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

OFFICE OF THE
U.S. INTELLECTUAL PROPERTY
ENFORCEMENT COORDINATOR

January 12, 2017

The Honorable Charles Grassley
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Enclosed is the third and final Annual Report that I have the pleasure of submitting to Congress as the Intellectual Property Enforcement Coordinator (IPEC) pursuant to Section 304 of the PRO IP Act of 2008 (15 U.S.C. § 8114).

The Annual Report focuses on the intellectual property enforcement (and related) activities of the Federal Government during Fiscal Year (FY) 2016, and in particular, represents my office's closing report on the implementation of the *2013 Joint Strategic Plan on Intellectual Property Enforcement* during its third and final year.

As you are aware, a primary focus of my tenure as the IPEC has been the strategic-planning process in connection with the preparation and delivery of the Nations' next 3-year Joint Strategic Plan. On December 9, 2016, I submitted to Congress the new *Joint Strategic Plan on Intellectual Property Enforcement (for FY 2017-2019)*, entitled "Supporting Innovation, Creativity & Enterprise: Charting a Path Ahead." The new three-year strategic plan is posted for public access on the website of the White House, pursuant to the PRO IP Act, at:

https://www.whitehouse.gov/sites/default/files/omb/IPEC/2016jointstrategicplan.pdf.

As we turn to implementing the Nation's new strategic plan, the enclosed Annual Report provides us with an opportunity to examine and reflect upon the breadth of activities that the U.S. Government has undertaken during the past fiscal year, to ensure that the United States remains a global leader in protecting innovation, creativity, and enterprise.

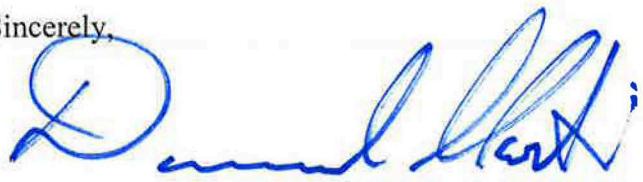
While there is always more work to be done, as reflected in greater detail in the 2017-2019 Joint Strategic Plan, the accomplishments identified in the Annual Report should make us all proud of the dedicated efforts of the U.S. Government to protect U.S. intellectual property (IP) rights. This work is the product of joint efforts within the Executive and Legislative branches, as well as by way of partnerships between Federal agencies, State and local governments, private industry, trade associations, civil society, and foreign governments.

Our creative and innovative communities that rely on IP protection occupy an important role in our cultural and economic lives, directly supporting over 27 million U.S. jobs and more than 50 percent of our exports. The protection of IP from unlawful misappropriation and exploitation is about supporting the rule of law and fair competition in world markets, promoting jobs, opening new markets for U.S. goods and services, and fostering innovation and investments in research and development. It is also about standing up for our values at home and abroad. Trade in counterfeit goods, for example, compromises the integrity of domestic and global supply chains, threatens public health and safety, and undermines a number of additional national interests.

It has been an honor to serve as the IPEC, and I extend my deep appreciation for the Committee's steadfast support for curbing IP-related illicit activities.

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
Intellectual Property Enforcement Coordinator

Enclosure

Identical Letter Sent to:

The Honorable Bob Goodlatte
The Honorable John Conyers, Jr.
The Honorable Charles Grassley
The Honorable Dianne Feinstein
The Honorable Rodney Frelinghuysen
The Honorable Nita Lowey
The Honorable Thad Cochran
The Honorable Patrick Leahy

2016 U.S. INTELLECTUAL PROPERTY ENFORCEMENT COORDINATOR ANNUAL REPORT ON INTELLECTUAL PROPERTY ENFORCEMENT

JANUARY 2017

ANNUAL REPORT FOR FISCAL YEAR 2016
UNDER SECTION 304 OF THE PRO IP ACT OF 2008
(15 U.S.C. § 8114)

INTRODUCTION

In June 2013, the Administration issued a three-year Joint Strategic Plan, reaffirming the Administration's continued efforts to elevate intellectual property enforcement issues across the U.S. Government and internationally.

This Annual Report covers Fiscal Year (FY) 2016, and represents the third and final report on the intellectual property enforcement (and related) activities of the Federal Government under the last year of the *2013-2016 Joint Strategic Plan on Intellectual Property Enforcement.*

On December 9, 2016, Intellectual Property Enforcement Coordinator Danny Marti delivered to Congress the new *Joint Strategic Plan on Intellectual Property Enforcement (for FY 2017-2019)*, titled: "Supporting Innovation, Creativity & Enterprise: Charting a Path Ahead." The new strategic plan is posted for public access on the website of the White House, pursuant to the PRO IP Act of 2008, at:

https://www.whitehouse.gov/sites/default/files/omb/IPEC/2016jointstrategicplan.pdf.

As we turn to the Nation's new three-year strategic plan, this Annual Report for FY 2016 provides an opportunity to examine and reflect upon the breadth of activities the U.S. Government has undertaken over the past fiscal year to ensure that the United States remains a global leader in protecting innovation, creativity, and enterprise. The FY 2016 Annual Report provides a detailed description of the efforts Federal departments and agencies have undertaken in support of an effective intellectual property rights environment, and is organized pursuant to the 26 action items set forth in the 2013 Joint Strategic Plan.

While there is more work to be done, as reflected in greater detail in the 2017-2019 Joint Strategic Plan, 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 U.S. creative and innovative communities that rely on intellectual property protection occupy an important role in our cultural and economic lives: supporting 40 million U.S. jobs, more than 50 percent of our exports. (See No. 25, below.) The protection of intellectual property from unlawful misappropriation and exploitation is about supporting the rule of law

and fair competition in world markets, promoting jobs, opening new markets for U.S. goods and services, and fostering innovation and investments in research and development. The FY 2016 Annual Report reflects the Administration's commitment to standing up for our values at home and abroad. Trade in counterfeit goods compromises the integrity of domestic and global supply chains, threatens public health and safety, and undermines a number of additional important national interests.

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

To address the avoidance of counterfeit electronic parts, DoD on August 2, 2016, published a final Defense Federal Acquisition Regulation Supplement (DFARS) rule 2014-D005, *Detection and Avoidance of Counterfeit Electronic Parts—Further Implementation* (81 FR 50635). The rule established 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. (The status of "open" DFARS cases is available at http://www.acq.osd.mil/dpap/dars/opencases/dfarscasenum/dfars.pdf.)

In addition, on August 30, 2016, DoD published a final Defense Federal Acquisition Regulation Supplement (DFARS) rule 2016-D010, *Costs Related to Counterfeit Electronic Parts* (81 FR 59510). The final rule implemented a statutory provision and took action on the proposed rule that DoD published on March 25, 2016 (81 FR 17055). As DoD explained in the final rule, "[t]he objective of this rule is to amend the allowability of costs for counterfeit parts or suspect counterfeit parts and the cost of rework or corrective action that may be required to remedy the use or inclusion of such parts. Such costs may be allowable if the parts were obtained by the contractor/subcontractor in accordance with DFARS clause 252.246–7008, Sources of Electronic Parts, and timely notice is provided to the Government." 81 FR at 59514.

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 created and implemented 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.

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/Acquisition%20Professional%20Training%20revised%20for%20public%20use.pdf/view). 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). In FY 2016, under *Operation Chain Reaction*, ICE HSI initiated 19 criminal investigations, conducted 15 criminal arrests, and helped secure 14 indictments and 9 convictions, as well as 103 seizure incidents of counterfeit goods with a total manufacturer's suggested retail price (MSRP) of approximately $3.5 million.

- In December 2015 and March 2016, personnel representing the IPR Center's *Operation Chain Reaction* worked with CBP's Electronics Center of Expertise and Excellence (Center) to conduct an express consignment blitz operation that looked for counterfeit microelectronics.

- In February 2016, the IPR Center and the Department of Justice (DOJ) Computer Crime and Intellectual Property Section (CCIPS) co-hosted the Counterfeit Microelectronics Working Group. The meeting focused on enhancing communication between law enforcement and industry. Seventy-two people from private industry and the government were in attendance.

- In December 2015, three Chinese nationals (Daofu Zhang, Jiang Yan, and Xianfeng Zuo) were arrested in connection with a scheme to obtain and illegally export sophisticated integrated circuits (ICs) stolen from the U.S. military; under this scheme, the stolen ICs would be replaced with counterfeits. All three pleaded guilty, in March and April 2016, to conspiracy to traffic in counterfeit goods. On July 8, 2016, Zhang was sentenced to 15 months imprisonment. On November 4, 2016, Zuo was sentenced to 15 months imprisonment. On December 20, 2016, Yan was sentenced to approximately 12 months imprisonment. They also forfeited $63,000 in cash seized incident to arrest.

Operation Chain Reaction continues to work 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 biannual 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 integrated circuits (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 the Office of Management and Budget's (OMB) 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 issued 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 issued by OMB in Memorandum M-16-12: "Category Management Policy 16-1: Improving the Acquisition and Management of Common Information Technology: Software Licensing" (June 2, 2016). As OMB explained in this Memorandum, this initiative "addresses a number of IT management challenges by directing agencies to buy and manage common commodities—commercial and commercial-off-the-shelf (COTS) software—in a more coordinated way." 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).

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) 2016, 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.

Development of the Joint Strategic Plan on Intellectual Property Enforcement (FY 2017-2019)

During FY 2016, and pursuant to Sections 301 and 303 of the PRO-IP Act (15 U.S.C. §§ 8111 and 8113) and Executive Order 13565 (Sections 1 and 2), the Joint Strategic Plan on Intellectual Property Enforcement was developed by the U.S. Interagency Strategic Planning Committees on IP Enforcement, which are chaired by the IPEC and comprised of a diverse array of Federal departments, offices, and agencies, including the Departments of Justice, Homeland Security, State, Commerce, the Treasury, Health and Human Services, and Agriculture, and the Office of Management and Budget, the Office of the U.S. Trade Representative, and the U.S. Copyright Office. The IPEC submitted the Joint Strategic Plan to Congress in December 2016.

In preparing the Joint Strategic Plan, the IPEC Office and the members of the interagency committees drew on their respective experience in IP enforcement. They also consulted with a wide variety of stakeholders across the Federal Government (including consultations with Members of Congress and their staff), and received input from state and local governments, industry, non-governmental organizations, educational institutions, trade organizations, public interest groups, and others. This included the consideration of the public comments that were submitted to the IPEC Office in October 2015, in response to its Federal Register notice of September 1, 2015 (80 FR 52800). The IPEC Office and members of the interagency committees also consulted and engaged with foreign governments, international organizations, and law

enforcement bodies to understand, for example, the global dimensions around the financing, production, trafficking and sale of counterfeit and infringing goods, and the opportunities to enhance the effectiveness of intellectual property enforcement in a global market. Lastly, in the preparation of the Joint Strategic Plan, the IPEC Office and members of the interagency committees relied on domestic and international reports and studies, testimony at congressional hearings, and other publicly-available materials.

U.S. Copyright Office

Since publication of IPEC's 2015 Annual Report, the U.S. Copyright Office has continued its commitment to transparency by ensuring that all members of the copyright community–including copyright owners, technology companies, consumers, public interest groups, academics, and the general public–have robust opportunities to participate and contribute to the U.S. Copyright Office's policy studies, reports, and recommendations.

In February 2016, the Copyright Office published a report on "The Making Available Right in the United States" following extensive public consultation, including two separate rounds of public comment and a full-day public roundtable. Pursuant to a request from Congress, the report addresses three issues: (1) how the existing rights under Title 17 cover the making available right in the context of digital on-demand transmission as well as more broadly in the digital environment; (2) how foreign laws have interpreted and implemented the making available right; and (3) the feasibility and necessity of amending U.S. law in this area. The variety of input from creators, academics, practitioners, foreign rights holders, and many others helped the Office to identify key issues and reach its ultimate conclusion that "the exclusive rights of copyright owners set forth under 17 U.S.C. § 106 collectively meet and adequately provide the substance of the making available right." All written comment submissions as well as the transcript and video recordings of the public roundtables are available on the Office's website at https://www.copyright.gov/docs/making_available/.

During FY 2016, the Copyright Office was engaged in nine active copyright policy studies. In December 2015, the Office formally requested comments from the public for a number of these studies, including studies of Sections 512 and 1201 of Title 17, the role of copyright in software-enabled consumer products, and modernization of Copyright Office information technology (IT). The Office received more than 92,000 written comments from the public as part of its Section 512 study and held two days of public roundtables for the study in both San Francisco and New York. The public roundtables involved dozens of registered participants, and during each roundtable the Office also provided the opportunity for members from the general public to make an oral statement during the closing session. Similarly, the Office held public roundtables as part of its Section 1201 and software-enabled consumer products studies in separate areas of the country to ensure greater public involvement, in both Washington, D.C. and San Francisco.

On April 18, 2016, the Office partnered with George Mason University School of Law and its Center for the Protection of Intellectual Property to host a full-day public symposium on moral rights to begin a conversation about the role of moral rights protection in the United States.

The video and official transcript of this event are available on the Office's website at https://www.copyright.gov/events/moralrights/. A notice of inquiry to seek formal public input is forthcoming.

Finally, during the summer of 2016, the Office held dozens of meetings and conference calls with a variety of interested parties to discuss revisions to Section 108 of Title 17. These meetings built upon more than ten years of Copyright Office review and discussion of potential improvements to Section 108, including its participation in an independent study group that released a set of recommendations in 2008, a full-day public conference on Section 108 co-sponsored with Columbia Law School in 2013, and a hearing addressing the topic before the House of Representatives, Subcommittee on Courts, Intellectual Property and the Internet, in 2014. At the conclusion of these meetings, the Office published on its website a list of all of the parties that participated to show the wide range of views and perspectives that contributed to the process (https://www.copyright.gov/policy/section108/summary.html). The Office is now in the process of developing its legislative recommendations on improvements to Section 108.

Access to the Federal Register notices, public comments, and roundtable transcripts for all of the Copyright Office's active studies are available through the Office's website at https://copyright.gov/policy/. Many of the Office's studies are taking place as part of its continued support for the ongoing Congressional review of the nation's copyright laws conducted by the House of Representatives Committee on the Judiciary. The Office also maintains hyperlinks on its website (https://copyright.gov/laws/hearings/) to enable the public to access the written testimony, transcripts, and videos of all twenty copyright review hearings that occurred before the Committee.

Department of Justice

DOJ's Antitrust Division continued to promote transparency regarding its views on the role of antitrust and intellectual property laws and enforcement in promoting innovation:

- In a September 2015 speech, Assistant Attorney General Bill Baer explained how intellectual property law and antitrust law should work together in the context of single-firm assertions of patent rights. He explained that anticompetitive behavior "that inflates the value of otherwise lawful intellectual property should be subject to antitrust scrutiny, for example, when a patent holder fails to honor its voluntary promise to a standards-setting organization to license a standards-essential patent on a fair, reasonable, and non-discriminatory basis. In those cases, antitrust enforcers can help ensure that standards-essential patents are not used to unreasonably limit competition." Bill Baer, Assistant Att'y Gen., Antitrust Div., U.S. Dep't of Justice, ***Cooperation, Convergence, and the Challenges Ahead in Competition Enforcement***, Remarks as Prepared for the Georgetown Law 9th Annual Global Antitrust Enforcement Symposium (Sept. 29, 2015), https://www.justice.gov/opa/file/782361/download.

- In a February 2016 speech, Principal Deputy Assistant Attorney General Renata Hesse provided examples of how the Division's approach to patents fosters innovation by

refraining from enforcement action when appropriate: "If a patent becomes more popular than expected, we don't seize control of it. If a patent becomes more useful than predicted, we don't mandate its licensing. And if a patent becomes commercially important, we don't impute F/RAND commitments." Renata Hesse, Principal Deputy Assistant Att'y Gen., Antitrust Div., U.S. Dep't of Justice, ***Antitrust: Helping Drive the Innovation Economy***, Remarks as Prepared for the Global Competition Review 5th Annual Antitrust Law Leaders Forum (Feb. 5, 2016), https://www.justice.gov/opa/file/820341/download.

- In a June 2016 speech, Principal Deputy Assistant Attorney General Renata Hesse addressed some differences in approaches in other jurisdictions regarding potentially exclusionary unilateral conduct by individual firms. She explained that Agencies and courts in the US have been more reticent than our global counterparts about finding unilateral conduct to be unlawfully exclusionary, with the differences being greatest when they involve conduct related to intellectual property rights. Although the Division and the FTC have a long history of acting to prevent uses of intellectual property rights in ways not authorized by intellectual property law, competition law is not understood to circumscribe those rights themselves. She noted that the Division has not yet found a circumstance in which a unilateral, unconditional refusal to license an intellectual property right violates our antitrust laws, stating that at most liability for a unilateral, unconditional refusal to license an intellectual property right should be a rare exception to the ordinary rules of modern competition laws. Renata Hesse, Principal Deputy Assistant Att'y Gen., Antitrust Div., U.S. Dep't of Justice, *Can There Be a "One-World Approach" to Competition Law?*, Remarks as Prepared for the Chatham House Conference on Globalization of Competition Policy (June 23, 2016), https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-renata-b-hesse-delivers-remarks-chatham-house.

- In August 2016, the Antitrust Division and the Federal Trade Commission sought public comment on a proposed update to modernize the *Antitrust Guidelines for the Licensing of Intellectual Property* ("IP Licensing Guidelines"). The IP Licensing Guidelines, which state the antitrust agencies' enforcement policy with respect to the licensing of intellectual property protected by patent, copyright, and trade secret law and of know-how, originally were issued in 1995. The agencies' general approach to analyzing IP licensing agreements has not changed. The proposed update includes revisions that reflect legal developments in U.S. intellectual property and antitrust law to continue to provide transparency to the public. Information about the proposed update, including the submitted comments, is publicly available on the Department's website at https://www.justice.gov/atr/guidelines-and-policy-statements-0/antitrust-guidelines-licensing-intellectual-property-proposed-update-2016.

- The Antitrust Division, often in conjunction with the U.S. Federal Trade Commission, actively engaged with our foreign counterparts to promote the sound application of competition laws to intellectual property rights based on analysis of competitive effects,

not domestic or industrial policy goals. The Division promotes both competitive markets and respect for intellectual property 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 intellectual property rights and the strengthening of those principles through shared learning benefits consumers.

- The Antitrust Division routinely coordinates with and advises other Executive Branch agencies on the application of antitrust laws to intellectual property rights to ensure a consistent message when communicating with other jurisdictions on these issues.

- The Antitrust Division participated in DOJ's consideration and submission of amicus briefs or government briefs related to intellectual property.

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 for, *inter alia*, works, phonograms, performances, brands, designs, 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, 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 in connection with the Special 301 review, 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 stakeholder comments submitted as part of the annual Special 301 process are available for inspection online and public hearings were held in FY 2016.

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 Trans-Pacific Partnership (TPP) negotiations in 2015, for example, 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

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

The IPR Center Outreach and Training Section engages in partnerships with the public and private sectors to combat IP infringement through its *Operation Joint Venture* (OJV) initiative. This IPR Center-led outreach initiative is designed to increase information sharing with public and private sectors to combat the illegal importation and distribution of counterfeit, substandard and tainted goods, as well as the evasion of duties. The initiative is aimed at fostering commercial fraud, public health and safety, and IP investigations. OJV targets rights holders, manufacturers, importers, customs brokers, freight forwarders, bonded facilities, carriers, and others to discuss the IPR Center's priorities of protecting public health and safety, the economy, and securing the Government's supply chain. Through outreach and public engagement, the IPR Center raises the public's awareness of the dangers of commercial fraud violations, such as IP, while serving as a public point of contact for investigative leads. The IPR Center's target audience includes a broad spectrum of industries and government agencies to include, but not limited to: pharmaceutical, entertainment, wearing apparel, sports, electronic,

and automobile manufactures, as well as customs bonded entities, importers, and law enforcement officials.

In FY 2016, the IPR Center, through OJV, reached out to more than 14,000 people at 310 outreach and training events.

In addition, in FY 2016, the IPR Center added a new position specifically to increase engagement with stakeholders in order to better fulfill the outreach portion of its mission and to educate the public about the dangers of counterfeit goods and pirated content.

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

- Regular conference calls with the IPR working group of the Commercial Customs Operations Advisory Committee (COAC) and quarterly public meetings with COAC members;

- Daily interaction with stakeholders affected by CBP's IP enforcement efforts at the ports of entry, and nationally through CBP's ten industry-aligned Centers of Excellence and Expertise (Centers), the IP-focused staff at headquarters, 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 FY 2016, rights holders conducted 11 webinar trainings for CBP personnel to increase Center and port expertise regarding their products. In addition, the IPR NTAG conducted three IPR roundtables: an audio visual, consumer electronics, and entertainment industries roundtable in San Francisco with over 50 attendees; a joint Consumer Products and Mass Merchandising (CPMM) Center roundtable in Atlanta with over 45 attendees; and a semiconductor and computer networking equipment industry roundtable at the IPR Center with over 35 attendees. The Intellectual Property Enforcement Coordinator (IPEC) spoke at the San Francisco event and the Deputy IPEC spoke at the Atlanta session. 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 Center and port expertise regarding their products, rights holders conducted 53 training sessions for CBP personnel during the first three quarters of FY 2016.

DHS Headquarters Outreach to the Private Sector

In January 2016, the U.S. Department of Homeland Security's Private Sector Office hosted their first Symposium on Illicit Trade. The goal of the symposium was to facilitate a conversation between industry and federal agencies to address not only IP concerns but the broader issue of illicit trade and related financing along with U.S. government equities dedicated to reducing and deterring these activities. The meeting was attended by high-level officials from DHS, Treasury, and the State Department including remarks by Assistant Secretary of State Charles Rivkin and DHS Chief of Staff Paul Rosen. Senior law enforcement officials from DOJ, FBI, ICE, Treasury, U.S. Secret Service, CBP, and the DHS Intelligence & Analysis Directorate all participated in the meeting. More than 50 businesses attended including representatives from the pharmaceutical, software, electronics, apparel, and tobacco industries, financial services companies, and transportation firms. The DHS Private Sector Office, along with the U.S. Chamber of Commerce, hosted a subsequent event on December 8, 2016, to further expand on this public-private initiative.

In addition to these efforts, the law enforcement agencies which support IP enforcement had numerous other engagements with stakeholders in 2016. 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. This campaign exists under the IPR Center's broader OJV initiative. Through *Project Trade Watch*, ICE and CBP field personnel provide information and red flag indicators of potential import fraud and importer identity theft.

- During 2016, the IPR Center continued to host numerous foreign government officials with an interest in intellectual property enforcement. Among the many international delegations presented to by the IPR Center were representatives from Armenia, Australia, Austria, Bangladesh, Belarus, Belgium, Bolivia, Bosnia and Herzegovina, Brazil, Bulgaria, Burma, Cambodia, Cameroon, Canada, China, Cyprus, Ecuador, Finland, France, Germany, Ghana, Hong Kong, Hungary, Iceland, India, Indonesia, Italy, Ivory Coast, Jamaica, Japan, Kazakhstan, Kosovo, Kyrgyzstan, Lebanon, Liberia, Lithuania, Macedonia, Malaysia, Mexico, Moldova, Mongolia, Morocco, Mozambique, Netherlands, Nigeria, Norway, Pakistan, Paraguay, Panama, Philippines, Poland, Romania, Russia, Saudi Arabia, Senegal, Singapore, Sri Lanka, Switzerland, Taiwan, Thailand, Togo, United Arab Emirates, United Kingdom, Venezuela, and Vietnam.

The IPR Center has a unique role within ICE by serving as a one-stop shop for IP enforcement efforts. The IPR Center has regular contact with the international community, the media, Members of Congress, trade organizations, industry leaders, and the general public. In FY 2016, the IPR Center created a monthly publication to keep stakeholders up to date on the most significant IPR Center enforcement efforts and outreach activities. Additionally, the IPR Center has begun collecting, tabulating, and cataloging the victim impact accounts of brand

holders and consumers with the aim to show more clearly the full effect of IP infringement and trade fraud on the U.S. and global economies, public health and safety, and any related threat to government supply chains.

- In support of *Operation Engine Newity*, ICE HSI and the Automotive Anti-Counterfeiting Council (A2C2) have worked together to provide training to ICE HSI field offices and CBP field offices regarding the identification of counterfeit automotive parts. DOJ's Computer Hacking and Intellectual Property (CHIP) Assistant United States Attorneys (AUSAs) have participated in these training sessions.

- In February and September 2016, DOJ/CCIPS and the IPR Center co-hosted meetings of the 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. Approximately 70 representatives from the microelectronics industry and law enforcement attended each meeting.

- In March 2016, the IPR Center hosted the A2C2 Symposium. The symposium provided the IPR Center partners, industry partners, and investigators an opportunity to share their knowledge concerning the automotive industry and their vulnerabilities with the distribution of counterfeit parts and accessories. The main goal of the event was to facilitate a meaningful conversation between rights holders, industry partners, and law enforcement to address IP concerns, discuss challenges with supply chain security, identify proactive measures recently taken by A2C2, and interact with subject matter experts to foster stronger and continued relationships within the IP protection community.

