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

OFFICE OF THE
U.S. INTELLECTUAL PROPERTY
ENFORCEMENT COORDINATOR

April 29, 2016

The Honorable Bob Goodlatte
Chairman
Committee on Judiciary
United States 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) 2015.

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*. Consistent strategic planning is key to ensuring our nation's enforcement actions keep pace with innovative industries and increasingly sophisticated criminal activities. Our objective is to submit the next 3-year plan to the Congress later this year. 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 the development of the joint strategic plan. As part of the planning process, IPEC issued a Federal Register notice on September 1, 2015 (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 2015
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 FY 2015 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 FY 2015 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 FY 2015 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.

Acquisition and Supply Chain Security

Acquisition Rulemakings by the Department of Defense, General Services Administration, and National Aeronautics and Space Administration

To address the avoidance of counterfeit electronic parts, DoD in 2015 published a proposed DFARS rule 2014-D005, *Detection and Avoidance of Counterfeit Electronic Parts—Further Implementation*. The proposed rule would establish requirements that DoD contractors and subcontractors shall acquire electronic parts from trusted suppliers (except in limited circumstances). A related DFARS Case is being developed: 2015-D020, *DoD Use of Trusted Suppliers for Electronic Parts*. The purpose of this rulemaking is to establish qualification requirements pursuant to which DoD may identify trusted suppliers.

This rulemaking builds off of past efforts to strengthen 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 (FAR) Case 2013-002: *Expanded Reporting of Nonconforming Supplies*—to revise the FAR to expand Government and contractor requirements for reporting of nonconforming goods with the intention of reducing the risk of defective and 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 (GIDEP) at www.gidep.org and to ensure that they do not supply counterfeit goods reported in GIDEP to the Government.

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) FAR Case 2012-032, *Higher-Level Contract Quality Requirements*, and (2) Defense Federal Acquisition Regulation Supplement (DFARS) 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, including counterfeit parts avoidance standards, should be used by the Government and its contractors. DFARS Case 2012-D055 outlines contractor responsibilities for the use of trusted suppliers; for detecting and avoiding the use or inclusion of counterfeit electronic parts or suspect counterfeit electronic parts; and for the reporting of counterfeit electronic parts and suspect counterfeit electronic parts.

Acquisition Training by the Department of Homeland Security

To address the systemic supply-chain threat posed by counterfeits, the U.S. Immigration and Customs Enforcement (ICE) led National Intellectual Property Rights Coordination Center (IPR Center) is providing training for public and private acquisition professionals.

In support of providing Federal acquisition professionals with the tools necessary to be vigilant in purchasing safe, legitimate products, the 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.

In April 2015, the IPR Center released on its website free training for public and private acquisition professionals ("Acquisition Professional Training: Counterfeit Awareness, Mitigation, Identification, and Reporting," at https://www.iprcenter.gov/reports/training). The training is designed to provide acquisition professionals with the knowledge and skills that they need to combat the counterfeit threat in the workplace, which depends on understanding the threat that counterfeits pose, mitigating their purchase and distribution, and identifying counterfeits and reporting them.

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 targets counterfeit items entering the military and U.S. Government supply chains, and is an IPR Center-coordinated effort led by ICE Homeland Security Investigations (HSI) and consisting of 16 Federal law enforcement agencies (including ICE, U.S. Customs and Border Protection (CBP), and DoD's criminal investigative offices). Under *Operation Chain Reaction*, ICE HSI initiated 36 criminal investigations in 2015, conducted 10 criminal arrests, and helped secure 13 indictments and 10 convictions, as well as 160 seizures of currency and counterfeit goods with a total Manufacturer's Suggested Retail Price (MSRP) of more than $8.8 million.

- In June 2014, a Massachusetts man pleaded guilty to importing thousands of counterfeit integrated circuits (ICs) 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. In October 2015, he was sentenced to 37 months in prison, ordered to pay $352,076 in restitution, and forfeit $70,050 and 35,870 counterfeit integrated circuits. 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.

- On October 19, 2015, ECL Solutions Limited, Inc., pleaded guilty and was sentenced in the Eastern District of Pennsylvania for violation of 18 U.S.C. § 371 (Conspiracy to Defraud the U.S.). ECL Solutions committed fraud regarding the importation of military steel storage racking components into the U.S. that are manufactured in China by concealing the country of origin. As a term of the sentence, ECL Solutions must pay a

fine in excess of $1 million to the U.S. Government. This is in conjunction with its efforts to move its production back to the European Union and establish a robust compliance program. All funds will be deposited into the Treasury Executive Office of Asset Forfeiture fund. At sentencing, ECL made an initial payment of $300,400 to the U.S. Government. This was the first of five scheduled payments over the next five years.

CBP continues to work with HSI and other IPR Center agencies participating in *Operation Chain Reaction* to curtail the flow of counterfeit items entering the U.S. Government supply chain.

Department of Justice

The Department of Justice (DOJ) has played an active role in supporting *Operation Chain Reaction*, assigning a Computer Crime and Intellectual Property Section (CCIPS) attorney to provide direct assistance in the case lead identification process with the IPR Center. CCIPS also works closely with the IPR Center to host the Counterfeit Microelectronics Working Group, which brings together law enforcement and a wide array of military and government suppliers on a quarterly basis to improve detection and deterrence of counterfeit computer chips and other microelectronics used in critical government systems.

Perhaps most importantly, DOJ pursues the prosecution of high-impact cases in this area. This included the sentencing on October 6, 2015, of a Massachusetts man (Peter Picone) who pleaded guilty on June 3, 2014, to conspiracy to traffic in counterfeit military goods (for importing thousands of counterfeit ICs from China and Hong Kong and reselling them to U.S. customers, including contractors supplying them to the U.S. Navy for use in nuclear submarines). U.S. District Judge Alvin W. Thompson sentenced Picone to 37 months in prison and, in addition, ordered Picone to pay $352,076 in restitution (to the 31 companies whose ICs he counterfeited) and to forfeit $70,050 and 35,870 counterfeit ICs.

“Picone risked undermining our national security so that he could turn a profit,” said Assistant Attorney General Caldwell at the time of his sentencing.”He sold counterfeit integrated circuits knowing that the parts were intended for use in nuclear submarines by the U.S. Navy, and that malfunction or failure of the parts could have catastrophic consequences.”

2. Use of Software by the Federal Government

IPEC continues to work 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: "Enhancing the Security of Federal Information and Information Systems" (November 18, 2013). 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 licensing agreement.

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. In December 2015, OMB released for public comment the draft of a government-wide OMB policy memorandum that focuses on improving the Federal Government's acquisition and management of software licensing ("Category Management Policy 16-1: Improving the Acquisition and Management of Common Information Technology: Software Licensing"; see 80 FR 79615 (Dec. 22, 2015) and https://www. whitehouse. gov/blog/2015/12/21/building-progress-improving-way-government-buys-it). The purpose of the memorandum is to promote greater efficiency in how the Federal Government manages and buys software, including through having agencies centrally manage their software buys (to reduce underutilization and maximize the use of best-in-class solutions, and to use existing enterprise-wide software agreements). After considering the public comments, as appropriate, OMB plans to issue a final version of the software-licensing memorandum.

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. A transparent environment provides policymakers access to a diverse set of views to draw upon as part of the policy development process and allows for greater accountability.

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; and the sharing and implementation of voluntary best practices to address online piracy and counterfeiting.

In Fiscal Year (FY) 2015, IPEC continued its longstanding tradition of an open door policy, meeting with numerous stakeholders, large and small, across a broad range of sectors in developing and implementing the Administration's strategy for intellectual property enforcement.

Additionally, IPEC and the interagency Intellectual Property Enforcement Advisory Committee is working on a new three-year strategic plan for 2016-2019, which we plan to present to the President and the Congress in the coming months. On September 1, 2015, IPEC issued a Federal Register Notice asking interested parties to provide their ideas on advancing the Nation's intellectual property enforcement agenda and related policy priorities. Through continued dialogue with a full range of interested stakeholders—such as IP rights holders, trade and professional associations, government contractors, public interest groups, and academia—IPEC and its Federal partners seek to advance a thoughtful, strong and effective strategy for addressing important challenges to enforcement of the Nation's intellectual property laws.

U.S. Copyright Office

Since publication of IPEC's 2014 Annual Report, the U.S. Copyright Office has continued its commitment to transparency by ensuring that all members of the copyright community – including users of works, copyright owners, technology companies, and the general public – have an opportunity to actively contribute to the U.S. Copyright Office's policy studies, reports, and recommendations. During FY 2015, the Office formally solicited written comments from the public to address several copyright policy issues, including a proposal to develop a pilot program to address mass digitization of copyrighted works, and a general inquiry to review how visual works such as photographs, graphic art works, and illustrations are monetized, enforced, and registered under the Copyright Act. The Office received hundreds of submissions on these issues and made comments publicly available on the U.S. Copyright Office website.

Section 1201 of Title 17 makes it illegal to circumvent technological measures designed to prevent unauthorized access to copyrighted works (also called "access controls"), including copyrighted books, movies, video games, and computer programs. The provision, however, also instructs the Librarian of Congress, upon the recommendation of the Register of Copyrights—who in turn is to conduct a rulemaking proceeding every three years, in consultation with the Assistant Secretary of Communication and Information at the Department of Commerce—to adopt limited exemptions from the general prohibition to allow users of copyrighted works to circumvent such protections to facilitate non-infringing uses. For the sixth triennial section 1201 rulemaking, the Office modified its administrative procedures in an effort to: (1) reduce burdens on both the participants and the Office; (2) make the process

more accessible and understandable to the public; (3) allow greater opportunity for participants to coordinate their efforts; and (4) encourage participants to submit effective factual and legal evidence in support of their positions. Accordingly, the Office issued specific guidance as to the format and substantive content of submissions, including templates for written comments and instructions for providing multimedia evidence. Additionally, the Office simplified the requirements for exemption requests by permitting initial petitions to be submitted with only basic information regarding the essential elements of the proposed exemption, rather than a complete legal and evidentiary basis for the proposal at the initial stage, as had been the practice in the past. The Office then provided additional guidance to commenters regarding legal and factual issues of particular interest to the Office. During the public comment phase of the rulemaking, the Office received nearly 40,000 comments from a wide range of interested parties, which were made available on the Office website. The Office also held seven days of public hearings in Los Angeles and Washington, D.C., at which it heard testimony from approximately sixty witnesses. The Register's recommendation proposing exemptions for twenty-two uses of works, along with the Librarian's final rule adopting the recommendation in full, was published in the Federal Register (80 FR 65944) and made effective on October 28, 2015.

Finally, in 2015 the Office continued its support for the ongoing Congressional review of the nation's copyright laws before the U.S. House of Representatives Committee on the Judiciary. The Office maintains hyperlinks on its website (http://copyright. gov/laws/hearings/) to enable the public to access the written testimony, transcripts, and videos of all twenty copyright review hearings that have taken place before the Committee over the past two years.

Department of Justice

DOJ's Antitrust Division continued to promote transparency regarding its views on intellectual property issues, including the role of antitrust and intellectual property laws and enforcement in promoting innovation, standards-essential patents and patent assertion entities.

- In a September 2015 speech, Assistant Attorney General Bill Baer explained that competition authorities have an important role in assuring that holders of standards-essential patents (SEPs) honor voluntary licensing commitments. Such voluntary commitments are designed to preserve the benefits of competition during the standards process. He also cautioned "[i]f there is no bad conduct by the patent holder, no improper use of enhanced market power, but rather an assertion of lawful patent rights, competition enforcers need to stand down." (http://www. justice. gov/opa/speech/assistant-attorney-general-bill-baer-delivers-remarks-19th-annual-international-bar)

- In February 2015, the Antitrust Division, through its business review process, issued a letter that analyzed a proposed update by the Institute of Electrical and Electronics Engineers, Inc. (IEEE) to its standards association's patent policy. The policy governs the incorporation of patented technologies in IEEE standards. The proposed update clarified the terms under which owners of patents, needed to implement IEEE

standards, would voluntarily agree to license such patents. The Division concluded that that it was unlikely to challenge the proposed update if IEEE were to adopt it, which IEEE later did. This letter exemplifies the Division's continuing efforts to provide standards-setting organizations and the high-tech community with guidance regarding competition issues associated with standards-setting activities. (http://www. justice. gov/archive/atr/public/busreview/311470. htm)

The Antitrust Division continued to encourage standards bodies to adopt clear, pro-competitive intellectual property policies that can facilitate the licensing of standards-essential patents. The Division coordinated its efforts with other Federal agencies, including the Federal Trade Commission (FTC), the Department of Commerce (DOC), and the U.S. Trade Representative (USTR), as well as the European Commission.

International Negotiations

U.S. Trade Representative

One of the Administration's goals 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, phonograms, performances, trademarks, trade secrets and inventions by U.S. creators, inventors, artists and businesses. During negotiations with foreign counterparts, USTR and other agencies explain the importance that the U.S. government places on protecting and enforcing intellectual property, including adequate limitations and exceptions, as it seeks 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 (WTO) provides opportunities for USTR to lead engagement with trading partners on intellectual property rights (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 2015, 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, including the role of intellectual property protection in venture capital investments in new businesses, the role of women in innovation and technology development, and the relationship between creative and innovative entrepreneurship and economic growth.

To help ensure 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 kind of dialogue is critical at every stage

of USTR's work, including in connection with the process of negotiating, implementing and enforcing 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 FY 2015.

In addition to requesting comments from the public and holding public hearings on IPR matters, intellectual property trade policy figured heavily in USTR's broader stakeholder and Congressional outreach. During the closing negotiations of the Trans-Pacific Partnership (TPP) negotiations in 2015, for example, Ambassador Froman and USTR staff conducted regular meetings and briefings on intellectual property issues with the business sector, non-government organizations, other members of the public, and Congressional stakeholders.

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.

Department of Homeland Security and Department of Justice

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 FY 2015, the IPR Center, through *Operation Joint Venture (OJV)*, reached out to 21,456 people in 422 outreach and training events. Between FY 2010 and FY 2015, outreach efforts have increased 46 percent from 14,684 to 21,456 people. Over 110,000 representatives from the private sector, foreign law enforcement, and domestic law enforcement have participated in more than 2,000 OJV outreach and training events.

CBP's multi-faceted communication with IPR stakeholders includes daily interaction with industry regarding enforcement activities, formal meetings involving both trade facilitation and enforcement efforts, and participation on national trade events. CBP's stakeholder engagement includes:

- Meetings with the Advisory Committee on Commercial Operations to the U.S. Customs and Border Protection (COAC) and quarterly public meetings;

- Daily interaction with stakeholders affected by CBP's IPR enforcement efforts at the ports of entry, and nationally through CBP's nine industry sector aligned Centers of

Excellence and Expertise (CEEs), the IPR-focused staff at headquarters, the IPR Center in the Washington D.C. metro area, and statistical analysis and industry experts at the IPR National Targeting and Analysis Group (NTAG) in Los Angeles and San Francisco;

- Participation in national and local trade events, industry meetings, speaking engagements, and rights holder and industry-specific right holder roundtables;

- In 2015, rights holders conducted 15 webinar trainings for CBP personnel to increase CEE and port expertise regarding their products. In addition, in 2015, the IPR NTAG conducted three IPR roundtables in 2015: a luxury/sporting goods roundtable in New York with over 30 right holder representatives; a sports league roundtable in New York with 12 right holder representatives (from Major League Baseball, the National Basketball Association, the National Football League, the National Hockey League, and the Collegiate Licensing Company); and an apparel and footwear goods roundtable in San Francisco with over 40 right holder representatives, held in collaboration with the Apparel, Footwear, and Textile Center of Excellence and Expertise (CEE). At these roundtables, CBP provided updates on new programs and seizure statistics, and discussed with the rights holders their issues and concerns.

CBP recognizes that rights 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 had numerous other engagements with stakeholders in 2015. 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 2015, the IPR Center continued to host numerous foreign governments with an interest in intellectual property enforcement. Among the many international delegations hosted by the IPR Center were representatives from the customs administrations of Mexico, Germany, France, United Kingdom, Australia, Pakistan, Spain, Paraguay, United Arab Emirates, Taiwan, Switzerland, Afghanistan, Bangladesh, India, Sri Lanka, and the People's Republic of China.

- On March 3, 2015, the IPR Center hosted the Original Equipment Manufacturers (OEM) Roundtable of brand protection managers from major automotive manufacturers. The purpose of this meeting, with representatives from the Automotive Anti-Counterfeiting Coalition (A2C2), was to discuss additional ways in which the Federal Government and industry can work together to provide protection against trademark theft involving

automotive parts. Since this first meeting, the IPR Center and the major automotive manufacturers brand protection managers continue to meet quarterly, working together to combat counterfeit automotive parts as an industry.

- In 2015, 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 specializing in brand protection and trademark enforcement). Relevant issues were discussed with industry experts from various disciplines. Several other roundtable workshops were held by representatives from social media sites, credit card networks, and online marketplaces.

- In 2015, 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 120 representatives from the microelectronics industry and law enforcement attended the February 2015 meeting, and over 200 representatives attended the September 2015 meeting.

DOJ Outreach to the Private Sector

During FY 2015, the DOJ continued to reach out to the victims of IP crimes in a wide variety of ways, including during the operational stages of cases and through more formal training programs and conferences. For example, the Criminal Division hosted CCIPS' Ninth Annual IP Industry and Law Enforcement Meeting in October 2015, in Washington, D.C. The yearly meeting provided 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 meeting was attended by high-level officials from the Department, and included remarks by Assistant Attorney General Leslie Caldwell. Senior law enforcement officials from DOJ, FBI, ICE, and the Food and Drug Administration (FDA) also participated in the meeting. More than 90 individuals attended the meeting, including senior representatives from a broad range of industries such as pharmaceuticals, software, luxury goods, electronics, apparel, motion pictures, music, consumer goods, and automobiles.

In the past year, the Criminal Division's high-level officials and CCIPS attorneys also presented at a variety of domestic and international conferences, symposia, and workshops attended by IP rights holders and law enforcement officials. These events included, among others: The Cyber Security Summit in October 2014; the California State Bar's 39th Annual Intellectual Property Institute in November 2014; the Computer Crime and Intellectual Property Symposium at Seton Hall Law School in November 2014; the Fifth Annual West Coast Compliance Pharmaceutical Conference in November 2014; the Practicing Law Institute's Conference on Intellectual Property Rights Enforcement in January 2015; a symposium at the Samford University Cumberland School of Law entitled "Practicing Law in the Age of Surveillance and Hackers" in February 2015; the American Bar Association's International Law

Section's Spring Meeting in May 2015; the Secure360 Conference in May 2015; a panel discussion at the American Bar Association's Public Contract Law Section Task Force in June 2015; the Annual Meeting of the Western District of Wisconsin Bar Association in June 2015; the Chamber of Commerce's Global Brand Council Strategy Session in July 2015; and the Annual Meeting of the Connecticut Intellectual Property Law Association in September 2015.

In addition, in the past year, the DOJ's National Security Division (NSD) announced strategic changes within the Division designed to put additional focus on the protection of national assets from the threats of nation states, including economic espionage and trade secret theft. These changes included creating a new Deputy Assistant Attorney General position focusing on protecting national assets and naming the first Director of the Division's Protection of National Assets Outreach Program. Pursuant to this increased focus, NSD leadership and other attorneys have reached out to senior managers and counsel at hundreds of companies over the last year to educate them about the Department's resources and efforts to combat economic espionage and trade secret theft and other national security threats. These outreach efforts have included presentations at universities and think tanks, cybersecurity summits and roundtable discussions, as well as one-on-one meetings with senior executives at Fortune 500 and other companies. The National Security Cyber Specialists (NSCS) Network also periodically disseminated resources to its members nationwide to facilitate their outreach to companies and other organizations in their home districts and facilitated FBI field offices' efforts to educate Assistant U.S. Attorneys (AUSAs) on the national security threats in their districts and to include them in FBI's outreach efforts in their districts.

Other DOJ outreach to industry groups affected by IP crime include:

- On October 17, 2014, the CCIPS Deputy Chief and representatives from the FBI met with the Interactive Advertising Bureau (IAB), an association comprised of more than 600 leading media and technology companies, to discuss the IAB's new Anti-Malware Working Group. Specifically, representatives discussed how to identify, mitigate, and neutralize cybercrime and IP crime threats.

- On October 20, 2014, CCIPS met with the American Bar Association's Public Contract Law Section to discuss their newly formed Task Force on Counterfeit Parts. CCIPS made a number of recommendations regarding specific topics and areas on which the Public Contract Law Section should focus and ways that public contract attorneys could assist their clients in providing well-developed referrals/leads to law enforcement.

- On February 18, 2015, CCIPS representatives met with executives from the Motion Picture Association of America to discuss a variety of issues involving audiovisual piracy and counterfeiting.

- On February 25, 2015, CCIPS and the IPR Center co-hosted a meeting of the Counterfeit Microelectronics Working Group, which focuses on the challenge of counterfeit microelectronics in the government supply chain and related issues. Over 120

representatives from the microelectronics industry and law enforcement attended the meeting.

- On March 4, 2015, the CCIPS Assistant Deputy Chief gave a speech at the Twelfth Annual Pharmaceutical Compliance Conference, focusing on recent Federal prosecution of counterfeit pharmaceutical cases. The conference brought together the enforcement community and pharmaceutical industry to discuss how to develop stronger public/private partnerships to combat trafficking in counterfeit pharmaceuticals. Attendees included over 400 pharmaceutical companies, law enforcement agents, and government officials.

- On April 15, 2015, CCIPS attorneys met with representatives of the Personal Care Products Industry Council to discuss the challenges of combating counterfeit cosmetics, fragrances, toiletries, and related personal care products in the marketplace. The program included the identification of emerging trends in counterfeiting and a discussion of ideas for improved cooperation between law enforcement and industry.

- On April 30, 2015, CCIPS attorneys met with representatives of the Association of American Publishers (AAP) regarding copyright/cyber issues affecting the industry. Among other things, the AAP discussed their concern over Library Genesis, a Russian-based project identified by AAP as a global source of copyright-infringing copies of books and journals.

- On May 29, 2015, CCIPS participated in the Department of Defense Systems Engineering Research Center's Anti-Counterfeiting Roundtable at the Pentagon.

- On June 17, 2015, CCIPS met with the International Anti-Counterfeiting Coalition to emphasize the importance of developing relationships with law enforcement before an IP or cyber incident occurs.

- On June 23, 2015, CCIPS met with companies in the energy sector to discuss the topic of trade secret theft and cybersecurity. Sponsored by the FBI, the event took place in Little Rock, Arkansas and was attended by executives from 40 oil and gas companies, as well as the U.S. Attorneys from the Eastern and Western Districts of Arkansas.

- On September 1, 2015, CCIPS and the IPR Center co-hosted another meeting of the Counterfeit Microelectronics Working Group, which focuses on the challenge of counterfeit microelectronics in the government supply chain and related issues. Over 200 representatives from the microelectronics industry and law enforcement attended the meeting.

- From September 8-10, 2015, the Office of Overseas Prosecutorial Development Assistance and Training (OPDAT) provided a symposium in Lima, Peru, for discussing IP enforcement coordination with international stakeholders, including FOX International, HBO Latin America, and Alianza c/o DirecTV Peru, as well as Peruvian judges and prosecutors. The OPDAT team of experts included a Computer Hacking/Intellectual Property Unit (CHIP) Attorney and representatives of USPTO and the Federal Trade Commission.

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

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 (USITC) 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 USITC in the course of issuing exclusion orders.

On February 23, 2015, USITC announced a pilot program aimed at providing more efficient determinations on the scope of remedial orders it issues under 19 U.S.C. § 1337, specifically with respect to redesigns and new products introduced after the original USITC investigation has been completed. The pilot program is aimed at improving USITC's procedures to help intellectual property rights holders and importers to obtain timely determinations as to whether imported products are within the scope of existing USITC remedial orders. This pilot program was 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 USITC exclusion order, cease and desist order, or consent 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 USITC 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 USITC 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 USITC'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 an administrative law judge with the tools available to receive and weigh evidence.

The USITC's pilot program represents a significant milestone to ensure the process and standards utilized during enforcement activities relating to USITC remedial orders are transparent, effective, and efficient.

Department of Homeland Security

CBP is drafting a regulatory proposal to establish an *inter partes* procedure for the issuance of administrative rulings relative to the administration and enforcement of ITC exclusion orders.

