the Department of Defense and other U.S. Government agencies. In FY2014, *Operation Chain Reaction* investigations worked by ICE-HSI resulted in 5 criminal arrests, 15 indictments, and 13 convictions, as well as 146 seizures of currency, and counterfeit goods, electronics, and vehicles worth $4.9 million (MSRP).

C. *Operation Engine Newity*: *Operation Engine Newity* is an IPR Center-led 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. In FY2014, *Operation Engine Newity* resulted in 32 cases, 19 arrests, 16 indictments, and 1 conviction, with $12.8 MSRP in seizures. There were approximately 38 active investigations involving counterfeit airbags in FY2014.

D. *Operation Apothecary*: *Operation Apothecary* is an IPR Center led subset of *Operation Guardian* 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 FY2014, *Operation Apothecary* investigations resulted in the initiation of 33 cases, arrested 32 individuals, indicted 36 individuals, and convicted 33 persons as well as seizing approximately $1.4 million MSRP in counterfeit items.

E. Illicit Cyber Commerce - *Operation in Our Sites*: The Illicit Cyber Commerce Program (ICC) is an on-going ICE-HSI initiative targeting entities that sell counterfeit products through the internet. The ICC program consists of a well-known operation dubbed *Operation in Our Sites* which was initiated in 2010 as a method to disrupt these rogue websites. By seizing the domain names, HSI disrupts the sale of counterfeit and pirated items by eliminating the point-of-sale access to consumers for criminals who are profiting from this illegal activity. In FY2014, HSI criminally seized a total of 460 domain names and arrested one individual. ICC's strategy is focused on developing investigations that identify targets, assets, and financial schemes used in operating the infringing websites domestically and internationally. ICC is providing support to HSI field offices to proactively target websites discovered in the course of IP investigations. These investigations are initiated and developed by HSI field offices through IPR Center leads, seizures, informants, complaints, industry leads, and/or other investigative techniques.

IV. Significant Criminal Cases

- In June 2014, as part of *Operation Chain Reaction*, a Massachusetts man pleaded guilty to importing thousands of counterfeit integrated circuits from China and Hong Kong and then reselling them to U.S. customers, including contractors supplying the integrated circuits to the U.S. Navy for use in nuclear submarines. The case was investigated by ICE-HSI, the Defense Criminal Investigative Service, and the Naval Criminal Investigative Service. This is one of the first convictions of trafficking in counterfeit military goods, a relatively new provision added to 18 U.S.C. § 2320 as part of the National Defense Authorization Act for Fiscal Year 2012.

- In July 2014, a defendant was sentenced to 41 months confinement for violations of 18 U.S.C. 371 (Conspiracy); 18 U.S.C. 2320 (Trafficking in Counterfeit Goods); and 21 U.S.C. 331 (Misbranded Drugs). In August 2014, a co-conspirator was sentenced to 11 months home confinement, and another conspirator was sentenced to 21 months. This investigation disrupted an international criminal organization trafficking in counterfeit pharmaceuticals operating in Houston, TX, Chicago, IL, and the country of Jordan. The investigation, led by ICE-HSI, was conducted in conjunction with the U.S. Food and Drug Administration (FDA) Office of Criminal Investigations, the Department of State Diplomatic Security, the Chicago Police Department, and the Houston Police Department.

- In September and October 2014, two brothers were sentenced to six and four months in prison, respectively, in the United States for their role in a counterfeit airbag scheme. ICE-HSI Blaine, Washington obtained information about the brothers who were selling counterfeit airbags on eBay. These counterfeit airbags had a high failure rate, putting anyone in danger who relied on one for safety. The brothers imported counterfeit airbags from China to Canada and smuggled the merchandise into the United States in the trunk of a personal vehicle. The brothers would then mail the airbags to customers

from within the United States. Working through the Joint Liaison Group (JLG) for Intellectual Property Criminal Enforcement Working Group, the Department of Justice Criminal Division Criminal Division Computer Crime and Intellectual Property Section HSI and the IPR Center facilitated a collaborative relationship with China's Ministry of Public Security (MPS). As a result of this partnership ICE-HSI, which was investigating the importation of counterfeit airbags, coordinated with the MPS in order to purse the entities in China involved in the manufacture and export of the counterfeit airbags. Four suspects were arrested in China. Additionally MPS seized 23 finished and 200 partially completed counterfeit airbags.

- In April 2014, as part of an ICE/HSI San Juan, Puerto Rico investigation, a Federal Grand Jury in the District of Puerto Rico returned an indictment against 7 individuals for violations of 18 USC 2320, trafficking in counterfeit goods. The investigation was initiated in June 2012 by ICE/HSI San Juan, Puerto Rico targeting several businesses trafficking in counterfeit goods, to include counterfeit contact lenses that posed a hazard to public health and safety due to the substandard conditions of their manufacturing and lack of quality control within the supply chain. In April 2014, HSI San Juan and HSI Orlando executed 6 arrest warrants in multiple cities within Puerto Rico and 1 within the state of Florida, resulting in the arrest of all seven individuals. Six subjects have plead guilty for 18 USC 2320, trafficking in counterfeit goods and charges dismissed on one subject. This investigation was conducted jointly and with the assistance of ICE/HSI Orlando, CBP, FDA, Puerto Rico Department of Health and Puerto Rico, Police Department.

- In FY2014, nine members of a large, international counterfeit goods conspiracy pleaded guilty in a Newark, New Jersey, federal district court to charges of, among other things, conspiracy to traffic in counterfeit goods and money laundering. According to court documents, from November 2009 through February 2012, the defendants conspired to import hundreds of containers of counterfeit goods, including handbags, footwear and perfume, from China into the United States. The goods, if legitimate, would have had a retail value of more than $300 million. ICE-HSI and FBI investigated the case, which was prosecuted by the U.S. Attorney's Office for the District of New Jersey.

- In June 2014, based on an ICE/HSI Providence Investigation, a Rhode Island man was sentenced to 50 months in federal prison for violation of 18 USC 2320, trafficking in counterfeit goods or services. As part of this investigation ICE/HSI Providence seized approximately 14,700 counterfeit sports jerseys, clothing accessories, and counterfeit health and beauty products valued at more than $1.02 million dollars. ICE/HSI Providence also seized $56,000 in cash, money orders and a bank check as well as a bank account containing $76,000.