- In March 2016, the A2C2 – in collaboration with the IPR Center/HSI – hosted an "A2C2 Training Event" in Arlington, VA. This training provided brand owners and their investigators an opportunity to collaborate and address issues pertaining to the distribution of counterfeit auto parts and accessories. Twelve brand owners provided training to an audience of personnel from HSI, CBP and other IPR Center partners, as well as DOJ.

- In April 2016, the A2C2 – in collaboration with the IPR Center/HSI and HSI Los Angeles – hosted an "A2C2 Training Event" in Long Beach, CA. This training provided brand owners and their investigators an opportunity to collaborate and address issues pertaining to the distribution of counterfeit auto parts and accessories. Three brand owners provided training to an audience of personnel from HSI and CBP.

- In May 2016, the A2C2 – in collaboration with the IPR Center and HSI-Orlando – hosted an "A2C2 Training Event." This training event provided brand owners and their investigators an opportunity to collaborate and address issues pertaining to the distribution of counterfeit auto parts and accessories. The training was

attended by DOJ, HSI and CBP.

- In September 2016, the IPR Center and the A2C2 provided training to 61 persons – including HSI and CBP staff, one State and Local Law Enforcement (STL) task force officer, and AUSAs – in multiple locations in the Midwest (Cincinnati, Louisville, Columbus and Cleveland). The training covered counterfeiting, product protection, and business action to stop counterfeiting and piracy.

- In September 2016, during the American Bearing Manufacturers Association (ABMA) fall conference in Chicago, the IPR Center participated as a panel member in a discussion that included an overview of *Operation Engine Newity*. The event was attended by members of the ABMA and the Bearing Specialists Association (BSA).

DOJ Outreach to the Private Sector

During FY 2016, 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 in October 2015 and September 2016, respectively, hosted CCIPS' Ninth and Tenth Annual IP Industry and Law Enforcement Meetings, in Washington, D.C. The yearly meetings 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 meetings were attended by high-level officials from the Department, and included remarks by Assistant Attorney General Leslie Caldwell. Senior law enforcement officials from DOJ, Federal Bureau of Investigation (FBI), ICE, CBP, and the Food and Drug Administration (FDA) also participated in the meetings. More than 90 individuals attended the meetings, 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: DRI's Annual Meeting in October 2015; the Practicing Law Institute's Conference on Intellectual Property Rights Enforcement in January 2016; the Middle District of Louisiana's Cyber Initiative and Roundtable in February 2016; the American Bar Association Public Contract Law Section's Federal Procurement Institute in March 2016; Florida Bar's Annual IP Symposium in April 2016; American Bar Association International Law Section's Spring Meeting in April 2016; ITC's Trade Secrets Roundtable in June 2016; ESA's Law Enforcement Roundtable in June 2016; and Seattle Export Controls Conference in July 2016.

In addition, the DOJ's National Security Division (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:

- In October 2015, DOJ announced a new strategy to combat IP crimes, which involves collaboration between the FBI and third-party online marketplaces, payment processors, and online advertising systems and platforms. As DOJ explained in announcing the strategy:

  > "The new FBI collaborative strategy builds upon the work previously done by the department while also working with industry partners to make enforcement efforts more effective. As part of the strategy, the FBI will partner with third-party marketplaces to ensure they have the right analytical tools and techniques to combat intellectual property concerns on their websites. The bureau also will serve as a bridge between brand owners and third-party marketplaces in an effort to mitigate instances of the manufacture, distribution, advertising and sale of counterfeit products. This new strategy will help law enforcement and companies better identify, prioritize and disrupt the manufacturing, distribution, advertising and sale of counterfeit products. Crimes will then be investigated by the FBI and other partners of the National Intellectual Property Rights Coordination Center and finally prosecuted by the Department of Justice."

  Department of Justice, "Justice Department Announces New Strategy to Combat Intellectual Property Crimes . . ." (October 2, 2015), at https://www.justice.gov/opa/pr/justice-department-announces-new-strategy-combat-intellectual-property-crimes-and-32-million; see Federal Bureau of Investigation, "Countering the Growing Intellectual Property Theft Threat: Enhancing Ties Between Law Enforcement and Business" (January 22, 2016), at https://www.fbi.gov/news/stories/countering-the-growing-intellectual-property-theft-threat.)

- In November 2015, CCIPS and IPR Center representatives met with the Alliance for Safe Online Pharmacies and pharmaceutical company representatives to discuss ways to increase information sharing and collaboration between industry and law enforcement.

- In November 2015, CCIPS met with representatives of the Entertainment Software Association, Business Software Association, Recording Industry Association of America, and Motion Picture Association of America to discuss how rights holders may best initiate a federal criminal investigation of intellectual property crimes and support criminal prosecutions of such crimes as well as how to improve public-private cooperation to combat IP crime.

- In December 2015, CCIPS and IPR Center representatives met with researchers from RiskIQ and representatives from Digital Citizens Alliance and NBC Universal to discuss the connections between content theft sites and malware distributions.

- In February and September 2016, CCIPS and the IPR Center co-hosted meetings of the Counterfeit Microelectronics Working Group, which focuses on the challenge of counterfeit microelectronics in the government supply chain and related issues. Approximately 70 representatives from the microelectronics industry and law enforcement attended each meeting.

- In March 2016, CCIPS and IPR Center representatives met with representatives of the Automotive Anti-Counterfeiting Council (A2C2) to discuss numerous topics, including emerging threats and challenges, key indicators for law enforcement, express consignment carriers, and payment systems.

- In March 2016, CCIPS participated in trade secret panel discussions at Iowa State University (focusing on agriculture and related industries) and at Drake University (focusing on financial sector businesses). Other participants in the panel included a local Assistant U.S. Attorney as well as FBI and NSD representatives.

- In June 2016, CCIPS presented a trafficking in counterfeit microelectronics case study at the University of Maryland's Symposium on Counterfeit Parts and Materials, which was organized by the Surface Mount Technology Association and the Center for Advanced Life Cycle Engineering.

IPEC Outreach

During FY 2016, the IPEC Office engaged with stakeholders (governmental, multinational, private sector, and public interest groups) in a variety of venues in support of enhancing the protection and enforcement of intellectual property rights. The engagements were across the Executive and Legislative Branches, as well as with state and local governments, the private sector, trade associations, and other entities, and included a focus on the development of a national strategy on IP enforcement. The engagements were also with foreign government officials, international governmental institutions (such as INTERPOL, Europol, and UN-constituent agencies), and private-sector associations and groups in other countries.

In these engagements, the IPEC Office underscored the importance of domestic and foreign actors undertaking initiatives to promote and reinforce a robust IP enforcement environment that reduces and minimizes counterfeiting, piracy, and other forms of IP infringement. In this regard, the IPEC Office emphasized, *inter alia*, the importance of strengthening the "rule of law"; of enhancing collaboration (within and between governments, between the public and private sectors, and within the private sector) in combatting illicit activities that undermine the integrity of global supply chains, and thereby in supporting legitimate commerce and trade; and of governments considering the adoption of the "Whole of Government" and "Specialized Office" approaches for strengthening the government's effectiveness in IPR protection and enforcement.

The following are examples of some IPEC engagements over the past fiscal year:

- In October 2015, the Intellectual Property Enforcement Coordinator attended and spoke at the Annual Fall Conference of the International Anti-Counterfeiting Coalition (IACC), held in Denver, Colorado.

- In October 2015, the Deputy Intellectual Property Enforcement Coordinator attended and spoke at the Fall General Assembly of the Pharmaceutical Security Institute, held in Bogota, Colombia.

- In November 2015, the Intellectual Property Enforcement Coordinator attended and spoke at the Leadership Meeting of the International Trademark Association (INTA), held in Panama City, Panama.

- In December 2015, the Intellectual Property Enforcement Coordinator travelled to Mexico City, Mexico and met with senior government officials and other entities, including within the Mexican Attorney General's Office, the Mexican Institute of Industrial Property, the National Institute for Copyrights, the Customs General Administration, and the Federal Court for Tax and Administrative Affairs, among others.

- In December 2015, the Intellectual Property Enforcement Coordinator attended and spoke at the Communications Roundtable with governmental leaders and public interest groups on "Educating consumers on the dangers of illegal online pharmacies," held at the State Department in Washington, D.C.

- In January 2016, the Intellectual Property Enforcement Coordinator attended and spoke at the Department of Homeland Security's "Symposium on Illicit Trade," held in Arlington, Virginia.

- In February 2016, the Intellectual Property Enforcement Coordinator attended and spoke at the 2016 Mid-Winter Meeting of The Copyright Society of the USA, held in New Orleans, Louisiana.

- In March 2016, the Intellectual Property Enforcement Coordinator attended and spoke at the General Annual Meeting of the Association of American Publishers, held in New York City.

- In April 2016, the Intellectual Property Enforcement Coordinator attended and spoke at the conference on "Promoting Intellectual Property Rights Enforcement Policy in Latin America: The Role of the IPO," held in Tequila, Mexico. The conference was co-hosted by the IPEC Office and the Instituto Mexicano de la Propiedad Industrial (IMPI), and was supported by the International Trademark Association (INTA), the Asociación Interamericana de la Propiedad Intelectual (ASIPI), and the Business Action to Stop Counterfeiting and Piracy (BASCAP).

- In April 2016, the Intellectual Property Enforcement Coordinator attended and spoke at 31st Annual Intellectual Property Law Conference of the American Bar Association's Section of Intellectual Property Law, held in Bethesda, Maryland.

- In June 2016, the Intellectual Property Enforcement Coordinator and Deputy IPEC travelled to Bogota, Colombia where they met with senior officials of the Colombia government.

- In June 2016, the Deputy Intellectual Property Enforcement Coordinator attended and gave a keynote address at a two-day summit of private sector and law enforcement officials, hosted by the International Anti-Counterfeiting Coalition (IACC) and Underwriters Laboratory (UL) and held in Miami, Florida. The conference focused on piracy and counterfeiting issues faced by law enforcement and private sector brand protection officials in Latin America. Senior representatives of the Department of Homeland Security and Department of Justice also attended and participated as speakers.

- In June-July 2016, the Intellectual Property Enforcement Coordinator travelled to Europe and met with officials of the United Kingdom and the European Union, as well as representatives of the private sector including the American Chamber of Commerce to the European Union (AmCham EU) and the International Anti-Counterfeiting Coalition (IACC). Among other engagements, the IPEC spoke at the July 2016 launch of Europol's IP Crime Coordinated Coalition (IPC3), held in The Hague, Netherlands.

- In July 2016, the Intellectual Property Enforcement Coordinator and Deputy IPEC travelled to – and met with senior officials and private sector leaders in – China, Hong Kong, and Taiwan. While in Taiwan, the IPEC delivered keynote remarks at a conference on "Best Practices for Stemming Digital Piracy."

- In September 2016, the Intellectual Property Enforcement Coordinator and Deputy IPEC travelled to Cuba, leading a U.S. delegation of senior officials from the U.S. Department of State, U.S. Patent and Trade Office (USPTO), and U.S. Copyright Office. The delegation met with senior officials of the Cuban government.

- In September 2016, the Intellectual Property Enforcement Coordinator and Deputy IPEC travelled to London, England where they met with senior officials of the United Kingdom and of the European Union. The IPEC also gave a keynote address at the INTERPOL 2016 International Law Enforcement Intellectual Property Crime conference.

- In addition, as noted above, the IPEC Office participated in two IPR roundtables conducted by the CBP IPR National Targeting & Analysis Group (IPR NTAG). The Intellectual Property Enforcement Coordinator (IPEC) spoke at the entertainment industries roundtable in San Francisco, California, held in May 2016, and the Deputy IPEC spoke at the joint Consumer Products and Mass Merchandising (CPMM) Center roundtable in Atlanta, Georgia, held in June 2016.

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 courts have 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 2016, the U.S. Copyright Office announced the one-year anniversary of the Fair Use Index, a searchable database of summaries of notable fair use cases from U.S. courts over the last 175 years. The Index was created in coordination with the Intellectual Property Enforcement Coordinator in 2015 and is hosted on the U.S. Copyright Office website at https://www.copyright.gov/fair-use/.

Although not a substitute for legal advice, the Index summaries provide a helpful starting point to make the principles and application of fair use more accessible and understandable to the general public. The cases summarized come from every appellate jurisdiction in the United States and cover a wide variety of uses and users in an effort to help lawyers and non-lawyers better understand the circumstances in which courts have determined uses of copyrighted works to be fair or not fair under Section 107 of the Copyright Act. In particular, each summary 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 infringing. The Index is designed to be user-friendly, allowing users to search by category of work, type of use, or deciding court. 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.

Over the past year, the Index has received tens of thousands of page views, which have led to thousands of downloads of the Office's case summaries. At the end of FY 2016, the Index contained 187 cases from 39 different courts and covering sixteen categories of works and uses.

Department of Commerce

In January 2016, the Department of Commerce Internet Policy Task Force (IPTF) released its "White Paper on Remixes, First Sale, and Statutory Damages: Copyright Policy, Creativity, and Innovation in the Digital Economy." The first of three substantive issues addressed in the White Paper, "The Legal Framework for the Creation of Remix," noted the central role the fair use doctrine plays in determining whether a remix – a work created through changing and combining one or more existing works to produce something new and creative – is lawful; observed that "fair use, which requires consideration of the purpose of the use, the nature of the copyrighted work, the amount of the work used, and its effect on the market or potential market, represents a nuanced and balanced approach that has worked well in the United States"; and concluded that "[i]t is important that the copyright framework continues to allow both to thrive, ensuring that a vibrant fair use space coexists with effective licensing structures." The White Paper encouraged stakeholders to develop guidelines and best practices for remixing, either independently or with the government serving as the convener, focusing on how fair use applies to remixes. The White Paper is at https://www.uspto.gov/sites/default/files/documents/copyrightwhitepaper.pdf.

The Global Intellectual Property Academy (GIPA) of the United States Patent and Trademark Office 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 a balanced approach to 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." In FY 2016, GIPA visited 12 cities throughout the United States.

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 2015 report, the U.S. Copyright Office has continued its active public outreach and education program, which includes numerous presentations on topics relating to copyright law, policy, and registration issues to a large variety of audiences, such as bar associations, universities, conferences and similar symposia.

- In June 2016, the Copyright Office hosted its bi-annual international training program for foreign officials, jointly sponsored with the World Intellectual Property Organization (WIPO). The week-long program was entitled "Copyright in a Global Network: Emerging Issues in Copyright and Related Rights for Developing Countries and Countries in Transition." The program brought together senior-level copyright officials and copyright specialists from twenty-two countries to learn from government, private industry, and civil society experts on a range of emerging issues in copyright law and policy. Panels addressed a variety of topics including international copyright harmonization and treaty implementation, challenges facing copyright law in the digital era, the role of limitations and exceptions, and development of intellectual property policy from the perspectives of the judicial, legislative, and executive branches of government.

- In FY 2016, the IPR Center added a new position specifically to increase engagement with stakeholders in order to better fulfill the outreach portion of its mission and to educate the public about the dangers of counterfeit goods and pirated content

- CBP proactively and frequently issues national and local press releases, and social media notifications to educate the public on counterfeiting. In FY 2015 and FY 2016, CBP issued 28 and 37 IPR-related press releases, respectively.

- CBP recently issued a new Customs Declaration Form 6059B which is the form international travelers need to complete upon entry into the United States. The new form was updated to educate the international travelers on the penalties and dangers associated with buying counterfeit and pirated goods and bringing them into the United States. The CBP Form 6059B now includes a warning to inform travelers that the importation of merchandise into the United States that infringes intellectual property rights may result in civil or criminal penalties and may pose serious risks to their health and/or safety. The online fillable form is currently available in 18 languages and can be found at https://www.cbp.gov/newsroom/publications/forms/new-customs-declaration-form-cbp-6059b.

- The IPR Center continues to make available the IPR Center/ICE HSI Civil Anti-Counterfeiting and Piracy 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 educates the public about IP theft and provides information to the public on how to report violations to the IPR Center.

- In FY 2016, the IPR Center conducted 310 outreach and training events with 14,382 attendees.

- The FBI produces Private Sector Advisories that 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 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 the State Department. In Pakistan, for example, the U.S. Embassy Public Affairs Section launched a week-long Facebook and Twitter campaign in April 2016 to raise awareness for World Intellectual Property Day, reaching a combined audience of over 200,000 Pakistanis. The predominantly young audience (of U.S. Embassy Islamabad's 1.9 million Facebook followers, 53% are ages 18-24) shared our posts and responded with unanticipated positive support for the largely ignored issue of intellectual property rights.

Global Intellectual Property Academy (GIPA) 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 on 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, such as, 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 and the Small Business Development Centers. In FY 2016, GIPA provided intellectual property education to over 1,100 participants. Also in 2016, USPTO participated in a three-day "roadshow" in Japan, focused on educating Japanese SMEs on U.S. practices, procedures and voluntary best practices.

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 https://www.justice.gov/iptf and https://www.cybercrime.gov.

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 2016, these efforts included the following:

- In FY 2016, the number of CBP and HSI IPR seizures increased more than nine percent, to 31,560 (from 28,865 in FY 2015). The total estimated Manufacturer's Suggested Retail Price (MSRP) of the seized goods, had they been genuine, increased to $1.383 billion.

- In FY 2016, CBP conducted 36 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, CBP is developing an IPR advanced training course with the Office of Training and Development (OTD). The goal of the IPR advanced training course is to expand on the existing Basic IPR Instructor Led Training and increase the student's knowledge of advanced IPR enforcement topics.

- In April 2016, CBP and the General Administration of Customs in China (GACC) conducted a successful joint IPR enforcement operation. During the one-month operation, China seized shipments of all types of IPR infringing products destined to the United Sates. CBP focused on shipments from China destined to the U.S. for four product categories: automobile parts, electronics, identification tags and labels, and certain pharmaceutical products. Together, the two countries' customs agencies made more than 1,400 seizures of shipments containing IPR-infringing goods.

- In FY 2016, CBP conducted eleven Mobile Intellectual Property Enforcement Team operations, resulting in 2,680 total seizures of IPR infringing products (valued at $85.3 million MSRP).

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.

ICE HSI

In FY 2016, ICE HSI initiated 863 intellectual property investigations and had 451 arrests, 304 indictments, and 272 convictions.

National Intellectual Property Rights Coordination Center (IPR Center)

In FY 2016, the IPR Center vetted 31,406 investigative leads; of these, 17,507 were referred to law enforcement partners. Additionally, the IPR Center de-conflicted 3,074 investigative targets for partner agencies and industry. While performing these de-conflictions, the IPR Center identified 359 "blue on blue" situations where two or more entities were investigating the same target. Finally, the IPR Center referred 611 leads to private industry for follow-up.

The HSI personnel at the IPR Center worked in conjunction with CBP to revamp the curriculum for the advanced commercial fraud training at the Federal Law Enforcement Training Center (FLETC) so as to ensure that it is relevant and useful to HSI and CBP field personnel. The new course – Intellectual Property and Trade Enforcement Investigations (IPTEI) – is a two week course, consisting of one week of IP training and one week of commercial fraud training. The first sessions of the revised course were held in June and August of 2016. Trainers for the course came from both the private sector and the government. Students were from both HSI and CBP.

In FY 2016, the IPR Center, under the auspice of OCR, presented seven webinars and two in-person training sessions to increase awareness of the OCR initiative and inform personnel for sources available to support OCR investigations. An HSI program manager, an HSI special agent, and a DOJ CCIPS attorney served as presenters. Additionally, DOJ CCIPS was an integral part of the collaboration to establish the content and format of the webinars. Personnel from HSI, Air Force Office of Special Investigations (AFOSI), Defense Criminal Investigative Service (DCIS), Naval Criminal Investigative Service (NCIS) and the National Aeronautics and Space Administration-Office of the Inspector General (NASA-OIG) received this training.

The IPR Center 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 Tax Recovery and Criminal Enforcement (TRaCE) Task Force is a pilot program facilitated by *California Assembly Bill 576*, Revenue Recovery and Collaborative Enforcement Team Act. TRaCE joins existing state and federal resources to collaboratively combat illegal business activities that rob California of public funds and its citizens of public services. HSI Sacramento is a TRaCE Task Force partner, and works with investigators and special agents from other partner agencies to investigate, prosecute and recover revenue lost to the underground economy. The IPR Center, through its provision of resources and capabilities to HSI Sacramento, supports the TRaCE Task Force and its efforts to combat the criminal activities of the underground economy. In June 2016, the TRaCE Task Force, including HSI, coordinated to serve seven search warrants resulting in the seizure of hundreds of boxes of foreign pharmaceuticals and thousands of articles of suspected counterfeit clothing.

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 June 30th of FY 2016, those receiving program grants have seized over $418 million worth of infringing goods and proceeds. Additionally, between from July 1, 2015 and June 30, 2016, grant recipients arrested 342 individuals for violation of IP laws, served 151 state and local search warrants in IP cases, and disrupted or dismantled 353 piracy/counterfeiting organizations. In coordination with the National White Collar Crime Center, DOJ held a total of 10 training events on IP for state and local law enforcement personnel nationally in FY 2016.

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

ICE HSI at the IPR Center collaborates with HSI's Cyber Crime Center (C3) to identify individuals who smuggle infringing goods into the US. The ICE HSI Illicit Cyber Commerce (ICC) Program utilizes C3's capabilities to corroborate leads and assist in investigation. The ICC Program also works with HSI DC Cyber Group to focus on cyber threats involving the intersection of online IP infringement and malware infection, and as well as other complex IPR investigations.

Update on CDx and use of ion mobility spectrometry (IMS)

In September 2012, FDA unveiled a handheld Counterfeit Detection (CD3 also known as CDx) 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 goal is to put an affordable tool for identifying counterfeit pharmaceutical products in the hands of global regulatory, law enforcement, and public health officials.

In FY 2016, a presentation describing the development and application of the CDx against counterfeit products was given at the American Association of Pharmaceutical Scientists convention. FDA conducted and received an award for Operation Pill Pusher, which was an operation that used the CDx to screen potential counterfeit products and to develop a library of

diverted or counterfeit products for use in future drug screenings. Based on successful use, demonstrated applications, and the need for additional devices, FDA is collaborating on developing and manufacturing a more advanced CD5 counterfeit device. In 2016, FDA hosted an "Industry Day" to private industry. Presentations were given on the evolution of the device, demonstration of the variety of applications of the device and future requirement needs for the CD5 device. The solicitation was posted in August 2016, with proposals from interested parties due by the end of September 2016. Proposal reviews will occur early in FY 2017. Also in 2016, an article was published in the peer-reviewed Malaria Journal, related to FDA's collaboration with the United States Pharmacopeia Convention Center for Pharmaceutical Advancement and Training in Accra, Ghana, the Ghana Food and Drug Authority (Ghana FDA) and other government agencies regarding evaluation of CD3+ performance against existing screening technologies for the evaluation of potential counterfeit anti-malarial products in the field. Also in FY 2016, FDA performed an inventory of the CD3 units available in all of the International Mail Facilities, and updated the units with the latest version of the CDx.

IMS

Since 2011, FDA has used Ion Mobility Spectrometry (IMS) technology to assist with the rapid field analysis of imported dietary supplement products suspected of containing undeclared drug ingredients. The portable and benchtop IMS instruments are used to shorten the time it takes to review and take action on tainted dietary supplements. The instruments detect the presence of certain Active Pharmaceutical Ingredients (APIs) through the migration speed and time of charged particles through a "drift tube" contained within the instrument. FDA continues to develop a strategy to use positive FDA rapid screening results, without confirmatory testing by a FDA laboratory, as a factor in meeting the appearance standard under section 801 of the FD&C Act. As a component of this, the scientific reliability of each instrument alarm, or API detected, must be evaluated.

In FY 2016, FDA evaluated data and determined that the portable IMS instrument is scientifically reliable in detecting sibutramine, and the benchtop IMS instrument is scientifically reliable in detecting sibutramine, phenolphthalein, and sildenafil. When the instruments detect these compounds in import samples, the results are scientifically reliable. As such, the samples do not require additional, confirmatory laboratory testing to use the results as one of the factors in the determining whether an article offered for import appears to be misbranded, adulterated, or an unapproved new drug in violation of the FD&C Act and therefore is subject to refusal of admission.[1]

[1] FDA laboratory confirmation is needed to meet the evidentiary standard required for destruction of goods under FDASIA section 708.

10. Improve Effectiveness of Personnel Stationed Abroad

In FY 2016, Federal agencies engaged in a number of activities to improve the effectiveness of USG personnel stationed abroad.

- USPTO continued to post IP attachés in high-priority countries including Brazil, Russia, India, China, Thailand and Mexico. The IP attachés continued to play active leadership roles on enforcement-related issues in IP Working Groups at Post. USPTO also facilitated interactions between IP attachés and U.S. stakeholders in order to improve stakeholder awareness of IP attaché services.