6. Educate Authors on Fair Use

Effective enforcement is critical to providing meaningful protection of intellectual property rights, but enforcement approaches should not discourage people from building appropriately on the copyrighted works of others. Relevant agencies across the U.S. Government have stepped up efforts to increase education and awareness about copyright law and exceptions in the digital environment. The fair use doctrine is a fundamental linchpin of the U.S. copyright system and allows the use of copyrighted works without the copyright holder's permission under certain circumstances. The Administration believes, and the U.S. Copyright Office agrees, that the general public would benefit from more guidance on the types of activities normally recognized as fair use. Efforts in this area also include activities within the Department of Commerce and its component agencies.

U.S. Copyright Office

In April 2015, the Office launched the Copyright Office Fair Use Index (http://copyright.gov/fair-use/fair-index.html), which is hosted on the U.S. Copyright Office website and provides a searchable database of summaries of major fair use judicial opinions in an effort to make the principles and application of fair use more accessible and understandable to the general public. The index tracks a wide variety of judicial decisions to help lawyers and non-lawyers better understand the types of uses of copyrighted works that courts have previously determined to be fair or not fair under section 107 of the Copyright Act. It is designed to be user-friendly, and for each decision it provides a clear description of the facts of the case, the relevant question(s) presented, and the court's determination as to whether the contested use of a copyrighted work was fair or an infringement. Although the Index does not include the actual court opinions themselves, it provides the full legal citation, enabling those who wish to read the actual decision to search for it through free online resources, commercial databases, or the Federal courts' electronic filing system. The Index covers decisions from multiple Federal jurisdictions ranging from district courts to the U.S. Supreme Court, and includes cases dating back to 1841. Users may search the Index by category of work, type of use, or deciding court. By the end of FY 2015, the Index contained 178 cases spanning 174 years from fourteen different courts and covering sixteen categories of works and uses.

Department of Commerce

The Global Intellectual Property Academy (GIPA) of the United States Patent and Trademark Office (USPTO) has continued its efforts to educate U.S. small- to medium-sized businesses, including the individual inventor and creator, as well as 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 within the business context. 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 FY 2015, GIPA visited 28 cities throughout the United States and specifically provided copyright presentations in 11 of these cities to nearly 1,600 participants.

Additionally, DOC's Internet Policy Task Force called for and reviewed public comments, and hosted roundtable discussions, relating to the creation of remixes or mashups (i.e., works created through changing and combining existing works to produce something new and creative), which is an activity in which fair use plays a significant role. The Task Force prepared a White Paper, addressing this issue (among others), including the need to provide more guidance with respect to fair use in the creation of remixes. This paper is titled "White Paper on Remixes, First Sale, and Statutory Damages: Copyright Policy, Creativity, and Innovation in the Digital Economy".

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), U.S. Copyright Office, and USPTO— have stepped up their efforts to increase public awareness. Activities include:

- Since the FY 2014 report, the U.S. Copyright Office has continued its active public outreach and education program, which includes numerous presentations to a large variety of audiences on topics relating to copyright law, policy and registration issues.

- CBP proactively issues frequent national and local press releases, and social media notifications to educate the public on counterfeiting. In FY 2014 and FY 2015, CBP issued 16 and 28 IPR-related press releases, respectively.

- In 2015, ICE HSI, as part of its role within the IPR Center, under *Operation in Our Sites* (IOS), created an IPR Center/ ICE HSI Anti-Piracy and Counterfeiting Banner (https://www.iprcenter.gov/ip-theft/digital-ip-theft) for industry rights holders to use on redirected domain name registrations seized in civil judicial proceedings. This informational banner enables the public to provide the IPR Center with information on IPR violations, and the banner educates the public about IP theft.

- In FY 2015, the IPR Center conducted 422 outreach and training events with 21,456 attendees.

- The FBI also produces Private Sector Advisories which rely on information provided by industry partners about company-specific threats. These Advisories alert companies to potential vulnerabilities, of which they may not have previously been aware. The companies can utilize this information to better secure their IP.

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

Global Intellectual Property Academy Programs for Small-to-Medium Sized Enterprises (SMEs) in the United States

For over ten years, GIPA has been engaged in educating U.S. small- to medium-sized enterprises (SMEs) and the general public in the importance of intellectual property in local, national and global economies. GIPA's programs and presentations reach its target audiences in a variety of ways, e.g., through US-based global markets forums, intellectual property expos, trade show booths, entrepreneurial centers, veterans conferences, minority business webinars, programming for Native American communities, and public libraries. GIPA also has increased public awareness through its educational programs for business counselors, including with the U.S. Export Assistance Centers, the Small Business Development Centers, the National Association of Small Business International Trade Educators, and the International Association of Commercial Administrators. In FY 2015, GIPA provided intellectual property education to over 2,700 participants.

USPTO Symposium on Trade Secrets

The USPTO held a trade secret symposium in January 2015 at its headquarters in Alexandria, Virginia. The symposium provided an opportunity to hear from academia, the legal profession, industry, and the government on trade secret issues of importance to innovators.

1) The first panel focused on the economics of trade secret theft. The panel noted the magnitude of trade secret theft, the importance of evaluating the threat, and the economic impact of trade secret theft. The panel also discussed, from an economic perspective, aligning private and social incentives and the roles of patents and trade secrets.

2) The second panel examined the changing ways innovators are looking to intellectual property laws to protect their assets and the intersection of patents and trade secrets. The panel discussed the distinct benefits of patent protection and trade secret protection, the manner in which stakeholders utilize trade secret protection, and whether a shift has occurred from relying on patents to trade secret protection.

3) The third panel explored issues arising during litigation of trade secret misappropriation. The panel discussed the considerations that plaintiffs must assess when developing and initiating a case, including pleading requirements and choosing where to file. The panel then discussed the problems inherent in conducting litigation (discovery and trial) when a plaintiff is still trying to preserve the confidentiality of the trade secret. Other topics included the inevitable disclosure doctrine and preliminary relief.

4) The fourth panel discussed trade secret protection internationally. International standards relating to trade secrets were discussed along with various frameworks utilized around the globe for the protection and enforcement of trade secrets and enforcement challenges globally.

5) The fifth and final panel highlighted developments in Congress in the area of trade secret protection, including legislative initiatives that would create a Federal civil cause of action.

USPTO's "Everything You Want to Know about China IP" Program

In July 2015, the USPTO held the tenth annual "All You Want to Know about China IP" Program. The audience includes Federal Government representatives from all three branches and industry representatives from trade association and individual companies. Since its inception ten years ago, the program has transformed from its original form (IP training to Foreign Service officials being posted to the Greater China region, including Hong Kong, Macau, and Taiwan) to its current form (a forum to review past engagements and preview the year ahead).

Advancing Empirical Data Driven Policy and Decision Making

As specifically set out in the USPTO's 2014-2018 Five-Year Strategic Plan, and to advance empirical, data-driven decision and policy making (including enforcement policy making), the USPTO established a China Resource Center for U.S. government, industry and academics. As part of this effort, in May 2015 the China Resource Center and University of California, San Diego co-organized a program entitled "New Perspectives on Innovation and Intellectual Property Policy in China: What Does the Evidence Say?" The USPTO's China Team along with the Office of Chief Economist spoke at the program. Other speakers included IP and innovation experts from both the industry and the academia in both U.S. and China. Topics included comprehensive benchmarking of IP protection and commercialization, the role of IP licensing, and what current data shows about China's own self-interests in protecting IP.

USPTO Programs with Academic Institutions in the United States

As part of the USPTO's continuing efforts to educate rights holders and support more informed strategies on IP issues in China, the USPTO collaborated with several universities in the United States and overseas, including Cardozo Law School (on fashion law issues in China), NYU Law School (on due process for foreigners in IP and other legal matters), UC Irvine (on IP enforcement), UC Berkeley (on IP enforcement and protection), and UC San Diego (on empirical data policy making).

Department of Justice

Through its IP Task Force and CCIPS, DOJ maintains two websites that, among other things, provide the public with information on the Department's IP enforcement efforts, assist victims in understanding where and how to report an IP crime, and provide guidance on case referrals. Those sites can be found at http://www.justice.gov/dag/iptaskforce/ and http://www.cybercrime.gov.

In addition, DOJ continues to contribute to the National Crime Prevention Council (NCPC) public awareness campaign, which was launched in November 2011. By raising the public's awareness of the harmful impacts of counterfeit and pirated products, the campaign aims to change the

widely-accepted belief that purchasing counterfeit and pirated products is not harmful, and thereby reduce consumer demand for counterfeit and pirated products. Since November 2011, the campaign has garnered more than $96.4 million in donated media, including more than 88,479 total airings on television in 209 of 210 nationwide markets and 27,618 airings on radio. In addition, 1,841 digital mall posters have been displayed in 43 nationwide markets; print support for the campaign continues to be strong, adding another $412,000 in donated media.

In August 2015, NCPC hosted a live Twitter town hall chat with industry experts and law enforcement to discuss IP theft and to promote the online video, "Get Hip to IP Theft." This video, targeted at an audience of 18 and 24 year olds, was developed by two students during their internship with NCPC. During the one hour town hall, there were a total of 1,500 tweets and the top tweet received 1,926 views.

Between September 7, 2015 and October 4, 2015, NCPC's latest IP theft public service announcement (PSA), "Phony," was featured on a digital billboard in Times Square courtesy of the CauseWay Agency (which developed and produced the PSA). The Times Square digital billboard media donation is valued at approximately $12,500 and received an estimated 1,849,860 views.

On October 2, 2015, Attorney General Loretta Lynch unveiled the NCPC's last set of videos geared towards law enforcement. The videos explain IP theft, its effect on the U.S. economy and our communities, and how combating IP crimes benefits law enforcement. Featured in the videos are eight IP experts ranging from law enforcement officers, representatives from the IPR Center, the U.S. Chamber of Commerce, and National Association of Attorneys General.

On October 7, 2015, NCPC released the IP newspaper advertorial in support of the public education campaign. The advertorial was distributed in the Washington Times to more than 100,000 subscribers. NCPC partnered with the Newspaper in Education Institute (NIEI) to distribute the supplement for use in schools across America. The outreach includes 1,000 NIEI programs that partner with more than 100,000 schools, 380,000 teachers, and 14 million students each year.

Ensuring Efficiency and Coordination

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

Department of Justice and Department of Homeland Security

Protection and enforcement of intellectual property rights is a national priority, and U.S. law enforcement stands at the forefront of these efforts. During 2015, these efforts included the following:

To protect both companies and U.S. consumers, CBP has made IPR enforcement a Priority Trade Issue (PTI). CBP enforces IPR by seizing products that infringe trademarks and copyrights and by enforcing exclusion orders. 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 use trade targeting best practices. CBP's CEEs also are developing industry-specific expertise to better identify infringement. For example, in 2015, CBP's Pharmaceutical and Electronics CEEs conducted special IPR enforcement operations targeting counterfeits in these sectors.

1) In FY 2015, the number of IPR seizures increased nearly 25 percent to 28,865 from 23,140 in FY 2014. The total estimated MSRP of the seized goods, had they been genuine, increased 10 percent to $1.35 billion.

2) In 2015, CBP conducted 34 specialized trainings of CBP port personnel involved in IPR enforcement which focused on identify shipments of IPR infringing merchandise and addressed specific IPR related challenges of each port. In addition, a pilot IPR training course for Border Patrol Agents was conducted the Rio Grande Valley Border Patrol Sector Station.

3) Between April 8 and May 4, 2015, CBP and French Customs seized approximately 31,000 counterfeit personal care products and electronic personal care devices during a bilateral enforcement operation. The joint operation resulted in a seizures of merchandise with an estimated combined MSRP value of $541,000. In September 2015, CBP conducted a joint operation with Singapore Customs involving counterfeit pharmaceutical products.

4) In FY 2015, five Mobile Intellectual Property Enforcement Team operations were conducted, resulting in 1,152 total seizures and an estimated combined MSRP of over $15 million.

DOJ focuses 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 CCIPS, 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 are listed in the Performance Data section of this Report at II.D.

The IPR Center's Outreach and Training Section 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 the New Hampshire State Police have detailed personnel to the IPR Center for 30-day assignments to work with ICE personnel to identify concerns and to develop action plans for enhancing ICE's engagement with state and local agencies.

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 FY 2014, those receiving program grants have seized over $351 million worth of infringing goods and proceeds. Additionally, between from July 1, 2014 and June 30, 2015, grant recipients arrested 545 individuals for violation of IP laws, served 175 state and local search warrants in IP cases, and disrupted or dismantled 474 piracy/counterfeiting organizations. In coordination with the National White Collar Crime Center, DOJ held a total of 12 training events on IP for state and local law enforcement personnel nationally in FY 2015.

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 suspected products and packaging such as in the case of counterfeit pharmaceuticals. FDA continues to refine this low-cost device which enables users to rapidly visualize differences between suspect products and authentic products and provides preliminary findings in the field. The patent for the CD1-CD3 application was revised, and applications for patents for the CD3+ and the CD4 were filed. Its use has expanded in FDA laboratories and at international mail facilities (IMF). In 2015, within the FDA, a presentation describing the evolution of the device and its applications was made to the staff of the Technology Transfer Program in the Office of the Chief Scientist. Training was provided to FDA's field import investigators, the Los Angeles Police Department's Anti-Piracy Investigative Unit, and to Customs and Border Patrol agents in the evaluation of packaging using visual cues, print processes and the CDx. A representative from the FDA's Office of Criminal Investigations was provided a presentation that was delivered to the Interpol North Africa Regional meeting to discuss the CDx's capabilities in stopping pharmaceutical crimes. FDA representatives discussed current applications and findings with international law enforcement officials at the Permanent Forum on International Pharmaceutical Crime meeting. Health Canada provided a preliminary report on their use of the CD3 to screen pharmaceutical products at Canadian IMFs, and was very favorable in describing the device's utility. Also, an assessment for anti-malarial products received from Kenya is underway.

Another example during FY 2015 of leveraging advanced technology and expertise is FDA's development of a rapid screening method using ion mobility spectrometry (IMS) to screen for adulterated dietary supplements directly on-site at import locations. From October 2014 through June 2015, the agency piloted the use of compact ion mobility devices at two international mail facilities in the U.S. to screen weight loss and male enhancement products labeled as dietary supplements for the presence of an undeclared active pharmaceutical ingredient (API). To assess the performance of the IMS screening methods, samples failing field

screening were sent to FDA laboratories for confirmatory analysis. Overall, 65 percent of the samples collected during the pilot study contained an undeclared API. For the samples containing an undeclared API, the IMS instrument accurately classified the sample as adulterated in 93 percent of the cases. Due to the success of the current IMS methods, the instruments are being utilized for field screening.

10. Improve Effectiveness of Personnel Stationed Abroad

USPTO continued to post IP Attachés in high-priority countries including Brazil, Russia, India, China, Thailand and Mexico. Last year, USPTO opened a new office in Brussels, Belgium. The IP Attachés continued to play active leadership roles on enforcement-related issues in IP 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 also facilitated interactions between IP Attachés and U.S. stakeholders. 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 members of the public, as well as a Business Council for International Understanding event with more than 50 senior industry representatives in attendance. 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 Attachés coordinated with a group of IP Attachés from Australia, Canada, France, Japan, Singapore, the United Kingdom, and the EU on IP issues in developing 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. In May of 2015, the IP Attachés from Brazil, Russia, India, China, Mexico and Kuwait conducted a set of outreach meetings in San Diego and Los Angeles. Participants included senior representatives of industry associations, legal associations, law schools, IP practitioners, and U.S. companies. Specific U.S. Government activities during FY 2015 include:

- 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.

- During FY 2015, and as discussed above, USPTO facilitated interactions between IPR Attachés and U.S. stakeholders on IP issues.

- In July 2015, State, along with USPTO, held its annual IPR course at GIPA for Foreign Service Officers who 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 to raise public awareness about the role of intellectual property rights (in building the

local, regional, and national economy) and about the dangers posed by counterfeits. The DOS 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 continued to conduct international outreach and training events. During FY 2015, the IPR Center conducted 125 such events (there were 71 in FY 2014).

- The IPR Center partnered with European Police Office (Europol), which, through its member countries, launched multilateral enforcement actions under Operation in Our Sites (IOS) Project Transatlantic. This ongoing operation targets criminals using websites to sell counterfeit merchandise online, and involves coordinating with other parties to obtain the suspension of domestic and foreign-based Internet domain name registrations in the United States and Europe. In FY 2015, 27 countries participated in Project TransAtlantic VI with 19 Europol countries represented and, for the first time, 8 INTERPOL countries also took part in the operation which yielded the seizure of 999 internet domain names. As part of its participation in *Operation TransAtlantic*, the IPR Center coordinated with multiple industry partners, in using civil/administrative action to shut down a total of 37,479 infringing websites/domain registrations.

- 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, and they work closely with host government counterparts and participate in IP working groups at post.

- FDA's China Office facilitated meetings and information exchange between China's Food and Drug Administration (CFDA) and FDA's Office of Criminal Investigations (OCI) regarding counterfeit drug operations. In 2012, FDA and CFDA created a working group on economically-motivated adulteration (EMA), which is the fraudulent substitution of a substance in a product to increase value or reduce production costs for the purposes of

economic gain. EMA 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 address the underlying incentives that prompt some perpetrators to adulterate products to make a quick profit. FDA's China Office continued collaborations with OCI in 2013 resulting in FDA criminal regulatory investigators organizing a workshop for CFDA regulatory investigators on cybercrime and internet investigations. Most recently, to help frame the work to be performed in China by FDA's regulatory investigators and create mechanisms for collaboration on inspections, FDA signed two Implementing Arrangements in late 2014—one with CFDA and another with China's General Administration of Quality Supervision, Inspection and Quarantine. FDA now is able to increase the number of food and drug regulatory investigators it places in China and thereby significantly enhance FDA's ability to conduct inspections in Chinese facilities producing food and drugs for export to the United States.

- Under the DOJ IP Law Enforcement Coordinator (IPLEC) program, DOJ has had a Department attorney stationed in Bangkok, Thailand, who has handled IP issues in Asia since January 2006. Between November 2007 and March 2011, a separate Department attorney was stationed in Sofia, Bulgaria, in order to handle IP issues in Eastern Europe. Following the success of these early IPLEC programs (that trained prosecutors, judges and police, and yielded multiple overseas prosecutions of trademark counterfeiting and copyright piracy in the respective regions), DOJ in FY 2015 posted a new regional IPLEC in Bucharest, Romania. In addition, working with the State Department, DOJ received funding for two new IPLECs in FY 2015, gained US Embassy approval for their postings in Brazil and Hong Kong, and commenced recruitment of DOJ expert attorneys for the positions to be filled in FY 2016.

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 (Commercial Law Development Program) Capacity Building and Training

The Commercial Law Development Program (CLDP) works to improve IP enforcement and protection in key countries around the globe. As the Office of General Counsel's technical assistance arm and as part of the strategic goal of the DOC (as stated in its 2014-2018 strategic plan), CLDP upholds the Department's mission to "Expand the U.S. economy through increased exports." The first objective is to "increase opportunities for U.S. companies by opening markets globally," and a key strategy is to "reduce trade barriers." The plan states that:

"Foreign government-imposed trade barriers cost U.S. exporters billions of dollars each year. Barriers include inadequate protections for IP rights."

Since CLDP's mandate is to help create a level playing field for US firms overseas, CLDP has a strong emphasis on enhancing, through technical assistance, the enforcement of IPR rights in other countries. CLDP does so through two types of programs: programs that help countries develop an effective IPR enforcement environment, and programs that help countries create their own intellectual property (which gives them a vested interest in enforcing IPR).

In cooperation with USPTO, other DOC bureaus, USTR and other U.S. Government agencies, CLDP's IPR activities include trainings, seminars, and meetings to address topics such as: IPR border enforcement, innovation and the role of IP in the economy, technology transfer, judicial training in adjudicating IP infringement cases, 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. In FY 2015, these activities were conducted in Pakistan, Ukraine, Georgia, Kyrgyzstan, Armenia, Iraq, Bosnia and Herzegovina, Azerbaijan, Tunisia and Mali.

Notable CLDP training and capacity building programs during FY 2015 include:

<u>Legislative Updates</u>:

- In July 2015, CLDP in close cooperation with USPTO proposed a phased work plan to the Intellectual Property Organization of Pakistan (IPO) to advance draft legislation to update Pakistan's intellectual property (IP) laws (e.g., patent, trade mark, copyright, and trade secret) and supporting regulations; in September 2015, at a meeting with CLDP, IPO adopted the proposed work plan and formed a working group; in October 2015, IPO identified inconsistencies in the IP laws and submitted such information to the working group for its consideration; and in November 2015, the working group met to resolve any issues and begin work on drafting proposed amendments to the IP laws and regulations.

<u>Border Enforcement</u>:

- In March 2015, CLDP held a workshop in Lybid, Ukraine for Ukrainian customs officials on the identification and interdiction of IPR-infringing products.

- In the fall of 2014, CLDP assisted the Malian government, civil society, and the private sector, in the formulation and implementation of a national strategy to prevent the spread of counterfeit, illegal, and adulterated agricultural products including pesticides, fertilizers, seeds and animal vaccines. Through a series of workshops and trainings conducted in conjunction with the Ministry of Agriculture, the Ministry of Justice and Malian Customs, CLDP was able to foster the adoption of best practices for protecting farmers and breeders from the effects of counterfeit and substandard products, in order to improve food security and to contribute to economic growth.

Judicial Capacity Building and Development of Judicial Benchbooks:

- In June 2015, CLDP, the Georgian Copyright Association, and the National Intellectual Property Center of Georgia held a workshop for Georgian judges on the adjudication of copyright and trademark disputes.

- In June-July 2015, CLDP held a workshop in Ukraine on drafting an intellectual property judicial benchbook. The benchbook serves as a guide for judges and prosecutors that can be used for training purposes, and addresses both civil and criminal procedural aspects of IP cases for a country. It can also be used to assist judges who do not have much experience with intellectual property cases.

- In August 2015, CLDP in cooperation with USPTO and DOJ held a two-week technical assistance program for eleven Justices of the High Court of Pakistan regarding best practices and tools for judicial enforcement of intellectual property rights. The program included peer-to-peer exchanges with members of the U.S. Court of Appeals for the Federal Circuit, of the Federal Judicial Center, and of the United States District Court for the District of Minnesota.

- In September 2015, CLDP and Kyrgyzstan's Judicial Training Center organized a workshop for Kyrgyz judges on the adjudication of intellectual property disputes.

Trainings of Attorneys:

- In June 2015, CLDP, the Intellectual Property Rights Center of Armenia, and the American University of Armenia organized the first Intellectual Property Summer Academy course for attorneys from Armenia, Latvia and Russia. The curriculum focused on IP protection legislation and on litigation on patents, copyright, and trademarks, including an overview of U.S. laws and experiences with this issue.

- In August 2015, CLDP in coordination with the Continuing Legal Education Institute of Pakistan (CLEIP) held continuing legal education (CLE) training on intellectual property law in Karachi, Pakistan. One hundred and five local Karachi attorneys, mostly newly practicing or junior attorneys, attended the CLE event, which was the third such event organized by CLEIP and CLDP in Pakistan.

- In September 2015, CLDP, the Georgian Copyright Association, and the National Intellectual Property Center of Georgia held a workshop on litigation of trademark and copyright disputes for Georgian attorneys, which addressed Georgian and U.S. approaches to current topics.

IPR Institutions:

- In June 2015, Iraq's Ministry of Science and Technology created the Scientific Information and Technology Transfer Center (SITTC). This is the direct result of a

sustained multi-year program of CLDP technical assistance, launched by Embassy Baghdad and NEA/I at the end of the Science Day organized at Embassy Baghdad in January 2011. A key mandate of SITTC is to promote the protection of intellectual property rights and the enforcement of these rights.

- In September 2015, CLDP and USPTO sponsored a two-week training of Georgian patent examiners based on a curriculum developed by GIPA. The participants were four experienced patent examiners from the National Intellectual Property Center of Georgia, who will share the experience from the training with other examiners from Georgia and surrounding countries.

Collective Copyright Management:

- In November 2014, CLDP held a regional collective copyright conference for participants from Georgia, Bosnia and Herzegovina, Armenia, Azerbaijan, and Ukraine. The conference focused on the sharing of experience to address problems, controversial issues, legislation, collective copyright management approaches, and international cooperation.