- In December 2015, USPTO organized a series of consultations between the IP attachés and stakeholders in the United States. These sessions included (i) a roundtable at the U.S. Chamber of Commerce's Global Intellectual Property Center with more than 150 U.S. Chamber members, other stakeholders, and members of the public, and (ii) an event hosted by the Business Council for International Understanding that was attended by more than 50 senior industry representatives. In addition, the attachés had separate meetings with other U.S. stakeholders, seven U.S. Government agencies, six USPTO business units, USPTO Director Michelle Lee, and teams of experts at the USPTO who focus on the various attachés' respective regions.

- USPTO's IP attachés coordinated with a group of IP attachés from Australia, Canada, European Union, Japan, and the United Kingdom on IP issues in developing countries. In May 2016, the USPTO IP attachés based in Brazil, Russia, China, Peru, European Union, and Thailand conducted a set of outreach meetings in Orlando and Daytona Beach. Participants included senior representatives of businesses in a wide-variety of industries including food, entertainment, aerospace/defense, and manufacturing.

- In July 2016, State, along with USPTO, held its annual IPR course at GIPA for Foreign Service Officers whose portfolios at their overseas posts include intellectual property. The course helps prepare the Foreign Service Officers to engage with their host governments on improving intellectual property-related legislation and enforcement, and to raise public awareness about the importance of intellectual property rights and about the dangers posed by counterfeits. The Department of State's Office of International Intellectual Property Enforcement (IPE) also integrated a session on intellectual property rights into the economic and commercial tradecraft courses that are offered about bi-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 2016, the IPR Center conducted 79 such events.

- 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.

- In October 2015, the IPR Center participated in the 5th IP Summit organized by the USPTO IP Attaché Thailand and the Intellectual Property Office of the Philippines to share best practices with Philippines law enforcement officials. In additional, the IPR Center and the ICE HSI Attaché in Manila coordinated an IP Workshop for Philippines law enforcement and prosecutors on combating IP crimes and collaborating with international law enforcement.

- The IPR Center, under the auspices of *Operation Team Player*, coordinated with Mexican Tax and Customs Administration Service (SAT) and HSI Attaché Hong Kong to conduct coinciding enforcement actions in Mexico and Hong Kong. In the furtherance of this operation, the IPR Center and HSI Hong Kong coordinated a training event with the National Football League and Hong Kong Customs and Excise Department (C&ED) conducted on December 8, 2015, in which 20 C&ED officers were instructed on the identification of counterfeit NFL products. From January 11 to February 8, 2016, SAT conducted 26 search warrants resulting in the seizure of 8,738 sports merchandise items with an estimated MSRP value of $132,000. Additionally, SAT conducted enforcement operations at ports of entry, resulting in the seizure of $1.1 million counterfeit items (MSRP value undetermined). During the same time frame, HSI Attaché Hong Kong assisted Hong Kong C&ED in conducting two blitz operations resulting in 22 seizures of approximately 275 counterfeit items. In addition, C&ED officers mounted an anti-counterfeit operation at Tung Choi Street on February 3, 2016, targeting one stall and one related storage space. As a result, C&ED arrested one Hong Kong female and seized 4,368 suspected counterfeit goods.

- In July 2016, an FDA Senior Special Agent was assigned to INTERPOL's Global Complex for Innovation (ICGI) in Singapore and specifically assigned as a Criminal Intelligence Officer to the Medical Products Counterfeiting and Pharmaceutical Crime sub-

directorate (MPCPC). This position expands the U.S. FDA Office of Criminal Investigation's (OCI) reach, knowledge and resources, and increases the agency's ability to protect U.S. consumers from unsafe FDA regulated products.

- 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. Most recently, in FY 2016, working with the State Department, DOJ posted new regional IPLECs in Hong Kong and São Paulo, Brazil. The State Department and DOJ expect to field a new IPLEC position in Abuja, Nigeria, in FY2017.

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 2016, these activities were conducted in Pakistan, Singapore, Kosovo, Bosnia and Herzegovina, Mali, Sri Lanka, Georgia, Armenia, and the United States.

Notable CLDP capacity building programs during FY 2016 include:

Legislative Updates:

- In May 2016, CLDP met with 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. IPO reported it had circulated the work product of the working group (e.g., identified inconsistencies in the IP laws and proposed solutions) to interested parties for review and comment. Moreover, IPO and CLDP agreed on a work plan to continue work on drafting proposed amendments to the IP laws and regulations.

Border Enforcement Capacity Building:

- On November 10-11, 2015, CLDP held a two-day workshop on Border Enforcement of Intellectual Property Rights in Kosovo. The workshop was led by experts from U.S. Customs and Border Protection, U.S. Patent and Trademark Office, U.S. Immigration and Customs Enforcement, and the U.K. Chartered Trading Standards Institute. The workshop, attended by approximately 20 customs officials from headquarters and border crossing points, addressed issues specifically identified by Kosovo Customs and the Kosovo business community, including risk assessments and targeting, identification of IPR violations at the border, and methods of enhancing coordination and cooperation.

- In March 2016, CLDP, in coordination with U.S. Customs and Border Protection and Singapore Intellectual Property Academy, held a workshop on "Customs, Intellectual Property Rights Enforcement and Counterfeiting" in Singapore. The program was held under the auspices of the Third Country Training Program (TCTP) in Singapore. Thirty-five government officials from Customs bureaus of the ASEAN countries (Brunei Darussalam, Burma, Cambodia, Laos, Malaysia, Indonesia, Philippines, Thailand, and Vietnam) attended this workshop. The program focused on investigation and collaborative techniques that governments use to stem the flow of counterfeits across borders.

Judicial Capacity Building and Development of Judicial Benchbooks:

- In October 2015, CLDP sent a letter to the Chief Justice of the Pakistan Supreme Court (PSC) suggesting development of an intellectual property (IP) benchbook as a resource for the judiciary and for the enhancement of the jurisprudence and efficiency of the courts in matters relating to IP; in December 2015, the U.S. Embassy Resident Legal Advisor met with the Chief Justice who agreed in concept with the IP benchbook proposal and referred the matter to his Senior Justice; in April 2016, CLDP met with the Intellectual Property Organization of Pakistan (IPO) to invite their involvement in the IP benchbook proposal, and the IPO Chairman agreed to support the proposal, including contacting the Senior Justice; and in June 2016, CLDP and the U.S. Federal Judicial

Center (FJC) drafted a written proposal for consideration by the PSC and other interested parties (e.g. IPO and the Pakistan Federal Judicial Academy) suggesting a methodology and process for drafting an IP benchbook.

- On February 24-25, 2016, CLDP conducted a Workshop for Judges on Decision-Making in Cases of Trademark and Copyright Infringement in Teslic, Bosnia and Herzegovina (BiH). CLDP brought together participants from each BiH constituency for the workshop, organized in partnership with the U.S. Embassy in BiH and the Centers for Judicial and Prosecutorial Training. The workshop trained 30 judges on decision-making in cases involving trademark and copyright infringement. The workshop also promoted the use of the Judicial Benchbook on Intellectual Property, written and published by BiH judges with CLDP support in 2013. The workshop was led by two U.S. Federal District Court judges, as well as a judge and a professor from BiH.

- In May 2016, CLDP and USPTO led a pair of two-day intellectual property (IP) workshops in Colombo and Jaffna, Sri Lanka, for High Court and District Court judges. Thirty Sri Lankan judges in Colombo and thirty judges in Jaffna were exposed to best practices in managing and adjudicating IP disputes in a fair, efficient, and predictable manner. The Honorable Susan Y. Illston and the Honorable William Orrick (both from Northern District of California) served as the primary experts speaking on patents, copyrights, trademarks, trade secrets, unfair competition, and alternative dispute resolution.

Attorney Capacity Building:

- In January 2016, CLDP, in coordination with the Continuing Legal Education Institute of Pakistan (CLEIP) and the Institute of Business Administration (IBA), and with additional support from the Anti-Counterfeit & Infringement Forum (ACIF), held continuing legal education (CLE) training in Karachi, Pakistan, on intellectual property (IP) issues arising within the context of ongoing business operations. Approximately thirty local Karachi attorneys and company officials paid tuition and attended this two-day program, including networking events within the legal, business, and educational communities involved in addressing IP matters related to businesses. This was the fourth such event organized by CLEIP and CLDP in Pakistan.

- On March 12-17, 2016, CLDP, in cooperation with the USPTO, hosted U.S. Consultations for the National Intellectual Property Center of Georgia (Sakpatenti), in Alexandria, Virginia. The program, hosted at USPTO's Global Intellectual Property Academy, provided an extensive training for four Sakpatenti attorneys on the appellate process before the Trademark and Patent Trial and Appeal Boards. Led primarily by patent and trademark attorneys from USPTO, the program also addressed trademark eligibility, patentability, drafting decisions, and interpreting and applying statutory and case law. This program is part of CLDP's ongoing efforts to build the capacity of Sakpatenti professionals to develop an intellectual property regime harmonized with international standards.

IPR Institution Capacity Building:

- In 2016, CLDP continued its assistance for the implementation of a program in Mali to prevent the spread of counterfeit, illegal, and adulterated agricultural and pharmaceutical products. A partnership between CLDP, USAID Mali, the International Crops Research Institute for the Semi-Arid Tropics, and private-sector company Sproxil is implementing a project deploying Sproxil's Mobile Product Authentication™ technology, which verifies products using special product labels and mobile phones.

- On November 2-6, 2015, CLDP sponsored the visit of a 5-member delegation of trademark administrators from the Georgia National Intellectual Property Center (Sakpatenti) for training at USPTO Global Intellectual Property Academy. The delegation included the Deputy Chairwoman of Sakpatenti. The program focused on administration, budgeting, recruitment and training, and Madrid protocol administration.

- On April 11-14, 2016, CLDP sponsored the travel of two USPTO advisors for Consultations for the National Intellectual Property Center of Georgia (Sakpatenti) Trademark Examiners, in Tbilisi, Georgia. The program focused on topics requested by Sakpatenti including international and U.S. best practices in examination of marks for distinctiveness and likelihood of confusion; bad faith trademark application; well-known marks; geographic marks; three-dimensional marks; and non-traditional marks. The advisors also discussed the Trademark Law Treaty and the Singapore Treaty, and shared the U.S. experience with examining international trademark applications.

Collective Copyright Management Capacity Building:

- On May 11, 2016, CLDP hosted a Workshop on Raising Awareness on Collective Copyright Management in Yerevan, Armenia. The program was held in cooperation with the Armenia Intellectual Property Rights Center (IPRC) and Armenia's only collective copyright management organization (CMO), Armauthor. Thirty participants representing rights holders, users of copyrighted materials, government organizations, and lawyers heard panel discussions and presentations from CMO representatives from Hungary and France. The program focused on the role and functions of CMOs, the relationship between CMOs and authors, CMO use of collected funds, the importance of licensing agreements, and the reasons and process for CMOs to bring legal action. This program established relationships between Armauthor officials and users of copyrighted materials, and contributed to predictable and harmonized copyright protection in Armenia.

Public Awareness of Intellectual Property Issues:

- In April 2016, CLDP, in coordination with ITA and U.S. Embassy Islamabad, co-sponsored a World IP Day conference in Islamabad conducted by the Intellectual Property Organization of Pakistan (IPO). The conference stressed the importance of a strong

intellectual property rights (IPR) regime in Pakistan, and the nexus between an effective IPR regime and a strong economy, including increased domestic and foreign investment. Its 200 attendees included representatives from the public and private sectors, and prominent speakers included IPO's Chairman, the EU Ambassador, and the Minister of State for National Health Services, as well as leading members of the film and music industry. Moreover, in addition to the benefits of the evolving digital technology and related IPR, speakers from CLDP and the U.S. embassy spoke on challenges that IPO, enforcement and customs officials, and the judiciary will face to effectively protect IPR in Pakistan.

Innovation and the Role of Intellectual Property in the Economy; Technology Transfer:

- In February 2016, CLDP conducted a technology transfer program in San Diego, CA, for an eighteen-member delegation of Pakistani and Tunisian university and government officials involved in the identification and exploitation of technology arising from the activities of universities. The seven-day program included participation in a multi-day conference of the Association of University Technology Managers (AUTM), presentations and discussions with the Vice-President for Technology Development at Oklahoma State University, and visits to California universities and local technology and business incubators.

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

Latin America

In June 2016, in cooperation with the IP Attaché, U.S. Embassy Mexico City, USPTO hosted a workshop on border enforcement of intellectual property rights in the Port of Manzanillo, Mexico's largest commercial seaport. More than 30 Mexican customs officials attended the program, which included two days of classroom sessions and discussion panels, and an additional day during which participants visited the inspection operation at the port, and saw a demonstration on counterfeit products, presented by a rights holder. Topics of discussion included: comparisons of U.S. and Mexican border measures regarding IP recordation, seizure, forfeiture, and destruction; targeting and risk indicators; identification of infringing goods; suspension of release; risk assessment and profiling in the container supply chain; coordination with other agencies; regional cooperation; criminal investigation of IPR cases; and rights holders complaints and investigations.

In September 2016, in cooperation with the HSI Deputy Attaché, U.S. Embassy Buenos Aires, USPTO hosted a workshop entitled "IP Enforcement at the Border" for Chilean police and customs officers. The 3-day program addressed a variety of topics including the intersection between drug trafficking and IP crimes, trade secrets theft, investigating IP crimes and cross-border cooperation among other topics. The program also included a visit to the Port of Baltimore.

The Balkans

In November 2015, the USPTO participated in a two-day program organized for Kosovo Customs' officials. USPTO provided presentations and materials on the importance of balanced intellectual property rights enforcement (focused on economic damage and public health); trade principles affecting customs and IP; and seizure, forfeiture and destruction of infringing goods. The program was held in Pristina, Kosovo.

Central Asia

In May 2016, USPTO conducted a three-day program on border enforcement for customs officials from Armenia, Belarus, Kazakhstan and the Kyrgyz Republic. The program took place in Almaty, Kazakhstan and topics included customs procedures, investigations, risk analysis and targeting, and destruction of counterfeits. The program included presentations, case studies and discussions. U.S. speakers included representative of USPTO, CBP and ICE.

In September 2016, USPTO held a judicial workshop in Astana, Kazakhstan. The program was attended by members of the Kazakhstan Supreme Court and trial courts around the country. U.S. participants included two U.S. Federal Judges, the DOJ IPLEC posted in Bucharest, Romania, and USPTO. Topics included trademark and copyright infringement cases in Kazakhstan and the U.S.; use of expert witnesses; provisional remedies and damages; judicial case management; and trade secret protection. The program included presentations, case studies and discussions.

Georgia

In July 2016, the USPTO participated in a two-day CLDP workshop in Tbilisi, Georgia on Internet Service Provider (ISP) liability for copyright infringing content. Participants included almost 20 government officials and approximately 25 representatives from the private sector. USPTO participants spoke about the importance of IP enforcement in general, and about liability of internet service providers in the United States under the Digital Millennium Copyright Act. Topics addressed by other speakers included the Georgia-European Union Association Agreement, and in particular, about the provisions in that agreement on ISP liability, Georgia's draft ISP legislation, and secondary liability in the United States.

In July 2016, USPTO and CLDP, in coordination with the Georgian industrial property office, Sakpatenti, the High School of Justice and the Georgian Copyright Association held a workshop on the adjudication of civil intellectual property infringement cases. The topics addressed included: adjudication of trademark and copyright infringement cases in Georgia and the U.S.; use of expert witnesses; provisional remedies and damages; analysis applied in trademark and copyright infringement; judicial case management; and trade secret protection and enforcement. Throughout the workshop case studies were presented by the U.S. and Georgian speakers applying concepts discussed in the presentation. Georgian participants included first instance and appellate judges in Georgia, Sakpatenti officials, Georgian Copyright Association representatives, and the High School of Justice.

Association of Southeast Asian Nations (ASEAN)

In May 2016, USPTO conducted two back-to-back workshops in Medan and Surabaya, Indonesia focusing on balanced intellectual property protection in the digital environment. Participants included investigators, police and prosecutors. The workshop addressed the various types of digital and Internet piracy, the laws governing copyright protection in the digital environment, and best practices in investigating and prosecuting intellectual property crimes.

In August 2016, the USPTO, in coordination with the ASEAN Secretariat, organized and participated in a colloquium for prosecutors and the judiciary on the enforcement of intellectual property rights in Kuala Lumpur, Malaysia. Approximately 60 judges and public prosecutors from all of the ASEAN member states attended and participated in the colloquium. The seminar focused on the adjudication and enforcement of intellectual property in the ASEAN region, including presentations and discussions on the importance of protecting and enforcing intellectual property as well as enforcement challenges in the online environment.

Middle East-North Africa Region (MENA)

In November 2015, USPTO in collaboration with the Moroccan Office of Industrial and Commercial Property (OMPIC), U.S. Department of Justice, U.S. Immigration and Customs Enforcement and Interpol, conducted a workshop training police and investigators on IPR Enforcement in Rabat, Morocco. Attendees included 26 police officials from throughout Morocco and two officials each from Ivory Coast, Senegal and Cameroon. The Workshop included a mix of presentations and panel discussions including topics on Criminal Investigations of IPR Crimes, Law Enforcement Cooperation and Coordination, Investigations of Online and Digital IPR Cases and Working with Industry in Investigating and Prosecuting IPR Cases. Case studies were also incorporated into the discussion, which generated a substantive exchange of IPR Enforcement best practices.

South Asia

In May 2016, USPTO in coordination with the U.S. Department of Commerce's Commercial Law Development Program (CLDP) conducted back-to-back two-day intellectual property judicial exchanges in Colombo and Jaffna, Sri Lanka in collaboration with the Sri Lankan Judicial Institute. Chief Judge Susan Y. Illston and Judge William H. Orrick III of the U.S. District Court of the Northern District of California facilitated several discussions, including trademark, patent and copyright infringement determinations, case management and alternative dispute resolution. The program also included participation from the Bangkok Intellectual Property Law Enforcement Coordinator for the Department of Justice who presented on IPR Criminal Enforcement and Online IPR Enforcement. The Exchange in Colombo and Jaffna included thirty Judges in each location with a mix of District Court and High Court Judges.

In August 2016, USPTO conducted a five-day IPR Judicial Exchange for Officials from Government of Pakistan, held at the USPTO's Global Intellectual Property Academy (GIPA). The

participants consisted of High Court Judges, District and Session Court Judges, Intellectual Property Tribunal Judges, Intellectual Property Organization (IPO) Officials, and Federal Bureau of Revenue Customs' Officials. The exchange between the US Judges and Pakistani delegates was cross cutting, including criminal IPR Enforcement, best practices on case management techniques, trial procedures and discovery process.

China

In April 2016, under the U.S./China Cooperative Framework Agreement, USPTO organized a study tour for fifteen Chinese officials, allowing them to learn more about the American judicial system for IP enforcement. The Chinese officials represented a wide range of agencies, including the Ministry of Commerce; the IP Courts of Beijing, Shanghai, and Guangzhou; the Law and Policy Committee of the National People's Congress; and the Supreme People's Procuratorate. In Washington, D.C., these officials heard from representatives of several federal agencies, including the following: The International Trade Commission; the U.S. Sentencing Commission; the Computer Crime and Intellectual Property Section of the Department of Justice; and the USPTO's Patent Trial and Appeal Board and Trademark Trial and Appeal Board. The group learned about various remedies available to IP litigants in administrative and criminal settings. The U.S. Chamber of Commerce organized a roundtable, affording rights holders the opportunity to express concerns about IP enforcement to the Chinese officials. The Chinese officials participated in an IP academic conference that USPTO and George Washington University Law School jointly organized and presented. The delegation then traveled to Madison, Wisconsin where they conferred with members of the federal bench and state supreme court. The group learned about remedies available in civil court, including temporary injunctive relief, evidentiary preservation, evaluating the qualifications of an expert witness, in camera review of sensitive and proprietary information, and the differences between federal and state courts.

In August 2016, USPTO participated in the first U.S.-China Judicial Dialogue in Beijing, China. Intellectual property issues were featured throughout the two-day event, reflecting the Chinese practice of experimenting with judicial reforms by first introducing them in the IP arena. The U.S.-China Judicial Dialogue is a high-level exchange between American and Chinese judges and legal experts, stemming from the September 2015 summit between Presidents Barack Obama and Xi Jinping. The two-day meeting included three half-day panel discussions on case management, evidence, and precedent, as well as a half-day visit to the recently established Beijing IP Court.

Global Copyright Program

In September 2016, USPTO hosted a week-long copyright seminar for foreign copyright officials, attended by 22 participants from 16 countries in Asia, Latin America, the Caribbean, Africa, Europe and China. Topics addressed included copyright subject matter and exclusive rights, exceptions and limitations, criminal enforcement of copyright and international cooperation in the prosecution of online piracy, copyright and enforcement provisions in recent FTAs, internet

service provider liability, voluntary stakeholder initiatives, the Administration's work on copyright policy, WIPO treaties and other activities, copyright policy and enforcement agencies in the U.S. Government, copyright in a changing world, key technologies and copyright, the economic impact of the copyright industries, U.S. Copyright Office activities, and a day of presentations on various copyright industry sectors (e.g. music, visual arts, motion pictures, publishing, computer software, and video games). Speakers included USPTO staff, representatives of other U.S. Government agencies (including USTR, DOJ CCIPS and the Copyright Office), academics, and speakers from the private sector and nonprofit organizations.

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 2016, the STOPfakes.gov Road Show traveled to multiple 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.

Additionally, during FY 2016 representatives from OIPR conducted outreach at several trade association-sponsored programs including Specialty Equipment Market Association (SEMA) and American Intellectual Property Law Association (AIPLA). Moreover, OIPR travelled to various U.S. cities through the Startup Global Initiative launched by Secretary Pritzker in 2015 designed to help more startup firms think global from the earliest stages. OIPR participated in half day educational seminars in partnership with local incubators and accelerators to educate on protecting intellectual property rights, a pressing issue startups face in the global business environment.

As part of the DOC's overall IPR-outreach related activities, ITA's OIPR continued its China Webinar Series during FY 2016. 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

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 State Department's Bureau of International Narcotics and Law Enforcement Affairs-funded country-specific and regional programs. In FY 2016, the IPR Center participated in 14 international trainings in support of these programs. ICE HSI continues to

work closely with its law enforcement counterparts, particularly those who received training in IP enforcement. For example:

- During FY 2016, the IPR Center and HSI Manila hosted multiple IP enforcement training programs. In February 2016, 34 officials from the Philippines government received IP enforcement training in Manila, and DOJ's regional IPLEC based in Bangkok, Thailand, participated in the training as well. This program was very well received. As a result, two additional programs were hosted in June 2016 for officials in Manila, as well as Cebu. These courses were attended by 63 officials from the Philippines government. The IP course presentations and best practices focused largely on health and safety investigations based upon the traditional platform of hard goods smuggling as well as through the Internet. The training was designed to highlight new threats and trends and to complement existing cooperative efforts in light of the alarming growth of IP crimes around the world, especially in the Asia Pacific Region.

- In April 2016, the IPR Center sent an HSI special agent to Panama in support of the World Customs Organization's *Operation Seascape*, which targeted counterfeit auto parts in South and Central America. The agent presented information on the IPR Center and the National Cyber & Forensic Training Alliance (NCFTA) support capabilities, best practices, and the importance of information sharing. The audience consisted of customs officers from South American countries and industry representatives.

- In May 2016, the IPR Center and HSI Brasilia, in coordination with USPTO, conducted two IP training workshops with a focus on the postal and express mail environment. These workshops were attended by 75 law enforcement and customs officials from Brazil, and were highly successful in bringing officials together from various Government of Brazil agencies. The importance of information sharing in IP investigations was particularly stressed in these courses, with presentations from Colombian and Chinese officials.

- In June 2016, the IPR Center hosted an IP Enforcement Workshop involving 37 foreign and domestic law enforcement and customs officials from Central and Eastern European countries as well as the United States. This workshop was hosted at the International Law Enforcement Academy (ILEA) Budapest and funded by the State Department Bureau of International Narcotics and Law Enforcement Affairs (INL). The training covered a variety of the trends, investigative techniques, best practices, and case examples covering all aspects of IP investigations with an emphasis on the postal and express mail environment. The IP workshop presentations and best practices focused largely on health and safety investigations based upon the traditional platform of hard goods smuggling as well as through the Internet. The presentations centered on enhanced cooperation with foreign counterparts to identify and combat criminal activity related to IP rights, border enforcement, commercial and trade fraud, international cooperation and asset sharing, money laundering fundamentals, brand protection,

counterfeit pharmaceuticals, public corruption/kleptocracy, and prosecution/legal issues related to IP crimes.

- In August 2016, the IPR Center – in collaboration with ICE HSI Frankfurt, Dakar and Casablanca – hosted an IP Enforcement Workshop for 30 African police and Customs officials from the Ivory Coast, Morocco, Nigeria, Senegal and Togo; the Workshop was held at the George C. Marshall European Center for Security Studies, in Garmisch-Partenkirchen, Germany. The training was funded by the DOS Bureau of International Narcotics and Law Enforcement Affairs and included a week-long program focused on the trends, investigative techniques, best practices, and case examples covering all aspects of intellectual property rights investigations. The presentations emphasized the value of sharing intelligence, along with other organizational assets and resources, in effectively investigating intellectual property violations.

- In FY 2016, CBP supported U.S. Government-sponsored IPR capacity building and training programs, providing instructors for training sessions for foreign customs officials in Manzanillo, Mexico and Almaty, Kazakhstan.

Department of State Capacity Building and Training

Government-to-Government Enforcement Training: The Department of State, using foreign assistance anti-crime funds managed by the 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 infringement that DOJ, DHS, and USPTO have delivered to Organization of American States and ASEAN member states. Also, INL funds have expanded the successful regional Intellectual Property Law Enforcement Coordinator (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 added three new regional IPLECS to be based at the U.S. Consulates at Hong Kong, São Paulo, Brazil and Abuja, Nigeria to work in, respectively, the Asia Pacific, Latin American and Sub-Saharan African regions. The Hong Kong and Sao Paulo IPLECs deployed in mid-2016, and INL and DOJ plan to field the Abuja IPLEC by early 2017.

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.

Areas in which U.S. Embassies work productively with their host governments include pharmaceutical market access, online piracy and counterfeit pharmaceuticals.

Multilateral Engagement: The Department of State continues its efforts to promote respect for IPR through international organizations and in other multilateral forums. Where relevant, the State Department 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. In July 2016, in Nairobi Kenya at the 14th session of the UN Conference on Trade and Development, the State Department co-sponsored a panel discussion on IP and illicit trade. Panelists from the government of Niger, the International Chamber of Commerce, INTERPOL, the Organization for Cooperation and Economic Development (OECD), and MERCK pharmaceuticals discussed the threat that illicit trade poses to security and development. They called for a more coordinated international response to threats posed by all forms of illicit trade.

The State Department continued efforts to address counterfeit medicines in Asia-Pacific Economic Cooperation (APEC) and the G7 summit. The State Department supported the IPEC on efforts to promote voluntary practices to address online piracy among G7 members. In APEC and ASEAN, the State Department 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 State Department 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 State Department 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 (IPEG). At its August 2016 meeting in Lima Peru, IPEC endorsed a draft document on best practices for trade secret protection.

Special 301 and Notorious Markets Contributions

The State Department/IPE provided extensive support to USTR and the interagency team as part of 2016's Special 301 process. 64 Posts submitted detailed analysis on the state of IPR protection and enforcement as part of the 2016 review. IPE also coordinated post input from 19 Posts for the Notorious Markets Report.

Supply Chain Integrity: Led by the Under Secretary for Economic Growth, Energy, and the Environment, the State Department 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 May 2016, FDA-OCI along with the Central Office against Environment and Public Health Criminality (OCLAESP), part of the National Gendarmerie of France, hosted the annual meeting of the Permanent Forum on International Pharmaceutical Crime in Paris. The working meeting focused on coordination of globally coordinated operations and emerging trends in pharmaceutical crime.

Also, in early 2016, an officer from the French National Gendarmerie attended FDA-OCI's Special Agent Training Program at the Federal Law Enforcement Training Center in Charleston, South Carolina from February 2016 to March 2016. The Special Agent Training Program is a comprehensive overview of the investigative priorities and legal authority for the FDA-OCI. This training provides the newly hired OCI agent the opportunity to develop a common foundation as they are incorporated into the OCI organization.

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, in April 2016, FDA-OCI provided cybercrime investigations training to law enforcement and regulatory personnel from the police, customs and health regulatory agencies of Panama. From May 30 – June 2, 2016, OCI agents joined with The Global Fund to Fight AIDS, Tuberculosis, and Malaria (TGF), an NGO based in Geneva, Switzerland, to host a training program in Lusaka, Zambia entitled, "Working with National Partners to Effectively Respond to the Challenges of Illicit Medicines." The attendees included members of the Zambian National Police, the Zambian Ministry of Health, and the Zambian Ministry of Justice. This training marked the first occasion in which members of the relevant Zambian governmental entities were present in the same location to discuss the scourge of counterfeit pharmaceuticals in their country. In September 2016, OCI provided training for the Malaysian Ministry of Health in collaboration with World Health Organization during their National Law Enforcement Inter-Agency Conference on "Combating Illicit and Illegal Online Sales of Medicine." The attendees included approximately 100 participants which included Law Enforcement and Public Health Officers from ASEAN countries.

<u>Laboratory/Analytical Capacity Building</u>

The International Laboratory Forum on Counterfeit Medicines (ILFCM) is an informal ad-hoc group comprised of scientific experts from National Regulatory Control Laboratories. It began in 1999 with a bilateral agreement between FDA and MHRA and gradually widened to member organizations in Europe, North America, Asia and Australia. Each member organization brings to the ILFCM a unique perspective on counterfeit and illegal medicines. In addition to counterfeit medicines the ILFCM also focuses on issues related to falsified/substandard medicines, adulterated dietary supplements and other serious public health topics. The ILFCM is closely aligned with the Permanent Forum on International Pharmaceutical Crime (PFIPC) and provides scientific guidance and laboratory support.

In 2016, the meeting was hosted by the Central Office against Environment and Public Health Criminality (OCLAESP) National Gendarmerie of France, and focused on Global Operations and

Emerging Trends in Pharmaceutical Crime. Information was shared between member laboratory organizations and in joint sessions with the PFIPC on encountered counterfeit medicines, illegally marketed medicines and unapproved drug substances, and adulterated herbal medicines and food supplements.

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 2016.

In conjunction with the Federal Trade Commission, the Antitrust Division conducted workshops at the Competition Commission of India covering a variety of competition and IP topics in November 2015 and August 2016.

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.

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.

U.S. Copyright Office Capacity Building and Training

During FY 2016, 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 U.S. Copyright Office.

The U.S. 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 2016, the Office hosted visitors from several foreign countries, including Antigua and Barbuda, Barbados, Canada, China, Dominica, Germany, Grenada, Pakistan, Saint Kitts and Nevis, Saint Vincent and the Grenadines, United Arab Emirates, and Vietnam.

As noted above, in June 2016, the Copyright Office hosted its bi-annual international training program for foreign officials, jointly sponsored with the World Intellectual Property Organization (WIPO). The week-long program was entitled "Copyright in a Global Network: Emerging Issues in Copyright and Related Rights for Developing Countries and Countries in Transition." The program brought together senior-level copyright officials and copyright specialists from twenty-two countries to hear from government, private industry, and civil society experts on a range of emerging issues in copyright law and policy. Panels addressed a variety of topics including international copyright harmonization and treaty implementation, challenges facing copyright law in the digital era, the role of limitations and exceptions, and development of intellectual property policy from the perspectives of the judicial, legislative, and executive branches of government. A copy of the agenda for the week-long program is available at https://www.copyright.gov/international-issues/2016-ici-program.pdf.

12. Consider Alternative Forums for Enforcement of Rights

As reported in FY 2014 and FY 2015, the U.S. Copyright Office conducted a study and issued a report on "Copyright Small Claims" in September 2013. This report 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 U.S. Copyright Office to administer streamlined proceedings through online and teleconferencing facilities (without the requirement of personal appearances). The Office's report can be found at https://copyright.gov/docs/smallclaims/usco-smallcopyrightclaims.pdf.

In July 2016, a bi-partisan bill to establish a small claims tribunal, the "Copyright Alternative in Small-Claims Enforcement Act of 2016" (or "CASE Act"), was introduced in the House of Representatives by Congressmen Hakeem Jeffries (D-NY) and Tom Marino (R-PA). The CASE Act largely adopts the recommendations of the U.S. Copyright Office's report for establishing a copyright small-claims tribunal as a voluntary alternative to federal litigation for copyright owners and alleged infringers. In particular, claims would be heard by a three-member

Copyright Claims Board, appointed by the Librarian of Congress, upon recommendation of the Register of Copyrights, and supported by at least two statutorily mandated Copyright Claims Attorneys. The tribunal would be centralized in the U.S. Copyright Office and proceedings would be administered remotely to address claims across the nation. Once a claimant has properly filed a claim with the Copyright Claims Board and served the respondent, the respondent would have 30 days to submit an opt-out notice. The CASE Act requires that all works that are the subject of an infringement claim in front of the tribunal must be registered before a final decision. Available relief for copyright claims and counterclaims would be actual damages and profits or statutory damages limited to $15,000 per work timely registered under Section 412 and $7,500 for works not timely registered. Overall damage awards would be capped at $30,000. Decisions of the Copyright Claims Board would be binding as to the parties and claims before the tribunal only, and would be appealable, in limited circumstances, to the U.S. District Court for the District of Columbia. In their press release, Congressmen Jeffries and Marino explained that the copyright small claims tribunal is intended "to provide a simple, quick and less expensive forum for copyright owners to enforce their intellectual property [rights]." The bill can be found at https://www.congress.gov/114/bills/hr5757/BILLS-114hr5757ih.pdf, and the press release at http://jeffries.house.gov/media-center/press-releases/democratic-rep-hakeem-jeffries-republican-rep-tom-marino-propose.

In its "White Paper on Remixes, First Sale, and Statutory Damages: Copyright Policy, Creativity, and Innovation in the Digital Economy," the Department of Commerce Internet Policy Task Force expressed the Administration's support for the creation of a streamlined procedure for adjudicating small claims of copyright infringement and stated that further consideration should be given to the proposal of the Copyright Office to establish a small claims tribunal.

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.

U.S. law enforcement and Federal agencies participated in *Operation Pangea IX*, which was conducted from May 3, 2016 to June 7, 2016, with the participation of 103 countries and 193 agencies, and culminated with a week of action from May 30 to June 7, 2016, where participating countries and agencies conducted and/or reported the results of their respective operations. On June 9, 2016, INTERPOL issued a press release highlighting the results of

Operation Pangea IX, which resulted in 4,932 websites taken off-line, 393 arrests worldwide, and the seizure of 170,340 packages with an estimated value of $53.2 million in potentially dangerous medicines (https://www.interpol.int/News-and-media/News/2016/N2016-076).

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 November 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.

Participating in *Project TransAtlantic VI* were 19 Europol member countries: Belgium, Bulgaria, Colombia, Croatia, Denmark, France, Former Yugoslav Republic of Macedonia, Greece, Hungary, Iceland, Italy, Latvia, Luxembourg, Poland, Portugal, Romania, Serbia, Spain, and the United Kingdom. An additional eight INTERPOL member countries also participated in the operation: Argentina, Chile, Japan, Hong Kong, Panama, Peru, South Korea, and Thailand.

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 (including ICE HSI and CBP) maintain a steady exchange of information and case leads with Chinese law enforcement, resulting in successful operations to disrupt the manufacture of counterfeit airbags, pharmaceuticals, batteries, electronic components, cell phones and luxury items. In FY 2016, 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. One example of this collaboration was the successful joint investigation into the manufacturing and distribution of counterfeit airbags resulting in the arrest of the manufacturer and distributer of the airbags, as well as the seizure of counterfeit airbags.

Cooperation with 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 IP 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 was 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 additional collaborative efforts in 2016. In April 2016, CBP and China Customs conducted a second joint IPR enforcement operation. Together, the two customs agencies made over 1400 seizures of shipments containing IPR-infringing products. In late September 2016, CBP and ICE/HSI officials met again with China Customs counterparts in Zhuhai, China and planned additional joint operational work for 2017. In addition, in FY 2016, CBP and ICE/HSI conducted a successful joint operation with Hong Kong Customs, and CBP also conducted joint operational work with Singapore Customs.

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.

FDA-OCI assigned a Senior Special Agent to the Interpol Global Complex for Innovation in Singapore in 2016. This criminal investigator will be attached to the Global Health and Safety Unit within the Organized and Emerging Crime Program at Interpol. The overall strategy of the Unit is to disrupt the transnational organized crime networks that endanger peoples' health and safety.

FDA-OCI continued to participate in the annual *Operation Opson*, which is a joint operation lead by Europol and INTERPOL that targets counterfeit and substandard food and beverages. Additionally, FDA-OCI participates annually in *Operation Pangea*, which is an international week of action tackling the online sale of counterfeit and illicit medicines and highlighting the dangers of buying medicines online. FDA-OCI's Senior Special Agent assigned to the Interpol Global Complex for Innovation in Singapore has taken on a leading role in the planning and coordination of future *Operation Pangea* operations.

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

- The IPR Center, in coordination with HSI attaché offices abroad, hosts many international IP enforcement programs that work to develop foreign IP enforcement capacity and foster critical relationships between foreign agencies. In May 2016, the IPR Center, in coordination with HSI Brasilia and USPTO, conducted two week-long IP Enforcement training workshops in the postal and express mail environment. These programs focused on developing enhanced cooperation with foreign counterparts to identify and combat criminal activity related to IP rights, border enforcement, commercial and trade fraud, and international cooperation and asset sharing. The programs were particularly noteworthy, as they brought together officials from Brazil, Colombia, and China to discuss cross-border IP violation and enforcement issues and the importance of information sharing as a layered bilateral approach to detection, seizure, and enforcement, specifically in the postal and express mail environment. The workshops were also ground-breaking in enhancing foreign law enforcement coordination, as they marked the first instance in which the General Administration of Customs, People's Republic of China presented and attended an IP training event in another BRIC (Brazil, Russia, India, China) country.

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

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 2016 include:

- CBP and the State Department 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.

- At the Asia Pacific Economic Cooperation (APEC) Subcommittee on Customs Procedures (SCCP) meeting held in Lima, Peru in February 2016, CBP proposed a multilateral IPR enforcement operation on counterfeit automobile and transportation items. The U.S. and eight other APEC economies (Chile, China, Hong Kong, China, Japan, Peru, the Philippines, Singapore, and Vietnam) participated in the operation in May 2016. A report on the joint enforcement operation was drafted by CBP and circulated to all of the APEC economies. In addition the results of the operation were presented at the August 2016 APEC SCCP meeting, which was also held in Lima, Peru.

- The IPR Center through ICE HSI has continued to expand its partnerships with international organizations, and in FY 2016 continued its partnership with Europol on an operation known as *Operation IOS Cyber Monday*/*Project Transatlantic*. 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 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 April 2016, USPTO supported INTERPOL's Trafficking in Illicit Goods Directorate in conducting a "Workshop on Fraudulent and Counterfeit Food Products," for law enforcement officials from Latin America and Africa. The training served as a platform for ongoing operations against fake food under the INTERPOL-led *Operation Opson*. As announced in April 2016, *Operation Opson V* resulted in the seizure of 10,000 tons and 1 million liters of hazardous fake food in actions across 57 countries.

- In August 2016, USPTO coordinated with INTERPOL's Trafficking in Illicit Goods Directorate in conducting a regional IP enforcement training in Argentina. The program included participation of ICE HSI Attaché Buenos Aires, as well as law enforcement officers from Brazil, Chile, Colombia, Ecuador, Peru, Paraguay, and Uruguay.

- In September 2016, the IPR Center participated in the Tenth Annual UL/INTERPOL International IP Crime Conference held in London. The theme of the Tenth Conference was "Celebrating a Decade of Success," and the Conference was co-hosted by INTERPOL and the City of London Police, in partnership with Underwriters Laboratories (UL). The Conference featured two days of plenary and panel sessions.

- In November 2015, USPTO actively participated in the 10th Session of the World Intellectual Property Organization (WIPO) Advisory Committee on Enforcement, the principal multilateral forum on intellectual property enforcement issues. Through the agency's successful engagement, the Committee agreed to adopt a US-initiated proposal on specialization of the judiciary and intellectual property courts, as a theme for future sessions. In September 2016, USPTO led the US delegation at the 11th Session of the World Intellectual Property Organization (WIPO) Advisory Committee on Enforcement. The IPR Center Director gave a presentation on the IPR Center's work in national intellectual property enforcement.

- In 2015 and 2016, the State Department continued its efforts to promote respect for IPR through international organizations and in other multilateral forums. Where relevant, State Department representatives requested that U.S. international development and trade agency partners actively educate their program recipients about the importance of intellectual property to support business development, entrepreneurship, and innovation. These agencies' efforts contributed to an increased focus on the role of intellectual property and development by the U.N. Conference on Trade and Development (UNCTAD). In 2016, the State Department worked closely with the U.S. Mission to the UN and UN member countries to shape the creation of a UN Technology Bank to assist LDCs in building capacity to use science, technology, and innovation and harness technology for development. Also in 2016, the State Department encouraged IT innovation and the development of associated IP protection mechanisms in Burma by facilitating connections between U.S. and Burmese academic institutions, including an academic exchange between the MIT Global Startup Labs program and a Burmese university.

- In 2016 the State Department, CBP, USTR, and USPTO supported the development of a report by OECD entitled "Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact" that can assist policymakers as they address IP enforcement challenges. The study identified the most affected countries, the most frequent source countries, and estimated that, in 2013, the worldwide value of imported fake goods (counterfeit and pirated hard goods) was as much as nearly half a trillion dollars a year ($461 billion) and as much as 2.5% of total world trade. (See OECD/European Union Intellectual Property Office, "Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact" (2016), available at

https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/Mapping_the_Economic_Impact_study/Mapping_the_Economic_Impact_en.pdf.)

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 enforcement and of 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, 45.5 million American jobs in 2014 were directly or indirectly supported by "IP-intensive" industries, and these jobs paid higher wages to their workers. In addition, in 2014, these IP-intensive industries accounted for $6.6 trillion in value added and 38.2 percent of the U.S. GDP. (See Department of Commerce, "Intellectual Property and the U.S. Economy" (2016), available at https://www.uspto.gov/sites/default/files/documents/IPandtheUSEconomySept2016.pdf.) 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 2016 include the following.

Trans-Pacific Partnership (TPP)

In February 2016, the United States and 11 partners (Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam) signed 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. Drawing from and building on other bilateral and regional trade agreements, the TPP Agreement includes commitments to protect IP and to combat counterfeiting, piracy, and other infringement, including trade secret theft; obligations to facilitate legitimate digital trade, including trade in creative content; and provisions to promote development of, and access to, innovative and generic medicines. Complete fact sheets summarizing the many ways in which the TPP is *Promoting Innovation and Creativity* and *Promoting Digital Trade* are available on https://ustr.gov/tpp/ as well as full summaries and text of all the commitments in the IP

Chapter. The TPP Agreement's Intellectual Property Chapter addresses many of the challenges to adequate and effective IPR protection and enforcement outlined in this Strategic Plan, including:

Copyright: The TPP IP Chapter encourages practices that are fair, efficient, transparent, and accountable regarding the collection and distribution of copyright royalties. The TPP requires countries to provide for works a minimum term of copyright protection of author's life plus 70 years, and for works that have terms calculated based on publication date, like movies and recordings, a term of copyright protection of 70 years. The TPP will also require Parties to establish systems to help address Internet copyright infringement in an effective manner through copyright safe harbors for legitimate ISPs. In addition, the TPP includes provisions prohibiting the circumvention of, and the trafficking in devices that circumvent, TPMs.

Trademarks and Geographical Indications: The TPP IP Chapter Agreement promotes efficient and transparent registration of trademarks, including through electronic trademark registration systems, streamlined procedures aimed at reducing red tape, and increased regional harmonization of trademark systems. The TPP also requires Parties to provide protection for certification and collective trademarks.

The TPP IP Chapter also contains a variety of transparency and due process safeguards that relate to domestic legal regimes regarding GIs. These safeguards aim to protect the interests of producers and traders that have pre-existing trademark rights or that rely on the use of common product names against market access barriers and other negative impacts caused by legal regimes that provide overly-broad protection of GIs. For example, the TPP requires Parties to provide opportunities to oppose the grant or recognition of new GIs, as well as opportunities to seek cancellation of previously granted or recognized GIs and specifies particular grounds that must be available in these proceedings. The TPP sets forth guidelines for determining generic (or commonly used) terms in each market. The TPP also extends many of these obligations to translations or transliterations of GIs. Collectively, these TPP provisions aim to help close loopholes that have hurt U.S. producers and traders.

Trade Secrets: The TPP IP Chapter requires Parties to provide the legal means to prevent the misappropriation of trade secrets and corporate espionage. The TPP is the first U.S. trade agreement to require criminal penalties for trade secret theft, including cyber theft. This is a significant step forward for TPP Parties, and an important precedent in a region where U.S. companies have faced significant challenges as a result of such activity. The TPP trade secrets provision does not prevent legitimate disclosures, such as disclosures by whistleblowers.

Patents: A strong, transparent and fair patent system is essential to protecting inventions and incentivizing new innovation. The TPP includes the obligation to make patents available for any invention including products and processes, in any field of technology if the invention is new, involves an inventive step, and is capable of industrial application. In addition, the TPP recognizes the importance of incremental innovation through an additional obligation that requires Parties to make patents available for a new use of a known product, a new method of

using a known product, or a new process of using a known product. This will help ensure that patent applications for inventions that are otherwise novel, non-obvious, and useful are not rejected merely because they are related to a known product. The TPP also confirms that patents are available for inventions derived from plants, another active area of innovation. Inventors will also benefit from a 12-month patent grace period to allow certain public disclosures without disqualifying an invention from meeting patentability requirements for novelty or non-obviousness. The TPP also provides for patent term adjustment for unreasonable patent office delays in the issuance of patents for inventions, including pharmaceuticals, such as those caused by the backlogs present in many countries on the Watch List and Priority Watch List.

Pharmaceuticals: The TPP sets a minimum standard of at least five years of data protection for new pharmaceutical products and, for the first time in any trade agreement, the TPP requires an extended period of effective market protection for new biologics. The TPP clarifies that the period of protection will start on the date of approval in each market, rather than from the first marketing approval in the world. In addition, the TPP requires Parties to provide for advance notice, adequate time and opportunity, and procedures for patent holders to seek timely resolution of patent disputes prior to the marketing of an alleged infringing product. The TPP also obligates Parties to provide an extension of the patent term when the marketing approval process unreasonably cuts into the effective term of a patent of a pharmaceutical product.

Enforcement: TPP Parties are obligated to provide mechanisms—including civil and administrative procedures and remedies, provisional measures, border measures, and criminal enforcement—to address many of the challenges of counterfeiting and piracy described in this Report, including digital IP theft and supply chains for the manufacture and distribution of counterfeit goods. The TPP requires Parties to adopt measures to address cable and satellite signal piracy and the unauthorized camcording of movies in theaters. Enforcement provisions are also designed to close loopholes exploited by counterfeiters in many countries and to target counterfeit products that pose threats to consumer health and safety. The TPP also ensures that border officials and enforcement authorities may act on their own initiative (*ex officio*) to identify and seize imported and exported counterfeit and pirated goods. Additionally, the TPP is the first trade agreement to clarify that Parties must subject state-owned enterprises (SOEs) to IP enforcement rules, subject to certain disciplines in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

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 2016, 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 2016, 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. The Special 301 Report is an important tool to engage with our trading partners to promote strong protection for U.S. creative and innovative industries, as well as to promote compliance with trade commitments. USTR actively employs the Special 301 process to identify and address key IPR challenges for American businesses and to document and encourage continued progress in countries that undertook important legislative and enforcement reforms following engagement under Special 301.

In the 2016 Special 301 Report released in April 2016, USTR highlighted serious and ongoing concerns with respect to the environment for IPR protection and enforcement in China, India, Indonesia, Russia, Ukraine, Argentina and other markets. USTR announced that it will conduct Out-of-Cycle Reviews to promote engagement and progress on IPR challenges identified in Colombia, Pakistan, Tajikistan, and Spain.

This Report reflects the Administration's continued resolve to encourage adequate and effective IPR protection and enforcement worldwide. The Report identifies a wide range of concerns, including: (a) the deterioration in IPR protection and enforcement in a number of trading partners; (b) reported inadequacies in trade secret protection in China, India, and elsewhere; (c) troubling "indigenous innovation" policies that may unfairly disadvantage U.S. right holders in markets abroad; (d) the continuing challenges of online copyright piracy; (e) measures that impede market access for U.S. products embodying IPR and 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 2016, the United States and Honduras agreed on an IP Work Plan under which the Government of Honduras committed to undertake a series of actions to strengthen the protection and enforcement of intellectual property. This breakthrough was reached after USTR carried out an Out-Of-Cycle Review of intellectual property protection in Honduras to increase engagement on IP enforcement and to determine if Honduras should be placed on USTR's Special 301 intellectual property Watch List.

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, and has published a List for every year since.

In the List, USTR highlights markets not only because they exemplify global concerns about counterfeiting and piracy, but also because the scale of infringing activity in such markets can cause significant economic harm to U.S. IPR holders. Some of the identified markets reportedly are host to a combination of legitimate and unauthorized activities. Others reportedly exist solely to engage in or facilitate unauthorized activity. The 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 or have been the focus of government enforcement efforts.