U.S. Patent and Trademark Office (USPTO) Capacity Building and Training

Europe

Workshop on Border Enforcement of Intellectual Property Rights for the Balkans Region

The workshop was held in Macedonia in June 2015 for customs officials from Macedonia, Albania and Serbia. The purpose of the program was to provide insight into an effective border enforcement framework using U.S. customs laws and practices as an example and to encourage sharing of knowledge amongst the participants. Topics included: The Importance of IPR Enforcement; IPR Border Measures; Applications for Action; Targeting and Risk Analysis; Criminal Investigation of IPR Violations; Seizure, Forfeiture and Destruction; and Case Development and Evidentiary Considerations.

Investigation and Prosecution of Digital Piracy for Police and Prosecutors

A specialized training course was given in July 2015 on the investigation and prosecution of digital piracy for officials at the International Law Enforcement Academy in Budapest. The program included police and prosecutors from Ukraine, Estonia, Latvia, Lithuania, Romania, and Sweden. The training focused on practical skills and techniques for law enforcement, such as successful strategies in the search and seizure of electronic evidence; forensic examination of evidence; and best practices in international cooperation, including under mutual legal assistance treaties. The program included a laboratory session where law enforcement officials were taught how to use various free software tools as part of their investigations, such as conducting hard disk imaging and encryption detection. Participants received copies of the free-software tools to take back to their agencies, as well as an investigative guide on obtaining

electronic evidence from the U.S. The training was coordinated with DOJ/CCIPS' Cybercrime Lab, the DOJ's regional IPLEC based in Bucharest, and the USPTO Regional IP Attaché.

Association of Southeast Asian Nations (ASEAN)

Workshop on Effective Practices in Transnational Cooperation in the Border Enforcement of Intellectual Property Rights

The Workshop on Effective Practices in Transnational Cooperation in the Border Enforcement of Intellectual Property Rights was held in Bangkok, Thailand in May 2015 with the participation of 16 customs officials from several ASEAN member states, including, India, China, Pakistan and Sri Lanka.

Workshop on Effective Practices in Transnational Cooperation in the Border Enforcement of Intellectual Property Rights

In March 2015, an ASEAN-USPTO Workshop was held in Malaysia on Effective Practices in Transnational Cooperation in the Border Enforcement of Intellectual Property Rights. In addition to custom and border officials, the workshop included regulatory and enforcement officials from the food and health ministries, environmental regulators, and agricultural officials from Brunei, Malaysia, Lao PDR, Cambodia, Vietnam, Singapore, Indonesia, Philippines and Thailand. The workshop focused on the problem of adulterated, substandard and counterfeit agricultural chemicals in the ASEAN region. The workshop included presentations and discussions on the nature and scope of counterfeit and fake agricultural products; the varied regulatory approaches in the ASEAN region for addressing illegal, banned, and counterfeit agricultural products; and the enforcement of intellectual property rights, including dealing with counterfeit products that harm health and safety. The workshop discussed the issue of counterfeit agricultural chemicals, introduced officials to their counterparts in other countries, and facilitated dialogue among the participants to improve the skills and knowledge of customs and border officials to better analyze, target and interdict IP counterfeit and pirated goods, especially those that harm health and safety.

ASEAN-USPTO Roundtable for the ASEAN Judiciary on Intellectual Property Rights Issues

The participants in this roundtable, which took place in Manila, Philippines in October 2014, were magistrates and judges from Brunei, Cambodia, Lao PDR, Malaysia, Myanmar, Singapore, Thailand and the Philippines. The program began with a presentation on the overview of IPR enforcement in the U.S. and a presentation on the economic importance of IPR protection and related health and safety issues. During the roundtable discussion, which was facilitated primarily by U.S. Federal Judges, the judges discussed best practices related to IP case management as well as the use of court experts, damage determinations, and judicial mediation.

Philippines Roundtable Discussion on Issues and Concerns Relating to Intellectual Property Rights Enforcement

The roundtable was conducted in Manila, Philippines in October 2014 in collaboration with the Supreme Court of the Philippines and the Intellectual Property Office of the Philippines. The roundtable was attended by Filipino Judges, officials from the Philippines Department of Justice, officials from the Philippines Intellectual Property Office, and judges from Myanmar and the United States. Presentations were made on the importance of IPR on the economy as well as health and safety issues pertaining to IPR protection. The program also included an overview of IPR Enforcement in the Philippines, U.S. IPR enforcement, and best practices from the Philippines perspective and from the U.S. perspective.

Workshop on Intellectual Property Enforcement

The workshop was held at the Global Intellectual Property Academy in June 2015 for a Thai delegation of prosecutors. USPTO provided an overview of U.S. IP laws and arranged a visit to the United States District Court for the Easter District of Virginia. The delegation received an overview of the US criminal laws that pertain to IP protection and enforcement. On the second day, several presentations were arranged with state and Federal law enforcement to speak about IP investigations. On the final day, participants from industry spoke about the specific challenges that they face with intellectual property protection and enforcement. The day ended with a presentation by a U.S. judge on criminal prosecutions and sentencing in IP cases and a mock sentencing hearing.

Workshop on the Protection of Trade Secrets for ASEAN Countries

The first USPTO international workshop on the protection of trade secrets was held in July 2015 at the Global Intellectual Property Academy (GIPA) for officials from nine ASEAN countries. The program included discussions on: importance of trade secret protection; elements of a trade secret; elements of trade secret misappropriation; challenges for small to medium-sized enterprises (SMEs); breakout group discussions on trade secret protection and enforcement in the region; trade secret protection and enforcement globally; discovering, establishing and pursuing a misappropriation case; prosecuting trade secret theft and sentencing; using digital forensics to investigate trade secret theft and a panel discussion on industry views.

ASEAN-USPTO Workshop on Consumer Protection, Unfair Competition and Protection of Trade Secrets

The first USPTO Workshop on Consumer Protection, Unfair Competition and Protection of Trade Secrets was held in Singapore in August 2015. Participants included judges, public prosecutors, and senior IP officials from Brunei, Malaysia, Lao PDR, Cambodia, Vietnam, Singapore, Indonesia, Philippines and Thailand. The workshop included presentations and discussions on the importance of trade secret protection and unfair competition laws to IP rights-holders; judicial perspectives on consumer protection, unfair competition, and the protection of trade secrets; legislative approaches and unfair competition and unfair business practices; and unfair competition and dilution claims in trademark infringement cases. One of

the many achievements of the workshop was to open discussion on the issue of trade secret protection and unfair competition among the ASEAN countries, in light of the impact that ASEAN Economic Integration will have on IP and business policies.

Workshop for Public Prosecutors on Best Practices in Combating Online Content Piracy

This workshop on online piracy and counterfeiting was co-organized with the Thai Attorney General Office and held in Chiang Mai, Thailand in March 2015. Conducted for Thai public prosecutors, the program involved the use of case studies, the participation of DOJ's regional IPLEC based in Bangkok, and speakers from the Intellectual Property Department of the Thai Attorney General Office.

Workshop on Prosecution of Intellectual Property Crime

The workshop, held in Udon Thani, Thailand in September 2015 was the latest in a series of capacity-building programs for local, provincial level public prosecutors, and it was co-organized with the Thai Office of the Attorney General and DOJ's Bangkok-based IPLEC. The two-day program, attended by approximately 50 local public prosecutors, focused on effective investigation and prosecution of online commercial content piracy and trademark counterfeiting cases.

Advanced Judicial Seminar on Criminal Adjudication and Enforcement of Intellectual Property

A three-day judicial education program in Hua Hin, Thailand, in September 2015 brought together more than 70 judges from the Thai Central Intellectual Property and International Trade Court and the Thai Supreme Court Division on Intellectual Property and International Trade Litigation for discussion and experience-sharing about aspects of criminal intellectual property prosecution and case-management. Topics included the use of expert advisors and witnesses, motions and orders, evidence, calculation of penalties and deterrent-sentencing issues. This program was co-organized with the Central Intellectual Property Court, and included the participation to two U.S. Federal judges (Chief Judge Susan Oki Mollway of the U.S. District Court for Hawaii, and Chief Judge Ramona V. Manglona of the U.S. District Court for the Commonwealth of the Northern Mariana Islands).

<u>Middle East-North Africa region (MENA)</u>

Workshop on IPR Border Enforcement

The workshop was held in Casablanca, Morocco in December 2014 in collaboration with the Moroccan Office of Industrial and Commercial Property, CBP, ICE, the U.S. Consulate General, and the World Customs Organization (WCO). Attended by customs officials from various ports of entry throughout Morocco, the workshop focused on IPR border enforcement. Topics included: the importance of IPR enforcement; IPR border measures; applications for action and recordation; targeting and risk indicators; identifying infringing goods and suspension of release; coordination with other agencies; evidentiary considerations; criminal investigations; seizure, forfeiture and disposition of infringing goods; challenges for rights holders; practical considerations in designing a national recordation system; and ex officio actions.

Judicial Program on Proceeds of IP Crimes and Money Laundering

USPTO participated in a DOJ Office of Prosecutorial Development, Assistance, and Training program for judges that was held in April 2015 at the Institute of Training & Judicial Studies in Sharjah, United Arab Emirates (UAE) and at the Dubai Judicial Institute in Dubai, UAE. In addition to USPTO, USG speakers included representatives from DOJ, ICE HSI, and private sector speakers from the Gulf Brand Owners' Protection Group and Microsoft. Topics included an overview of UAE copyright and trademark law; the importance of IP enforcement; best practices for investigating and prosecuting IP crimes; using money laundering laws to combat IP crimes; seizure and forfeiture of assets; and working with the private sector to combat IP theft.

Inter-regional (MENA and South Asia) Counterfeit Medicines Program

USPTO hosted a program on investigation methods for counterfeit medicines in Manama, Bahrain in April 2015. The program included participants who work in fields combating counterfeit medicines such as public health, customs, law enforcement, and trademark and patent offices. The program raised awareness among officials about the harmful impacts of counterfeit medicines, and developed stronger collaboration on enforcement activities within the regions with an emphasis on sharing best practices for investigation of counterfeit medicines. The program facilitated discussion between health regulatory agencies and enforcement agencies. Participants included officials from Bhutan, India, Sri Lanka, Jordan, UAE, Egypt, and Bahrain. Presentations were made by ICE HSI and FDA Office of Criminal Investigations, Interpol, the Bahrain National Health Regulatory Authority, and others.

Colloquium on Intellectual Property Rights Enforcement for Judges and Prosecutors

The program was held at the USPTO Global Intellectual Property Academy in Alexandria, VA, in May 2015 for sixteen officials from the Middle East–North Africa Region. Topics addressed in the workshop included: trademark infringement analysis, IP criminal investigations, prosecuting IP crimes, judicial case management, trade secret protection and various case studies and exercises.

China

U.S.-China Judicial Engagement Generally

The USPTO has a long record of engaging with the Chinese judiciary on IP-related matters and, in recent years, on the overall structure of the courts. In that connection, USPTO has supported the following: establishing specialized IP courts; combining civil, criminal, and administrative courts into one panel (known in China as "3-in-1" tribunals); establishing more local-level IP tribunals; and establishing a national-level dialogue between the judiciaries of the U.S. and China to discuss how the legal environment in China affects U.S. businesses. On judicial engagement generally, USPTO has organized and presented training programs featuring involving members of the U.S. judiciary, particularly those with an IP background or IP-trial experience.

In 2015, USPTO's judicial outreach consisted primarily of one-on-one direct dialogues with judges from China's Supreme People's Court and the newly-established IP courts.

USPTO Consular Activities

Judicial Exchange Program in Shanghai

Shanghai and Beijing USPTO and headquarters assisted the Federal Circuit Court Bar Association and East China University of Politics and Law in organizing the International Forum on Intellectual Property and Trade Adjudication, Administration, and Innovation. Held in Shanghai, China in October 2015, the conference assembled key leaders in judicial, intellectual property, and trade related systems from around the world to focus on opportunities to encourage innovation in those systems. The conference covered a number of topics, including an exchange of views on government patent offices, the courts, patent quality, damages, injunctions, patent office perspectives, trade, and alternative dispute resolution. Participants included 12 judges from the United States Court of Appeals for the Federal Circuit, the United States International Trade Commission, the United States Court of International Trade, and the United States District Courts; leaders from China government and U.S. Embassy and Consulate in Shanghai; USPTO; China's State Intellectual Property Office; and over 40 judges from China's Supreme People's Court, the new specialized courts, and others. In addition, the conference included industry representatives, practitioners, litigators, academics and other IPR law experts.

Taizhou Trade Secret Program

Shanghai USPTO and headquarters presented at a program in October 2015 in Taizhou, Zhejiang that was organized by the State Administration for Industry and Commerce (SAIC). The program focused on protection and enforcement of trade secrets. USPTO engaged with numerous SAIC offices with trade secret responsibility from provincial and local levels around the country. USPTO addressed U.S. law and practice, including U.S. trade secret enforcement and obligations, as well as practices for maintaining secrecy of trade secrets in the course of judicial proceedings and regulatory reporting actions.

Shanghai Roundtable and Direct Line to U.S. Business Call on Protecting IP in E-Commerce

In April 2015, USPTO Shanghai organized a roundtable and Direct Line to U.S. Business Call addressing the topic of "East China: Protecting Intellectual Property in E-Commerce." In addition to USPTO, the panel included the Consul General for Shanghai, the head of the Agriculture and Trade Office, the head of the Foreign Commercial Service (FCS), the FCS official who is in charge of e-commerce, and the Economic Officer of IP at the U.S. Consulate General Shanghai. About 45 U.S. companies participated in this program. USPTO provided a briefing and overview of East China IP environment and explained USPTO's role in helping U.S. companies protect their IP, followed by a question and answer session.

Media Box Piracy Program in Guangzhou, China

In partnership with the Shenzhen Copyright Association, USPTO Guangdong organized a half day seminar focusing on copyright piracy from illegally modified media top boxes. Speakers included Chinese and foreign content providers, a local Chinese judge from Shenzhen, and a representative from the Shenzhen Market Supervision Authority. The IP Attaché Guangdong gave a brief presentation on media boxes in the US and current litigation in California concerning Chinese and Hong Kong television producers against a Chinese media box producer (CCTV et al. vs. Create New Technology (HK) Ltd. et al.)

Latin America

Workshop on Copyright Enforcement in the Digital Environment for the Central American Judiciary

The workshop was held in San Jose, Costa Rica in July 2015 with the participation of judges from Costa Rica, Panama, Honduras, El Salvador, and Guatemala. Discussions addressed the importance of intellectual property protection and enforcement as well as best practices in combating counterfeit products.

IP Enforcement Program for Brazilian Customs and Police

The USPTO co-sponsored and spoke at a three day event for Brazilian Federal police officers that was held in Foz de Iguasu in August 2015. The program focused on the tri-border region, and also included DOJ and ICE HSI representatives as well as officials from Argentina and Paraguay.

Training on Intellectual Property Rights

The USPTO sponsored and spoke at this three day event in July 2015 in which police officers, prosecutors, and judges received trained on intellectual property enforcement matters. This was the first such training that the USPTO has conducted in Vitoria, an important port city in Brazil. DOJ and ICE HSI officials also participated in the training.

Training on Combating Notorious Markets and Violations of Intellectual Property Rights

Training on Combating Notorious Markets and Violations of Intellectual Property Rights was conducted for local, State and Federal police officials in Porto Alegre, Brazil in September 2015. The program included opening remarks by the Vice Prosecutor General for the State of Rio Grande do Sul, and closing remarks by the Brazilian Congressman who serves as the head of a Caucus to Defend Intellectual Property and Combat Piracy within the Brazilian Parliament.

Symposium on IP Enforcement

A Symposium on IP Enforcement was conducted in Rio de Janeiro in August 2015. The program was organized by the DOJ Intermittent Legal Advisor/IPLEC and the ICE HSI Attaché with

support from USPTO, was attended by police and prosecutors, and included a session on combating counterfeit medicines.

Judicial Dialogue on Intellectual Property Rights Enforcement

USPTO supported a DOJ-sponsored Judicial Dialogue on Intellectual Property Rights Enforcement, which was held in Lima, Peru in September 2015. USPTO provided presentations on trade secrets and combating counterfeit medicines and also participated in panel discussions. Other speakers included judges from various branches of the Peruvian judiciary, including the Supreme Court.

Intellectual Property Rights Workshop for Prosecutors: Combating Internet Piracy and Transition to the Adversarial System

USPTO conducted this workshop in Mexico in September 2015 for Mexican Federal prosecutors and government officials, in cooperation with the IP Attaché U.S. Embassy Mexico City and DOJ CCIPS. Also participating in the program was the Mexican Attorney General's Office (PGR) Specialized Intellectual Property Unit that is dedicated to investigating and prosecuting IP crimes under the direction of the Deputy Attorney General for Federal Crimes. The program addressed internet IP violations, (including investigating and prosecuting digital, online piracy) and Mexico's transition from a (Napoleonic) civil code, paper-record based prosecution trial procedure to an adversarial, witness and best evidence-based trial procedure. Presentations included: investigating and prosecuting online digital piracy; explanation on how pirate internet sites are set up, operate, and make money; how local industry representatives from film /video, music, and software, can and will work to support PGR investigations and prosecutions; a case study about a pirate website and participant presentations on how to investigate and prosecute such a website; a review of emerging case law in the U.S. regarding border enforcement of digital content that infringes a patent; practice tips for effective evidence presentation and advocacy before a Federal trial judge, including a live demonstration on ineffective and effective techniques for witness examination; and a summary of a recent, successful, administrative take-down by the Mexican IP Office, IMPI, of the largest pirate internet website used in Mexico.

<u>Commonwealth of Independent States and Georgia</u>

Judicial Workshop on Intellectual Property Protection

The program was held at the USPTO Global Intellectual Property Academy (GIPA) in April 2015 for judges from Georgia, Kazakhstan and Kyrgyzstan. Program faculty included two US District Court judges, an Assistant US Attorney, a senior representative from DOJ CCIPS, USPTO, and industry. Topics included: overviews of substantive IP laws, judicial challenges in handling IP cases, sentencing issues, docket management and prosecution of IP cases, and asset forfeiture.

Workshop for Police and Prosecutors on the Protection of Intellectual Property Rights

A workshop was held at the USPTO GIPA in July 2015 for police and prosecutors from Tajikistan and Kazakhstan on IP enforcement. Topics included the importance of IP protection, overviews

of US IP laws, investigative techniques, international coordination, and prosecutorial issues. The delegations discussed their legal systems and IP protection laws, participated in group discussions, and met with a U.S. District Court judge.

South Asia

Criminal and Border IPR Workshop for Bangladesh

The first enforcement program tailored for Bangladesh enforcement officials was held at the USPTO GIPA in May 2015. The participants included representatives from Bangladesh's IP Offices, Customs, Ministry of Justice, police and prosecutors.

Africa

USPTO African Regional IP Enforcement Workshop

USPTO held a workshop for African IP government officials in Accra, Ghana in September 2015, in cooperation with the U.S. Embassy Accra, Ghana and the African Regional Intellectual Property Organization (ARIPO). Presentations included: a USPTO overview and summary of IP in the United States; copyright, trademark, and industrial property rights in ARIPO member states; investigating counterfeit medicine cases in Ghana (by the Chief Ghana National Police Fraud Division); international standards for IP enforcement; challenges regarding counterfeit medicines in west Africa; FDA roles and functions for investigating counterfeit medicines crimes; and the national-coordination "whole of government" model (as embodied in the USG's IPR Center).

International Trade Administration Capacity Building and Training

- ITA's Office of Intellectual Property Rights (OIPR) continues 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 the World Intellectual Property Organization (WIPO) on the Road Shows. During FY 2015, the STOPfakes.gov Road Show traveled to four U.S. cities to raise public awareness on avoiding IPR pitfalls when exporting to foreign markets. The Road Shows also provide opportunities for small-to-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 during FY 2015. 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 to intellectual property protection and enforcement. The China IPR Webinars can be found here: http://www.stopfakes.gov/china-ipr-webinar.

Department of Homeland Security Capacity Building and Training

In FY 2015, CBP supported U.S. Government-sponsored IPR capacity building and training programs, providing instructors for training sessions for foreign customs officials in Argentina, Brazil, France, Kuwait, Mexico, the Netherlands, the United Arab Emirates, and the United Kingdom.

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 USPTO and INTERPOL; and the DOS's Bureau of International Narcotics and Law Enforcement Affairs-funded country-specific and regional programs. In FY 2015, the IPR Center participated in 22 international trainings in support of these programs (the IPR Center participated in 20 international trainings in FY 2014). ICE HSI continues to work closely with its law enforcement counterparts, particularly those who received training in IP enforcement. For example:

- In June 2015, and in conjunction with ICE Hong Kong (and using funding from the DOS Bureau of International Narcotics and Law Enforcement Affairs), the IPR Center hosted an Advanced IPR Enforcement Workshop that involved 35 U.S. law enforcement and 64 foreign law enforcement, customs, and judicial officials. Participating in the workshop were officials from the Governments of India, Bangladesh, China, Macau, Hong Kong, Vietnam, Malaysia, Thailand, Cambodia, Korea, Philippines, Indonesia, and Singapore. The training focused on public health and safety violations, and the U.S. and foreign law enforcement officials exchanged techniques and experiences for combating counterfeit goods.

- The IPR Center workshops promote stronger relationships and information sharing between the U.S. and the participating governments; increase subject matter knowledge and investigative capacity for the participants; and inform participants about recent or anticipated trends in IPR-related crimes and enforcement. Also advancing these goals was the temporary assignment, from November 1, 2014 through December 13, 2014, of two ICE HSI special agents to serve (at the Attaché Bangkok) as Technical Advisors to the Thailand National Intellectual Property Rights Centre for Enforcement. The ICE 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 approximately $2 million.

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), has a long-standing program to provide USG capacity-building training and technical assistance to foreign law enforcement partners to combat IPR crime. The DOS works with other USG agencies to prioritize assistance to the developing countries in the Middle East, Latin

America, Africa and the Asia Pacific that are named in USTR's 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 government-to-government bilateral training, the Embassy in Mexico has worked closely with the DOJ since 2012 to use INL funds to conduct trainings on IP-related computer forensics and digital evidence in order to address infringement in the digital environment. Examples of multilateral assistance are regional trainings to combat IP theft that DOJ, DHS, and USPTO have delivered to Organization of American States and ASEAN member states. Also, INL funds have expanded the successful regional DOJ IPLEC program to not only extend the term of the existing advisor for Central and Eastern Europe located in U.S. Embassy Bucharest, but they add two new advisors to U.S. Consulates Hong Kong and Sao Paulo to work in the East Asia Pacific and Latin American regions.

Bilateral Engagement: U.S. Embassies around the world continued to make IPR an integral part of their bilateral policy dialogues with host governments. 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. For example, the U.S. Embassies in Armenia, the United Kingdom, and Ukraine work productively with their host governments on pharmaceutical market access areas, online piracy and counterfeit pharmaceuticals.

Multilateral Engagement: The DOS continues its efforts to promote respect for IPR through international organizations and in other multilateral forums. Where relevant, the DOS representatives have requested that U.S. international development and trade agency partners educate their program recipients about the importance of IP to support business development, entrepreneurship, and innovation.

The DOS continued efforts to address counterfeit medicines in Asia-Pacific Economic Cooperation (APEC) and the G7 summit. The DOS supported the IPEC on efforts to promote voluntary practices to address online piracy among G7 members. In APEC and ASEAN, the 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. The DOS participated in the Transatlantic Intellectual Property Rights Working Group to implement a number of key objectives, including those related to third countries such as China, Brazil, and India, and to enhance collaboration on fighting trade secret theft in China adversely affecting US and EU interests. The DOS initiated creation of an APEC trade secret report and an August 2015 trade secrets best practices event, both of which were endorsed by APEC's Intellectual Property Experts Group.

Public Diplomacy Counterfeit Medicines and Internet Piracy Initiatives: During FY 2015, the DOS devoted public diplomacy funds toward its international "Campaign against Counterfeit Medicines, Counterfeit Products, and Internet Piracy." The programs are noted below by region.

Africa

In **Algeria**, Embassy Algiers – in collaboration with the American Chamber of Commerce in Algeria and the National Office of Copyrights and Related Rights – organized a seminar that focused on comparisons among the U.S., European, and Algerian legal frameworks for IPR protections.

In **South Africa**, Consulate General Durban proposes utilizing the public audience it has captured in past trade promotion events to sponsor a one-day "Best Practices in IPR" seminar and reception.