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, U.S. 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:

- A workshop on copyright policies, held in April 2016 in Alexandria, VA, which included the participation of numerous high-level officials from 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 committed 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 committed that CBP, and ICE and China Customs commit to continue deepening IPR enforcement cooperation, including by conducting working group meetings and joint operations on a regular basis, under the frameworks of their IPR enforcement agreements.

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 2016, 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 June 2016, the United States and several other WTO countries shared experiences and exchanged best practices, including their laws, policies and other IPR initiatives that advance resource conservation and emissions reductions, and how technological innovation features in such strategies. In March 2016, the United States and several other developed, developing and least-developed countries engaged in a detailed exchange regarding how their education policies catalyze innovation and creativity in terms of generating ideas as well as diffusing innovation and creativity. In October 2015, numerous WTO countries, including 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.

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 OECD, WIPO, APEC forum and various U.N. bodies. The Department of State supported research on an OECD publication (*Trade in Counterfeit and Pirated Goods)* that measured the economic impact of fake products on the global economy. U.S. Customs and Border Patrol (CBP) contributed data to the report.

In November 2016, the APEC leaders endorsed a set of Best Practices in Trade Secret Protection and Enforcement Against Misappropriation. The Best Practices document is the culmination of a multi-year initiative led by the United States with the support of APEC Leaders and Ministers, which also included a four-volume report on Trade Secrets Protection in APEC Economies. Recognizing the important role that trade secrets play in many industries, APEC economies identified eight best practices that will serve as a toolkit for good policy development across the region. Among these best practices are broad standing to claims for the protection of trade secrets and enforcement against trade secret theft; civil and criminal liability, as well as remedies and penalties, for trade secret theft; robust procedural measures in enforcement proceedings; and adoption of written measures that enhance protection against further disclosure when governments require the submission of trade secrets. These best practices also recognize the important role of appropriate safeguards, such as measures protecting good faith lawful disclosures to provide evidence of a violation of law. The Best Practices document is at https://ustr.gov/sites/default/files/11202016-US-Best-Practices-Trade-Secrets.pdf;

background information is at https://ustr.gov/about-us/policy-offices/press-office/press-releases/2016/november/obama-administration-welcomes-apec.

Additionally, in 2016, the United States reviewed the intellectual property laws and practices of Colombia, Costa Rica, and Lithuania as these countries seek to join the OECD. Latvia became a member of the OECD in June, 2016, indicating its IPR regime supports economic development and market openness similar to other Member States.

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.

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.

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 2016, CcIU agents made 8 arrests and secured 10 convictions. CcIU also submitted abuse complaints on over 4,500 websites with U.S. and foreign-based domain name registrars.

In addition, in February 2016, FDA entered into a confidentiality commitment with the British Columbia College of Pharmacists (CPBC). This agreement will serve as a mechanism for information sharing on joint cross-border efforts effecting public health.

Representatives from the pharmaceutical industry have introduced a new verified Top Level Domain (vTLD) ".pharmacy" as a secure and trustworthy TLD and a way of combating illegal online pharmaceutical companies. The registry would verify that the vTLD applicant is a

legitimate pharmaceutical company before it is given ".pharmacy." The vTLD will ensure that the medications the consumers are purchasing online are safe.

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 in 2010 as a method to disrupt this illegal online activity. ICC's strategy is focused on developing long-term 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 also coordinates with rights holders, who utilize civil and administrative remedies to shut down infringing sites.

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 November 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.

Most recently, in July 2016, Artem Vaulin was arrested in Poland, and charged in the U.S. with owning and operating Kickass Torrents (KAT), a commercial website that has enabled users to illegally reproduce and distribute hundreds of millions of copyrighted motion pictures, video games, television programs, musical recordings and other electronic media since 2008. According to the complaint, KAT's net worth has been estimated at more than $54 million, with estimated annual advertising revenue in the range of $12.5 million to $22.3 million. Vaulin's extradition from Poland is currently pending.

In addition, with respect to trade secret theft, 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 authorizes imposing sanctions on individuals or entities that engage in certain significant, malicious cyber-enabled activities, including those activities that have the purpose of causing a significant misappropriation of trade secrets for commercial or competitive advantage. 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 Xi Jinping of China agreed to a set of bilateral commitments on cyber, one of which was a commitment that neither government would conduct or knowingly support cyber-enabled theft of intellectual property, including trade secrets or other confidential business information, for commercial gain. 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.

17. Protect Intellectual Property at ICANN

The National Telecommunications and Information Administration (NTIA), in active collaboration with the USPTO, IPEC, and other Federal agencies, continued to advance the effective implementation by the Internet Corporation for Assigned Names and Numbers (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, 1,129 have been delegated; 176 are currently moving through the program; 577 applications have been withdrawn; and 48 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. These actions represent positive steps, and the Federal Government will continue to work

within the interagency and through the GAC process to further to support intellectual property rights through ICANN.

Additionally, NTIA, USPTO and IPEC continue to monitor the development of various private, voluntary best-practice initiatives to curtail different types of domain name abuse, including one initiative that is exploring the possibility of a dispute resolution mechanism to address copyright infringement disputes.

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 protect and enforce their IPR in foreign markets.

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 2016 continued to highlight the portal in its respective stakeholder outreach and roadshows.

For more than ten years, the USPTO Global Intellectual Property Academy (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, use and balanced 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 United States businesses better understand how they can protect against intellectual property infringement by actors located in other countries, including countries in which these firms are not doing business. In FY 2016, GIPA provided 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.

The Department of State 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

During FY 2016, IPEC coordinated with the State Department, Department of Labor (DOL), DHS, the IPR Center, and others (including private-sector stakeholders) 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 facilitated dialogue regarding how to obtain additional information on labor conditions associated with the manufacture and distribution of infringing goods.

This dialogue helped to inform the development of the recently-issued Joint Strategic Plan on Intellectual Property Enforcement (FY 2017-2019). The Joint Strategic Plan begins by addressing these labor conditions in Section I, which is the Plan's overview discussion of the current state of IP infringement (see the "Exploits Labor" discussion in Section I, which begins with the statement that: "The behind-the-scenes production of counterfeit goods often involves human rights violations, including the use of child labor, forced labor, human trafficking, long hours and dangerous "sweatshop" working conditions, and payment of unlawfully low wages that do not cover living expenses."). In addition, the Joint Strategic Plan addresses these labor conditions in Section IV. The labor conditions are one of the subject-areas that are addressed in the Section IV discussion on promoting the "enforcement of U.S. intellectual property rights through trade policy tools." And, one of the "Calls for Research" in Section IV is a request for public research on the "nexus between counterfeit trade and exploitative labor practices."

Going forward, as part of the implementation of the Joint Strategic Plan, IPEC will continue to facilitate this dialogue and collaboration between governmental entities, private-sector stakeholders, and others.

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 (Centers) have been heavily involved in the development and implementation of the trade intelligence concept, a CBP effort to establish formal linkages with the private sector to develop actionable intelligence. As part of these efforts, the Centers engage in continual dialogue, information sharing, and trend analysis (*e.g.*, with the pharmaceutical industry) in order to safeguard the American public from 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 FR 56370), and this rule was implemented during FY 2016. The rule adopted, with certain changes, the Interim Final Rule that CBP published on April 24, 2012 (77 FR 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, FDA, and United States Postal Inspection Service continued to conduct *Operation Safeguard* in FY 2016. *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. During FY 2016, *Operation Apothecary* resulted in 46 new cases, 32 arrests, 36 indictments, and 16 convictions, as well as 519 seizure incidents of counterfeit items.

CBP's IPR Policy and Programs Division has finalized an assessment report on the IPR Voluntary Abandonment Pilot, providing recommendations on the future of the program for Executive Leadership's review and approval. During the one-year assessment of the operation, aspects of the IPR Voluntary Abandonment Pilot were proven to be viable for implementation in future potential operational activities in the express and small packages environments. In FY 2016, CBP processed 3,763 shipments through the program, with an estimated cost savings to CBP of more than $3 million. The pilot ran only in the small package express environment.

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 products marketed as foods and/or dietary supplements containing undeclared drug ingredients. 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 international mail facilities. FDA-DIO is currently working to expand the use of both the CD3 and portable IMS to identify more potential counterfeit pharmaceuticals.

In May 2016, USPTO – in close partnership with DHS ICE – conducted two workshops on IP enforcement in the context of express-mail deliveries, at two international airports in Brazil. The programs were held in coordination with Brazilian Customs ("Receita Federal") and involved three days of training instruction, followed by two days of inspections of small consignments in cooperation with local and international express carriers. Participants included law enforcement officials from Brazil, as well as Colombia and China.

Operation Safeguard

Operation Safeguard mail blitzes are conducted by FDA, CBP and other partner government agencies (PGAs) on a regular, rotating schedule at the international mail facilities (IMFs.) Beginning in March, 2007, these blitzes have been conducted on a monthly basis, with few exceptions. The format for each blitz is based on the same premise: for each of 3 days, CBP reviews up to 100 mail parcels each day which are suspected to contain pharmaceuticals. This format provides an idea of the wide variety of pharmaceutical products that pass through each IMF. FDA participates by providing technical assistance to CBP and conducting an FDA admissibility review of each of the parcels referred as FDA-regulated articles. Upon review and examination, some parcels are subsequently referred to other PGAs as being articles under their jurisdiction, such as controlled substances to DEA. For those articles found to be subject to FDA jurisdiction and found to be violative, the articles are generally refused admission into the U.S. and returned to the sender, unless evidence is provided to overcome the violation. FDA will soon have a new enforcement tool to combat illegal drug importation when FDA

implements the authority granted to the agency to destroy violative drug products valued at less than $2,500, under section 708 of the Food and Drug Administration Safety and Innovation Act (FDASIA). FDA plans to implement this authority nationwide in FY2017.

In FY 2016, FDA participated in one or more *Operation Safeguard* blitzes in all nine of the international mail facilities throughout the country. During the FY 2016 blitzes, FDA examined a total of 1,840 parcels, containing 3,230 products, 2,442 of which were detained by FDA. Of those 2,442 detained articles, FDA refused admission to 2,249 violative articles and returned them to the sender. Based on additional evidence collected or provided by the responsible parties, FDA released 38 articles, while the balance of the lines (155) are still within FDA's detention & hearing process where the responsible parties may provide evidence to refute the violation.

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.

Additionally, the Verified Top-Level Domain Consortium (vTLD Consortium) is comprised of entities in the pharmaceutical, banking, insurance and medical communities. They held their initial meeting to establish this consortium on March 15, 2016 to explore how a restricted Generic Top Level Domain program can help secure consumer's safety and protection online. More specifically, the members of the vTLD Consortium have established a vetting process that is administered prior to any entity being granted access to one of their restricted TLDs. The vTLD Consortium currently administers the following vTLDs: ".Pharmacy," ".Bank," ".Insurance" and ".Med."

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.

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, in February 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 by three advertising organizations: the Association of National Advertisers (ANA); the American Association of Advertising Agencies (4A's); and the Interactive Advertising Bureau (IAB).

During FY 2016, there were significant developments involving the advertising industry. For example, TAG developed – and many firms have signed-onto – an "Anti-Piracy Pledge," under which an advertiser or ad agency "pledges to take commercially reasonable steps to minimize the inadvertent placement of digital advertising on websites or other media properties that have an undesired risk of being associated with the unauthorized dissemination of materials protected by the copyright laws and/or illegal dissemination of counterfeit goods." In December 2015, TAG announced that "many of the world's largest brand advertisers and agencies have pledged to require their ad partners to take aggressive steps to help fight the $2.4 billion lost to pirate sites each year." In a related anti-piracy development, TAG also discussed – in its December announcement – the progress that had been made in establishing "TAG-validated providers of anti-piracy services." In a subsequent update on the validation process, TAG stated that "TAG's anti-piracy program has moved into full public deployment." Another significant development was the announcement of an industry-wide anti-fraud program to fight digital ad fraud and bring new transparency across the digital ad ecosystem. The program "has two core and interlocking elements: the TAG Registry of legitimate advertisers and publishers . . . and a Payment ID system . . . that will connect all ad inventory to the entities receiving payments for the ads." Through the registry, "buyers will be able to ensure that they are working with trusted parties at every step of their campaigns, while the Payment ID system will ensure that payments only go to legitimate players, choking off the cash to criminals." TAG also launched the "Certified Against Piracy" Program that "helps marketers identify sites that present an unacceptable risk of misappropriating copyrighted content and selling counterfeit goods, and remove those sites from their advertising distribution chain." Under the Program, "TAG works with authorized independent third-party validators . . . to certify advertising technology companies as Digital Advertising Assurance Providers (DAAPs).

To be validated as a DAAP [and to obtain the "Certified Against Piracy" seal], companies must show they can provide other advertising companies with tools to limit their exposure to undesirable websites or other properties by effectively meeting one or more criteria." (The above information is available on TAG's website, which is at https://tagtoday.net/.)

An additional development has been increased public-private collaboration. A roundtable discussion was held in February 2016 that included TAG staff, the leadership of the IPR Center, and representatives from the FBI and ICE. The purpose of the roundtable was "to review priorities, set common goals and objectives and determine opportunities for successful collaboration." As ICE noted in its press release, key agencies "are collaborating with leading digital marketing associations to prevent digital advertising fraud, eliminate the spread of malware and fight online piracy." (The DHS/ICE press release of March 22, 2016, "IPR Center strengthens relationships to fight online crime," is at https://www.ice.gov/news/releases/ipr-center-strengthens-relationships-fight-online-crime. The roundtable discussion is also highlighted on the TAG website, at https://www.tagtoday.net/tag-partners-promote-industry-progress/.)

In addition, during FY 2016, a new initiative – to address large-scale piracy – was launched on domain name registry best practices. This initiative is a partnership between the Motion Picture Association of America (MPAA) and the Donuts and Redix domain name registry platforms. Under the program, a "trusted notifier" system has been established to mitigate blatantly illegal online activity. (See MPAA, "Donuts and the MPAA Establish New Partnership to Reduce Online Piracy," (February 9, 2016), at http://www.mpaa.org/wp-content/uploads/2016/02/Donuts-and-MPAA-Establish-New-Partnership-2.9.16.pdf , and MPAA, "Radix and the MPAA Establish New Partnership to Reduce Online Piracy," (May 13, 2016), at http://www.mpaa.org/wp-content/uploads/2016/05/Radix-and-the-MPAA-Establish-New-Partnership-to-Reduce-Online-Piracy.pdf.)

Voluntary Initiatives and Effectiveness

The 2013 Joint Strategic Plan on Intellectual Property Enforcement 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." USPTO has received public comments pursuant to a Federal Register notice, describing the purpose and policies of various initiatives (including online pharmacies, copyright alerts, payment processors, and ad networks), and has met with the participants in these initiatives to explore their functioning to date. IPEC and USPTO, with private sector and academic input, will promote benchmarking studies of current voluntary initiatives designed to combat revenue flow to rogue sites to determine whether existing voluntary initiatives are functioning effectively, and thereby promote a robust, data-driven voluntary initiative environment.

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 Center, 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. CBP has expanded a program to train port personal by having drug manufacturers and other industry partners to provide CBP with materials on how to identify counterfeit pharmaceuticals.

In addition, the Center 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 Center 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.

During FY 2016, *Operation Apothecary* resulted in 46 new cases, 32 arrests, 36 indictments, and 16 convictions, as well as 519 seizure incidents of counterfeit items. Other important efforts by the U.S. Government to curb the prevalence of counterfeit pharmaceuticals and medical devices include the following:

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

In FY 2016, U.S. law enforcement and Federal agencies, including the IPR Center through ICE HSI, CBP, and FDA, participated in *Operation Pangea IX*, a global enforcement effort led by INTERPOL that is aimed at disrupting organized crime networks behind the illicit online sale of fake drugs. *Operation Pangea IX* was conducted from May 3, 2016 – June 7, 2016 with the participation of 103 countries and 193 agencies, and culminated with a week of action from May 30 to June 7, 2016, when participating countries and agencies conducted and/or reported the results of their respective operations. On June 9, 2016, INTERPOL issued a press release highlighting the results of the Global Operation Pangea which resulted in 4,932 websites taken off line, 393 arrests worldwide, and 170,340 packages seized with an estimated value of $53.2 million worth of potentially dangerous medicines.

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 medical 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.

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>Drug Track and Trace</u>

FDA continues to implement provisions of the Drug Supply Chain Security Act (DSCSA) (Title II of the Drug Quality and Security Act) that was enacted on November 27, 2013. The DSCSA

helps to improve the security of the pharmaceutical distribution supply chain by building an electronic, interoperable system to identify and trace certain prescription drugs they are distributed in the United States by 2023, in addition to developing national standards for licensure of 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.

In FY 2016, the FDA issued two guidance documents that describe the agency's compliance policy on product tracing requirements for dispensers and transactions with first responders. These guidance documents are "DSCSA Implementation: Product Tracing Requirements for Dispensers – Compliance Policy Guidance for Industry (Revised)," published in November 2015, and "Requirements for Transactions With First Responders Under Section 582 of the Federal Food, Drug, and Cosmetic Act--Compliance Policy Guidance for Industry," published in February 2016. To help inform the development of FDA's pilot projects, FDA held a public workshop in April 2016 on potential pilot project objectives and evaluation methods to gain input from members of the supply chain on methods to enhance the safety and security of the supply chain. In addition, FDA conducted an intergovernmental meeting in November 2015 with State government officials to discuss implementation issues related to the DSCSA and to identify potential areas for FDA and state collaboration. To help stakeholders, FDA in February 2016 published "Frequently Asked Questions" on its DSCSA webpage that address product-tracing questions that the agency frequently receives. For updates about DSCSA implementation and copies of the guidance documents, see http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm.

Secure Supply Chain Pilot Program (SSCPP)

The Secure Supply Chain Pilot Program (SSCPP) was a voluntary program initiated in February 2014 to assist the FDA in its efforts to prevent the importation of adulterated, misbranded, or unapproved drugs. The goal of the program was 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. Upon completion of the pilot, in February 2016, FDA met with the participants to share lessons learned and exchange feedback which was overall positive. 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 Security

FDA is leading an effort under APEC to develop a Roadmap for Global Medical Product Quality and Supply Chain Security, with involvement from industry, regulatory authorities, and academia across the APEC economies. In February 2016, a five-day workshop was held during

APEC's first Senior Official's Meeting (SOM) in Lima, Peru. While workshops at previous SOMs centered around in-depth trainings on the various work group toolkits, this workshop shifted gears toward the creation of the comprehensive *Roadmap for Supply Chain Security* document and interactive tool. The comprehensive Roadmap document and tool will pull together the toolkits and trainings of the ten work groups and demonstrate how all parts of the supply chain fit together, ultimately serving as a guide for economies to develop their supply chain infrastructure.

FDA/World Health Organization (WHO) Global Surveillance and Monitoring System for Substandard, Spurious, Falsely-Labeled, Falsified, Counterfeit (SSFFC) Activities

FDA has supported the World Health Organization to establish the WHO Global Surveillance and Monitoring System for SSFFC Medical Products, a project within the scope of the WHO Member State Mechanism (MSMech) on SSFFC Medical Products. The purpose of the Monitoring System is to assist in determining: 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, 115 Member States, 350 regulatory personnel, and 18 international procurement agencies have been trained to report SSFFC information, creating a global network of professionals. So far, over 1250 products have been reported to the system, rolled out in 5 of the 6 WHO regions. The last region, South East Asia Regional Office, will be done in October 2016, through 13 regional workshops. WHO has issued 17 Global Medical Product Alerts and numerous regional warnings. Technical support has been provided in over 100 cases. The system is available in English, French, Spanish, and Portuguese. The online portal, search facility, and access to the photo library were rolled out to focal points in 2016. A smartphone application for easier reporting from healthcare professionals to national regulatory agencies is being piloted in the Regional Office for Africa in 2016.

In addition to supporting the Global Surveillance and Monitoring System, in 2016, FDA provided resources and technical expertise on related activities within the MSMech on SSFFC Medical Products. Such activities include 1) the development of recommendations for Health Authorities engaged in the detection of SSFFC medical products and a tool-generating program to contribute to Member States' training; 2) a survey of technologies, methodologies, and "track and trace" models; 3) recommendations for effective risk communication and awareness campaigns on SSFFC medical products; 4) a study of the socio-economic and public health impact of SSFFC medical products; and 5) refining SSFFC working definitions.

Consumer Education

BeSafeRx

In FY 2016, FDA continued the BeSafeRx campaign by marketing public service announcements (PSA) on television, radio and the Internet. 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. Overall, in FY 2016, the television PSA aired 6,275 times, garnering 70.5 million impressions. Digital radio yielded 15.3 million impressions. In doctors' waiting rooms, the PSA aired 2.13 million times, garnering 13.5 million impressions. The BeSafeRx campaign garnered an estimated 100.8 million total gross impressions.

Outreach to Health Care Providers

On May 7, 2015, TC Medical pleaded guilty to orchestrating a multi-year conspiracy to smuggle misbranded prescription pharmaceuticals into the United States. From 2011 through 2014, the company smuggled orthopedic injections, rheumatology infusions, cosmetic devices, ophthalmology products, and oncology drugs into the United States from foreign countries.

On March 21, 2016, FDA sent more than 1400 letters to medical practices in the United States that purchased unapproved prescription drug(s) and/or injectable devices (products) from TC Medical. On March 30, 2016, FDA mailed different letters to over 100 doctors/clinics who purchased products from TC Medical and had *also* purchased from a different unlicensed distributor previously. FDA's letters provided a list of unapproved drugs and devices sold by TC Medical until 2014. Both letters are posted on FDA's website at http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm439169.htm, along with the names of the medical practices (doctors/clinics) that were issued a letter.

Counterfeit/Unapproved Drugs Public Health Alerts

On May 12, 2016, FDA informed health care professionals that a counterfeit version of the FDA approved cancer drug, BiCNU (carmustine for injection), had been detected in some foreign countries. There was no indication that counterfeit BiCNU had entered the legitimate U.S. drug supply chain. However, as an added precaution, FDA provided product photos and affected lot numbers and advised health care professionals to carefully inspect the BiCNU vial to ensure the product administered to patients was authentic. More information can be found here: http://www.fda.gov/Drugs/DrugSafety/ucm500705.htm.

Enforcement Actions

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

Operation Pangea

In June 2016, FDA contributed to the success of efforts under INTERPOL's *Operation Pangea IX* initiative, an operation that involved 115 participating countries. The FDA's Office of Criminal Investigations, Office of Regulatory Affairs, and Center for Drug Evaluation and Research participated in the enforcement action, which ran from May 31 to June 7, 2016. The FDA conducted extensive inspections of packages at International Mail Facilities (IMFs) in

coordination with U.S. Customs and Border Protection, and sent formal complaints to domain registrars requesting the suspension of the 4,402 websites. Included are 110 websites that sell the chemical 2,4-Dinitrophenol (DNP) as a weight-loss product. FDA inspectors collaborated with other federal agencies to screen and detain illegal drug products received through IMFs in San Francisco, Chicago, and New York. For FDA's part, these screenings resulted in the detention of 797 parcels which, if found to violate the Federal Food, Drug, and Cosmetic Act, will be refused admission into the country. FDA also issued warning letters to the operators of 53 websites illegally offering unapproved and misbranded prescription drug products for sale to U.S. consumers. *See* "FDA targets unlawful internet sales of illegal prescription medicines during International Operation Pangea IX" (June 9, 2016), at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm505921.htm.

Data-Driven Government

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

In FY 2016, the U.S. Copyright Office continued to provide substantial assistance and support to the House of Representatives Committee on the Judiciary ("House Judiciary Committee") on a range of issues in connection with Congress' comprehensive review of U.S. copyright law and enforcement mechanisms. As noted in the FY 2015 annual report, the 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-takedown regime).

At the last review hearing in April 2015, Register Pallante provided the U.S. Copyright Office's perspective on the copyright review, identifying issues that were ripe for legislative action, as well as several topics that may require more study and public engagement. During the hearing, the House Judiciary Committee's Ranking Member asked the U.S. Copyright Office to conduct studies of Sections 512 and 1201 of Title 17 as well as the issue of moral rights for authors.

In December 2015, the U.S. Copyright Office published requests for public comment in the Federal Register initiating studies of Sections 512 and 1201 as well as a study on software-enabled consumer products, which was requested by the Senate Committee on the Judiciary. S*ee* "Software-Enabled Consumer Products Study: Notice and Request for Public Comment," 80 FR 77668 (Dec. 15, 2015); "Section 1201 Study: Notice and Request for Public Comment," 80 FR 81369 (Dec. 29, 2015); "Section 512 Study: Notice and Request for Public Comment," 80 FR 81862 (Dec. 31, 2015). Access to the Federal Register notices, public comments, and roundtable transcripts for all of the U.S. Copyright Office's active studies are available through the Office's website at http://www.copyright.gov/policy/.