Europe

In **Switzerland**, Embassy Bern is supporting the "Helvetia Pro-Musica: Swiss Artists for Intellectual Property Protection" campaign. The Embassy also runs a broad educational program to help Swiss nationals, Swiss content creators, and the Swiss government better understand the extent of online piracy within Switzerland, the consequences of piracy, and possible solutions.

Latin America

In **Costa Rica**, Embassy San Jose continues to work with Costa Rica's American Chamber of Commerce (AmCham) and the Costa Rican Finance Ministry to publicize www.mercadoilegal.com, a website that allows for the reporting of tips on counterfeit merchandise for public health awareness. DOS funds have been provided for this effort and will be publicized www.mercadoilegal. com at bus stops, in the nation's most read newspaper, and at border crossings.

Training Foreign Service Officers

IPE, along with USPTO, held its annual IPR course in July 2015 at the Alexandria, Virginia-based GIPA. Among the participants in the course were Foreign Service officers that will have intellectual property as part of their portfolio at an overseas post. The course equips Foreign Service Officers to actively engage their host governments to improve IPR-related legislation and enforcement and raise public awareness of the role of IPR in creating innovation and economic growth and the danger of counterfeit goods. IPE integrated a session on IPR into the economic/political and commercial tradecraft courses offered at the Foreign Service Institute and improved its website to facilitate closer collaboration between Washington and international posts on IP issues.

Special 301 and Notorious Markets Contributions

The DOS/IPE provided extensive support to USTR and the interagency team as part of 2015's Special 301 process. 74 Posts submitted detailed analysis on the state of IPR protection and enforcement as part of the 2015 review. IPE also coordinated post input from 14 Posts for the Notorious Markets Report.

Supply Chain Integrity: Led by the Under Secretary for Economic Growth, Energy, and the Environment; the DOS continued to work to improve the integrity and security of international supply chains. One key private sector partner is the Center for Responsible Enterprise and Trade (CREATe.org), which is focused on supply chain integrity and related issues, including IP protection. CREATe.org promotes policies among suppliers and business networks in global supply chains that ensure respect for IP, put in place strong anti-corruption measures, and insist on transparency and accurate record-keeping.

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

In FY 2015, FDA-OCI assumed a leadership position in the Permanent Forum on International Pharmaceutical Crime (pfipc.org). PFIPC is a global network designed for the rapid exchange of information pertaining to criminal investigations involving counterfeit and substandard FDA-regulated products. 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. As part of this agreement, an officer from the French National Gendarmerie will attend FDA-OCI's Special Agent Basic Training at the Federal Law Enforcement Training Center in Charleston, South Carolina from February 2016 to March 2016.

FDA-OCI is recognized as a world leader in the investigation of pharmaceutical and other medical crimes and is often asked to share its knowledge, expertise and experience with foreign counterparts. For example, during FY 2015:

- In November 2014, FDA-OCI's Deputy Director delivered a keynote speech at the Interpol Conference on Pharmaceutical Crime and Drug Counterfeiting in Dublin, Ireland.

- In March 2015, FDA-OCI provided training on countering counterfeit drug trafficking to multiple law enforcement and public health agencies from Mexico and Latin America.

- In May 2015, FDA-OCI provided two-day cybercrime investigations training to police, customs and MedSafe from New Zealand in coordination with presentations on illegal online pharmacies at the annual meeting of the Permanent Forum on International Pharmaceutical Crime.

- In July 2015, FDA-OCI provided cybercrime investigations training to personnel from the Royal Canadian Mounted Police and Health Canada in Ottawa.

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 FY 2015.

DOJ has actively engaged with its foreign counterparts to promote an application of competition laws to intellectual property rights that is based on analysis of competitive effects, not domestic or industrial policy goals. The Division promotes both competitive markets and respect for IP rights, devoting substantial time and effort to advocating in bilateral discussions that competition laws be enforced in ways that maintain incentives for innovation. Consumers benefit from consistent application of sound antitrust principles to IP rights and the strengthening of those principles through shared learning.

DOJ continued its work with international organizations on issues involving the intersection of antitrust and IP. In December 2014, the Division participated in a hearing on competition, standards, and patents sponsored by the Competition Committee of the Organization for Economic Cooperation and Development (OECD). In addition, jointly with the FTC and USPTO, the Division engaged with WIPO's Intellectual Property and Competition Policy Division on several reports involving competition and IP.

With respect to international IP criminal enforcement efforts, DOJ has long recognized that IP 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 IP crimes and other computer crimes originate in other countries, DOJ has made a top priority the strengthening of its international law enforcement relationships.

DOJ has collaborated with other U.S. agencies and foreign law enforcement counterparts to address international IP 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 IPLEC program, 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 develop contacts in the region with appropriate IP law enforcement officials and assist in the regional and bilateral training of prosecutors and regulatory investigators in the area of IP crimes. Additionally, the IPLECs foster improved communication between and among the law enforcement officials in their respective regions, in order 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.

In two countries that operate outside of the IPLECs' regions, the Department provided bilateral assistance on IP, including an introductory level assistance program for judges in Namibia in July 2015, and an advanced level assistance program for judges in Peru in September 2015.

U.S. Copyright Office Capacity Building and Training

During FY 2015, the U.S. Copyright Office continued to provide outreach and education on copyright issues for members of the public and foreign visitors. Throughout the past year, 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.

Experts from the U.S. Copyright Office and USPTO have worked together on several training programs, including a week-long seminar in September 2015 on "Copyright, Culture, Art and Science in the Digital Age" at USPTO's GIPA. This seminar included a special visit with the U.S. Copyright Office's Office of Registration Policy and Practice for GIPA program attendees. Other programs during FY 2015 included judicial training in the United States and abroad.

The Copyright Office also continued to host smaller groups of international visitors to discuss and exchange information on the U.S. copyright system and important international copyright issues. In FY 2015, the Copyright Office hosted visitors from 19 foreign countries, including visitors from Algeria, Bangladesh, Botswana, China, Colombia, Egypt, Germany, Holland, India, Indonesia, Jamaica, Kosovo, the Kyrgyz Republic, Mexico, Nigeria, Paraguay, Peru, Taiwan, and Turkey. In Spring/Summer 2016, the Copyright Office will host its biannual international training program for foreign officials, jointly sponsored with WIPO. The week-long program is entitled "Copyright in a Global Network: Emerging Issues in Copyright and Related Rights for Developing Countries and Countries in Transition." The program brings together senior-level copyright officials and copyright specialists from over a dozen countries to hear from government, private industry, and civil society experts on a range of emerging issues in copyright law and policy.

12. Consider Alternative Forums for Enforcement of Rights

IP rights holders and others have expressed frustration that the current Federal court litigation framework for pursuing civil enforcement of 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.

As we explained in the FY 2014 annual report, the Copyright Office released a report in September 2013, detailing the findings of its two-year study of copyright small claims. In this report on "Copyright Small Claims," the Office documented the significant costs and other challenges of copyright claims that have a relatively low economic value, and recommended that Congress create a centralized small-claims tribunal within the Copyright Office to administer streamlined proceedings through online and teleconferencing facilities (without the requirement of personal appearances). Under the Office's recommendation, the tribunal would be a voluntary alternative to Federal court with a focus on infringement cases valued at no more than $30,000 in damages; copyright owners would be required to register (or to apply to register) their works before bringing an action; and the tribunal's decisions would be binding only with respect to the parties and claims at issue (and would have no precedential effect).

The report can be found at http://copyright.gov/docs/smallclaims/usco-smallcopyrightclaims.pdf.

Additionally, this topic is explored in the Department of Commerce's "White Paper on Remixes, First Sale, and Statutory Damages: Copyright Policy, Creativity, and Innovation in the Digital Economy" (discussed above, in the section on action-item #6 of the 2013 Joint Strategic Plan).

USPTO

As we explained in the FY 2014 annual report, USPTO has been exploring the possibility of patent small-claims proceedings 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 respondents. 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.

USPTO maintains ongoing efforts to evaluate enforcement mechanisms for patent holders. As Congress considers further patent reform legislation, USPTO will continue to monitor developments and provide input as appropriate.

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. In FY 2015, U.S. law enforcement and Federal agencies, including the IPR Center (through ICE HSI, CBP, and FDA), participated in *Operation Pangea VIII*, a global enforcement effort led by INTERPOL and the WCO that is aimed at disrupting organized crime networks behind the illicit online sale of fake drugs. *Operation Pangea VIII* involved 115 participating INTERPOL member countries and 236 different agencies from police, customs, and health regulatory agencies and resulted in the seizure of 50,852 packages with an estimated value of 75 million dollars and the shutdown of approximately 2,700 websites engaged in illegal activity.

In addition, during FY 2015, 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 criminals using websites to sell counterfeit merchandise online, and involved coordinating with other parties to obtain suspension of domestic and foreign-based Internet domain name registrations in the United States and Europe.

ICE HSI continues to participate in the IP Criminal Enforcement Working Group of the U.S.-China Joint Liaison Group (JLG) on Law Enforcement Cooperation. Participation in the JLG furthers efforts to exchange of information between United States and Chinese law enforcement. In FY 2015, successful collaboration between the Ministry of Public Security (MPS) of the People's Republic of China and ICE HSI through the ICE Attaché office in Beijing continued on a number of health and safety-related investigations.

Cooperation with our Asian law enforcement counterparts to address infringement is critical, and U.S. law enforcement marked a significant milestone in 2013: CBP 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. In December 2015, CBP and China Customs officials met in Washington D.C. to plan for additional collaborative efforts in 2016. DOJ works extensively to improve coordination and cooperation in international criminal IP enforcement through the IPLEC program (discussed earlier in this report) and through bilateral engagement.

Perhaps the single most important relationship for criminal IP enforcement is the interaction with China. Through the U.S.-China Joint Liaison Group's IP Criminal Enforcement Working Group, DOJ and U.S. law enforcement maintain a steady flow of information and case leads, resulting in successful operations to disrupt the manufacture of counterfeit airbags, pharmaceuticals, batteries, electronic components, cell phones and luxury items.

FDA-OCI now has a headquarters-based Senior Operations Manager assigned to International Affairs. This position is charged with maintaining counterpart liaison to foreign embassy staff as well as coordinating FDA-OCI's international investigations, outreach and training.

In June 2015, FDA-OCI and the U. K. Medicines and Healthcare Products Regulatory Authority (MHRA) exchanged regulatory investigators at each other's headquarters offices for 30 days. As a result of this exchange, FDA-OCI and MHRA will coordinate on future joint operations involving potential counterfeit drug manufacturers.

FDA-OCI also participates in *Operation Opson*, an annual Europol - INTERPOL joint operation targeting counterfeit and substandard food and beverages. In December 2014 through January 2015, as part of *Operation Opson IV*, enforcement operations resulted in the seizure of more than 2,500 tons of counterfeit and illicit food, including mozzarella, strawberries, eggs, cooking oil and dried fruit. Police, customs, national food regulatory bodies and partners from the private sector inspected shops, markets, airports, seaports and industrial estates.

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

- In November 2014 and July 2015, ICE HSI sent two special agents to Thailand as technical advisors. The agents oversaw the startup of the Thailand National Intellectual Property Rights Centre for Enforcement (NICE) and assisted the Thai Department of Special

Investigations. During the two details, the agents advised on 20 operations, which resulted in 82 seizures and 16 criminal arrests. The seizures totaled over $18 million MSRP.

- 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 late 2014, DOS 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.

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 during FY 2015 include:

- CBP and DOS continued to support the further development and deployment of the WCO Cargo Targeting System (CTS) which was successfully piloted in 2013. The CTS has the potential to enhance cooperation between the United States and foreign partners through targeting efforts to identify and interdict 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. Attachés at the WCO continue to train and support customs administrations in CTS operation.

The IPR Center through ICE HSI has continued to expand its partnerships with international organizations, and in FY 2015 continued its partnership 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:** 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:** 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:** This 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 also 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 regulatory investigators to address the counterfeiting issue and to provide strategies for strengthening IP enforcement efforts.

In 2014 and 2015, DOS 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 United Nations 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. This allows those artisans and micro-entrepreneurs to earn a higher wage.

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

The U.S. Government uses a broad 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 negotiations, monitoring and enforcement of those agreements, participation in the TRIPS Council, and high-level engagement in multilateral and bilateral meetings.

Given the international competitiveness of U.S. innovative and creative industries, the United States considers strong and effective protection and enforcement of IP rights as critical to U.S. economic growth and American jobs. According to the U.S. Department of Commerce, 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 compete on a level playing field around the world, the U.S. Government uses all the tools at its disposal to promote effective IPR protection and enforcement by its trading partners. Trade-related initiatives that have advanced IPR protection in 2015 include:

Trans-Pacific Partnership (TPP)

In 2015 the United States and 11 partners (Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam) completed the negotiation of the comprehensive, high-standard Trans-Pacific Partnership agreement that will expand U.S. access to the markets of the dynamic Asia-Pacific region, and support the increase of exports, economic growth, and jobs in the United States.

TPP raises the standards for IPR protection in the Asia-Pacific region. TPP requires the availability of mechanisms to effectively enforce intellectual property rights, consistent with U.S. law, including civil and administrative procedures and remedies, border measures, and criminal enforcement. It also requires TPP trading partners to adopt or maintain strong anti-counterfeiting measures designed to close loopholes used by counterfeiters and make enhanced penalties available for particularly serious cases, such as trafficking in counterfeit trademark products that threaten health and safety. In addition, it requires availability of criminal penalties to deter unauthorized camcording. It comprehensively addresses the problem of trade secret theft, including theft conducted by State-owned enterprises. TPP also—for the first time in a trade agreement—requires TPP parties to adopt or maintain criminal procedures and penalties for trade secret theft, including cyber theft.

Transatlantic Trade and Investment Partnership (T-TIP)

The United States and the European Union (EU) provide among the highest levels of IPR protection and enforcement in the world. In the T-TIP, the United States is pursuing a targeted and value-added approach on IPR that will reflect the shared U.S.-EU objective of high-level IPR protection and enforcement and sustained and enhanced joint leadership on IPR issues, including through transatlantic cooperation.

In 2015, the United States continued to seek opportunities to advance and defend the interests of U.S. creators, innovators, businesses, farmers, ranchers, and workers with respect to strong

protection and effective enforcement of IPR, including the ability to compete in foreign markets through T-TIP negotiations and other engagement in Europe.

Ongoing Trade Agreement Implementation and Enforcement

In 2015, the U.S. continued to engage with Free Trade Agreement (FTA) partners (including Korea, Colombia, and Honduras) 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. USTR issued its annual Special 301 Report in May 2015.

In the Special 301 Report released in May 2015, USTR highlighted serious and ongoing concerns with respect to the environment for IPR protection and enforcement in China, India, Turkey, Indonesia, Russia, Argentina and other markets. USTR announced that it will conduct Out-of-Cycle Reviews to promote engagement and progress on IPR challenges identified in the 2015 reviews of Honduras, Paraguay, Tajikistan, Turkmenistan, and Spain.

The Report identified a wide range of concerns, including: (a) the deterioration in IPR protection, enforcement, and market access for persons relying on IPR in a number of trading partners; (b) reported inadequacies in trade secret protection in China, India, and elsewhere, as well as an increasing incidence of trade secret misappropriation; (c) troubling "indigenous innovation" policies that may unfairly disadvantage U.S. rights holders in China; (d) continuing online copyright piracy and trademark counterfeiting in countries such as Brazil, China, India, and Russia; (e) reportedly nontransparent and potentially discriminatory measures, including measures that could impede market access for U.S. entities that rely upon IPR protection; and (f) other ongoing, systemic IPR enforcement issues in many trading partners around the world.

Also in 2015, the United States and Paraguay signed a Memorandum of Understanding (MOU) on Intellectual Property Rights resulting in the removal of Paraguay from the Special 301 Watch List pursuant to the Out-of-Cycle Review. As part of the MOU, Paraguay committed to take specific steps to improve its IPR protection and enforcement environment. Additionally, the MOU creates a bilateral partnership in which the United States intends to support Paraguay's efforts to strengthen the legal protection and enforcement of IPR, including through the enhancement of creative and innovative industries, to promote Paraguay's strategic priorities of growth and development.

Notorious Markets List

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

The most recent Notorious Markets out-of-cycle review was initiated September 10, 2015 through the publication in the Federal Register of a request for comments from the public. USTR issued the 2015 List on December 17, 2015.

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

The operators of several websites identified in the List in the past have begun to work with rights holders to address counterfeiting and piracy. Several markets have also ceased operations.

India

The U.S. has increased its bilateral engagement with India on IPR issues through the High Level Working Group on IP under the United States – India Trade Policy Forum (TPF). USTR, working with interagency partners (USPTO, DOC, DOJ, Copyright Office, Health and Human Services, FTC, and others), held numerous technical engagements with Indian government counterparts to promote robust protection and enforcement of IPR, with a focus on areas such as copyright, trade secrets, patent protection, and standard essential patents.

Among the important IPR commitments reached at the 2015 TPF, were the following:

- The scheduling of a workshop on copyright policies and implementation in Washington in 2016 with the participation of relevant agencies from both countries;

- Positive reforms relating to anti-camcording measures proposed in forthcoming amendments to India's Cinematograph Act;

- A commitment by both sides to the strong protection of trade secrets;

- A bilateral commitment to exchange information and best practices relating to trade secret protection; and

- A bilateral commitment to convene a joint workshop involving interested stakeholders on effective trade secret protection mechanisms.

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

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

- The U.S. secured a commitment by China welcoming U.S.-invested firms in China to participate in the development of standards in certain Chinese standards setting bodies on a non-discriminatory basis.

- China committed that licensing commitments for standard-essential patents should be made voluntarily and without government interference in negotiations, except where legally prohibited;

- The United States secured China's commitment to a transparent and expeditious process for developing geographical indication-related measures that will help keep this significant market open to U.S. agricultural and other products;

- China identified several intended efforts to revise China's trade secrets system to deter and respond to the misappropriation of trade secrets, including through legislative amendment and efforts to clarify rules on preliminary injunctions, evidence preservation orders and damages.

- China agreed to participate in a government-industry dialogue to enhance the systems available to address IPR challenges and to increase information sharing and cooperation on cross-border enforcement between the United States and China.

- The U.S. and China agreed to deepen cooperation on IPR enforcement and plan a second joint customs operation on IPR enforcement to identify counterfeit merchandise for seizure.

World Trade Organization Council on Trade-Related Aspects of 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 TRIPS Council, and the Dispute Settlement Body. In 2015, the United States

advanced its IP and Innovation agenda in the TRIPS Council through a series of initiatives designed to facilitate greater understanding regarding the critical role IPR protection and enforcement plays in the innovation lifecycle. In October 2015, the United States advanced an agenda on the integral linkage between innovation, entrepreneurship and economic growth, including exchanges of information between a broad and diverse set of developed and developing countries on economic data, commercial experience and government policymaking in this area. In June of 2015, the United States led an initiative in the TRIPS Council to emphasize the vital role IP plays in attracting capital and investment to fuel innovation. In March 2015, as part of International Women's Day, the United States facilitated a first-of-its-kind exchange in the Council on the role of women in innovation.

World Trade Organization Accession

Governments in the process of negotiating the terms for accession to the WTO work with WTO Members, including with the United States, to appropriately update and strengthen their intellectual property regimes, as well as to expand trade and enhance the investment climate for innovative and creative industries. In 2015, USTR worked with Kazakhstan and Afghanistan to finalize their WTO accession process and with Belarus and the Bahamas to advance their WTO accession process.

Multilateral Organizations

In addition to the WTO (which is the principal forum for addressing trade-related aspects of intellectual property), the United States also advances these issues in other multilateral fora, including the Organization for Economic Cooperation and Development (OECD), WIPO, APEC forum and various U.N. bodies. In APEC, the United States actively led engagement to improve trade secrets protection and enforcement in APEC economies. In November 2015, APEC Ministers welcomed a report on trade secrets protection and enforcement in APEC economies as well as progress toward developing APEC best practices in trade secrets protection and enforcement. The United States took a coordinating role in the drafting of this report and best practices document. Additionally, in 2016, the United States plans to review the intellectual property laws and practices of Colombia, Costa Rica, Latvia and Lithuania as these countries seek to join the OECD.

Additional Areas of IPR Engagement through Trade Policy

- Taiwan made important IPR-related commitments at the 2015 Trade and Investment Framework Agreement Council meetings to further enhance protection for innovation, curb piracy and infringement (particularly those occurring online), and deepen engagement on trade secrets protection and enforcement.

- Denmark established a unit to be housed under the Danish Patent and Trademark Office that will assist in enforcement efforts by serving those consumers and businesses that have allegedly been the victims of patent, design and trademark infringement.

- Paraguay has committed to a whole-of-government approach to IPR enforcement that has been critical to enhancing the effectiveness of IPR enforcement and resulted in positive reports from a number of affected stakeholder groups.

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.

Two presidential actions regarding this issue took place in FY 2015. On April 1, 2015, the President issued Executive Order 13694 (EO) ("Blocking the Property of Certain Persons Engaging in Significant Malicious Cyber-Enable Activities"), which authorized actions to combat cyber threats, including the theft of trade secrets. The EO can be found here: https://www.whitehouse.gov/the-press-office/2015/04/01/executive-order-blocking-property-certain-persons-engaging-significant-m. Furthermore, in September 2015, President Obama and President Jinping of China reached an agreement regarding cyber-enabled theft of IP, including trade secrets, during China's State Visit to the U.S. More information can be found here: https://www.whitehouse.gov/the-press-office/2015/09/25/fact-sheet-president-xi-jinpings-state-visit-united-states.

FDA-OCI's Cybercrime Investigation Unit (CcIU) protects public health by working with DOJ and other domestic and international law enforcement and regulatory agencies to disrupt and dismantle criminal networks that illegally sell counterfeit or adulterated medicines, medical devices, cosmetics, tobacco, and food products online. These regulatory investigators follow the cyber-trail of these sophisticated criminals and often go undercover to infiltrate the illicit criminal networks. CcIU also works with FDA-regulatory personnel to provide training and support to FDA's regulatory efforts in the online environment.

In 2015, CcIU agents made 11 arrests, secured 10 convictions and collected fines totaling $300,200. CcIU also submitted abuse complaints on 749 websites with U.S. and foreign-based domain name registrars.

The sale of counterfeit pharmaceuticals is only one example of IP infringement in the online environment. Some criminals use websites to 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 over the internet. The ICC program consists of a well-known operation dubbed *Operation in Our Sites*, which was initiated as a method to disrupt this illegal online activity. By working with domain name registrars to suspend domain name registrations, 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 name registrations had been seized, of which 1,760 were forfeited to the Federal Government. Of these sites, 686 were used to sell counterfeit pharmaceuticals.

ICC's strategy is focused on developing investigations that identify targets, assets, and financial schemes used in operating these 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 National Cyber-Forensics and Training Alliance (NCFTA) leverage the resources and analytical tools of the NCFTA to identify domain names and networks affiliated with infringing activity in support of criminal investigations or potential civil enforcement action.

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 involved the execution of coordinated seizures of domestic and foreign-based Internet domain name registrations in the United States and Europe. In 2015, the IPR Center and Europol concluded *Operation IOS Cyber Monday/Project TransAtlantic VI* in collaboration with INTERPOL. The total number of infringing domains seized was 999.

DOJ continues to pursue websites used for large-scale counterfeiting and piracy, including websites that are hosted overseas where DOJ can obtain jurisdiction over the sites, responsible individuals, or assets. Perhaps the clearest example of this type of case (and the related challenges) is the prosecution of the MegaUpload conspiracy in New Zealand. Megaupload.com was a commercial website and service operated by the Mega Conspiracy that reproduced and distributed copies of popular copyrighted content over the Internet without authorization. The copyrighted material included motion pictures, television programs, musical recordings, electronic books, images, video games, and other computer software. During the existence of the conspiracy, the conspirators collected an estimated $150 million in subscription fees. Online advertising revenue generated by megaupload.com and its associated websites, which was heavily dependent on the popularity of copyright-infringing content to attract website visits, exceeded $25 million. Following this widely-publicized raid and arrest in January, 2012, DOJ has engaged in extensive efforts to successfully detain and forfeit assets held overseas and to pursue the extradition of the defendants to face charges in the Eastern District of Virginia. In December 2015, a New Zealand district court judge ruled that the defendants were eligible for extradition to the U.S. to face all charges.