The Section 512 study was undertaken to evaluate the current impact and effectiveness of the Copyright Act's notice-and-takedown system and safe harbor provisions. In particular, the study is examining how successfully Section 512 addresses online infringement, facilitates digital innovation, and protects free speech. More than 92,000 submissions were received during the first round of public comments, filed by a variety of stakeholders, including large and small creators and service providers, users, and academics. In May 2016, the Office held public roundtables in New York and San Francisco and heard from over 130 participants. The Office is seeking further input through a second round of public comments that will help the Office craft its final report to Congress focused on striking the proper balance between effective online protection for copyrighted works and stimulating innovation.

The U.S. Copyright Office is also conducting a study to assess the operation of the anti-circumvention provisions of Section 1201 of Title 17, including the triennial rulemaking process to adopt exemptions to the Copyright Act's prohibition against circumvention of technological measures that control access to copyrighted works. As noted above, the Office published a notice in the Federal Register in December 2015 seeking public comment, including on several issues that the Office had identified as being ripe for review. Stakeholders submitted 84 total comments in two rounds of public comment. The Office received further input in May 2016 through public roundtables held in Washington, D.C. and San Francisco. In September 2016, the Office published a notice in the Federal Register seeking an additional round of written comments and written reply comments, due in October and November 2016, respectively, and the Office received a total of 57 additional comments. *See* "Section 1201 Study: Request for Additional Comments," 81 FR 66296 (Sept. 27, 2016). The Office is in the process of evaluating the public comments and is in the early stages of developing its report to Congress to improve the operation of the rulemaking process and underlying provisions.

In April 2016, the Copyright Office partnered with the George Mason University School of Law and its Center for the Protection of Intellectual Property to host a full-day public symposium on the protection of moral rights for authors. The symposium provided an opportunity for practitioners, members of the public, and other interested parties to gain a detailed understanding about the goals and development of moral rights both in the United States and internationally. The Office is now preparing a notice of inquiry seeking public input on a variety of questions related to moral rights in the United States.

In addition to the active studies, the U.S. Copyright Office issued a report on "The Making Available Right in the United States" in February 2016, fulfilling a request from Congress made in FY 2014. The "making available" right is the exclusive right of authors to authorize the "making available to the public of works in such a way that members of the public may access these works from a place and time individually chosen by them." This right was internationally recognized in two World Intellectual Property Organization ("WIPO") treaties in 1996, collectively, the WIPO Internet Treaties. Concluding that the existing exclusive rights enumerated in Section 106 of the U.S. Copyright Act already provided such protection, Congress ratified and implemented the WIPO Internet Treaties in 1998 without expressly adopting a new "making available" right. Some courts, however, have questioned the existence of the right under U.S. law, ultimately failing to recognize a cause of action where

copyright owners cannot prove that downloads or receipt of the work occurred. The Copyright Office report re-affirmed the long-standing U.S. government position that copyright owners have the authority under the Copyright Act to authorize on-demand transmissions of their works to the public, including at a time and place chosen by the particular members of the public. Moreover, the report underscored that copyright owners have the right to assert infringement claims based on the making available right, meaning that courts cannot dismiss such claims, including those based on "the offer of public access" as opposed to proof of "whether a copy has been disseminated or received." The report notes the centrality of the making available right to infringement litigation in the digital age, emphasizing the need for clear and consistent evidentiary rules for bringing a *prima facie* infringement case and the critical role of the courts in ensuring the balance between protection and limiting overbroad claims that would impede innovation. The Copyright Office's 2016 report is available at https://www.copyright.gov/docs/making_available/making-available-right.pdf, and all other current policy reports are available at https://copyright.gov/policy/policy-reports.html.

In addition, the Commerce Department's Internet Policy Task Force, in its White Paper on "Remixes, First Sale, and Statutory Damages: Copyright Policy, Creativity, and Innovation in the Digital Economy" (discussed above), made recommendations regarding statutory damages and the first sale doctrine. The Task Force's report recommended amending the Copyright Act to incorporate a list of factors for courts and juries to consider when determining the amount of a statutory damages award. In addition, it suggested changes to remove a bar to eligibility for the Act's "innocent infringer" provision, and to lessen the risk of excessively high statutory damages in the context of secondary liability for online service providers. The report also noted that some concerns raised about damages levels in cases against individuals could be alleviated if Congress were to establish a small claims tribunal with caps on damages awards. With respect to the first sale doctrine, the report concluded that the evidence did not establish a need for changes to the Copyright Act at this time. However, it did recommend the development of best practices by stakeholders to improve consumers' understanding of the terms of online transactions involving creative works, and it noted the need to continue to monitor legal and marketplace developments to ensure that library lending and preservation concerns are addressed. In addition, the White Paper encouraged stakeholders – creators, publishers, and Internet users alike – to develop a set of guidelines for the fair use of copyrighted works in remixes.

In May 2016, the Defend Trade Secrets Act (DTSA; Pub. L. No. 114-153) was enacted, providing for a federal civil cause of action for trade secret misappropriation. USPTO provided technical assistance to Congress and worked within the Administration and with stakeholders to help enact the DTSA.

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

The USPTO Office of Chief Economist, in collaboration with the DOC Economics & Statistics Administration, updated the 2012 report on IP-intensive industries. Issued in September 2016, the new report – "Intellectual Property and the U.S. Economy: 2016 Update" – builds on the 2012 report by using the most recent data to assess the impact of IP and by taking a fresh look

at the approach used to measure those results. The 2016 update continues to focus on measuring the intensity of IP use, and its persistent relationship to economic indicators such as employment, wages, value added, and exports. In 2014, IP-intensive industries directly and indirectly supported 45.5 million jobs, about 30 percent of all U.S. employment. Private wage and salary workers in IP-intensive industries continue to earn significantly more than those in non-IP-intensive industries. In 2014, workers in IP-intensive industries earned an average weekly wage of $1,312, 46 percent higher than the $896 average weekly wages in non-IP-intensive industries in the private sector. Between 2010 and 2014, the value added by IP-intensive industries increased substantially, both in total amount and as a share of GDP. The 2016 update reinforces the earlier finding that protecting intellectual property is vital to maintaining the incentives for research and development and driving our economic prosperity. The 2016 update is available at https://www.uspto.gov/learning-and-resources/ip-motion/intellectual-property-and-us-economy.

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

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 explains, 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. As indicated in the 2014 and 2015 annual reports, IPEC considered this issue further as part of the development of the three-year Joint Strategic Plan that was issued in December 2016.

Performance Data

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

In FY 2016, the number of IPR seizures increased more than nine percent to 31,560 from 28,865 in FY 2015. The total estimated Manufacturer's Suggested Retail Price (MSRP) of the seized goods, had they been genuine, increased to $1.383 billion.

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

In FY 2016, the top three categories of Health, Safety, and Security seizures were Pharmaceuticals/Personal Care, Consumer Electronics, and Critical Technology Components. The total number of seizures in these three categories was 4,233, which is over 86 percent of the 4,897 of Health, Safety, and Security seizures made during FY 2016.

- ***Seizures Across Shipping Environments***

In FY 2016, there were 28,689 seizures in the express consignment and international mail environments (approximately 91% of all seizures).

- ***Seizures of Circumvention Devices***

In FY 2016, there were 70 seizures of circumvention devices that violate the Digital Millennium Copyright Act.

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

In FY 2016, there were 52 seizures for violations of ITC Exclusion Orders, which had a total estimated MSRP of $3,254,654.

B. Law Enforcement Investigations and Prosecutions

- ***FBI***

At the end of FY 2016, the FBI had 269 pending IPR investigations with the following areas of focus:

- 82 investigations of theft of trade secrets
- 28 investigations of copyright infringement related to software
- 56 investigations of other copyright infringement
- 33 investigations of trademark infringement
- 8 investigations of copyright infringement related to signal theft
- 9 investigations of counterfeit aircraft parts
- 13 investigations of counterfeit electrical parts
- 7 investigations of counterfeit automotive parts

- 31 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 2016:

  - 52 new investigations initiated
  - 29 arrests
  - 28 information/indictments
  - 28 convictions
  - Seizures totaling $1,080,224
  - Forfeitures totaling $428,594
  - Restitution totaling $4,341,557
  - FIRE (Frozen, Indicted, Restrained, Encumbered) totaling $1,628,394

- ***ICE HSI***

  In FY 2016, ICE HSI initiated 863 intellectual property investigations and had 451 arrests, 304 indictments, and 272 convictions.

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

  In FY 2016, the IPR Center vetted 31,406 investigative leads; of these, 17,507 were referred to law enforcement partners. Additionally, the IPR Center de-conflicted 3,704 investigative targets for partner agencies and industry. While performing these de-conflictions, the IPR Center identified 359 "blue on blue" situations where two or more entities were investigating the same target. Finally, the IPR Center referred 611 leads to private industry for follow-up.

- ***DOJ FY 2016 Intellectual Property Prosecutions***[2]

District Totals	FY2010	FY 2011	FY2012	FY2013	FY2014	FY2015	FY2016
Investigative Matters Received by AUSAs	402	387	390	334	256	229	243
Defendants Charged	259	215	254	213	200	161	104
Cases Charged	177	168	178	163	142	102	77
Defendants Sentenced	207	208	202	205	184	160	73
No Prison Term	121	102	95	96	92	89	41
1-12 Months	38	27	46	35	30	26	12
13-24 Months	27	33	26	29	30	23	8
25-36 Months	10	17	15	21	14	7	3
37-60 Months	7	21	17	19	13	7	6
60 + Months	4	8	3	5	5	8	3

[2] Case statistics were compiled by the Executive Office for United States Attorneys (EOUSA). The chart includes data on criminal cases/defendants where the following charges were brought as any charge against a defendant: 17 U.S.C. §506 (criminal copyright infringement); 17 U.S.C. §§ 1201 to 1205 (circumvention of copyright protection systems); 18 U.S.C. §§ 1831 (economic espionage) & 1832 (theft of trade secrets); 18 U.S.C. § 2318 (counterfeit labeling); 18 U.S.C. § 2319 (criminal copyright infringement); 18 U.S.C. §2319A (live musical performance infringement); 18 U.S.C. § 2319B (unauthorized recording of motion pictures); 18 U.S.C. § 2320 (trafficking in counterfeit goods); and 47 U.S.C. §§ 553 or 605 (signal piracy). The statutes were grouped together in the data run in order to eliminate any double-counting of cases and/or defendants where more than one statute was charged against the same defendant. However, this chart may not include cases or defendants if only a conspiracy to violate one of these offenses was charged. (Note regarding the figures for FY 2015: These figures have been revised, based on a further review, from the FY 2015 figures that were in the annual report for FY 2015.)

The chart below depicts FY 2016 statistics for criminal IP cases based on type of charge.[3]

Charge	Cases charged	Percentage
Trademark *Trafficking in counterfeit goods, 18 U.S.C. § 2320*	55	71%
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*	 10 6 1	 13% 8% 1%
Economic Espionage Act *Economic espionage, 18 U.S.C. § 1831* *Theft of trade secrets, 18 U.S.C. § 1832*	 1 5	 1% 6%
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	**78**	**100%**

C. DOJ Intellectual Property Prosecutions FY 2016, by Statute

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

1. ***Brothers Sentenced for $12.9 Million Software Piracy Scheme.*** On August 10, 2016, Donnetto Deantoni, 44, of St. Michael, Minnesota, was sentenced to one year and one day in prison for his role in a $12.9 million software piracy scheme. Deantoni was also ordered to forfeit over $4.4 million in proceeds and to pay the victim, Autodesk, Inc., over $12.9 million in restitution. Donnetto Deantoni's brother, Deonnetti Deantoni, who led the conspiracy, was sentenced to 40 months in prison in April, and ordered to pay over $6.5 million in forfeiture and over $7.7 million in restitution. Donnetto Deantoni pleaded guilty on April 12. According to court documents, over the course of a 26 month conspiracy the brothers conspired to distribute pirated versions of nearly $13 million worth of copyrighted

[3] The Executive Office for United States Attorneys (EOUSA) 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 https://www.justice.gov/iptf/pro-ip-act-reports.

engineering and design software belonging to Autodesk, Inc. They sold this software to engineering firms at deeply discounted prices using websites designed to make the software appear legitimate and went to great lengths to conceal their scheme. For example, the brothers interacted with customers under the false name "Monica Simpson," and created a false entity, the "National Software Licensing Association," to endorse their products. (https://www.justice.gov/usao-edva/pr/brothers-sentenced-129-million-software-piracy-scheme)

2. ***U.S. Authorities Charge Owner of Most-Visited Illegal File-Sharing Website with Copyright Infringement.*** On July 20, 2016, Artem Vaulin, 30, of Kharkiv, Ukraine, was arrested in Poland and charged by criminal complaint, filed in U.S. District Court in Chicago, with one count of conspiracy to commit criminal copyright infringement, one count of conspiracy to commit money laundering and two counts of criminal copyright infringement. The United States will seek to extradite Vaulin to the United States. He is the alleged owner of the most visited illegal file-sharing website and U.S. authorities have seized domain name registrations associated with the website. According to the complaint, Vaulin allegedly owns and operates Kickass Torrents or KAT, a commercial website that has enabled users to illegally reproduce and distribute hundreds of millions of copyrighted motion pictures, video games, television programs, musical recordings and other electronic media since 2008. The copyrighted material is collectively valued at well over $1 billion, according to the complaint. The complaint alleges that KAT receives more than 50 million unique visitors per month and is estimated to be the 69th most frequently visited website on the Internet. (https://www.justice.gov/opa/pr/us-authorities-charge-owner-most-visited-illegal-file-sharing-website-copyright-infringement)

3. ***Chinese National Indicted for Software Piracy Scheme.*** On June 29, 2016, Wen Tao Liu, also known as Orland Liu, 36, a citizen of the People's Republic of China, was charged in a four-count indictment that replaces a federal criminal complaint filed against Liu on June 13, 2016, and contains additional charges. Liu, was arrested on June 15, 2016, at Dallas Fort Worth International airport before his return flight to China. Liu allegedly obtained and sold counterfeit, illicit, and/or unauthorized Microsoft software, software products and related components, including unauthorized product key codes and counterfeit product key cards, causing the Microsoft Corporation millions of dollars in losses. According to an affidavit filed in support of the original criminal complaint, investigators identified at least 4,659 individual product activation key codes distributed by Liu to various resellers across the United States, which were collectively activated over 36,000 times. Microsoft had already blocked 1,111 of those keys due to suspicions of piracy and 2,267 of the keys were already identified in the course of other Microsoft fraud investigations. Microsoft's loss from the repeated activations of the 4,659 product keys could total approximately $9 million. In addition to the conspiracy, the indictment charges Liu with one count of trafficking in counterfeit goods, one count of smuggling goods into the United States, and one count of the entry of goods by means of false statements. (https://www.justice.gov/usao-wdmo/pr/chinese-national-indicted-software-piracy-scheme)

4. ***Beaver Falls Man Pleads Guilty to Wire Fraud and Copyright Infringement.*** On June 6, 2016, Michael K. See, 34, of Beaver Falls, Pennsylvania, pleaded guilty to charges of wire fraud and copyright infringement. In connection with the guilty plea, the court was advised that from in and around January 2010, to in and around January 22, 2015, See purchased and imported copyright infringing DVDs of television shows and movies. See then sold these copyright infringing DVDs on eBay. See was sentenced to five years of probation in November 2016. (https://www.justice.gov/usao-wdpa/pr/beaver-falls-man-pleads-guilty-wire-fraud-and-copyright-infringement)

5. ***Arkansas Man Pleads Guilty to Selling Counterfeit Garmin Maps.*** On May 23, 2016, William Yates, 26, Fort Smith, Arkansas, pleaded guilty to one count of copyright infringement. In his plea, he admitted selling map products that were copyrighted by Garmin. Garmin International, Inc. is located in Olathe, Kansas. Yates sold counterfeit Garmin map cards on eBay, Amazon and Craigslist. An investigator with the FBI purchased cards from Yates. He sold at least 874 counterfeit map products for more than $23,000. The products were valued at more than $67,000. (https://www.justice.gov/usao-ks/pr/arkansas-man-pleads-guilty-selling-counterfeit-garmin-maps)

6. ***Bahamas Man Pleads Guilty To Hacking Scheme To Steal Celebrities' Copyrighted And Personal Information.*** On May 9, 1916, Alonzo Knowles pled guilty to criminal copyright infringement of scripts of movies and television shows that had not yet aired, as well as identity theft of personal identification information, all of which Knowles obtained by hacking into the personal e-mail accounts of numerous individuals in the entertainment, sports, and media industries (the "Victims"). As a result of his hacking scheme, Knowles obtained the Victims' copyrighted and confidential documents, including scripts of movies and television shows that had not yet been publicly released, personal identifying information such as Social Security numbers, and private sexually explicit photographs and videos. Over the course of two weeks in December 2015, Knowles and an undercover law enforcement agent (the "UC") communicated about the material Knowles sought to sell to the UC. On December 21, 2015, Knowles met with the UC in New York, New York, and described two methods he used to hack each Victim's e-mail account. Knowles attempted to sell numerous movie and television scripts and personal identifying information that he had unlawfully obtained from the Victims to the UC in exchange for thousands of dollars, whereupon Knowles was arrested. (https://www.justice.gov/usao-sdny/pr/bahamas-man-pleads-guilty-hacking-scheme-steal-celebrities-copyrighted-and-personal)

7. ***Conspirators in Two Android Mobile Device App Piracy Groups Plead Guilty.*** On May 2, 2016, Aaron Blake Buckley, 22, of Moss Point, Mississippi, pleaded guilty to one count of conspiracy to commit criminal copyright infringement and to one count of criminal copyright infringement for his role in a scheme to distribute more than four million pirated copies of copyrighted Android apps with a total retail value of more than $17 million. Gary Edwin Sharp II, 29, of Uxbridge, Massachusetts, a co-conspirator, pleaded guilty to one count of conspiracy to commit criminal copyright infringement on January 13, 2016. According to statements made in court, the conspirators identified themselves as members

of the Applanet Group. From May 2010 through August 2012, they conspired to reproduce and distribute more than four million copies of copyrighted Android apps through the Applanet alternative online market without permission from the victim copyright owners, who would otherwise sell copies of the apps on legitimate online markets for a fee. On August 21, 2012, the FBI seized the Applanet website, which marked the first seizure of the domain name for a website involving a mobile device app marketplace. Buckley is scheduled to be sentenced in January 2017, and Sharp is scheduled to be sentenced in February 2017. (https://www.justice.gov/opa/pr/conspirators-two-android-mobile-device-app-piracy-groups-plead-guilty-0)

8. ***Three Sentenced for Extensive Counterfeit Media Conspiracy in Central Valley.*** On May 2, 2016, Efrain Lozada Rosas, 34, and Victor Flores Fuentes, 39, both of San Jose, were sentenced to 50 months incarceration respectively for criminal copyright infringement and related crimes. On the same day, Jesus Cuevas Lopez, 25, of Southern California, was sentenced to 21 months incarceration for the same crimes. Rosas, Fuentes and Lopez had pleaded guilty on December 7, 2015. On the same day, another co-defendant, Edgar Hipatl Rodriguez, 36, of San Jose, was sentenced to twenty-seven months in prison for his role in the counterfeit media conspiracy. 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, including movie titles that were in theatrical release and not yet available for legitimate sale on DVD. (https://www.justice.gov/usao-edca/pr/three-plead-guilty-one-sentenced-extensive-counterfeit-media-conspiracy-central-valley)

9. ***Baltimore Man Sentenced for Illegally Reproducing and Distributing Copyrighted Movies.*** On April 22, 2016, Dwayne Scott, 55, of Baltimore, Maryland, was sentenced to three years of probation and ordered to pay $15,001.00 in restitution. On December 10, 2015, Scott pleaded guilty to copyright infringement in connection with his reproduction and distribution of copyrighted works, including movies. According to his plea agreement, Scott was a corporate officer and registered agent of Hard Times Discount Clothing and Accessories in Baltimore. On four occasions between September 11, 2012 and August 6, 2015, law enforcement executed search warrants at Hard Times. On each occasion, law enforcement seized large numbers of CDs and DVDs of copyrighted works, which Scott had reproduced and distributed without the permission of the copyright holders. In addition, law enforcement located laptop computers actively downloading copyrighted movies from Internet file sharing programs. (https://www.justice.gov/usao-md/pr/baltimore-man-pleads-guilty-copyright-infringement-illegally-reproducing-and-distributing)

10. ***Louisiana Man and His Harahan-Based Company Sentenced for Manufacturing and Selling Pirated Mercedes-Benz Software.*** On January 14, 2016, Rainer Wittich, 66, of River Ridge, and his Harahan, Louisiana-based aftermarket auto parts distributor, The Brinson Company ("TBC"), were each sentenced after previously pleading guilty to criminal copyright infringement and conspiracy to commit criminal copyright infringement and to violating the Digital Millennium Copyright Act, respectively. Wittich and TBC were sentenced to five

years of probation. In addition, TBC was ordered to forfeit $150,000 and assist the victim, Daimler AG (parent company of Mercedes-Benz), in compiling a list of all customers to whom it provided the infringing devices or software, and Wittich was ordered to pay a $3,000 fine. According to court documents, Wittich owned TBC, which sold replacement parts and diagnostic equipment for Mercedes-Benz vehicles. 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. (https://www.justice.gov/usao-edla/pr/river-ridge-man-and-his-harahan-based-company-sentenced-manufacturing-and-selling)

11. ***New Orleans Man Sentenced to 41 Months for Manufacturing and Selling More Than $1 Million in Counterfeit Coupons on Silk Road.*** On January 13, 2016, Beau Wattigney, 30, of New Orleans, was sentenced to 41 months in prison for his role in a coupon counterfeit ring using the Silk Road online marketplace. Wattigney previously pleaded guilty to conspiracy to commit wire fraud and conspiracy to commit trademark counterfeiting. Wattigney admitted that between May 2012 and November 2014, he used the online monikers PurpleLotus, GoldenLotus and CouponKing to sell counterfeit coupons for various goods and services on the Silk Road, a covert online marketplace largely for illicit goods. According to the plea agreement, Wattigney sold over $1 million worth of counterfeit coupons and victimized more than 50 United States-based businesses. (https://www.justice.gov/opa/pr/new-orleans-man-sentenced-41-months-manufacturing-and-selling-more-1-million-counterfeit)

12. ***Prattville Man Pleads Guilty to Copyright Infringement.*** On January 11, 2016, Ivory Vernell Nevels, 53, entered a plea of guilty to criminal copyright infringement and possession of counterfeit currency. Nevels, who referred to himself as "Mr. Everything," had a store in Prattville, Alabama, known as Stack A Dollar. At Stack A Dollar, Nevels sold counterfeit handbags, purses, wallets, watches, and other goods which bore counterfeit marks. During the investigation, federal agents executed a search warrant at Stack A Dollar and seized approximately $160,000 in counterfeit goods. Nevels also illegally copied copyrighted music and movies, and sold these recordings at his store. Nevels was sentenced to seven months in prison in June 2016. (https://www.justice.gov/usao-mdal/pr/prattville-man-pleads-guilty-copyright-infringement)

13. ***Operation Software Slashers: Six Defendants Plead Guilty to $100 Million Software Piracy Scheme.*** On December 16, 2015, Rex Yang Jr., 37, of Seattle, waived his right to a grand jury and pleaded guilty to a federal information that charged him with participating in a criminal conspiracy from January 1, 2009, to December 10, 2014. Yang, who owned and operated Digisoft LLC and Premiere Software Inc., is the sixth and final defendant to plead guilty in separate, but related, in this stage an ongoing criminal investigation that originated with a Kansas City, Missouri, company. The multimillion-dollar scheme, which involved co-conspirators operating overseas in the People's Republic of China, Singapore, and Germany

and across the United States, illegally sold millions of dollars of Microsoft Corporation and Adobe Systems Inc. software product key codes through a charitable organization and several online businesses. Product key codes are used to obtain full access to unlocked, licensed versions of various copyrighted software programs. The conspirators distributed more than 170,000 product activation key codes and many of these key codes were each used and activated numerous times. Investigators seized more than $20.6 million in assets, including $10,188,777 seized from bank and investment accounts, and 10 luxury automobiles and 27 parcels of real estate with a total market valuation of $9,739,399, through federal forfeitures. Affidavits filed in those forfeiture complaints estimate that conspirators reaped about $30 million in profits from customers who paid more than $100 million for the software. Search warrants have been executed at 13 separate residential and business locations in five different states in the course of this investigation. Yang is scheduled to be sentenced in 2017. (https://www.justice.gov/usao-wdmo/pr/six-defendants-plead-guilty-100-million-software-piracy-scheme)