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 generic top-level domain (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, 835 have been delegated; 480 are currently moving through the program; 560 applications have been withdrawn; and 37 applications will not proceed/have not been approved. As new gTLDs are in various stages of becoming operational, NTIA, IPEC, and other interagency colleagues will direct 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. Such work will focus in particular on: the new gTLD program implementation review; the review of the competition, consumer trust and consumer choice effects of the new gTLD program; and the review of the effectiveness of the rights protection mechanisms in the new gTLD program. 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 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. IP 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 Department of Commerce (DOC), which remains committed to ensuring that IP remains a driver of innovation and that our IP-intensive industries can compete effectively in the international market place. DOC bureaus, namely USPTO and the International Trade Administration (ITA), work alongside the IPEC and other U.S. agencies involved in IP 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 IPR. The Federal agencies behind STOPfakes.gov have developed a number of resources to educate and assist businesses, including small-to-medium sized enterprises (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 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 EU 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 IP rights in both the US and the EU are highlighted on the portal. In light of the Transatlantic Trade and Investment Partnership (T-TIP) negotiations and the tremendous interest and opportunities generated as a result, ITA and DG GROW during FY 2015 continued to highlight the portal in its respective stakeholder outreach and roadshows.

For more than ten years, USPTO's GIPA has provided information and instruction to U.S. SMEs on intellectual property, in the U.S. and abroad. GIPA's outreach includes the full range of intellectual property, including patents, trade secrets, trademarks and copyrights. Moreover, its outreach focuses not only on protection and enforcement of intellectual property rights in the United States, but also on intellectual property abroad. Instruction is designed to help all businesses that are exporting or thinking about exporting or manufacturing products or parts of products overseas. GIPA also helps U.S. businesses better understand how they may become victims of intellectual property theft from other countries, even where they are not exporting or manufacturing outside the country.

In FY 2015, GIPA continued its strong commitment to supporting U.S. veteran entrepreneurs, conducting workshops at several programs for entrepreneurs and small businesses focusing on protection and enforcement, including programs for disabled veteran entrepreneurs and women veteran entrepreneurs. Providing returning veterans with basic information about intellectual property, including trademarks and copyrights as well as IP in a company website, is essential in helping to establish viable and thriving small businesses.

DOS increased the level of detail in the IP section of the Investment Climate Statement (ICS) that is 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 (http://www.state.gov/e/eb/rls/othr/ics/).

19. Examine Labor Conditions Associated with Infringing Goods

IPEC has coordinated with the DOS, Department of Labor (DOL), and DHS, and the IPR Center to identify and examine existing empirical information on the nexus between poor labor conditions (including forced labor) and the overseas manufacture and distribution of infringing products. As part of that examination, IPEC has facilitated dialogue between DOS, DOL, DHS, and the IPR Center and trade associations that represent IP rights holders who may obtain information on labor conditions as part of their anti-counterfeiting work abroad. IPEC will continue to facilitate this dialogue and collaboration between government and industry with the aim of increasing the information that is available to the public regarding the labor conditions that are associated with the overseas manufacture of infringing goods.

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.

CBP's Centers of Excellence and Expertise (CEEs) have been heavily involved in the development and implementation of the trade intelligence concept, a CBP effort to establish formal linkages with the private sector to develop actionable intelligence. As part of these efforts, the CEEs engage 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.

On September 18, 2015, CBP published in the Federal Register a final rule entitled "Disclosure of Information for Certain Intellectual Property Rights Enforced at the Border" (80 Fed. Reg. 56370). The rule adopted, with certain changes, the Interim Final Rule that CBP published on April 24, 2012 (77 Fed. Reg. 24375). Among other things, the final rule enhanced information-sharing procedures by requiring CBP to release certain information no later than the time of the issuance of the detention to the importer, rather than within 30 business days of the date of detention.

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

CBP, ICE HSI, FDA, and United States Postal Inspection Service continued to conduct *Operation Safeguard* in FY 2015. *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.

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 FY 2015, *Operation Apothecary* resulted in 71 new cases, 34 arrests, 30 indictments, and 34 convictions, as well as 204 seizure incidents of counterfeit items with a potential retail value of approximately $834,419.

To address the increasing volume of express courier shipments, CBP has established, in partnership with the Express Association of America and its members, a new streamlined administrative process for the voluntary abandonment of small shipments of potentially-counterfeit goods. This pilot program is supported through a May 22, 2014, formal recommendation of the Advisory Committee on Commercial Operations to the U.S. Customs and Border Protection (COAC). On November 1, 2014, CBP successfully implemented a pilot of the streamlined abandonment procedures at the United Parcel Service (UPS) Express Consignment Facility in Louisville, KY. The program was later expanded in FY 2015 to the DHL Express Consignment Facilities in Cincinnati, OH, Los Angeles, CA, Miami, FL, and New York City, NY. There have been over 3000 abandonments under the program.

As noted above, FDA is an active partner and supporter of CBP's *Operation Safeguard*, through FDA's Division of Import Operations (DIO). In addition, 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 regulatory 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 portable Ion Mobility Spectrometry (IMS) devices to identify counterfeit pharmaceuticals and dietary supplements tainted with Sibutramine at internal mail facilities. FDA-DIO is currently working to expand the use of both the CD3 and portable IMS to identify more potential counterfeit pharmaceuticals.

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

Private sector stakeholders play a critical role in combating online intellectual property infringement and illegal Internet pharmacies. Content owners need to work with Internet Service Providers (ISPs) 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.

IPEC has participated in numerous gatherings, domestic and abroad, to bring broader public awareness around and to champion the message of how private industry has and can continue to be part of the solution to the problem of the proliferation of online IP crime, including illegal Internet pharmacies peddling fake "medicines."

- In August 2015, IPEC spoke at the APEC Senior Officials Meeting in the Philippines to encourage other APEC economies to consider encouraging industry (particularly Internet intermediaries) to adopt voluntary measures to combat online illegal internet pharmacies.

- In October 2015, IPEC spoke at a summit of security executives of pharmaceutical companies on how private sector voluntary measures can combat online illegal pharmacies.

To date, private-sector stakeholders have entered into—with IPEC's encouragement and support—five voluntary initiatives to combat IP infringement in the digital environment:

- Combating Rogue (Fake) Internet "Pharmacies";

- Combating Online Piracy through the Copyright Alert System;

- Reducing Online Piracy by Withdrawing Payment Services for Online Sales of Infringing Goods;

- Online Advertisers' Pledge Not to Support Online Piracy and Counterfeiting with Ad Revenue; and

- The "Ad Networks" Best Practices Guidelines.

IPEC continues to review the effectiveness of these five IPEC-supported voluntary initiatives. This ongoing review includes IPEC hearing directly from stakeholders who are involved in or otherwise affected by these initiatives. In addition, on February 10, 2015, the advertising industry announced the launch of the Brand Integrity Program Against Piracy. This initiative was launched by the Trustworthy Accountability Group (TAG), an organization created last fall by three advertising organizations: 1) the Association of National Advertisers (ANA); 2) the American Association of Advertising Agencies (4A's); and 3) the Interactive Advertising Bureau (IAB). According to IAB's website, one of TAG's objectives is to "Fight Internet Piracy" by "[p]revent[ing] advertising revenue from flowing to criminals who steal copyrighted material and place it on 'pirate' sites." In addition, TAG's February 10th announcement states that "[c]ompanies in the online and mobile advertising ecosystem can participate in the voluntary Brand Integrity Program Against Piracy by using validated tools and services to identify and prevent advertising from running on websites and other properties that present an unacceptable risk of being associated with infringing activities, including copyright piracy and the illegal dissemination of counterfeit goods." IPEC has met with and supported this new industry-led voluntary initiative that is an outgrowth of the initiatives IPEC facilitated with ad networks to combat advertising revenue from reaching infringing sites.

Voluntary Initiatives and Effectiveness

In 2013, IPEC and the interagency committee published the *Joint Strategic Plan for Intellectual Property Enforcement.* The Plan provided that "[a]s part of the effort to determine whether

voluntary initiatives have had a positive impact on reducing infringement, USPTO will solicit input from the public and other parts of the U.S. Government and will initiate a process to assess the effectiveness of voluntary initiatives." Accordingly, USPTO has solicited public input, met with three groups involved with voluntary initiatives, and surveyed research literature. To initiate discussion on the impact of voluntary best practices, in June 2013 the USPTO invited all interested parties to comment on how best to assess the effectiveness of cooperative agreements and other voluntary initiatives to reduce online infringement. After reviewing the comments, the USPTO met with groups involved in promulgating and implementing voluntary initiatives in the United States that are meant to decrease the likelihood that a consumer will access and/or purchase counterfeit goods or copyright-infringing content online. Going forward, USPTO will investigate the data needs for conducting an analysis of one or more of the voluntary initiatives currently underway and then compare these data needs to the data that can be made available for such an analysis, to determine feasibility.

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 number of mechanisms, which may include 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 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.

In addition, the CEE has 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 Guardian*. *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 FY 2015, *Operation Apothecary* resulted in 71 new cases, 34 arrests, 30 indictments, and 34 convictions, as well as 204 seizure incidents of counterfeit items with a potential retail value of approximately $834,419.

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 eighth 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. 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.

In FY 2015, U.S. law enforcement and Federal agencies, including the IPR Center through ICE HSI, CBP, and FDA, participated in *Operation Pangea VIII*, a global enforcement effort led by INTERPOL and the WCO that is aimed at disrupting organized crime networks behind the illicit online sale of fake drugs. *Operation Pangea VIII* involved 115 participating INTERPOL member countries and 236 different agencies from police, customs, and health regulatory agencies resulted in the seizure of 50,852 packages with an estimated value of 75 million dollars and shut down approximately 2,700 websites engaged in illegal activity.

DOJ's Consumer Protection Branch in the Civil Division conducts civil and criminal litigation under the Food, Drug, and Cosmetic Act, including prosecuting counterfeit drug and medical device offenses, and assists AUSAs throughout the country with their counterfeit pharmaceutical and device cases.

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, as well as programs specifically designed to combat counterfeit medicines.

Interregional Counterfeit Medicines Program

The program, held in Bahrain in April 2015, was organized in cooperation with the USPTO IP Attachés for South Asia and for the Middle East and North Africa. The program increased awareness amongst officials from the regions about the issues and gravity of the situation relating to counterfeit medicines. In addition, the program developed stronger collaboration on enforcement activities (with an emphasis on sharing best practices for the investigation of counterfeit medicines), and it facilitated discussion between health regulatory agencies and enforcement agencies, including customs. The program included twelve delegates (from Bhutan, India, Sri Lanka, Jordan, the United Arab Emirates, Egypt and Bahrain), who came predominately from health regulatory agencies and customs.

Combating Counterfeit Pharmaceutical Sales on the Internet

The program, held at GIPA in March 2015, focused on combating the online sale of counterfeit medicines for Brazil, Paraguay, Uruguay, Chile, Panama and Mexico. The program included presentations from U.S. Government (USG) and private sector representatives. The USG speakers included DOJ, FDA, and ICE HSI. The private sector speakers addressed topics such as the role of online pharmacies and technology and global health.

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 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.

Legislation

<u>The Food and Drug Administration Safety and Innovation Act (FDASIA) Title VII—Drug Supply Chain</u>

In July 2012, President Obama signed into law Public Law 112-144 (FDASIA), which incorporates several of the IPR enforcement recommendations contained in the March 2011 Administration White Paper. FDASIA provided for enhanced penalties for intentional adulteration and trafficking in counterfeit drugs and it directed the U.S. Sentencing Commission to review and amend, if appropriate, its guidelines and policy statements related to counterfeit drugs. On April 10, 2013, the U.S. Sentencing Commission promulgated a new amendment to create a two level enhancement for offenses involving counterfeit drugs, and this amendment has been in effect since November 1, 2013.

In addition, FDASIA authorized FDA, upon issuance of regulations, to destroy – without the opportunity to export – adulterated, misbranded or unapproved drugs (including counterfeits) imported to the U.S. that are valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation). On May 6, 2014, FDA published a proposed rule to implement this administrative-destruction authority and, after receiving and considering the public comments, FDA published the final rule on September 15, 2015 (80 FR 55237). With the administrative-destruction authority in place, FDA is now working with its Federal Government partners to implement the destruction process.

Drug Track and Trace

The Drug Supply Chain Security Act (DSCSA) (Title II of the Drug Quality and Security Act) was signed into law by President Obama on November 27, 2013. The 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, in addition to enhancing standards for licensure for wholesale distributors and third-party logistics providers. The DSCSA aims to facilitate the exchange of information to verify product legitimacy, enhance detection and notification of an illegitimate product, and facilitate product recalls. Prescription drug manufacturers, wholesale distributors, repackagers, and dispensers (primarily pharmacies) will be called on to work in cooperation with the FDA to develop the new system over the next 8 years.

The DSCSA requires the FDA to establish standards, issue guidance documents, and develop regulations, in addition to other efforts, to support effective implementation and compliance. In FY 2015, the FDA issued two guidance documents that describe the agency's compliance policy and conducted one webinar related to annual reporting requirements for prescription drug wholesale distributors and third party logistics providers (http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm426818.htm). In addition, in FY 2015, FDA began developing a pilot project program to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain, and will engage and coordinate with members across the supply chain, including manufacturers, repackagers, wholesale distributors, and dispensers. Also, in FY 2015, FDA launched its wholesale distributor and third-party logistics provider public database (based on information that was submitted to FDA to comply with annual reporting requirements) and a resource webpage for state officials. For updates about DSCSA implementation and copies of the guidance documents, 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 the end of 2013, 13 firms were selected to participate. The FDA continues to 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 Medical Product Quality and Supply Chain Integrity

FDA is leading an effort under the APEC to develop a Roadmap for Global Medical Product Quality and Supply Chain Integrity. During a Senior Officials Meeting, held in Clark, Philippines, on January 26-29, 2015, trainings were conducted and discussions held on the areas of Good Distribution Practices, Good Import/Export Practices, Single Point of Contact, and Product Security. During another Senior Officials Meeting in Cebu, Philippines, on August 24-28, 2015, training and discussions were held in two concurrent tracks, and covered Detection Technology, Internet Sales, Good Import/Export Practices, Good Manufacturing Practices and Track and Trace. Each session included discussion of best practices for industry and regulators, current challenges and gaps in the global supply chain, and the toolkits and training materials being developed by each work stream. Nearly every APEC economy was represented at each of the meetings. Present and participating in the discussions were non-profit organizations, medical product industry firms, national regulatory authorities, and law enforcement agencies.

FDA/World Health Organization (WHO) Global Surveillance and Monitoring System for Substandard, Spurious, Falsely-Labeled, Falsified, Counterfeit (SSFFC) Medical 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. Since its inception, 90 Member States, 250 regulatory personnel, and 18 procurement agencies have been trained to report SSFFC information, creating a global network of professionals. The system has been rolled out in Africa and parts of Asia, Europe and the Middle East. As of the end of FY 2015, over 840 medical products have been reported to the system, resulting in numerous warnings to focal points and 12 international drug alerts.

Consumer Education

BeSafeRx

In FY 2015, FDA expanded the BeSafeRx campaign by creating two Public Service Announcements (PSA). The 30 second general PSA informs viewers that medicines bought from unlicensed online pharmacies can be dangerous and educates them about ways to ensure they do not put their health at risk when buying online. The 60 second PSA tells the story of a victim of online pharmacy fraud. Both PSAs were aired in physician waiting rooms, on e-commerce sites, and online publications. Print versions were placed in health publications circulated to patients' homes, physician offices, and as banners in e-newsletters. Overall, in FY 2015, the general PSA aired 1,846,416 times, garnering 11,354,825 impressions and the story aired 1,738,880 times, garnering 10,693,515 impressions. Both videos also aired on 2,000 airport screens in the 50 busiest airports nationwide, garnering an estimated 15. 5 million impressions.

Impressions refer to the reach of the various tactics used to promote the campaign, i.e. the number of people who may have seen a video or web banner; heard it on the radio or in a podcast; watched on television; or read it on a web page or blog post. More information can be found here: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/BuyingMedicinesOvertheInternet/BeSafeRxKnowYourOnlinePharmacy/.

Outreach to Doctors

On April 1, 2015, FDA sent more than 300 letters to medical practices in the United States that may have purchased unapproved prescription drugs, or unapproved injectable devices, from a foreign supplier, Gallant Pharmaceutical International, Inc., also known as Gallant Medical International, Inc. Several individuals associated with Gallant, including a doctor and an office manager, have been convicted for their roles in distributing illegal drugs and devices. Gallant obtained these products from foreign sources and shipped and stored them outside of the regulated supply chain. FDA's letters to medical practices provided a list of unapproved chemotherapy and injectable cosmetic drugs and devices sold by Gallant, along with FDA contact information (http://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM446811.pdf).

Counterfeit/Unapproved Drugs Public Health Alerts

In April 2015, FDA informed the healthcare community and the public about a counterfeit version of Botox that was being sold to U.S. medical practices. Both the outer carton and the vial on the suspect product were confirmed counterfeit. FDA issued letters to medical practiced that may have purchased or administered the counterfeit version of Botox or other unapproved drugs or un-cleared medical devices. This is the first time FDA has included medical devices in the letter to medical practices (http://www.fda.gov/Drugs/DrugSafety/ucm443217.htm).

Enforcement Actions

In addition to ICE HSI, FDA also has a leadership role in combating counterfeit pharmaceuticals and medical devices. Below are several notable examples of FDA's enforcement activities (additional FDA cases are discussed in the "Performance Data" section at the end of this report).

Operation Pangea

In June 2015, FDA contributed to the success of efforts under INTERPOL's *Operation Pangea* initiative, an operation that involved more than 100 countries. These actions include the issuance of regulatory warnings to the operators of offending websites and seizure of illegal medicines and medical devices worldwide. FDA's Pangea working group members from the Center for Devices and Radiological Health (CDRH), Center for Drug Evaluation and Research (CDER), and the Division of Import Operations (DIO) focused on websites illegally selling medical devices, including dental equipment and contact lenses as well as illegal online pharmacies.

In support of *Operation Pangea*, FDA sent Warning Letters to the operators of nearly 400 websites offering unapproved or misbranded prescription medicines to U.S. patients and to nine firms distributing unapproved or un-cleared medical devices online (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm451755.htm). Furthermore, FDA and CBP inspected packages at the mail facilities in Chicago, Miami and New York, and detained over 800 packages. Preliminary findings from drug products screened show that certain drug products from abroad (such as antidepressants, hormone replacement therapies, sleep aids, and other drugs to treat erectile dysfunction, high cholesterol and seizures) were in route to U.S. consumers. These packages contained products that originated from the United Kingdom, Turkey, India, Canada, France, Barbados, the Netherlands Antilles, Singapore, Curacao, El Salvador, Mexico, and Pakistan.

Data-Driven Government

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

During FY 2015, DOC continued to follow up on the issues raised in its July 2013 Green Paper on *Copyright Policy, Creativity, and Innovation in the Digital Economy*. The Green Paper acknowledged the balance that copyright law forges between rights holders and users, which is necessary for the Constitutionally-based promotion of "the Progress of Science and useful Arts."

The Multistakeholder Forum on the DMCA Notice and Takedown System, initially convened by DOC in 2014, continued to meet until the release in April 2015 of the *DMCA Notice-and-Takedown Processes: List of Good, Bad, and Situational Practices*. Developed with the input of stakeholder participants, the List identifies a number of "good", "bad" and "situational" practices that can improve the efficiency of the handling and processing of DMCA takedown notices by both senders and recipients.

Furthermore, the previously discussed *White Paper on "*Remixes, First Sale, and Statutory Damages: Copyright Policy, Creativity, and Innovation in the Digital Economy"*,* issued by DOC's Internet Policy Task Force, reviews extensive written comments and roundtable discussions and makes policy recommendations on three issues: (1) the appropriate calibration of statutory damages in the contexts of individual file sharers and secondary liability for large-scale infringement, (2) the role of fair use in the context of the creation of remixes or mashups, and (3) the application of the first sale doctrine to digital transmissions.

During FY 2015, the U.S. Copyright Office continued to provide substantial assistance and support to the House Judiciary Committee and its Subcommittee on Courts, Intellectual Property and the Internet (previously, the Subcommittee on Intellectual Property, Competition, and the Internet) on a broad range of issues in connection with Congress' comprehensive review of U.S. copyright law and enforcement mechanisms. House Judiciary Committee Chairman Bob Goodlatte announced the congressional review in April 2013 after Register of Copyrights Maria A. Pallante testified in a March Subcommittee hearing entitled "The

Register's Call for Updates to U.S. Copyright Law." Since 2013, the Committee has held twenty formal congressional hearings that have involved 100 witnesses and have explored a broad range of copyright topics, several of which have addressed enforcement-related issues, including the role of voluntary agreements, the scope of copyright protection, the scope of fair use, copyright remedies, and Section 512 of Title 17 (exploring the DMCA's notice and take down regime). On April 29, 2015, Register Pallante testified in a hearing entitled "The Register's Perspective on Copyright Review." Register Pallante provided the Office's perspective on the themes explored throughout the hearings and identified copyright-related topics that were currently ripe for legislative action, as well as topics that may require more study and public engagement. Access to the Register's testimony, as well as the testimony and transcripts of all twenty hearings, is available through the Office's website.

In October 2015, the Committee announced that it would be seeking additional public input for the congressional review process by conducting additional meetings in Washington, D.C., as well as beginning a "listening tour" in regions throughout the country. To date, Committee staff members have held more than fifty follow-up meetings in Washington, D.C., and the Committee has traveled to roundtables in Nashville, Tennessee (September 22, 2015), Santa Clara, California (November 9, 2015), and Los Angeles, California (November 10, 2015).

DOJ's ability to pursue large-scale pirate streaming operations criminally is limited because existing copyright law does not provide felony penalties for infringement of the type of exclusive rights implicated by Internet streaming. There has been some congressional interest to include felony penalties set forth in legislation. Felony penalties for unauthorized streaming was one of the recommendations in the Administration's White Paper on Intellectual Property Enforcement Legislative Recommendations (March 2011). In FY 2015 DOJ publicly supported the proposed change to the criminal copyright statute to address unauthorized online streaming as well as modification of Federal Rule of Criminal Procedure 4 to allow for simplified service of foreign corporations in trade secret theft and other cases.

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

During FY 2015, the USPTO Office of Chief Economist continued to collaborate with the DOC Economics & Statistics Administration in updating the inaugural 2012 report on IP-intensive industries. In this effort, the Office of Chief Economist has applied previously used methodologies to identify IP-intensive industries using more recent data. Preliminary results suggest that there was little change compared to the previous report in both the industries categorized as IP-intensive and their economic characteristics. USPTO continues to see IP-intensive industries support significant employment and output, across sectors. And a revised report is planned for FY 2016.

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 collected resource-related information from these agencies,

through data collections issued by the Office of Management and Budget (which are referred to as Budget Data Requests—BDRs).

As IPEC explained more fully in the 2014 Annual Report (at pages 63-64), IPEC has reviewed the agencies' responses to the BDRs that covered fiscal years 2009 through 2012, as well as the separate reporting that agencies have done regarding their IP enforcement activities—which include resource-related information. As the 2014 Annual Report explained, we believe that a further continuation of the BDRs is not warranted at this time, in light of the increased attention that agencies have devoted to IP-enforcement in recent years and the separate reporting that agencies have done (and will continue to do) regarding their IP enforcement activities. IPEC will consider this issue further as it develops the next three year Joint Strategic Plan, which IPEC plans to issue in FY 2016.

Performance Data

A. Intellectual Property Related Seizures (DHS ICE and CBP seizures)[1]

In FY 2015, the number of IPR seizures increased nearly 25 percent to 28,865 from 23,140 in FY 2014. The total estimated Manufacturer's Suggested Retail Price (MSRP) of the seized goods, had they been genuine, increased 10 percent to $1.35 billion.

- ***Seizures of Consumer Safety and Critical Technology Products***

In FY 2015, the top three categories of Consumer Health, 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 4,577 with a total estimated MSRP of $126,895,550.

- ***Seizures Across Shipping Environments***

In FY 2015, 90 percent of all seizures occurred in the express carrier shipping and international mail environments. There were 14,897 seizures in the express carrier shipping environment and 10,834 seizures occurred in the international mail shipping environment.

- ***Seizures of Circumvention Devices***

In FY 2015, 62 shipments of circumvention devices were seized by CBP for violations of the Digital Millennium Copyright Act.

- ***Seizures Pursuant to an ITC Exclusion Order Enforcement***

In FY 2015, CBP completed 152 exclusion order enforcement actions (shipments seized and shipments excluded), an increase from 53 in FY 2014.

B. Law Enforcement Investigations and Prosecutions

- ***FBI***

At the end of FY 2015, the FBI had 317 pending IPR investigations with the following areas of focus:

- 91 investigations of theft of trade secrets
- 39 investigations of copyright infringement related to software
- 65 investigations of other copyright infringement
- 37 investigations of trademark infringement

[1] For more details, see DHS's "Intellectual Property Rights Seizure Statistics: Fiscal Year 2015" available here: http://www.cbp.gov/sites/default/files/assets/documents/2016-Apr/FY%202015%20IPR%20Stats%20Presentation.pdf.

- 11 investigations of copyright infringement related to signal theft
- 8 investigations of counterfeit aircraft parts
- 18 investigations of counterfeit electrical parts
- 10 investigations of counterfeit automotive parts
- 36 investigations of counterfeit health products
- 2 investigations of other counterfeit health and safety products

- The following is a summary of statistics for IPR investigations for FY 2015:

  - 65 new investigations initiated
  - 63 arrests
  - 39 information/indictments
  - 38 convictions
  - Seizures totaling $3,068,155
  - Forfeitures totaling $770,289
  - Restitution totaling $9,104,912
  - FIRE (Frozen, Indicted, Restrained, Encumbered) totaling $185,074,234

- ***ICE HSI***

  In FY 2015, ICE HSI initiated 1,013 intellectual property investigations and had 538 arrests, 339 indictments, and 357 convictions.

- ***National Intellectual Property Rights Coordination Center (IPR Center)***

  In FY 2015, the IPR Center vetted 17,990 investigative leads, of these, 15,627 were referred to law enforcement partners. Additionally, the IPR Center de-conflicted 2,380 investigative targets for partner agencies and industry. While performing these de-conflictions, the IPR Center identified 197 "blue on blue" situations where two or more entities were investigating the same target. Finally, the IPR Center referred 888 leads to private industry for follow-up.

- ***DOJ 2015 Intellectual Property Prosecutions***

District Totals	FY2010	FY 2011	FY2012	FY2013	FY2014	FY2015
Investigative Matters Received by AUSAs	402	387	390	334	256	236
Defendants Charged	259	215	254	213	200	177
Cases Charged	177	168	178	163	142	114
Defendants Sentenced	207	208	202	205	184	183
No Prison Term	121	102	95	96	92	100
1-12 Months	38	27	46	35	30	27
13-24 Months	27	33	26	29	30	31
25-36 Months	10	17	15	21	14	7
37-60 Months	7	21	17	19	13	10
60 + Months	4	8	3	5	5	8

The chart below depicts FY 2015 statistics for criminal IP cases based on type of charge. [2]

Charge	Cases charged	Percentage
Trademark *Trafficking in counterfeit goods, 18 U.S.C. § 2320*	68	59. 6%
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*	36	31. 6%
Economic Espionage Act *Theft of trade secrets, 18 U.S.C. § 1831* *Economic espionage, 18 U.S.C. § 1832*	10	8. 8%
Signal Piracy *Unauthorized reception of cable service, 47 U.S.C. § 553* *Unauthorized publication or use of communications, 47 U.S.C. § 605*	0	0. 0%
Total	**114**	**100%**

DOJ 2015 Intellectual Property Prosecutions, by Statute

Copyright/ Pre-Release / Camcording / Counterfeit Labels (17 U.S.C. § 506, 18 U.S.C. §§ 2319, 2318)

1. Auto Parts Distributor Pleads Guilty to Manufacturing and Selling Pirated Mercedes-Benz Software.

On September 10, 2015, an aftermarket auto parts distributor in Harahan, Louisiana, pleaded guilty to manufacturing and selling over 800 copyright-infringing copies of Mercedes-Benz diagnostic software valued at over $17 million. The Brinson Company (TBC), and its owner, Rainer Wittich of River Ridge, Louisiana, pleaded guilty to an information charging them, respectively, with conspiracy to commit criminal copyright infringement and to violate the DMCA, and criminal copyright infringement. According to TBC's plea agreement, beginning in about 2001, in conjunction with two other companies, TBC began developing, manufacturing and selling non-authentic versions of the Mercedes-Benz Star Diagnostic System (SDS), a portable tablet-type computer that contains proprietary software created by Mercedes-Benz to diagnose and repair its automobiles and that requires a code or "license key" to access. TBC

[2] 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/.

admitted that, in total, it sold approximately 725 non-authentic SDS devices, and that one of its co-conspirators sold at least 95 devices. Sentencing was scheduled for January 16, 2016. http://www.justice.gov/opa/pr/auto-parts-distributor-pleads-guilty-manufacturing-and-selling-pirated-mercedes-benz-software)

2. *Operator of Music Piracy Websites Pleads Guilty to Criminal Copyright Infringement.*

On August 21, 2015, Rocky P. Ouprasith of Charlotte, North Carolina, pleaded guilty to reproducing and distributing without permission millions of infringing digital copies of copyrighted works, including copies of popular songs and albums before they were commercially available. According to admissions made in connection with his guilty plea, between May 2011 and October 2014, Ouprasith operated RockDizMusic.com, a website originally hosted on servers in France and later in Canada, from which Internet users could find and download infringing digital copies of popular, copyrighted songs and albums. Ouprasith admitted that he obtained digital copies of copyrighted songs and albums from online sources, and that he encouraged and solicited others, referred to as "affiliates," to upload digital copies of copyrighted songs and albums to websites, including RockDizFile.com, that were hosted on servers in Russia, France and the Netherlands, and that hosted hyperlinks to content being offered for download on RockDizMusic.com. Ouprasith admitted that the market value of his illegally pirated material was more than $2. 5 million. On November 17, 2015, Ouprasith was sentenced to 36 months in jail, ordered to forfeit $50,851. 05, and to pay $48,288. 62 in restitution. (http://www.justice.gov/opa/pr/operator-music-piracy-websites-pleads-guilty-criminal-copyright-infringement)

3. *Metairie, Louisiana Man Pleads Guilty to Recording Movies in a Local Theater and Criminal Infringement of a Copyright.*

On August 5, 2015, Derrick Holloway, of Marrero, Louisiana pleaded guilty to both counts of a two-count Bill of Information charging him with unauthorized recording of a motion picture and criminal infringement of a copyright. According to court documents, in 2014, Holloway used a digital camcorder to record approximately ten first-run motion pictures at the AMC Westbank Palace, located in Harvey, including *When the Game Stands Tall* and *The Equalizer*. Holloway subsequently duplicated and sold copies of some or all of the motion pictures. Additionally, Holloway manufactured and sold CDs and DVDs containing copyrighted musical works and motion pictures from his business, Gold Teeth Kingz, located in Harvey. In early January 2015, law enforcement authorities found and seized approximately 2,932 pirated DVDs containing copyrighted motion pictures, including *When the Game Stands Tall* and *American Sniper*, and 749 pirated CDs containing copyrighted musical works, including "Kingdom Come," by Jay-Z and "Dangerously in Love," by Beyoncé. Holloway was sentenced on November 4, 2014 to four year of probation, fined $1,000, and to pay $12,539. 66 in restitution. (http://www.justice.gov/usao-edla/pr/metairie-man-pleads-guilty-recording-movies-local-theater-and-criminal-infringement)

4. *New Orleans Man Sentenced for Selling Counterfeit Movie DVDs and Music CDs.*

On July 9, 2015, Darnell Reed of New Orleans, was sentenced to five years of probation. On April 2, 2015, Reed pleaded guilty to two counts of criminal copyright infringement. According to court documents, Special Agents from the Homeland Security Investigations (HSI), Regulatory Investigators from the Louisiana Department of Justice/Attorney General Investigations Division (LDOJ/AG), and a regulatory investigator from the Recording Industry Association of America, Inc. (RIAA) and the Motion Picture Association of America (MPAA) conducted a controlled buy from Reed. Law enforcement agents seized approximately 7,187 counterfeit DVDs and 7,315 counterfeit CDs from Reed's vehicle. (http://www.justice.gov/usao-edla/pr/new-orleans-man-pleads-guilty-selling-counterfeit-movie-dvds-and-music-cds-0)

5. *San Francisco Man Sentenced to 15 Months for Importing and Selling Counterfeit DVDs.*

On June 9, 2015, Christopher Breejen, was sentenced to 15 months in prison and ordered to pay $117,439. 50 in restitution for criminal copyright infringement. Breejen pleaded guilty on November 18, 2014, to one count of criminal copyright infringement. According to the plea agreement, Breejen admitted to importing counterfeit DVD's and then selling them on the eBay website. Between 2011 and August 2014, he sold approximately 20,000 counterfeit DVDs Nationwide. Breejen was charged on September 26, 2014. Prior to the charges, Inspectors from U.S. Customs and Border Protection seized 16 separate shipments of counterfeit DVDs sent to Breejen from Asia. He was notified about the counterfeit goods in each of these shipments by CBP. Despite these seizures and notifications, Breejen continued to import and sell counterfeit DVDs until agents from ICE HSI executed a search warrant at his residence in San Francisco, where they seized additional counterfeit DVDs. The investigation began with a tip from the Motion Picture Association of America. (http://www.justice.gov/usao-ndca/pr/san-francisco-man-sentenced-15-months-importing-and-selling-counterfeit-dvds)

6. *Oakland Man Sentenced for Counterfeit Media Scheme in Fresno, California*.

On April 20, 2015, Emilio Perez-Solis of Oakland, California, was sentenced to three years and 10 months in prison, for conspiring to sell counterfeit CDs and DVDs. According to court documents, Perez-Solis used a building in a rural area of Fresno as a distribution point for counterfeit CDs and counterfeit DVDs. From the building, he sold counterfeit CDs and DVDs, including movies that were only in theatrical release and not yet available on DVD. On February 21, 2014, the building was searched and found to contain approximately 70,000 counterfeit music CDs and movie DVDs. Perez-Solis pleaded guilty on January 26, 2015, to conspiracy to commit criminal copyright infringement and traffic in counterfeit labels, documentation, and packaging as did co-defendant Hernan Cortes of Tulare, California, on December 15, 2014 (Cortes was sentenced on June 8, 2015, to two years imprisonment and three years of supervised release). (http://www.justice.gov/usao-edca/pr/oakland-man-sentenced-counterfeit-media-scheme-fresno)

7. Counterfeit DVD Trafficker Sentenced.

On March 30, 2015, Christian Patrick Lusardi of Fayetteville, North Carolina, was sentenced to 60 months in prison and 3 years of supervised release for Copyright Infringement and Trafficking in Counterfeit Labels. Lusardi was ordered to pay $1,137,864. 01 restitution. He previously pled guilty to the charges on September 2, 2014. The investigation revealed that several boxes of counterfeit DVDs mailed from China were intercepted by the IPR Center and U.S. Customs and Border Protection. The search resulted in the discovery of over 35,500 counterfeit DVDs. The investigation revealed that between June 2010 and July 2012, Lusardi was in the business of receiving, manufacturing, and selling counterfeit DVDs in both the United States and Canada. It was determined that Lusardi received over $1. 3 million in his PayPal account during this time period. (http://www.justice.gov/usao-ednc/pr/counterfeit-dvd-trafficker-sentenced)

8. Ten Men Indicted For Trafficking Counterfeit Media In Central Valley, California.

On March 26, 2015, a Federal grand jury returned a two-count indictment against 10 defendants, charging them with conspiracy to commit criminal copyright infringement and related crimes, and trafficking in counterfeit labels, documentation and packaging. According to court documents, on March 13, 2015, warehouse and office space used by the defendants were found to contain tens of thousands of counterfeit music CDs and movie DVDs. The counterfeit materials included movie titles that were in theatrical release and not yet available for legitimate sale on DVD. The defendants distributed the counterfeit CDs and DVDs for resale throughout California. (http://www.justice.gov/usao-edca/pr/ten-men-indicted-trafficking-counterfeit-media-central-valley)

9. Member of Megaupload Conspiracy Pleads Guilty to Copyright Infringement Charges and is Sentenced to One Year in U.S. Prison.

On February 13, 2015, a computer programmer for the Mega copyright piracy conspiracy, Andrus Nomm, of Estonia, pleaded guilty in connection with his involvement with Megaupload. com and associated piracy websites. He was sentenced to a year and a day in Federal prison for conspiring to commit felony copyright infringement. Nomm was initially charged along with six other individuals and two privately-held corporations by a Federal grand jury on January 5, 2012, and a superseding indictment with additional charges was subsequently returned on Feb. 16, 2012. The superseding indictment charged the defendants with three separate conspiracies (to commit racketeering, to commit copyright infringement, and to commit money laundering), five counts of criminal copyright infringement, and five counts of wire fraud. The indictment alleged that, for more than five years, the Mega Conspiracy operated websites that willfully reproduced and distributed infringing copies of copyrighted works, including works that had not been commercially released. In court papers, Nomm agreed that the harm caused to copyright holders by the Mega Conspiracy's criminal conduct exceeded $400 million, and he acknowledged that the group obtained at least $175 million in proceeds through their conduct. Megaupload. com had claimed that, at one time, it accounted for four percent of total Internet

traffic, having more than one billion total visits, 150 million registered users and 50 million daily visitors. In December 2015, a New Zealand district court judge ruled that the defendants were eligible for extradition to the U.S. to face all charges. (http://www.justice.gov/opa/pr/member-megaupload-conspiracy-pleads-guilty-copyright-infringement-charges-and-sentenced-one)

10. Counterfeit DVD Movie Supplier Sentenced to Federal Prison.

On January 12, 2015, Yakov Meir Chazanow, was sentenced to serve 21 months in prison for conspiring to commit criminal copyright infringement, manufacturing counterfeit goods and to traffic in goods bearing counterfeit Dolby trademarks and counterfeit labels. According to the evidence set forth in the record and at sentencing, from 2004 to 2011, Chazanow supplied over 30,000 high-quality pirated DVDs containing infringing copies of copyright-protected Asian action movies and corresponding counterfeit labels and packaging. He then distributed them to co-conspirators, who in turn sold them to consumers in stores and online. Chazanow, Sharon Josef and Jeffrey Alan Stockton were all charged in June 2013, and Stockton pleaded guilty to the charged conspiracy and two counts of trafficking in counterfeit labels on September 19, 2013. On Feb. 3, 2014, Chazanow pleaded guilty to the above charges, and Josef pleaded guilty to misdemeanor copyright infringement. On May 12, 2014, the court sentenced Stockton to 21 months in prison, ordered him to pay restitution of $150, and entered a preliminary order directing Stockton to forfeit $250,000 in illegal proceeds, $32,154 in U.S. currency, a 2003 Toyota Tundra, 29 gold bars, 62 gold coins, six palladium coins and five silver coins. Josef, who supplied pirated DVDs from 2011 to 2012, was also sentenced on January 12, 2015, to serve four months in prison. (http://www.justice.gov/opa/pr/counterfeit-dvd-movie-supplier-sentenced-federal-prison)

11. Former Macy, Nebraska Residents Sentenced for Copyright Infringement.

On January 8, 2015, Carroll Webster, III, and Kayla Parker, of Wanblee, South Dakota, were sentenced to five years' probation for their convictions of copyright infringement. While on probation, Webster and Parker will each have to perform 150 hours of community service and they will each have to pay $500 in restitution. Webster and Parker resided together in Macy, on an Omaha Indian Reservation during 2012 and 2013. From March of 2012 through May 6, 2013, Webster and Parker obtained pirated copies of copyrighted motion pictures which they reproduced and sold to persons in the community without the consent of the copyright holders. The investigation revealed that Webster and Parker sold approximately 600 DVDs during this time period. (http://www.justice.gov/usao-ne/pr/former-macy-residents-sentenced-copyright-infringement)

12. Conspirator in Android Mobile Device App Piracy Group Pleads Guilty.

On November 3, 2014, Scott Walton, of Cleveland, Ohio, a leading member of an online piracy group, pleaded guilty for his role in a scheme to distribute more than one million pirated copies of copyrighted Android mobile device applications, or "apps," with a total retail value of more than $1. 7 million. According to statements made in court, Walton and his fellow conspirators identified themselves as members of the SnappzMarket Group. From May 2011 through

August 2012, they conspired to reproduce and distribute over one million copies of copyrighted Android mobile device apps. The apps had a total retail value of over $1. 7 million and were distributed through the SnappzMarket alternative online market without permission from the copyright owners, who would otherwise sell copies of the apps on legitimate online markets for a fee. The indictment charges Walton and two other leading members of the SnappzMarket Group with conspiracy to commit criminal copyright infringement and related charges for allegedly distributing the copyrighted Android mobile devices apps through the group's website, www.snappzmarket.com. On August 21, 2012, the FBI executed a seizure order against the website, which was the first time a website's domain name registration involving mobile device app marketplaces had been seized. (http://www.justice.gov/opa/pr/conspirator-android-mobile-device-app-piracy-group-pleads-guilty)

Digital Millennium Copyright Act (17 U.S.C. §§ 1201, 1204)

Trafficking in Counterfeit Goods (18 U.S.C. § 2320) (Non-Pharmaceutical)

1. California Business Owner Admits Trafficking in Millions of Dollars of Counterfeit Cell Phone Parts.

On September 24, 2015, Imperial Valley businessman Octavio Cesar Sana, a Spanish National with legal U.S. residency, pleaded guilty to running a years-long conspiracy to traffic in millions of dollars of counterfeit Chinese cell phone parts. Sana pleaded guilty to conspiring to traffic in counterfeit goods and related money laundering charges. According to the plea agreement, Sana sold at least $3. 2 million worth of counterfeit Chinese cell phone parts through businesses he has operated since 2007—including through a website called "Flexqueen.com." Sana was arrested February 3, 2015 at the Imperial Valley Airport, along with Chinese National Hongwei Du. Du has also been charged with conspiracy to traffic in counterfeit goods. Sana admitted in his plea agreement that he and Du were attending meetings in the United States to set up further counterfeit trafficking ventures. The two were arrested in connection with a multi-year investigation spearheaded by ICE HSI and the Internal Revenue Service, Criminal Investigations. HSI executed a series of searches nationwide, coordinated with the arrest of Sana and Du that resulted in the seizure of more than 55,000 counterfeit items and additional criminal charges in several jurisdictions. Sentencing for both defendants was scheduled for January 4, 2016. (http://www.justice.gov/usao-sdca/pr/imperial-business-owner-admits-trafficking-millions-dollars-counterfeit-cell-phone)

2. Metairie, Louisiana Man Charged With Trafficking of Counterfeit Goods.

On August 18, 2015, Boubacar Diallo, of Metairie, was charged in a one-count Bill of Information with trafficking in counterfeit goods. According to the Information, on March 12, 2015, DIALLO trafficked and attempted to traffic in a variety of counterfeit goods, including approximately 111 pairs of "True Religion" blue jeans, 166 "Michael Kors" purses, 67 "Michael Kors" pocketbooks, 87 "Michael Kors" watches, 6 pair of "Nike" tennis shoes, 9 pair of "Polo" pants, and 8 pair of "Polo" shirts. (http://www.justice.gov/usao-edla/pr/metairie-man-charged-trafficking-counterfeit-goods)

3. Chula Vista Man Sent To Penalty Box For Trafficking in Over $100,000 Worth of Counterfeit World Cup Jerseys.

On August 17, 2015, Clemente Leon of Chula Vista was sentenced to four months in custody followed by five months in a halfway house for selling counterfeit World Cup soccer jerseys valued at between $120,000 and $320,000 over the internet. Leon was also ordered to forfeit $50,000 of the proceeds and all the counterfeit merchandise seized by Federal agents. Leon pleaded guilty in May, admitting that he sold soccer jerseys bearing counterfeit trademarks over Amazon as well as from his own website, www.playerasfutbol.com. Among other methods, he used PayPal to process the proceeds of his crime. Leon imported the counterfeit soccer jerseys from China even after receiving a Cease and Desist letter from Nike in August of 2013. This allowed him to capitalize on the popularity of the World Cup. Leon further modified the counterfeit team jerseys in his garage in Chula Vista by attaching counterfeit World Cup team patches and stencils with World Cup player's names on the backs of the jerseys, in order to be able to charge a higher price. (http://www.justice.gov/usao-sdca/pr/chula-vista-man-sent-penalty-box-trafficking-over-100000-worth-counterfeit-world-cup)

4. Illinois Man Sentenced For Trafficking In Counterfeit Rolex Watches.

On August 10, 2015, Frank Alvarado, of Chicago, Illinois, who was convicted of trafficking in counterfeit goods, was sentenced to time served (10 months) and three years' supervised release. On July 17, 2013, Alvarado entered a jewelry store located in Amherst, NY and offered a counterfeit "pre-owned" Rolex watch for sale. The jeweler paid $2,200 by check for the watch, which Alvarado subsequently cashed at a bank across the street. An expert for Rolex Watch, U.S.A. subsequently examined the watch and determined that it bore a counterfeit Rolex "Crown Device" mark and that the watch and movement of the watch were not made or manufactured by Rolex. The retail pre-owned value of the genuine Rolex watch was $6000. (http://www.justice.gov/usao-wdny/pr/illinois-man-sentenced-trafficking-counterfeit-rolex-watches)

5. Maine Corporation Fined $10,000 for Counterfeit Goods Trafficking.

On August 7, 2015, Robert Berg Enterprises, Inc. , d/b/a "Berg Sportswear" of Corinna, Maine, was fined $10,000 for trafficking in counterfeit goods. The defendant was also placed on probation for one year and ordered to pay $11,855. 67 in restitution. The defendant pleaded guilty to the charge on June 23, 2014. According to court records, between January 2006 and January 2011, the defendant counterfeited apparel bearing the trademarks of the Boston Red Sox, Boston Celtics, New England Patriots, New York Yankees, Harley Davidson, John Deere, Jack Daniels, Orange County Choppers and Playboy. (http://www.justice.gov/usao-me/pr/maine-corporation-fined-10000-counterfeit-goods-trafficking)

6. Four Men Charged with Trafficking in Pet Products with Counterfeit Labels.

On July 28, 2015, an indictment was unsealed charging four men with various offenses based on their roles in smuggling pet products with counterfeit labels into the United States. Iain Nigel MacKellar, of England; Lam Ngoc Tran, aka Mark Tran, of Fountain Valley, California; Allen

Smith, of Phoenix; and William Humphreys, of Laguna Hills, California, were indicted on July 9, 2015. They are charged with conspiracy to commit wire fraud, mail fraud and trafficking in counterfeit labels, and smuggling goods into the United States. Mackellar and Tran also are charged with additional counts of wire fraud, mail fraud, trafficking in counterfeit labels and smuggling. The defendants were suspected members of one of the largest known groups of importers of counterfeit packaged pet products. The indictment alleges the defendants smuggled veterinary products that were not manufactured for the U.S. market into the United States for distribution under false labels, including Frontline and Frontline Plus pesticides manufactured by Merial Pharmaceutical Company (Merial). In some cases, according to the indictment, the defendants allegedly imported the products into the U.S. under the pretense that the products were destined for use by charitable organizations, but instead distributed the products to large retail outlets for commercial sale. In December 2015, two of the defendants pleaded guilty. (http://www.justice.gov/opa/pr/four-men-charged-trafficking-pet-products-counterfeit-labels)

7. California Man Sentenced to One and a Half Years in Prison for Trafficking in Counterfeit Goods.

On July 27, 2015, Joe L. Regalado, of Stockton, CA, was sentenced to one and one half years in prison for trafficking in counterfeit goods. According to court documents, over a nearly two-year period, Regalado trafficked in goods bearing counterfeit trademarked insignia. When he was arrested in December 2011, Regalado was selling counterfeit college sports jerseys, Major League Baseball jerseys and hats, National Basketball Association jerseys, National Football League jerseys and caps, National Hockey League jerseys, and counterfeit clothing bearing trademarks from Chanel, Prada, Juicy Couture, Louis Vuitton, Christian Audigier, Polo, True Religion, Coach, Burberry, Gucci, and Nike. As part of his sentence, Regalado was ordered to pay over $111,000 in restitution to sports teams whose logos were on the goods that he was caught selling, and to forfeit ownership of two cars and a garage full of counterfeit goods that were recovered by the FBI when they searched his house. (http://www.justice.gov/usao-edca/pr/stockton-man-sentenced-one-and-half-years-prison-trafficking-counterfeit-goods)