14. ***Operator of Second-Largest Music Piracy Cyberlocker in United States Sentenced to 36 Months in Prison for Criminal Copyright Infringement.*** On November 17, 2015, Rocky P. Ouprasith, 23, of Charlotte, North Carolina, was sentenced to 36 months in prison, two years of supervised release, and was ordered to forfeit $50,851.05 and pay $48,288.62 in restitution. On August 21, 2015, Ouprasith pleaded guilty to one count of criminal copyright infringement. 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 – including "pre-release" songs that were not yet commercially available to consumers – from online sources and 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. According to the Recording Industry Association of America, in 2013, RockDizFile.com was the second-largest online file-sharing website specializing in the reproduction and distribution of infringing copies of copyrighted music in the United States. In October 2014, federal law enforcement authorities shut down RockDizMusic.com and RockDizFile.com, and law enforcement authorities in the Netherlands and France seized file-hosting servers utilized by Ouprasith. According to court documents, the market value of Ouprasith's illegally-pirated material was more than $6 million. (https://www.justice.gov/opa/pr/operator-second-largest-music-piracy-cyberlocker-united-states-sentenced-36-months-prison)

15. ***Metairie Man Sentenced After Pleading Guilty to Recording Movies in a Local Theater and Criminal Infringement of a Copyright.*** On November 4, 2015, Derrick Holloway, 32, of Marrero, Louisiana, was sentenced after previously pleading guilty to a two-count Bill of Information charging him with unauthorized recording of a motion picture and criminal infringement of a copyright. Holloway was sentenced to serve four years of probation with

the first eight months in home confinement. Holloway was fined $1,000 and ordered to pay restitution in the amount of $12,539.66. According to court documents, in 2014, Holloway used a digital camcorder to record approximately ten first-run motion pictures, and 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 out from his business, Gold Teeth Kingz. Specifically, during the execution of a search warrant at Gold Teeth Kingz in early January 2015, law enforcement authorities found and seized approximately 2,932 pirated DVDs containing copyrighted motion pictures and 749 pirated CDs containing copyrighted musical works. (https://www.justice.gov/usao-edla/pr/metairie-man-sentenced-after-pleading-guilty-recording-movies-local-theater-and)

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

1. ***Louisiana Man and His Harahan-Based Company Sentenced for Manufacturing and Selling Pirated Mercedes-Benz Software.*** On January 14, 2016, Rainer Wittich, 66, of River Ridge, and his Harahan, Louisiana-based aftermarket auto parts distributor, The Brinson Company ("TBC"), were each sentenced after previously pleading guilty to criminal copyright infringement and conspiracy to commit criminal copyright infringement and to violating the Digital Millennium Copyright Act, respectively. Wittich and TBC were sentenced to five years of probation. In addition, TBC was ordered to forfeit $150,000 and assist the victim, Daimler AG (parent company of Mercedes-Benz), in compiling a list of all customers to whom it provided the infringing devices or software, and Wittich was ordered to pay a $3,000 fine. According to court documents, Wittich owned TBC, which sold replacement parts and diagnostic equipment for Mercedes-Benz vehicles. 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. (https://www.justice.gov/usao-edla/pr/river-ridge-man-and-his-harahan-based-company-sentenced-manufacturing-and-selling)

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

1. ***Virginia Man Sentenced for Smuggling Fake Apple and Samsung Products.*** On September 23, 2016, Bao Doan, 32, of Falls Church, Virginia, was sentenced to one year and one day in prison for conspiring to traffic in counterfeit Apple and Samsung products and smuggling. Doan was also ordered to forfeit over $115,000 in proceeds and to pay Apple and Samsung over $20,000 in restitution. Doan was found guilty by a federal jury on June 16, after a three-day trial. According to evidence presented at trial and sentencing, Doan operated the conspiracy from his store, called iFaifo, in Falls Church. Over the course of approximately two years, Doan received hundreds of shipments containing counterfeit Apple and Samsung products from co-conspirators in China and Hong Kong, and then distributed these items wholesale to stores in the area. Since October 2014, Doan received several warnings to

cease and desist from both U.S. Customs and Border Protection and representatives from Apple and Samsung. Rather than heed these warnings, Doan developed new ways to evade customs, such as by having counterfeit goods sent to his home address under his mother's name. (https://www.justice.gov/usao-edva/pr/falls-church-man-sentenced-smuggling-fake-apple-and-samsung-products)

2. ***Online Seller Of Counterfeit Luxury Items Sentenced.*** On September 22, 2016, David Joseph Gruber, 53, of Jacksonville Beach, Florida, was sentenced to 30 months in federal prison for conspiracy to traffic in counterfeit goods, conspiracy to commit money laundering, and failure to appear. The Court also ordered him to forfeit three pieces of real property located in Jacksonville, which are traceable to proceeds of the offenses. Further, the U.S. Immigration and Customs Enforcement has administratively forfeited $42,217.94 from accounts held by Gruber, which were further proceeds of his offenses. Gruber pleaded guilty in March 2016. According to court documents, from at least as early as April 2007 through March 2014, Gruber, aka "China Dave," owned and operated a website through which he and his wife sold goods and products bearing counterfeit trademarks owned by Burberry, Gucci, Louis Vuitton, Chanel, Juicy Couture, Rolex, Hermes, Dolce & Gabbana, Versace, Tiffany & Co., Prada, Coach, Breitling, Nike, and Fifth & Pacific Companies. The products included handbags, watches, shoes, and clothing. Gruber's wife, Xiao Ling Liu, aka Shally Gruber, was also charged for her role in this case. She remains a fugitive. (https://www.justice.gov/usao-mdfl/pr/online-seller-counterfeit-luxury-items-sentenced-federal-prison)

3. ***Owner of Major Online Colored Contact Lens Business Pleads Guilty.*** On September 8, 2016, Dmitriy V. Melnik, of Las Vegas, the owner and operator of Candy Color Lenses, a major online retailer of colored contact lenses in the United States, pleaded guilty to running an international operation importing counterfeit and misbranded contact lenses from suppliers in Asia and then selling them over the internet without a prescription to tens of thousands of customers around the country. According to the plea agreement, Melnik imported large quantities of colored contact lenses from the People's Republic of China and South Korea that he knew were counterfeit and/or unauthorized by the FDA for sale in the United States. Melnik sold "authentic" contact lenses to tens of thousands of customers around the United States without a prescription, adequate directions for use and adequate warnings. Melnik admitted that some of the contact lenses he sold were tested and found to be contaminated with potentially hazardous bacteria. As stated in the plea agreement, Melnik received at least $1.2 million in gross revenue from this illegal enterprise. (https://www.justice.gov/opa/pr/owner-major-online-colored-contact-lens-business-pleads-guilty-largest-ever-investigation)

4. ***Pennsylvania Man Convicted of Distributing Dangerous Counterfeit Viagra and Cialis.*** On August 15, 2016, Victor Lamar Coates, of Philadelphia, Pennsylvania, pleaded guilty to conspiring with convicted co-conspirator Martez Gurley, 41, of Napa, California, to traffic in counterfeit and misbranded Viagra and Cialis, and introducing those drugs in interstate

commerce. Coates admitted to illegally distributing at least 10,288 counterfeit and misbranded tablets, including tablets he illegally imported directly from China. FDA, Eli Lilly and Company and Pfizer Inc. conducted testing on the counterfeit tablets which revealed the tablets did not contain the ingredients listed on the labeling. Some of the Viagra tablets contained the compound 2-MBT, an ingredient not part of authentic Viagra. Sentencing is scheduled for November 2016. Gurley was convicted in June 2015 for his role in the conspiracy. Sentencing for both Coates and Gurley is scheduled for December 2016. (https://www.justice.gov/usao-sdtx/pr/second-trafficker-convicted-distributing-dangerous-counterfeit-viagra-and-cialis)

5. ***Three Chinese Nationals Convicted of Trafficking in Counterfeit Computer Chips.*** In December 2015, three Chinese nationals (Daofu Zhang, Jiang Yan, and Xianfeng Zuo) were arrested in connection with a scheme to obtain and illegally export sophisticated semiconductors stolen from the U.S. military. On March 7, 2016, Yan pleaded guilty to one count of conspiracy to traffic in counterfeit goods, and one count of attempt to export integrated circuits ("ICs") without the required export license. On March 16, 2016, Zuo pleaded guilty to one count of conspiracy to traffic in counterfeit goods. On April 15, 2016, Zhang pleaded guilty to conspiring to sell counterfeits of sophisticated integrated circuits to a purchaser in the United States.

   On July 8, 2016, Zhang was sentenced to 15 months imprisonment. On November 4, 2016, Zuo was sentenced to 15 months imprisonment. On December 20, 2016, Yan was sentenced to approximately 12 months imprisonment. They also forfeited $63,000 in cash seized incident to arrest.

   According to court documents and statements made in court, the three co-conspirators each operated businesses in China that bought and sold electronic components, including ICs. In the summer of 2015, Zuo asked Yan to locate and purchase several advanced ICs made by Xilinx Corp., which had military applications, including radiation tolerance for uses in space. Yan then asked a U.S. individual to locate the Xilinx ICs and sell them to Yan. The U.S. individual explained that the ICs cannot be shipped outside the U.S. without an export license, but Yan still wished to make the purchase. When the U.S. individual expressed concern that the desired ICs would have to be stolen from military inventory, Yan proposed to supply the U.S. source with "fake" ICs that "look the same," to replace the ones to be stolen from the military. In November 2015, Zhang shipped from China, to the U.S. individual, two packages containing a total of eight counterfeit ICs, each bearing a counterfeit Xilinx brand label. After further discussions between Yan and the U.S. individual, Yan, Zhang, and Zuo flew together from China to the U.S. in early December 2015 to complete the Xilinx ICs purchase. On December 10, 2015, the three conspirators drove to a location near Route 95 in Milford, Connecticut, where they planned to meet the U.S. individual, make payment, and take custody of the Xilinx ICs. Federal agents arrested all three at the meeting location.
   (https://www.justice.gov/usao-ct/pr/citizen-china-who-attempted-illegal-export-advanced-military-computer-chips-sentenced; https://www.justice.gov/usao-ct/pr/citizen-china-

sentenced-15-months-prison-trafficking-counterfeit-computer-chips-0; https://www.justice.gov/usao-ct/pr/citizen-china-sentenced-15-months-prison-trafficking-counterfeit-computer-chips; https://www.justice.gov/usao-ct/pr/citizen-china-pleads-guilty-trafficking-counterfeit-computer-chips; https://www.justice.gov/usao-ct/pr/three-chinese-nationals-arrested-scheme-steal-and-illegally-export-military-grade)

6. ***Storeowner Admits Selling Drug Paraphernalia, Counterfeit Sports Hats.*** On June 23, 2016, Akhil Mishra, 72, of Glenshaw, Pennsylvania, pleaded guilty to charges of selling and offering for sale drug paraphernalia, conspiracy to sell and offer for sale drug paraphernalia, and trademark counterfeiting. In February 2013, agents executed search warrants at the Mishra family businesses (Giggles and Rock America), and at the homes of both Akhil Mishra and his son, Mayank Mishra, and found evidence of drug paraphernalia, including products used to dilute heroin, glassine stamp bags for packaging heroin, various marijuana-related paraphernalia, and more than $900,000 in cash. Based on information received from a confidential informant (CI), agents obtained another set of search warrants for Mayank Mishra's business and home. Once again, agents seized additional heroin cutting agents, glassine bags, marijuana paraphernalia, and cash ($86,000). The arrest of his son did not stop Akhil Mishra from continuing to sell cut and stamp bags to heroin dealers. The agents received information that Akhil Mishra was continuing to sell that merchandise, and a CI was able to make a controlled purchase from his store in June 2014. That evidence led to the execution of a third set of search warrants at various locations associated with the Mishra family and their businesses in July 2014. Once again, the agents found cut, stamp bags, and marijuana-related paraphernalia. Separate and apart from the drug paraphernalia investigation, investigators with the Pennsylvania State Police received information that Akhil Mishra was selling counterfeit Major League Baseball hats. In December 2014, an investigator entered Giggles and observed counterfeit Pittsburgh Pirates winter hats and baseball hats. On February 25, 2015, the same investigator purchased a counterfeit Pittsburgh Pirates winter hat. The following day, Pennsylvania State Police investigators obtained and executed a search warrant at Giggles, resulting in the seizure of the following counterfeit merchandise. In August 2016, Mishra was sentenced to time served, and ordered to forfeit over $1 million in U.S. currency as well as additional property. (https://www.justice.gov/usao-wdpa/pr/storeowner-admits-selling-drug-paraphernalia-counterfeit-sports-hats)

7. ***Metairie Man Pleads Guilty to Trafficking in Over $150,000 in Counterfeit Goods.*** On June 16, 2016, Boubacar Diallo, 36, of Metairie, Louisiana, was sentenced after previously pleading guilty on October 30, 2015, to trafficking in counterfeit goods. Diallo was sentenced to five years of probation and ordered to pay restitution as follows: $760.65 to Polo by Ralph Lauren; $980 to Louis Vuitton; $400 to Hermes; and $170 to Nike. According to court documents, on March 12, 2015, investigators with the Office of the Attorney General Investigation Division and agents with the ICE-HSI, acting on information that Diallo was involved in the purchase and subsequent sale of large quantities of counterfeit merchandise, met Diallo at his residence in Metairie. Law enforcement officials observed

numerous cardboard boxes full of counterfeit merchandise. They subsequently verified as counterfeit apparel and accessories with a collective fair market value of approximately $158,049. (https://www.justice.gov/usao-edla/pr/metairie-man-sentenced-trafficking-over-150000-counterfeit-goods)

8. ***Coconut Grove Resident Sentenced to Two Years in Prison for Trafficking in Counterfeit Goods, Concealing Assets and Money Laundering.*** On June 14, 2016, a Coconut Grove resident was sentenced to 24 months in prison, to be followed by two years of supervised release following her conviction for trafficking in counterfeit merchandise, concealing assets, and laundering money. Tatiana F. Tascon, 40, previously pled guilty to trafficking in counterfeit goods, concealing assets, and money laundering. As part of Tascon's sentence, the defendant agreed to forfeit $78,949.45, as well as two properties in Miami, Florida. According to court documents, Tascon trafficked in counterfeit goods, including high-end designer handbags, wallets and watches, out of a showroom in her Coconut Grove residence. In the defendant's bankruptcy filings the defendant failed to report that she had earned over $700,000 from her illicit counterfeit goods business. Tascon laundered the earnings from her illegal business through the bank accounts of third parties. (https://www.justice.gov/usao-sdfl/pr/coconut-grove-resident-sentenced-two-years-prison-trafficking-counterfeit-goods)

9. ***Five Charged In National Counterfeit Perfume Ring.*** On May 25, 2016, Patrick Badal, Kaium Shah, Kenny Ni, Abul Kashem, and Parvez Shazzed were arrested for participating in a scheme to distribute counterfeit perfumes in New York and around the United States. All are charged with one count of trafficking in counterfeit packaging. Badal and Shah are also charged with smuggling goods into the United States. From December 2014 to May 2016, the defendants and others imported generic liquid fragrances from China, separately imported boxes and packaging bearing counterfeit trademarks from China, packaged the generic liquid fragrances into the branded and trademarked packaging, and then sold counterfeit perfumes to wholesalers in New York and at least six other states. (https://www.justice.gov/usao-sdny/pr/5-charged-national-counterfeit-perfume-ring)

10. ***Grand Prairie Man Sentenced for His Role in Counterfeit Goods Trafficking Conspiracy.*** On May 16, 2016, Evan Patterson, 31, of Grand Prairie, Texas, was sentenced to 24 months imprisonment, two years supervised release, and ordered to pay $27,670.07 in restitution. On October 13, 2015, Patterson pleaded guilty to his role in a conspiracy to traffic counterfeit goods. According to documents filed in the case, from approximately January 2010 through December 2013, Patterson and a co-defendant conspired together to traffic in counterfeit clothing, apparel, and accessories. Patterson and his co-defendant displayed and sold the counterfeit goods to customers at a showroom and warehouse located in Grand Prairie, and also established and maintained at least 17 websites where customers could order and pay for the goods online. (https://www.justice.gov/usao-ndtx/pr/grand-prairie-man-admits-role-counterfeit-goods-trafficking-conspiracy)

11. ***Chinese Citizen Admits Selling $1.5 Million in Counterfeit Cell Phone Parts.*** On May 11, 2016, Hongwei "Nick" Du, a Chinese national, pleaded guilty to conspiring to traffic in counterfeit goods and related money laundering charges. According to the plea agreement, Du sold at least $1.5 million worth of counterfeit Chinese cell phone parts from Shenzhen to Spanish national Octavio Cesar Sana, in order to supply Sana's former business, "Flexqueen.com." Du was arrested on February 3, 2015 at the Imperial Valley Airport. Du had traveled to the United States from Shenzhen in order to meet with Sana and others to coordinate further counterfeit trafficking ventures. According to the plea agreement, since 2007, Sana's businesses sold approximately $6.5 million in cell phone parts and accessories to businesses and consumers throughout the United States. In turn, Sana paid approximately $3.1 million to Du, his primary Chinese supplier. Du admitted that roughly half of those parts were counterfeit. Sana pled guilty to similar charges in September 2015, and, in July 2016, was sentenced to 41 months in prison. In August 2016, Du was sentenced to 36 months in prison, and was ordered to forfeit $1.5 million. (https://www.justice.gov/usao-sdca/pr/chinese-citizen-admits-selling-15-million-counterfeit-cell-phone-parts)

12. ***Saugus Store Owner and Brother Sentenced for Trafficking in Counterfeit iPhone Components.*** On May 4, 2016, Mickey Punjabi, 36, was sentenced to six months of home incarceration, two years of probation, 200 hours of community service and a fine of $7,500. His brother, Hitesh Punjabi, 33, was sentenced to three months of home confinement, two years of probation, 100 hours of community service and a fine of $7,500. Both men were jointly ordered to pay restitution of $114,751 and forfeit assets seized from their home, which includes over $200,000 in cash and cash equivalents. In January 2016, the men were charged with conspiring to traffic in counterfeit goods, specifically iPhone components. Micky Punjabi, who owned the store, was also charged with trafficking in the counterfeit Apple components. From December 2010 to February 2015, the Punjabis sold counterfeit Apple merchandise at Accessory Depot. Micky Punjabi also repaired genuine iPhones using counterfeit components purchased from sources outside the United States and from a supplier within the United States. (https://www.justice.gov/usao-ma/pr/saugus-store-owner-and-brother-sentenced-trafficking-counterfeit-iphone-components)

13. ***Rhode Island Man Sentenced to Prison for Trafficking in Counterfeit Viagra from China.*** On March 31, 2016, Ricky Lugo, 49, was sentenced to a year and a day in prison and ordered to pay restitution of $104,239 for trafficking in counterfeit prescription medications. In October 2015, he was charged with four counts of trafficking in counterfeit versions of erectile dysfunction medications. From June 2013 to March 2014, Lugo sold counterfeit Viagra, Cialis, and Levitra on Craigslist and in person. Lugo purchased the counterfeit pharmaceuticals from sources outside the United States, including from China. (https://www.justice.gov/usao-ma/pr/rhode-island-man-sentenced-prison-trafficking-counterfeit-viagra-china)

14. ***Central Coast Man Pleads Guilty to Federal Copyright Infringement Offense Related to Online Sales of Pirated Adobe Software Packages.*** On March 21, 2016, Jeffrey Scott Patterson, 52, pleaded guilty to trafficking in counterfeit goods using two websites to market and sell counterfeit versions of Adobe software. Patterson admitted that, over the course of approximately eight years, he used two websites to advertise and sell counterfeit Adobe software at prices below retail. The software sold by Patterson – sometimes under the assumed name of "Bruce Allen" – included Adobe Acrobat, Adobe Photoshop and Adobe Creative Suite. Patterson offered victims either a digital download or a CD version of the pirated Adobe software. To bypass Adobe's security protocols, Patterson altered the software and used a "key generator" to give his customers a counterfeit "key code" that must be entered by a user when the software is installed on a computer. Sentencing has been set for January 2017. (https://www.justice.gov/usao-cdca/pr/central-coast-man-pleads-guilty-federal-copyright-infringement-offense-related-online)

15. ***New York Man Sentenced to Federal Prison for Selling Counterfeit Merchandise.*** On February 22, 2016, Yahya Jawad, age 57, from Binghamton, New York, was sentenced to 41 months' imprisonment and three years of supervised release after a September 29, 2015, guilty plea to one count of trafficking in counterfeit goods. Jawad had sold counterfeit merchandise at a "Clearance Sale" located on 16th Ave. S.W. in Cedar Rapids, Iowa. In a plea agreement, Jawad admitted that on January 9, 2015, he was selling counterfeit merchandise at a "Clearance Sale." Law enforcement officers purchased a pair of counterfeit headphones and two counterfeit purses from the defendant. After confirming that the items were counterfeit, law enforcement officers returned to the "Clearance Sale" and seized additional counterfeit items, including more headphones and purses, as well as other clothing items. In total, law enforcement seized more than $150,000 worth of counterfeit merchandise. Evidence at the sentencing hearing also established that in December 2015, while on release pending sentencing, Jawad ran a similar "Liquidation Sale" in Topeka, Kansas. Law enforcement in Kansas also conducted a search of this sale, and seized more than $280,000 worth of additional counterfeit merchandise. (https://www.justice.gov/usao-ndia/pr/new-york-man-sentenced-federal-prison-selling-counterfeit-merchandise)

16. ***Nebraska Man Sentenced for Counterfeit iPad Return Scam.*** On February 17, 2015, Ernesto Leyva, 27, of Lincoln, Nebraska, was sentenced to 15 months in prison, three years of supervised release and ordered to pay $27,745.33 in restitution. Leyva was indicted in July 2015, and subsequently pleaded guilty in October 2015, to one count of conspiracy to traffic in counterfeit goods and transport stolen goods. Co-defendants, Yoan Sanchez Rodriguez, 26, and Yulaisy Dominguez, 27, were also charged in the same conspiracy. Between December 2012 and December 2013, Leyva engaged in a conspiracy to purchase genuine iPads from Walmart and Target and then return counterfeit iPads to the stores, for a full refund. He would then resell the genuine iPads. The scheme began shortly after Christmas in 2012 and was concentrated on Walmart stores in the Northeast (Massachusetts, New Jersey, New Hampshire, Maine, and Connecticut) between December

2012 and February 2013, and Target stores in Florida in July 2013. The total retail losses to both store chains were over $80,000. Leyva was arrested in Nebraska in July 2015, and in October 2015, the case was transferred for a plea and sentencing from the District of Massachusetts to the District of Nebraska. Defendants Rodriguez and Dominguez are fugitives. (https://www.justice.gov/usao-ma/pr/nebraska-man-sentenced-counterfeit-ipad-return-scam)

17. ***Charleston Man Pleads Guilty to Trafficking in Counterfeit Sports Apparel.*** On January 28, 2016, Kenneth Wayne Wilkinson, age 59, of Charleston, plead guilty to a single-count information charging him on January 11, 2016, with trafficking in counterfeit sports apparel in 2012 and 2013. (https://www.justice.gov/usao-sc/pr/charleston-man-charged-trafficking-counterfeit-sports-apparel)

18. ***Pakistani Convicted in U.S. District Court in Denver Following Indictment and Arrest for Sale and Distribution of New, Misbranded and Counterfeit Prescription Drugs***. Junaid Qadir, age 33, of Karachi, Pakistan, was charged with multiple counts of illegal importation and sale of misbranded and unapproved drugs, some of which are further alleged to have been counterfeit or controlled substances, and all of which were manufactured overseas and shipped to the United States. Qadir was indicted by a federal grand jury in Denver on August 22, 2012. A superseding indictment was obtained on June 25, 2015. He was arrested in spring of 2015 in Germany. He appeared on January 28, 2016, for arraignment, where he entered a pro-forma not guilty plea, and was ordered held in custody without bond pending a resolution. According to court documents, Qadir and his brother, Shehzad, who is not in custody, are principals of a family owned and operated business in Karachi, Pakistan, known as JNS Impex. This company held itself out to be, among other things, a leading and long-standing exporter of branded and generic pharmaceutical drugs and surgical products. They falsely claimed it had access to and could supply most brand name pharmaceutical products; that it was affiliated with many multinational pharmaceutical manufacturers; and that it was licensed to distribute and export over-the-counter, prescription and narcotic pharmaceutical drugs. It was part of the conspiracy that Junaid Qadir, acting in concert with his brother and others known and unknown, used advertisements on Internet websites on behalf of their prescription drug distribution company JNS Impex and through business-to-business Internet website platforms, to solicit orders for a variety of brand name and generic pharmaceutical prescription, mostly in commercial and wholesale quantities. The defendants would take in orders over the Internet primarily from individuals and entities operating Internet pharmacy websites and other types of illicit pharmacy operations who, in turn, were undertaking to sell these drugs to their retail customers without valid prescriptions from licensed medical professionals. As part of the conspiracy, the defendants, using a series of email addresses, would forward the drug orders to a network of drug suppliers in Pakistan, India, the United Kingdom, and China. The illegal drugs imported by the defendants include counterfeit or unapproved versions of Viagra, Lorazepam, Alprazolam, Diazepam, Zolpidem, and Phentermine. Qadir was sentenced to 24 months in prison in October 2016.