8. Lafayette, Louisiana Store Owner Pleads Guilty to Selling Counterfeit Merchandise.

On July 24, 2015, Tawfic Ahmed Saleh, of Lafayette, Louisiana pleaded guilty to one count of trafficking in counterfeit goods. According to the guilty plea, law enforcement agents on November 18, 2014, searched AA Discount Plus LLC doing business as "Urban Buzz," a clothing and variety store in Lafayette. During the search, agents found and seized numerous suspected counterfeit items including: 258 articles of clothing and 20 watches labeled "Ralph Lauren Polo"; 42 phone cases labeled "Otterbox"; 25 women's purses, four watches and 25 wallets labeled "Michael Kors"; 45 watches labeled "Casio"; 15 belts labeled "Guicci"; and eight belts labeled "Louis Vuitton." Saleh was later questioned and admitted to selling counterfeit items. Saleh operated the business from 2005 to 2007 and reopened it in 2009. (http://www.justice.gov/usao-wdla/pr/lafayette-store-owner-pleads-guilty-selling-counterfeit-merchandise)

9. Leader of Coupon Counterfeiting Ring on Silk Road Websites Pleads Guilty.

On July 22, 2015, a leader of a coupon counterfeiting ring, Beau Wattigney, of New Orleans LA, pleaded guilty to participating in a conspiracy to sell counterfeit coupons using the "Silk Road" online marketplace. In connection with his plea, Wattigney admitted that, between May 2012 and November 2014, he used the online monikers "PurpleLotus" and "GoldenLotus" to sell counterfeit coupons for various goods and services on Silk Road 1. 0, which was a hidden website through which users around the world bought and sold illegal drugs, goods and services. Wattigney further admitted that he engaged in the same conduct on Silk Road 2. 0, a successor to Silk Road 1. 0, using the monikers "PurpleLotus" and "CouponKing." The coupons allowed purchasers to obtain significant discounts on a variety of goods and services offered by the victim companies, including Hopster, Veri-fi, SmartSource, RedPlum and Visa. For example, Wattigney sold a counterfeit coupon that allowed users to purchase $50. 00 Visa Gift Cards for $0. 01 each. Wattigney admitted that he created and manufactured the fraudulent coupons with the assistance of several co-conspirators, and that they designed the coupons to look like original print-at-home manufacturers' coupons by using the companies' trademarks. He also admitted that the scheme affected more than 50 U.S.-based businesses, and caused or attempted to cause more than one million dollars in intended losses. (http://www.justice.gov/opa/pr/leader-coupon-counterfeiting-ring-silk-road-websites-pleads-guilty)

10. Four Individuals Charged for Importing and Trafficking Counterfeit Apple and Sony Products into the United States.

On July 1, 2015, four individuals were arraigned based on charges for allegedly smuggling counterfeit Sony Camcorders, Apple iPhones, iPads and iPods, from China for sale in the United States. Andreina Becerra, a Venezuelan National, and Roberto Volpe, an Italian National, both residing in Miami; Jianhua Li, a Chinese National and resident of Guangzhou, China; and Rosario La Marca, an Italian National and resident of Italy, are charged in an eight-count indictment with importing and trafficking fake iPhones, iPads and iPods bearing counterfeit Apple trademarks and fake Camcorders bearing counterfeit Sony trademarks, as well as smuggling, structuring and international money laundering. The indictment alleges that, to avoid detection by U.S. Customs officials, the devices often were shipped separately from the labels bearing counterfeit trademarks, and then were labeled and packaged after they passed through U.S. Customs and Border Protection. According to the indictment, the defendants then re-shipped the devices throughout the United States to co-conspirators. According to the indictment, proceeds from the sales of the devices were funneled back to the defendants' accounts in Florida and New Jersey via structured cash deposits broken into multiple deposits of less than $10,000 each to avoid bank reporting requirements. The defendants made more than 100 illegal wire transfers totaling over $1. 1 million to Li's Hong Kong accounts to facilitate their criminal activity. (http://www.justice.gov/opa/pr/four-individuals-charged-importing-and-trafficking-counterfeit-apple-and-sony-technology)

11. Minnesota Man Sentenced for Conspiracy to Traffic in Counterfeit Sports Jerseys.

On July 1, 2015, Brian Todd Gore, of Inver Grove Heights, Minnesota, was sentenced to 37 months imprisonment and three years of supervised release for conspiracy to traffic in counterfeit goods. Gore had pleaded guilty on December 9, 2014. Gore's July 2014 indictment alleged that from November 2009 through September 2012, he conspired with other individuals to traffic in goods, specifically counterfeit sports jerseys, imported from China. As part of the conspiracy, Gore would order the counterfeit sports jerseys from suppliers in China, have them delivered to him in the United States, and then sell them to a co-conspirator with the knowledge that the counterfeit jerseys would be sold to the public. (http://www.justice.gov/usao-mn/pr/inver-grove-heights-man-sentenced-37-months-prison-conspiring-traffic-counterfeit-jerseys)

12. Eleven Defendants Charged in Nationwide Conspiracy to Manufacture and Distribute Counterfeit 5-Hour ENERGY Drink.

On June 19, 2015, 10 people were arrested after being charged with conspiracy to traffic in counterfeit goods, conspiracy to commit criminal copyright infringement and conspiracy to introduce misbranded food into interstate commerce. The defendants were arrested on charges stemming from the illegal distribution and counterfeit of the liquid dietary supplement 5-Hour ENERGY. One further defendant was not arrested but remains subject to an arrest warrant. According to the indictment, all 11 defendants were involved in the illegal repackaging and eventual counterfeiting of 5-Hour ENERGY. According to the indictment, defendants Joseph Shayota and Adriana Shayota, his wife, through their company Baja Exporting LLC, agreed with Living Essentials to distribute 5-Hour ENERGY in Mexico. Living Essentials manufactured the liquid 5-Hour ENERGY product and provided Spanish-language labeling and display boxes to Baja Exporting. Living Essentials additionally provided Baja a complete product package under the agreement that the 5-Hour ENERGY with Spanish-language labeling was only to be distributed by Baja in Mexico. The defendants repackaged over 350,000 bottles of 5-Hour ENERGY and sold them in the United States at a price that was 15 percent lower than what Living Essentials charged for authentic United States 5-Hour ENERGY. By early 2012, the defendants had moved into counterfeiting the entire 5-Hour ENERGY product. The defendants manufactured the counterfeit 5-Hour ENERGY liquid at an unsanitary facility using untrained day workers. The defendants mixed unregulated ingredients in plastic vats while attempting to mimic the real 5-Hour ENERGY products. In addition, the indictment alleges that from May 2012 to October 2012, Midwest Wholesale Distributors, a company owned by Jamil, distributed more than four million bottles of counterfeit 5-Hour ENERGY into commercial channels throughout the United States. (http://www.justice.gov/opa/pr/eleven-defendants-charged-nationwide-conspiracy-manufacture-and-distribute-counterfeit-5-hour)

13. Defendants Sentenced for Importing and Selling Hazardous and Counterfeit Toys in New York.

Five individuals and five corporations were sentenced in June 2015 for importing children's toys with copyright-infringing images and counterfeit trademarks of popular children's characters, as well as unsafe lead levels, small parts that presented risks of choking or ingestion, easily-accessible battery compartments, and other potential hazards. On June 9, Chenglan Hu was sentenced to two years of probation with special conditions, and Hua Fei Zhang, was sentenced to three years of probation with special conditions. Both are from Bayside, New York. On June 16, each of the five corporations were sentenced to five years of probation with special conditions. In pleading guilty to trafficking in hazardous consumer goods in violation of Consumer Product Safety Act, Hu and Zhang also agreed to forfeit $700,000 and more than 120,000 unsafe children's toys. The government previously seized three luxury vehicles and six bank accounts, and filed a *lis pendens* notice against two real properties owned by Zhang in Queens, New York. According to court filings and facts presented at the plea hearings, from July 2005 through January 2013, Hu, Zhang, and the other individual defendants used the companies they owned to import and sell toys from China from a storefront and warehouse in Ridgewood, New York, and other locations in Brooklyn, New York and Queens, New York. According to the indictment, CBP seized toys imported by the defendants from shipping containers entering the United States from China on 33 separate occasions. Seventeen of the 33 seizures contained toys prohibited from import into the United States because of excessive lead content, excessive phthalate levels, small parts that presented risks of choking, aspiration or ingestion, and easily-accessible battery compartments. Sixteen of the 33 seizures contained toys bearing copyright-infringing images and counterfeit trademarks, including a wide variety of popular children's characters. (http://www.justice.gov/opa/pr/two-individuals-plead-guilty-importing-and-selling-hazardous-and-counterfeit-toys-new-york)

14. Ohio Men Indicted for Sale of $275,000 Worth of Counterfeit Goods.

On June 3, 2015, four men from the Youngstown, Ohio area (Ashraf Mishmish of Boardman; Raed Khatib of Boardman; Wesam Mishmish, of Austintown; and Khaled Wakhyan of Boardman) were indicted for trafficking in counterfeit goods. The indictment alleges that in or about December 2013 through July 2014, Ashraf and Wesam Mishmish, Khatib, and Wakhyan conspired and agreed to intentionally traffic in counterfeit goods – specifically, perfume, cologne, purses, headphones, jackets and boots. It was a part of the conspiracy that the defendants obtained perfume, cologne, boots, purses and headphones bearing counterfeit marks. The defendants then sold the counterfeit goods at a price below the MSRP for the authentic goods. In total, the defendants possessed and offered for sale counterfeit items with the MSRP of $273,872. (http://www.justice.gov/usao-ndoh/pr/youngstown-area-men-indicted-sale-275000-worth-counterfeit-goods)

15. Woman Sentenced for Selling Counterfeit Samsung Batteries.

On April 17, 2015, Graciella Balderrama-Acevedo pleaded guilty and was sentenced for her part in a conspiracy to sell counterfeit Samsung batteries. Balderrama was ordered to pay more

than $90,000 in restitution to Samsung and will serve 12 months and 1 day in Federal prison. Balderrama is a Mexican citizen who had resided in Houston, Texas and is expected to face deportation proceedings following her release from prison. Balderrama engaged in a conspiracy to traffic in counterfeit goods. She received the lithium-ion batteries from an individual in China (who was engaged in sending them in bulk to people in the U.S.), and she then forwarded the counterfeit products on to individual eBay purchasers. (http://www.justice.gov/usao-sdtx/pr/woman-sentenced-selling-counterfeit-samsung-batteries)

16. Texas Man Heads to Prison for Trafficking in Counterfeit Louis Vuitton, Coach and Other Merchandise.

On March 16, 2015, Han Woon Liew of Sugar Land was sentenced to 70 months Federal imprisonment followed by three years of supervised release for his conviction of conspiracy to traffic in counterfeit goods. Liew was ordered to pay $2. 6 million in restitution. Liew pleaded guilty Nov. 18, 2014. He admitted that from January 2012 through April 2014, he intentionally trafficked in goods, specifically counterfeit Louis Vuitton, Michael Kors, Coach and Gucci purses and wallets. Liew knowingly used counterfeit marks, which were registered trademarks, in an attempt to make the items appear legitimate. (http://www.justice.gov/usao-sdtx/pr/sugar-land-man-heads-prison-trafficking-counterfeit-louis-vuitton-coach-and-other)

17. Pennsylvania Man Sentenced for Trafficking in Counterfeit Goods.

On February 3, 2015, Michael Kurnik of York, Pennsylvania, was sentenced five years of probation and ordered to pay $25,000 in restitution. On October 22, 2014, Kurnik pleaded guilty to conspiring to traffic in counterfeit goods. According to court records, Kurnik regularly purchased what purported to be OtterBox cell phone cases from suppliers in China and resold them to individuals in the United States. One of the resellers, who lived in Maine, told Kurnik in May 2013 that he had been contacted by OtterBox and told that he was going to be sued for selling counterfeit cases on eBay. Despite being told of the OtterBox lawsuit, Kurnik continued to buy the phone cases from China and resell them in the United States. In December 2013, he sent a shipment of counterfeit cases to the reseller in Maine, who by that point was cooperating with law enforcement. A search warrant was executed in Manchester, Pennsylvania at a warehouse used by Kurnik, and agents seized about 6,700 counterfeit OtterBox cases. Kurnik admitted in an interview that by May 2013 he knew the cases he was selling were counterfeit, but he continued buying cases from China to resell in the United States until December 2013. (http://www.justice.gov/usao-me/pr/pennsylvania-man-sentenced-five-years-probation-trafficking-counterfeit-goods)

18. Operator of Local Flea Market Sentenced on Federal Intellectual Property Charges.

On January 29, 2015, Jack Frison, Sr., of Frontenac, Missouri, was sentenced to two years of imprisonment on multiple charges relating to his involvement in the sale of counterfeit goods and DVDs. According to testimony presented at trial in June, for more than two decades, Frison owned and operated the Frison Flea Market in Pagedale, MO. Vendors paid Frison a rental fee to rent and operate sales booths at his Flea Market. For more than ten years, many of Frison's

vendors openly sold counterfeit goods from their booths at the Market. The counterfeit goods included clothing, footwear, purses, accessories, movie DVDs and music CDs. Some of the vendors sold counterfeit purses and similar luxury items bearing marks owned by Coach, Louis Vuitton, Dolce & Gabbana and others. Frison knew that the goods were counterfeit and allowed vendors to continue selling such goods. Rather than removing vendors selling illegal goods, Frison fined them instead, adding to his income. (http://www. justice. gov/usao-edmo/pr/operator-local-frison-flea-market-indicted-federal-fraud-charges)

19. Two Chinese Nationals Sentenced for Trafficking Counterfeit Cell Phone Cases.

On December 11, 2014, Zexiong Chen and Haotian Chen, who are unrelated, were sentenced for trafficking in counterfeit goods. Zexiong Chen was sentenced to 18 months in prison, one year of supervised release, a fine of $6,000, and restitution in the amount of $4,820. Haotian Chen was sentenced to time served (which was one day in prison), one year of supervised release, a fine of $4,000, and restitution in the amount of $4,829. In February 2013, the defendants incorporated Max Wireless Group, Inc. as a vehicle for importing and reselling cell phone cases, many of which were counterfeit. Through Max Wireless, the defendants imported counterfeit cell phone cases from China, sold a small percentage of them through their Wakefield MA store, and sold the vast majority of them to individuals and companies who resold them at retail locations. Many of these retail locations were kiosks in shopping malls, some of which were in Massachusetts. On 12 occasions from November 2012 through August 2013, CBP officials inspected shipments the defendants imported from China to the United States and determined that these shipments contained counterfeit items. These 12 seizures included more than 10,000 counterfeit cell phone cases, bearing marks of manufacturers including OtterBox, Speck, Kate Spade, Hello Kitty, Ferrari and LifeProof. On September 4, 2013, Federal agents searched the Max Wireless store and found more than 2,500 counterfeit cell phone cases and accessories. The total of the retail price for the authentic versions of all of the products seized totaled more than $350,000. (http://www.justice.gov/usao-ma/pr/two-chinese-nationals-sentenced-trafficking-counterfeit-cell-phone-cases)

20. New York Man Sentenced for Selling Counterfeit Goods.

On October 17, 2014, Samuel Ascolese was sentenced to 12 months and 1 day of imprisonment, and 3 years of supervised release, and was ordered to pay $72,652. 99 in restitution. In August 2013, Ascolese – owner of Custom Tattoo Apparel – knowingly sold counterfeit T-Shirts during the Sturgis Motorcycle Rally. (http://www.justice.gov/usao-sd/pr/new-york-man-sentenced-selling-counterfeit-goods)

21. St. Louis County Man Sentenced for Trafficking Counterfeit Goods.

On October 10, 2014, Rashad Shabazz, of St. Louis, Missouri was sentenced to three years of probation. Shabazz pleaded guilty on June 2, 2014, to trafficking in counterfeit goods. According to the plea agreement, on November 5, 2013, Shabazz operated an open-air store offering counterfeit apparel from brands including Polo Ralph Lauren, Nike, Timberland, and True Religion, as well as counterfeit electronic media. (http://www.justice.gov/usao-edmo/pr/st-louis-county-man-pleads-guilty-trafficking-counterfeit-goods)

22. Houston Man Charged with Trafficking in Counterfeit Beats by Dr. Dre.

On October 8, 2014, Nick Chen, a Vietnamese National legally residing in Houston, TX was arrested on charges of conspiracy and trafficking in counterfeit goods. The indictment alleges Chen was the CEO of NPC Enterprises and that he allegedly conspired to traffic in counterfeit Beats products from June 2013 through February 2014. The retail price of each Beats product ranges between $99. 95 and $599. 95. The total value of counterfeit products alleged in the indictment exceeds $560,000. A jury trial was set for December 14, 2015. (http://www.justice.gov/usao-sdtx/pr/houston-man-charged-trafficking-counterfeit-beats-dr-dre)

Trafficking in Counterfeit Pharmaceuticals

1. Mansfield, Ohio Man Pleads Guilty to Sale of Counterfeit Prescription Pills.

On September 3, 2015, Tamacio Walls of Mansfield pleaded guilty to trafficking in counterfeit drugs. On June 18, 2015, Walls was indicted on one count of introducing misbranded drugs into interstate commerce and one count of trademark violations. Walls purchased, warehoused, dispensed and offered for sale, counterfeit versions of Viagra (active ingredient Sildenafil), Cialis (active ingredient Tadalafil) and Levitra (active ingredient Vardenafil) to consumers without requiring consumers to provide any form of prescription from a licensed medical practitioner, as required by law, according to the indictment. The indictment charged that Walls did not inform consumers that said drugs were prescription drugs and that they should seek medical advice before consuming the drugs, and that Walls failed to provide any warnings to consumers concerning potential dangers associated with taking the drugs. Walls obtained the drugs from unauthorized sources in China and India. (www.justice.gov/usao-ndoh/pr/mansfield-man-indicted-sale-counterfeit-prescription-pills)

2. Two Canadians Sentenced for Distributing Counterfeit and Adulterated Botox to Local Doctors.

On August 4, 2015, Kamaldeep Sandhu and Navdeep Sandhu, both residents of Vancouver, British Columbia, Canada, pleaded guilty and were sentenced for distributing counterfeit, misbranded and adulterated Botox® into the United States, including multiple shipments to two doctors located in St. Louis County, Missouri. Kamaldeep Sandhu received a sentence of 24 months of imprisonment, while Navdeep Sandhu received a sentence of 3 months. According to defendants' plea agreements, defendants operated a sophisticated wholesale drug distribution business involving multiple persons in Canada, Panama, and Turkey. Defendants sourced Botox® from Turkey and shipped it to multiple U.S. doctors in Missouri and other states. According to the label for FDA approved Botox® Cosmetic, unopened vials of Botox® Cosmetic should be stored in a refrigerator at temperatures between 2° to 8° Celsius before dispensing to patients. Defendants' drugs were adulterated because defendants' business did not keep the Botox® Cosmetic at constant cold temperatures, and sometimes shipped and stored these drugs with no refrigeration or insulation. Further, some of the Botox® Cosmetic sold by defendants had counterfeit exterior packaging, and the manufacturing lot numbers on the exterior of the drugs' cartons did not match the lot numbers on the drug vials inside the

cartons. (http://www.justice.gov/usao-edmo/pr/two-canadians-sentenced-distributing-counterfeit-and-adulterated-botox-local-doctors)

3. Final Defendant Pleads Guilty in Multistate Conspiracy to Sell over $1 Million in Counterfeit Erectile-Dysfunction Drugs.

On August 3, 2015, John Derek Gitmed of Los Angeles, CA pleaded guilty to one count of trafficking in counterfeit goods. According to court documents, Gitmed, along with his ex-wife, Holly Gitmed of Riverbank, his daughter Felicia Gitmed of Los Angeles, and his nephew Anthony Pollino of Los Angeles, conspired to obtain counterfeit copies of the erectile-dysfunction drugs Viagra®, Cialis®, and Levitra®, along with their packaging, and sell them to consumers throughout California and in the Las Vegas, Nevada area. The defendants assured buyers their products were genuine, when they were actually cheaply made foreign copies of the drugs. The defendants operated as a business, calling their operation the "California Confidence Company." Gitmed admitted that the value of the counterfeit products attributable to him as over $1. 2 million. Each of Gitmed's co-defendants previously pleaded guilty to one count of trafficking in counterfeit goods. Holly Gitmed pleaded guilty on June 8, 2015, and was sentenced on August 24 to five months of imprisonment and 24 months supervised released and was ordered to pay $832. 68 in restitution. Anthony Pollino pleaded guilty on July 20, 2015. Felicia Gitmed pleaded guilty on June 22, 2015. (http://www.justice.gov/usao-edca/pr/final-defendant-pleads-guilty-multistate-conspiracy-sell-over-1-million-counterfeit)

4. Trafficker Guilty of Distributing Dangerous Counterfeit Viagra® and Cialis®.

On June 29, 2015, Martez Alando Gurley of Napa, California, pleaded guilty to conspiracy to traffic in counterfeit Viagra® and Cialis® and introducing misbranded prescription drugs into interstate commerce. Gurley admitted that he purchased 15,000–18,000 counterfeit Viagra® and counterfeit Cialis® tablets from an individual in China he knew as "Alice," as well as an additional 3,600–4,800 tablets from another individual within the U.S. He admitted he knew the drugs were prescription medications and that he could not legally distribute them. He also said he knew the drugs were counterfeit. Gurley sold the counterfeit drugs to at least 11 individuals across the country for between $40 and $50 a bottle. Testing on samples of the counterfeit Viagra® revealed the drugs contained less than the 100 mg of active pharmaceutical ingredient (API), while the testing on the counterfeit Cialis® revealed small quantities of the Viagra® API and none of the Cialis® API. In addition, some of the counterfeit Viagra® tablets were found to contain the unrelated compound 2-MBT. (http://www.justice.gov/usao-sdtx/pr/trafficker-guilty-distributing-dangerous-counterfeit-viagra-and-cialis)

5. South Carolina Man Sentenced for Trafficking in Counterfeit Medications.

On June 22, 2015, Arthur Fleming Moler of Gaston was sentenced to 78 months imprisonment, and three years of supervised release, and was ordered to pay $33,380. 05 in restitution. On December 5, 2014, Moler, was found guilty, after a jury trial, of trafficking in counterfeit goods, smuggling illegal medications, and theft of government services. Facts presented during the trial showed that Moler sold and shipped counterfeit goods and medications, including illegal replicas of Viagra and Cialis, from his Columbia based business, South Carolina Liquidations.

According to testimony presented during the case, CBP inspectors discovered counterfeit golf equipment being shipped from China to South Carolina Liquidations in Columbia, South Carolina. When ICE HSI agents entered the warehouse, they discovered hundreds of counterfeit designer handbags, sunglasses, electronic equipment and over 2 million dollars' worth of counterfeit erectile dysfunction medications. On June 25, 2015, Moler filed an appeal of the final judgment in the Fourth Circuit Court of Appeals. (http://www.justice.gov/usao/sc/news/12.15.14.moler.html)

6. Texas Man's Appeal Dismissed Following Conviction of Trafficking in Counterfeit Pharmaceuticals.

On May 13, 2015, the Fifth Circuit dismissed the appeal of Defendant Jamal Khattab of Katy, Texas. He had appealed his 21-month sentence for conspiring to traffic in counterfeit pharmaceuticals. Khattab was sentenced on August 14, 2014 -- to 21 months in prison, and ordered to pay a personal money judgment of $24,650, and $7,000 in restitution – for trafficking in counterfeit goods, trafficking in at least 13,621 counterfeit pharmaceuticals, and conspiracy. Khattab was part of a conspiracy to import counterfeit medicine into the United States from China between June 2010 and March 2012. (http://www.justice.gov/opa/pr/illinois-man-sentenced-smuggling-counterfeit-goods-and-drugs-us)

7. Suspended Chicago Pharmacist Pleads Guilty to Trafficking Counterfeit Viagra.

On April 2, 2015, Michael Markiewicz of Norridge (a suspended Chicago pharmacist) pleaded guilty to illegally obtaining counterfeit Viagra and Cialis from China and illegally dispensing the bogus medications at his north side pharmacy. According to the plea agreement, between 2010 and 2012, via the Internet, Markiewicz ordered approximately 1600 counterfeit Viagra and Cialis tablets from China. The customs declaration on each outer packaging stated that it contained a "gift pen," and the counterfeit drugs were hidden in unlabeled clear plastic baggies underneath the pen in the package. Markiewicz then sold the counterfeit drugs at his pharmacy to customers who had sought to purchase the medications without a prescription. Sentencing is reset for December 4, 2015. (http://www.justice.gov/usao/iln/pr/chicago/2015/pr0402_01.html)

8. Broward County, Florida Resident Sentenced for Selling Counterfeit Xanax.

On February 5, 2015, Frank Fiore of Parkland, Florida was sentenced to 32 months imprisonment for conspiring to traffic in counterfeit Xanax and illegally distributing steroids. According to court documents and statements made by the parties at the sentencing hearing, Fiore sold counterfeit Xanax and Viagra to undercover officers as well as to a cooperating source Carbone was previously convicted of conspiracy to traffic in a counterfeit drug and distribution of controlled substances and was sentenced to 24 months imprisonment. Co-defendant Gary Lee Jones of Boca Raton, Florida, was convicted of conspiracy to traffic in a counterfeit drug and possession of a firearm after conviction for a felony and also sentenced to 24 months imprisonment. (http://www.justice.gov/usao/fls/PressReleases/150205-02.html)

Trade Secret Theft (18 U.S.C. § 1832)

1. Members of Computer Hacking Ring Sentenced for Hacking and Intellectual Property Theft Conspiracy.

On June 11, 2015, Nathan Leroux of Bowie, Maryland was sentenced to 24 months imprisonment and three years of supervised release. On the same day, Sanadodeh Nesheiwat of Washington, New Jersey was sentenced to 18 months imprisonment and three years of supervised release. Both had pleaded guilty to conspiracy to commit computer intrusions and criminal copyright infringement based for their roles in the cyber theft of software and data related to the Xbox One gaming console and Xbox Live online gaming system, and popular games such as the "FIFA" online soccer series; "Call of Duty: Modern Warfare 3"; and "Gears of War 3." In July 2013, the FBI intercepted a counterfeit console built by Leroux, which was destined for the Republic of Seychelles. Leroux also admitted that he developed a software exploit that allowed him and others to generate millions of "coins" for the FIFA soccer games playable on the Xbox Live platform. These coins are the virtual, in-game currency used to build a "FIFA Ultimate Team" in the games. Without the authorization of Electronic Arts, the intellectual property rights holder to the FIFA games, Leroux and others sold bulk quantities of the "FIFA coins" via online black markets. The United States has seized over $620,000 in cash and other proceeds related to the charged conduct. David Pokora of Mississauga, Ontario, Canada previously pleaded guilty to the same conspiracy charge on Sept. 30, 2014. He was sentenced on April 23, 2015, to 18 months imprisonment and three years unsupervised release. Austin Alcala of McCordsville, Indiana pleaded guilty on April 1, 2015, to the same charge. (http://www.justice.gov/opa/pr/fourth-member-international-computer-hacking-ring-pleads-guilty-hacking-and-intellectual)

2. Former PPG Employee Charged with Theft of Trade Secrets.

On May 7, 2015, a former PPG Industries, Inc. employee, Thomas Rukavina of Plum Borough, PA was arrested and charged with theft of trade secrets. The criminal complaint alleges that Rukavina retired from PPG in July of 2012. As early as June 2014, Rukavina passed proprietary and confidential information to J.T.M.G. Co., a glass company based in Jiangsu, China, that specializes in automotive and other specialty glass. The trade secret information he passed included PPG's manufacturing specifications for windows, which are made of synthetic plastics and used for high-speed transportation, including airplanes. On August 19, 2015, the district court granted the government's Motion to Dismiss the Indictment. (http://www.justice.gov/opa/pr/former-ppg-employee-charged-theft-trade-secrets)

3. Kolon Industries Inc. Pleads Guilty for Conspiring to Steal DuPont Trade Secrets Involving Kevlar Technology.

On April 30, 2015, Kolon Industries Inc. , a South Korean industrial company, pleaded guilty to conspiracy to steal trade secrets involving E. I. DuPont de Nemours & Co. 's (DuPont) Kevlar technology. The company was sentenced to pay $85 million in criminal fines and $275 million in restitution. Kolon Industries Inc. , appearing through two successor entities—Kolon Industries Inc. and Kolon Corporation (collectively, Kolon)—pleaded guilty to one count of

conspiracy to convert trade secrets. According to the statement of facts filed with the plea agreement, from June 2006 to February 2009, Kolon conspired with former DuPont employees and others to steal DuPont's trade secrets for making Kevlar, a high-strength, para-aramid synthetic fiber. Kevlar, a trademarked name, is one of DuPont's most well-known products and is used in a wide range of commercial applications such as body armor, fiber optic cables, and automotive and industrial products. Kolon personnel met repeatedly with former DuPont employees, to obtain confidential and proprietary DuPont information about Kevlar. Schulz pleaded guilty to conspiracy to steal trade secrets in September 2014 and was sentenced on July 31, 2015, to two years supervised probation with six months home detention and GPS monitoring, and 500 hours of community service, and was fined $75, 000. Mitchell pleaded guilty to theft of trade secrets and obstruction of justice in December 2009 and was sentenced to 18 months in prison. This case represents the first time that foreign corporations with no direct presence in the United States were successfully served with U.S. criminal process, over their objections, based on service pursuant to an international treaty. In December 2014, the district court found that both of the successor companies were properly served, and ordered them to appear for arraignment. In February 2015, the Fourth Circuit Court of Appeals denied Kolon's petition for extraordinary relief seeking reversal of the district court's order. Additionally, five former Kolon executives and employees, all of South Korea, were charged in an August 2012 indictment. (http://www.justice.gov/opa/pr/kolon-industries-inc-pleads-guilty-conspiring-steal-dupont-trade-secrets-involving-kevlar)

4. Computer Analyst Sentenced to Three Years In Prison for Stealing Trade Secrets from Citadel and Previous Employer.

On January 15, 2015, a highly-skilled computer science engineer, Yihao Pu – who a prosecutor said "meticulously planned and brazenly executed" stealing sensitive trade secrets from two former employers (a trading firm in New Jersey and later Citadel, LLC, a Chicago-based financial firm) – was sentenced to three years in Federal prison and ordered to pay restitution in the total amount of $759,649. 55. Pu's colleague, Sahil Uppal, who worked with and aided Pu at both firms, was sentenced to three years' probation for obstruction of justice. Pu began working at Citadel in May 2010 as a quantitative financial engineer, and his responsibilities included working with analysts and researchers to develop and enhance Citadel's high frequency trading strategies. As part of his duties, Pu was permitted to use his office computer to access a folder stored on Citadel's servers that contained information and data related to predictions signals commonly referred to as "alphas," which are the building blocks of Citadel's automated electronic trading algorithms and strategies. Pu bypassed Citadel's security measures and stole thousands of files that contained Citadels' alpha outputs. Pu then used those alphas in his own high frequency trading strategy for his own personal investment account in an effort to replicate Citadel's trading for his own benefit. When Uppal joined Pu at Citadel, they continued their scheme to benefit themselves during the summer of 2011. Uppal transferred to Pu three computer files containing Citadel trade secrets without Citadel's authorization. On Aug. 26, 2011, Citadel confronted Pu about suspicious activity on his work computer, and Pu returned home and began destroying evidence. With Uppal's help, Pu took a half dozen hard drives to a friend's apartment, and a few days later Pu instructed his friend to

get rid of them. Uppal obstructed justice by helping Pu conceal evidence and he lied when he too was confronted and questioned by Citadel. In late January, 2015, Pu filed a notice of appeal as to his and Uppal's sentences in the Court of Appeals for the Seventh Circuit. (http://www.justice.gov/usao/iln/pr/chicago/2015/pr0115_01.html)

5. Former Winchester Brake Pad Engineer Sentenced for Theft of Trade Secrets Charge.

On October 6, 2014, David Lewis was sentenced to three years of probation and ordered to pay $32,000. 00 in restitution. Lewis had pleaded guilty on March 3, 2014, to conspiracy to steal trade secrets, in violation of 18 U.S.C. § 1832(a)(5). From 1998-2008, Lewis was employed as Principal Development Engineer at Brake Parts, Inc. ("BPI") in Winchester, Kentucky, where he specialized in the development of ceramic brake pads; the formulas for these pads were BPI trade secrets. Beginning in 2008, in exchange for a cash payment and the promise of future employment, Lewis secretly began transmitting the formulas to Satisfied Brake Parts, a Canadian competitor of BPI, which exploited them to produce virtual clones of BPI's brake pads. Fired by BPI at the end of 2008, Lewis went to work for Satisfied where he helped engineers there to produce brake pads based on BPI's proprietary formulas. By its own estimate, Satisfied grossed $40 million from the sale of those brake pads. (http://www.justice.gov/usao/kye/news/2014/2014-03-05-lewis. html)

Economic Espionage (18 U.S.C. § 1831)

1. Chinese Professors Among Six Defendants Charged with Economic and Theft of Trade Secrets for Benefit of People's Republic of China.

On May 16, 2015, Tianjin University Professor Hao Zhang was arrested upon entry into the United States from the People's Republic of China (PRC) in connection with a recent superseding indictment. The 32-count indictment, which had previously been sealed, charges a total of six individuals with economic espionage and theft of trade secrets for their roles in a long-running effort to obtain U.S. trade secrets for the benefit of universities and companies controlled by the PRC government. According to the indictment, PRC Nationals Wei Pang and Hao Zhang met at a U.S. university in Southern California during their doctoral studies in electrical engineering. While there, Pang and Zhang conducted research and development on thin-film bulk acoustic resonator (FBAR) technology under funding from U.S. Defense Advanced Research Projects Agency (DARPA). After earning their doctorate in approximately 2005, Pang accepted employment as an FBAR engineer with Avago Technologies (Avago) in Colorado and Zhang accepted employment as an FBAR engineer with Skyworks Solutions Inc. (Skyworks) in Massachusetts. The stolen trade secrets alleged in the indictment belong to Avago or Skyworks. According to the indictment, in 2006 and 2007, Pang, Zhang and other co-conspirators prepared a business plan and began soliciting PRC universities and others, seeking opportunities to start manufacturing FBAR technology in China. Through efforts outlined in the superseding indictment, Pang, Zhang and others established relationships with officials from Tianjin University. As set forth in the indictment, in 2008, officials from Tianjin University flew to San Jose, California, to meet with Pang, Zhang and other co-conspirators. Shortly thereafter, Tianjin University agreed to support Pang, Zhang and others in establishing an FBAR fabrication

facility in the PRC. In mid-2009, both Pang and Zhang simultaneously resigned from the U.S. companies and accepted positions as full professors at Tianjin University. Tianjin University later formed a joint venture with Pang, Zhang and others under the company name ROFS Microsystem intending to mass produce FBARs. The indictment alleges that Pang, Zhang and other co-conspirators stole recipes, source code, specifications, presentations, design layouts and other documents marked as confidential and proprietary from the victim companies and shared the information with one another and with individuals working for Tianjin University. According to the indictment, the stolen trade secrets enabled Tianjin University to construct and equip a state-of-the-art FBAR fabrication facility, to open ROFS Microsystems, a joint venture located in PRC state-sponsored Tianjin Economic Development Area, and to obtain contracts for providing FBARs to commercial and military entities. (http://www.justice.gov/opa/pr/chinese-professors-among-six-defendants-charged-economic-espionage-and-theft-trade-secrets)

Alternative Charges:

Smuggling (18 USC § 545)

1. Second Turkish Man Sentenced for Smuggling Counterfeit Cancer Drugs.

On January 23, 2015, Sabahaddin Akman, from Turkey, was sentenced to 30 months imprisonment and two years supervised release, and ordered to pay of fine of $150,000. 00 for smuggling goods into the United States. Akman pleaded guilty, on August 12, 2014, to conspiracy and smuggling goods into the United States. On October 28, 2014, Ozkan Semizoglu, the "Foreign Trade Director" of a Turkish drug wholesaler, was sentenced to 27 months in prison for smuggling counterfeit, misbranded and adulterated cancer treatment drugs into the United States, including multiple shipments of Altuzan® (the Turkish version of Avastin®) that he sent from Turkey to Chesterfield, Missouri. Both Semizoglu and co-defendant Akman were indicted on January 16, 2014. According to Semizoglu's plea agreement, Semizoglu used shipping labels that concealed the illegal nature of the prescription drug shipments, including customs declarations falsely describing the contents as "gifts" or "documents" or "product sample" with no (or low) declared monetary values. Semizoglu also ensured that large drug shipments were broken into several smaller packages to reduce the likelihood of seizures by U.S. Customs authorities. Additionally, Semizoglu shipped some prescription cancer treatment drugs that needed constant cold temperatures to maintain their stability and effectiveness in shipping boxes without insulation or any temperature protection whatsoever. Given the length of time required to ship products from Turkey to Missouri, Semizoglu admitted he was aware that the packages would frequently arrive in the United States at temperatures outside the constant cold temperature range discussed on the drugs' labeling. http://www.justice.gov/usao/moe/news/2014/october/semizoglu_ozkan._html)

Wire Fraud (18 USC § 1030)

1. Massachusetts Man Pleads Guilty and is Sentenced for Stealing Former Employer's Intellectual Property.

On December 19, 2014, Nabeel Memon of Quincy, MA was sentenced to five years of probation on the same day he pleaded guilty to wire fraud. Memon was indicted on May 7, 2014, in connection with a scheme to steal valuable intellectual property from his former employer, Daedalus Software, Inc. , of Cambridge. According to the indictment, in 2011, Memon worked for Daedalus as a software developer while living in Pakistan, and again in 2013 at Daedalus's Cambridge office. Daedalus provides the health care industry with software that manages the storage and analysis of biological samples. In December 2013, Memon copied the source code for Daedalus's product, called "BTM Research," onto a personally-owned hard drive. When asked by Daedalus's CEO if he was copying any company information, he lied and said that he was not. The indictment alleges that the next day, Memon quit his job at Daedalus and went to work for a company, identified in the indictment only as Company A, that is not a competitor of Daedalus's but also designs software for analysis of large volumes of data. When an attorney for Daedalus sent Memon a letter demanding that he return all Daedalus information in his possession, he responded by falsely stating, in an e-mail, that he no longer had any Daedalus information. In fact, he continued to possess the entire BTM Research source code months after he quit his job at Daedalus.
(http://www.justice.gov/usao/ma/news/2014/May/MemonNabeelindictedPR. html)

C. Major Enforcement Activities

FDA:

1. Three Indicted in Prescription Drug Smuggling Ring.

On October 6, 2014, three Athens, Texas, residents were indicted in the Eastern District of Texas on charges associated with their alleged smuggling of imitation, unapproved and misbranded prescription drugs from China. According to the indictment, the defendants conspired to smuggle at least 30 known shipments, totaling approximately 100,000 pills, from China to Texas. As alleged in the indictment, the shipments contained bogus imitations of Xanax, Valium, Sibutramine, Cialis, Viagra and Stilnox, which is marketed in the United States as Ambien. None of the pills seized and tested were legitimate, and all either contained incorrect active ingredients or were sub-potent. The defendants also attempted to conceal their smuggling by using shipping labels that concealed the contents of their shipments, including customs declarations falsely describing the contents as "gifts" or "toys" with low declared monetary values, and by using multiple addresses in an effort to reduce the likelihood of seizures by U.S. Customs authorities. Additionally, the indictment stated that the defendants instructed family members to destroy evidence once they became aware that the FDA was investigating them. After pleading guilty in April 2015, Giddens and Hollis were each sentenced in October 2015 to serve 15 months in prison. Nix, who also pleaded guilty in April 2015, was scheduled to be sentenced in February 2016. This case was investigated by the FDA's Office of

Criminal Investigations and ICE HSI, and was prosecuted by the U.S. Attorney's Office for the Eastern District of Texas and the Civil Division's Consumer Protection Branch.

2. Cancer Center Purchased Counterfeit and Misbranded Foreign Drugs.

On April 23, 2015, Dr. Mohamad Ayman Ghraowi entered a guilty plea on behalf of Corpus Christi-based South Texas Comprehensive Cancer Centers PLLC (STCCC) to a violation of the Federal Food, Drug and Cosmetic Act (FDCA). STCCC was charged with causing the introduction into interstate commerce of misbranded prescription cancer drugs worth more than $900,000, between Feb. 22, 2010, and Jan. 17, 2012. STCCC was a professional association existing under Texas state law with clinics located within the Southern District of Texas, which provided care and treatment for patients with cancer and blood diseases. In 2012, FDA-OCI received information from the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) regarding the appearance of counterfeit versions of the cancer drug Avastin. Regulators determined that some of these counterfeit drugs may have been illegally imported into the U.S. FDA-OCI regulatory investigators tracked the counterfeit drugs to a distributor offering numerous misbranded foreign drugs for sale to cancer clinics in the U.S. STCCC was determined to be one of the clinics purchasing misbranded foreign drugs from the distributor. Following the guilty plea, the corporation was sentenced to serve five years of probation and forfeit $900,000, an amount equivalent to the purchase price of the misbranded drugs. The case was investigated by FDA-OCI, the U.S. Department of Health and Human Services – Office of Inspector General, Defense Criminal Investigative Service and the Texas Attorney General's Office-Medicaid Fraud Control Unit. The case was prosecuted by the U.S. Attorney's Office for the Southern District of Texas.

3. Four Men Charged with Trafficking in Pet Products with Counterfeit Labels *(as discussed on page 80).*

4. Eleven Defendants Charged in Nationwide Conspiracy to Manufacture and Distribute Counterfeit 5-Hour Energy Drink *(as discussed on pages 81-82).*

5. Florida Man Sentenced for Selling Counterfeit Xanax.

On February 5, 2015, Frank Fiore of Parkland, Florida was sentenced to 32 months imprisonment for conspiring to traffic in counterfeit Xanax and illegally distributing steroids. According to court documents and statements made by the parties at the sentencing hearing, Fiore sold counterfeit Xanax and Viagra to undercover officers, as well as to a cooperating source. Carbone was previously convicted of conspiracy to traffic in a counterfeit drug and distribution of controlled substances and was sentenced to 24 months imprisonment. Co-defendant Gary Lee Jones, of Boca Raton, Florida, was convicted of conspiracy to traffic in a counterfeit drug and possession of a firearm after conviction for a felony and also sentenced to 24 months imprisonment. This case was investigated by FDA-OCI, the Palm Beach County Sheriff's Office and prosecuted by the U.S. Attorney's Office for the Southern District of Florida.

6. Suspended Pharmacist Pleads Guilty To Trafficking of Counterfeit Pharmaceuticals Purchased Online.

On April 2, 2015, a suspended Chicago pharmacist admitted to illegally obtaining counterfeit Viagra and Cialis from China and illegally dispensing the bogus medications at his north side pharmacy. The defendant, Michael Markiewicz, who owns Belmont Pharmacy, pled guilty to trafficking counterfeit Viagra from his pharmacy between 2010 and 2012. The Illinois Department of Professional Regulation suspended Markiewicz's pharmacist license and revoked the license of Belmont Pharmacy in November 2012. Markiewicz was charged in April 2013 with eight counts of violating the Federal Food, Drug and Cosmetic Act; four counts of trafficking in counterfeit drugs or goods using a counterfeit mark; and three counts of smuggling. A superseding indictment was returned in March 2015 by a Federal grand jury. Markiewicz pled guilty to trafficking and attempting to traffic in counterfeit Viagra and holding for sale and dispensing counterfeit Viagra. According to the plea agreement, between 2010 and 2012, Markiewicz ordered approximately 1600 counterfeit Viagra and Cialis tablets from China, via the Internet. The customs declaration on each outer packaging stated that it contained a "gift pen," and the counterfeit drugs were hidden in unlabeled clear plastic baggies underneath the pen in the package. Markiewicz then sold the counterfeit drugs at his pharmacy to customers who had sought to purchase the medications without a prescription. This case was investigated by FDA-OCI, the U.S. Postal Inspection Service and prosecuted by the U.S. Attorney's Office for the Northern District of Illinois.

7. Missouri Man Pleads Guilty to Selling Counterfeit Cosmetics.

On January 15, 2015, Terry Leverett pleaded guilty in U.S. District Court, Western District of Missouri, to one count of trafficking in counterfeit goods. Leverett, owner of One Tree Investments, an online health and beauty products vendor in Grandview, MO, sold counterfeit Clinique skin care products. This case was investigated by FDA-OCI and prosecuted by the U.S. Attorney's Office for the Western District of Missouri.

DHS:

***1. Operation Team Player*.** This targets the sale and trafficking of coutnerfeit sports merchandise, apparel and tickets, a multi-million dollar criminal industry. The culmination of the sports season—playoffs and finals games—are events that stimulate the sale of counterfeit items. 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, after the 2015 Super Bowl, more than 377,371 counterfeit sports memorabilia worth $22.9 million were seized and 76 individuals were arrested by law enforcement. In FY 2015, the IPR Center expanded *Operation Team Player* by coordinating enforcement actions at multiple high-profile sporting events, including the Major League Baseball World Series, National Hockey League (NHL) Winter Classic, National Collegiate Athletic Association 2015 College Football Pacific 12 championship, NHL and National Basketball Association (NBA) All-Star games, NHL and NBA Championship series, and the NHL Stadium Series.

2. Operation Chain Reaction. This is an IPR Center coordinated effort led by ICE HSI and consisting of 16 Federal law enforcement agencies including CBP and DoD's criminal investigative offices that work to target counterfeit items entering the military and U.S. Government supply chains. Under *Operation Chain Reaction*, ICE HSI initiated 36 criminal investigations in 2015, conducted 10 criminal arrests, 13 indictments, and 10 convictions, as well as 160 seizures of currency and counterfeit goods with a MSRP of more than $8.8 million.

***3. Operation Engine Newity*.** This is an IPR Center and ICE HSI-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 FY 2015, ICE HSI initiated 35 cases, conducted 12 arrests, and helped secure 16 indictments and 15 convictions.

***4. Operation Apothecary*.** This 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 FY 2015, ICE HSI investigations resulted in the initiation of 71 cases, the arrest of 34 individuals, the indictment of 30 individuals, and the conviction of 34 persons, as well as the seizure of counterfeit items with a MSRP of approximately $499,420.

5. *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* (IOS) which was initiated in 2010 as a method to disrupt this activity online. ICE HSI has evolved this strategy to focus on developing long term investigations that identify targets, assets, and financial schemes used in operating infringing websites. Through IOS, the IPR Center also coordinates with rights holders, who utilize civil and administrative remedies to shutdown infringing sites. In FY 2015, ICE HSI initiated 20 investigations, conducted 20 arrests, and helped secure 18 indictments and 15 convictions. These investigations are initiated and developed by ICE HSI field offices through IPR Center leads, seizures, informants, complaints, industry leads, and/or other investigative techniques.

6. *Operation Plastic Beauty.* In January 2015, the IPR Center initiated *Operation Plastic Beauty* to combat the sale of counterfeit personal healthcare and beauty products. Through *Operation Plastic Beauty* (which combines the expertise of ICE HSI, CBP, and FDA-OCI), the IPR Center partners with industry and other entities associated with the healthcare and beauty product community.

D. Significant Criminal Cases

- In FY 2015, the IPR Center efforts for Super Bowl XLIX (February 7, 2014 to February 8, 2015) resulted in 76 arrests (16 Federal, 60 state and local), 61 convictions (4 Federal, 57 state and local), and the seizure of approximately 377,371 items of counterfeit sports merchandise with an estimated MSRP of $22,879,033. These results were made possible through the cooperative efforts of the IPR Center, ICE HSI, CBP, and state and local partners across the United States.

- As part of its continued efforts under *Operation Engine Newity*, CBP and ICE HSI collaborated to conduct *Operation Faux Parts*, an enforcement surge operation, in Miami in January 2015. A total of 15,532 pieces were seized for IPR infringement or violation of the Department of Transportation Federal Motor Vehicle Safety Standards with a total MSRP of $1,232,103.05. Examples of items seized include turbochargers, key blanks, timing belts, ignition coils, bearings, and starters.

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. The ICE HSI office in Blaine, Washington obtained information about the brothers, who were selling counterfeit airbags on eBay. These counterfeit airbags had a high failure rate, endangering anyone who relied on one for safety. The scheme worked as follows: the brothers imported the counterfeit airbags from China to Canada; then smuggled the merchandise into the U.S. in the trunk of a personal vehicle; and then mailed the airbags to customers. Through a collaborative relationship with China's Ministry of Public Security (MPS), ICE HSI – which was investigating the importation of counterfeit airbags – coordinated with the MPS in order to purse the entities in China that were involved in the manufacture and export of the counterfeit airbags. MPS arrested four suspects in China and seized 23 finished and 200 partially completed counterfeit airbags.