(https://www.justice.gov/usao-co/pr/pakistani-man-makes-appearance-us-district-court-denver-following-indictment-and-arrest)

19. ***San Joaquin County Man Charged with Trafficking in Counterfeit Sports Apparel and Other Counterfeit Goods.*** On January 14, 2016, a federal grand jury returned a two-count indictment against Seyyed Ali Noori, 48, of Mountain House, charging him with trafficking and attempted trafficking in counterfeit goods. According to court documents, Noori owned and operated Goldstar Wholesale LLC, a wholesale and retail business selling apparel, accessories and other goods. He stored Goldstar's inventory in a warehouse in Tracy and sold Goldstar's goods from the warehouse and also from a reserved space at the Galt Flea Market. Court documents allege that in December 2013, Noori intentionally trafficked and attempted to traffic in goods that had counterfeit trademarks belonging to the Oakland Raiders, the San Francisco 49ers, the San Francisco Giants, and Monster Energy. (https://www.justice.gov/usao-edca/pr/san-joaquin-county-man-charged-trafficking-counterfeit-sports-apparel-and-other)

20. ***"Purse Man" Pleads Guilty to Trafficking Counterfeit Goods.*** On November 30, 2015, Lassana Nianghane, 52, of Philadelphia, Pennsylvania, pleaded guilty to trafficking in counterfeit goods. Nianghane had been charged on September 30, 2015, by an information. Nianghane, also known as "the Purse Man," sold counterfeit women's designer purses and counterfeit sneakers, among other items, on the sidewalk near Germantown and Chelten Avenues in Philadelphia. According to the information, between September 2011 and June 2014, Nianghane intentionally trafficked in approximately $127,200 worth of counterfeit goods. (https://www.justice.gov/usao-edpa/pr/purse-man-charged-trafficking-counterfeit-goods)

21. ***Former Rosemead Resident Sentenced to nearly Five Years in Federal Prison for Trafficking in Counterfeit Marlboro Cigarettes.*** On November 24, 2015, Su Qin Yang, 45 and former resident of the San Gabriel Valley, and a major distributor of counterfeit cigarettes in the Los Angeles area, was sentenced to nearly five years in federal prison for trafficking in counterfeit goods, and ordered to pay $308,894 in restitution to Phillip Morris USA. The investigation in this case started after Phillip Morris USA brought information related to the trafficking of counterfeit Marlboro cigarettes to federal authorities. When searches were conducted, authorities seized approximately 27,500 cartons of counterfeit cigarettes and approximately $440,000 in cash. She was named in an indictment returned by a federal grand jury in August 2013. Also charged in the 16-count indictment was Yang's husband, Antonio Limbeek. While engaged in discussions with prosecutors in 2012 about potentially pleading guilty, Yang and Limbeek "fled the country, leaving their minor children behind," according to the government's sentencing memo. "Thereafter, [Yang] arranged for her minor children to be transported to Washington State and then flown to China, attempting to smuggle over $300,000 in additional cash with them." Yang pleaded guilty in May 2015 to one count of trafficking in counterfeit goods, and admitted in her plea agreement that she trafficked in almost 4 million counterfeit Marlboro cigarettes and almost 4,000

counterfeit Viagra pills. The counterfeit products were seized during searches of Yang's residence and storage locations. Limbeek remains a fugitive and is believed to be in Indonesia. (https://www.justice.gov/usao-cdca/pr/former-rosemead-resident-sentenced-nearly-five-years-federal-prison-trafficking)

22. ***Delaware County Businessman Sentenced For Selling Counterfeit Goods.*** On November 19, 2015, Stephen Voudouris, Sr., 60, of Newtown Square, Pennsylvania, was sentenced to a year and a day in prison and six months home detention pursuant to his prior guilty plea to conspiracy, trafficking in counterfeit goods, smuggling counterfeit goods, and wire fraud. In addition, the defendant was ordered to pay $150,346 in restitution to the victim companies and individuals, as well as a fine of $10,000. Voudouris owned and operated Misikko.com, headquartered in Newtown Square, Pennsylvania, an online retailer of luxury hair care appliances, including flat irons and blow dryers. Voudouris admitted that he sought out Chinese manufacturing companies from which he and his employees could purchase cheap goods bearing counterfeit trademarks of CHI, T3 and Babyliss, and then resold the counterfeit goods to the American public. In addition, at the direction of Voudouris, in a scheme to drive consumers to their website and maximize profits, Misikko.com also purported to sell "Breast Cancer Awareness" products, for which $25 from every purchase would allegedly benefit a prominent breast cancer foundation, but no donations were ever made to a breast cancer charity. (https://www.justice.gov/usao-edpa/pr/delaware-county-businessman-sentenced-selling-counterfeit-goods)

23. ***Husband And Wife Charged In Manhattan Federal Court With Conspiring To Traffic Millions Of Dollars' Worth Of Counterfeit Goods.*** On October 15, 2015, defendants Le Fu Chen, 40, and Hai Fan Huang, 36, of Roslyn Heights, New York, were each charged with one count of conspiring to traffic in counterfeit goods, and one count of trafficking in counterfeit goods. According to the allegations in the complaint, from at least in or about November 2014 up to and including in or about October 2015, Chen and Huang, who are husband and wife, imported counterfeit luxury and designer brand goods into the United States from China. On October 15, 2015, federal law enforcement agents conducted searches of Chen and Huang's storage units, business suites, and residence, and found over 130,000 pieces of luxury and designer brand counterfeit goods, including watches and jewelry. In October 2016, Chen and Huang each pleaded guilty to conspiring to traffic in counterfeit goods. Also in October 2016, Chen was sentenced to 24 months in prison, and Huang was sentenced to one year of probation. Both defendants were ordered to pay $2,961,428 in restitution. (https://www.justice.gov/usao-sdny/pr/husband-and-wife-charged-manhattan-federal-court-conspiring-traffic-millions-dollars)

24. ***Massachusetts Man Sentenced to 37 Months in Prison for Trafficking Counterfeit Military Goods.*** On October 6, 2015, Peter Picone, 42, of Methuen, Massachusetts, was sentenced to 37 months in prison for importing thousands of counterfeit integrated circuits (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. In addition to his prison term, Picone

was ordered to pay $352,076 in restitution to the 31 companies whose ICs he counterfeited, and to forfeit $70,050 and 35,870 counterfeit ICs. In April 2005, Picone founded Tytronix Inc., and served as its president and director until August 2010, when the company was dissolved. In addition, from August 2009 through December 2012, Picone owned and operated Epic International Electronics (Epic) and served as its president and director. On June 3, 2014, Picone pleaded guilty to trafficking in counterfeit military goods. Picone admitted that, from February 2007 through April 2012, first through Tytronix and later through Epic, he purchased millions of dollars' worth of ICs bearing the counterfeit marks of approximately 35 major electronics manufacturers from suppliers in China and Hong Kong. (https://www.justice.gov/opa/pr/massachusetts-man-sentenced-37-months-prison-trafficking-counterfeit-military-goods-0)

Trade Secret Theft (18 U.S.C. § 1832)

1. ***Local Chemical Engineer Must Pay Approximately $4 Million in Restitution for Unlawfully Possessing Trade Secrets.*** On August 19, 2016, a Ph.D. chemical engineer from Sunnyvale, Texas, Dr. Mattias Tezock, 53, who admitted unlawfully possessing trade secrets from his former employer, Voltaix LLC, was ordered to pay approximately $4 million in restitution to this former employer as part of the five-year term of probation that resulted from his guilty pleas. The trade secrets at issue concerned the manufacture, synthesis, and purification of germane gas, a specialty chemical used in the semiconductor and solar energy industries. In August 2015, Tezock pleaded guilty to four counts of unlawful possession of a trade secret. Voltaix terminated Tezock's employment in September 2005. (https://www.justice.gov/usao-ndtx/pr/local-chemical-engineer-must-pay-approximately-4-million-restitution-unlawfully)

2. ***Glendale Man Sentenced for Stealing and Distributing Avionics Trade Secrets Belonging to Former Employer.*** On June 6, 2016, Derek Wai Hung Tam Sing, 44, an electrical engineer from Glendale, California, was sentenced to one year and one day in prison. He was found guilty in January 2016 (following a bench trial in September 2015) of 32 counts of violating the Economic Espionage Act for stealing trade secrets belonging to his former employer – a Pasadena-based aircraft avionics company – and distributing the proprietary material to three competitors. Sing worked at Rogerson Kratos (RK) in 2012, and, until he was fired by the company, Sing had access to RK trade secrets. After being terminated, Sing retained materials that he had collected while working at RK, despite being specifically asked to return all trade secrets. Instead, Sing prepared packages that included schematics of RK products and prepared a "readme" document that explained the importance of the proprietary information and instructed competitors to reverse engineer the products. Using email addresses created under a false name and a public Wi-Fi connection, Sing sent the stolen trade secrets in early 2013 to other companies that produced avionics, including a company outside of the United States. Sing also used physical flash drives to send the trade secrets to companies. (https://www.justice.gov/usao-cdca/pr/glendale-man-who-stole-and-distributed-trade-secrets-belonging-former-employer)

3. ***Irvine Engineer Named in New Indictment Alleging Theft of Trade Secrets from Two Medical Device Companies.*** On May 11, 2016, a federal grand jury issued a superseding indictment charging an Irvine, California, engineer with stealing and possessing trade secrets belonging to two former employers, both of which develop and manufacture medical devices used to treat cardiac and vascular ailments. Wenfeng Lu, 43, of Irvine, was named in the 12-count superseding indictment. The indictment alleges that Lu stole the confidential and proprietary trade secrets from two different medical device companies with research facilities in Irvine, where Lu worked from January 2009 until he was arrested in 2012. During this time, Lu travelled to the People's Republic of China (PRC) multiple times – sometimes soon after allegedly downloading trade secrets from an employer's computer and emailing information to his personal email account. Lu was arrested as he prepared to board a plane to the PRC. (https://www.justice.gov/usao-cdca/pr/irvine-engineer-named-new-indictment-alleging-theft-trade-secrets-two-medical-device)

4. ***Chinese National Pleads Guilty to Conspiring to Steal Trade Secrets.*** On January 27, 2016, Mo Hailong, aka Robert Mo, 46, pleaded guilty to conspiracy to steal trade secrets. According to the plea agreement, Hailong admitted to participating in long-term conspiracy to steal trade secrets from DuPont Pioneer and Monsanto. Hailong further admitted to participating in the theft of inbred – or parent – corn seeds from fields in the Southern District of Iowa for the purpose of transporting those seeds to China. The stolen inbred seeds constitute the valuable intellectual property of DuPont Pioneer and Monsanto. During the conspiracy, Hailong was employed as director of international business of the Beijing Dabeinong Technology Group Company, a Chinese conglomerate with a corn seed subsidiary company, Kings Nower Seed. Hailong is a Chinese national who became a lawful permanent resident of the United States. In October 2016, Hailong, was sentenced to 36 months in prison for conspiracy to steal trade secrets, and ordered to pay restitution in an amount to be determined at a later date. In addition, the Court ordered the forfeiture of two farms in Iowa and Illinois that were purchased and utilized by Mo Hailong and others during the course of the conspiracy. (https://www.justice.gov/opa/pr/chinese-national-sentenced-prison-conspiracy-steal-trade-secrets; https://www.justice.gov/opa/pr/chinese-national-pleads-guilty-conspiring-steal-trade-secrets)

5. ***Scientists Indicted For Allegedly Stealing Biopharmaceutical Trade Secrets.*** On January 20, 2016, an indictment was filed charging five people in an alleged scheme to steal biopharmaceutical trade secrets from pharmaceutical company GlaxoSmithKline (GSK). Charged in the conspiracy were Yu Xue, 45, of Wayne, Pennsylvania; Tao Li, 42, of Nanjing, China; Yan Mei, 36, of Nanjing, China; Tian Xue, 45, of Charlotte, North Carolina; and Lucy Xi, 38, of West Lake Village, California. The indictment includes charges of conspiracy to steal trade secrets, conspiracy to commit wire fraud, conspiracy to commit money laundering, theft of trade secrets, and wire fraud. Yu Xue and Lucy Xi were scientists working at GSK's research facility in Upper Merion, Pennsylvania. According to the indictment, the defendants engaged in a scheme to steal trade secrets related to GSK research data, procedures, and manufacturing processes for biopharmaceutical products.

Many of the biopharmaceutical products targeted were designed to treat cancer or other serious diseases. Yu Xue, Tao Li, and Yan Mei formed a corporation in China called Renopharma allegedly to market and sell the stolen trade secret information. (https://www.justice.gov/usao-edpa/pr/scientists-indicted-allegedly-stealing-biopharmaceutical-trade-secrets)

6. ***Chinese Businessman Charged With Theft Of Trade Secrets.*** On October 1, 2015, Xiwen Huang, 55, of Charlotte, North Carolina, was charged with one count of theft of trade secrets. According to court documents, from about 2006 through May 2015, Huang engaged in a scheme to steal trade secrets from multiple companies within the United States, and intellectual property from the United States government, to further his aspirations of forming and operating his own company in the People's Republic of China (China). From approximately December 2004 until he was fired by his employer in approximately March 2014, court records show that Huang stole proprietary and confidential information, including trade secret information and other intellectual property belonging to a government research facility and two United States companies, with the intent to use the stolen information for the economic benefit of himself, a Chinese company, and others. Court documents show that upon being fired in 2014, Huang returned to China with the stolen trade secrets and began working for a Chinese company in a managerial role. Huang pleaded guilty in October 2015, and was sentenced to 60 months in prison in October 2016. (https://www.justice.gov/usao-wdnc/pr/chinese-businessman-charged-theft-trade-secrets)

Economic Espionage (18 U.S.C. § 1831)

1. ***Manhattan U.S. Attorney Announces Economic Espionage Charges Against Chinese Man For Stealing Valuable Source Code From Former Employer With Intent To Benefit The Chinese Government.*** On June 14, 2016, Jiaqiang Xu was charged, in a six-count superseding indictment, with economic espionage and theft of trade secrets, in connection with the theft of proprietary source code from Xu's former employer, with the intent to benefit the National Health and Family Planning Commission of the People's Republic of China. From November 2010 to May 2014, Xu worked as a developer for a particular U.S. victim company. As a developer, Xu enjoyed access to certain proprietary software, as well as that software's underlying source code. In May 2014, Xu voluntarily resigned from the Victim Company. Xu subsequently communicated with one undercover law enforcement officer ("UC-1"), who posed as a financial investor aiming to start a large-data storage technology company, and another undercover law enforcement officer ("UC-2"), who posed as a project manager, working for UC-1. In these communications, Xu discussed his past experience with the victim company and indicated that he had experience with the proprietary software and the proprietary source code. On March 6, 2015, Xu sent UC-1 and UC-2 a code, which Xu stated was a sample of Xu's prior work with the victim company and which a victim company employee later confirmed included proprietary material. After subsequent communications between Xu and UC-2, the FBI arranged for an undercover computer network to be set up, consistent with Xu's specifications, to which Xu uploaded a

functioning copy of the proprietary software. (https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-economic-espionage-charges-against-chinese-man-stealing)

Alternative Charges:

1. ***Missouri Woman Pleads Guilty to $80 Million Fraud Scheme to Sell Counterfeit Cell Phone Parts.*** On May 26, 2016, Sherrie Householder, 59, of Nixa, Missouri, pleaded guilty to an information charging her with one count of mail fraud, one count of money laundering, and one count of tax evasion. Householder admitted that she received more than $80 million from the sale of counterfeit items over approximately three years, from December 3, 2012, to January 14, 2016. Householder managed and operated Flash Technology, LLC, also known as Flash Tech, a business that sold cell phone components (such as replacement screens, lithium batteries, weight scales, phone cases and internal circuitry) over the Internet and at a Springfield store. Although each part contained trademarks and markings that made it appear the legitimate holder of the trademark had manufactured the parts, and although Householder used the trademarks and logos of these companies on her Web sites, the components were actually counterfeit. Wang "Frank" Lou, a Chinese citizen, owned Flash Tech, while Householder managed the company's activities in the United States. Lou shipped the cell phone component parts to Householder. Nearly 5,000 international shipments were sent to Flash Tech from China. On February 2, 2016, search warrants were simultaneously executed at Householder's Nixa residence and at the Flash Tech store in Springfield. At each location, thousands of counterfeit cell phones, electronics and component parts were seized. The total amount of items seized was worth approximately $5.5 million and filled two large moving trucks. Householder's sentencing is scheduled for January 2017. (https://www.justice.gov/usao-wdmo/pr/nixa-woman-pleads-guilty-80-million-fraud-scheme-sell-counterfeit-cell-phone-parts)

2. ***Hundreds of Counterfeit Oxycodone Tablets Seized at Port of Entry Contained Ultra-Deadly Fentanyl.*** On April 14, 2016, Sergio Linyuntang Mendoza Bohon of Tijuana, Mexico, was arraigned on a charge that he unlawfully imported a controlled substance. According to a charging document, Bohon attempted to smuggle 1,183 tablets of fentanyl that were labeled as oxycodone, and 5.4 grams of powdered fentanyl. The seizure is believed to be the first time that federal officials along the California-Mexico border have intercepted counterfeit oxycodone tablets containing fentanyl as they were being smuggled from Mexico into the United States. According to court records, on February 10, 2016, defendant Mendoza Bohon entered the United States at the Otay Mesa Port of Entry as a pedestrian, where CBP officers found the tablets labeled as oxycodone concealed in his underwear. (https://www.justice.gov/usao-sdca/pr/hundreds-counterfeit-oxycodone-tablets-seized-port-entry-contained-ultra-deadly)

3. ***Bradenton Man Sentenced To Federal Prison For Selling Counterfeit, Unapproved, And Misbranded Drugs.*** On April 12, 2016, Robert Lohr, 72, from Bradenton, Florida, was sentenced to 21 months in federal prison and 36 months supervised release for conspiracy

to smuggle misbranded and counterfeit drugs into the United States. He was ordered to pay $4,276.00 in restitution and the Court entered an order forfeiting Lohr's interest in approximately $926,466, the proceeds of the conspiracy. According to court documents, from July 2009 through September 25, 2015, Lohr operated a business in Bradenton known as "Canadian American Drug Club" or "American Drug Club of Bradenton." The business sold and distributed illegally smuggled prescription drugs, including Viagra, Cialis, Achiphex, and Lipitor, as well as other drug products that were falsely represented as "herbal," but that contained active prescription ingredients. Lohr generated more than $1 million in sales of these misbranded and counterfeit drugs. Between March 21, 2014, and September 15, 2015, several undercover purchases of misbranded, unapproved, and counterfeit prescription drugs were made from Lohr's business. (https://www.justice.gov/usao-mdfl/pr/bradenton-man-sentenced-federal-prison-selling-counterfeit-unapproved-and-misbranded)

4. ***New York Man Sentenced For Attempting To Sell Counterfeit Goods.*** On March 3, 2016, Xian Chen, 39, of Flushing, New York, was convicted and sentenced for attempting to sell counterfeit goods in the Wheeling, West Virginia and Boston, Massachusetts areas. Chen pleaded guilty to an information charging him with one count of "Entry of Good by Means of False Statements." Chen also pleaded guilty to a separate Information charging him with the same offense which was transferred to the Northern District of West Virginia from the District of Massachusetts. He was sentenced to an 11 month combination of imprisonment and community confinement on each count. The sentences will run concurrently. He was also ordered to pay $12,500 in restitution to the victim companies. (https://www.justice.gov/usao-ndwv/pr/new-york-man-convicted-sentenced-attempting-sell-counterfeit-goods)

D. Major Enforcement Activities

DHS:

1. *Operation Team Player*. This targets the sale and trafficking of counterfeit sports merchandise, apparel and tickets, a multi-million dollar criminal industry. The culmination of the sports season—playoffs and finals games—are events that stimulate the sale of counterfeit items. 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 2016 Super Bowl, more than 450,000 items counterfeit sports merchandise worth $39 million were seized and 41 individuals were arrested by law enforcement. In FY 2016, the IPR Center expanded *Operation Team Player* by coordinating enforcement actions at multiple high-profile sporting events, including the Major League Baseball (MLB) World Series, National Hockey League (NHL) Winter Classic; National Collegiate Athletic Association 2016 College Football Championship; NHL, MLB, and National Basketball Association (NBA) All-Star games; NHL and NBA Championship series; the 2016 NHL Stadium Series; and the 2016 COPA America Tournament.

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. In FY 2016, under *Operation Chain Reaction*, ICE HSI initiated 19 criminal investigations, conducted 15 criminal arrests, and helped secure 14 indictments and 9 convictions, as well as 103 counterfeit goods seizure incidents with a Manufacturer's Suggested Retail Price (MSRP) of approximately $3.5 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 2016, ICE HSI seized more than $5.5 million in counterfeit goods.

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 2016, ICE HSI investigations resulted in the initiation of 46 cases, the arrest of 32 individuals, the indictment of 36 individuals, and the conviction of 16 persons, as well as 519 seizure incidents of counterfeit items.

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 2016, ICE HSI initiated 25 investigations, conducted 7 arrests, and helped secure 16 indictments and 21 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. In FY 2016, ICE HSI initiated 19 cases, conducted 4 arrests, helped secure 7 indictments and 6 convictions, and seized approximately $1.1 million in counterfeit products.

FDA

1. Las Vegas Resident Indicted For Running Counterfeit and Misbranded Contact Lens Operation

On September 8, 2016, Dmitriy V. Melnik, of Las Vegas, the owner and operator of Candy Color Lenses, a major online retailer of colored contact lenses in the United States, pleaded guilty to running an international operation importing counterfeit and misbranded contact lenses from suppliers in Asia and then selling them over the internet without a prescription to tens of thousands of customers around the country. According to the plea agreement, Melnik imported large quantities of colored contact lenses from the People's Republic of China and South Korea that he knew were counterfeit and/or unauthorized by the FDA for sale in the United States. Melnik sold "authentic" contact lenses to tens of thousands of customers around the United States without a prescription, adequate directions for use and adequate warnings. Melnik admitted that some of the contact lenses he sold were tested and found to be contaminated with potentially hazardous bacteria. As stated in the plea agreement, Melnik received at least $1.2 million in gross revenue from this illegal enterprise.

The prosecution is the result of an ongoing multiagency effort to combat counterfeit, illegally imported and unapproved contact lenses called *Operation Double Vision*. The FDA's Office of Criminal Investigations led the investigation, with significant support from the U.S. Postal Inspection Service and the U.S. Immigration and Customs Enforcement's Homeland Security Investigations.

https://www.justice.gov/opa/pr/owner-major-online-colored-contact-lens-business-pleads-guilty-largest-ever-investigation

2. Second Trafficker Convicted of Distributing Dangerous Counterfeit Viagra and Cialis

On August 15, 2016, Victor Lamar Coates, of Philadelphia, Pennsylvania, pleaded guilty to conspiring with convicted co-conspirator Martez Gurley, 41, of Napa, California, to traffic in counterfeit and misbranded Viagra and Cialis, and introducing those drugs in interstate commerce. Both drugs are prescription medications. Coates admitted to illegally distributing at least 10,288 counterfeit and misbranded tablets, including tablets he illegally imported directly from China. FDA, Eli Lilly and Company and Pfizer Inc. conducted testing on the counterfeit tablets which revealed the tablets did not contain the ingredients listed on the labeling. Some of the Viagra tablets contained the compound 2-MBT, an ingredient not part of authentic Viagra.

Coates and Gurley each face up to five years in prison for the conspiracy and for introducing misbranded drugs into interstate commerce, as well as up to three years for introducing misbranded drugs into commerce. Sentencing for both Coates and Gurley is scheduled for December 2016. FDA-OCI and ICE-HSI conducted the investigation.

http://www.fda.gov/ICECI/CriminalInvestigations/ucm517255.htm

3. Rhode Island Businessman Pleads Guilty to Running International Scheme to Label and Sell Misbranded Drugs.

On June 20, 2016, Arif Diwan, 60, owner of Lifescreen LLC, a Cranston, R.I., based company that labeled, advertised, and sold drugs and pharmaceutical products under the brand name "LifeLogic," pleaded guilty in federal court in Providence today to conspiring with others to purchase drugs manufactured in India and other countries, repackaging and relabeling them making it appear that they were manufactured in the United States and Europe, and had been approved by the United States Food and Drug Administration (FDA), and then reselling them.

According to court documents, between 2012 and 2015, Diwan received and filled numerous orders for high-cost pharmaceutical products, including a number of products used in the treatment of cancer. Diwan admitted that he rebranded and relabeled drugs manufactured in India, including adding bogus FDA codes and markings to make it appear that the drugs had been manufactured in the United States or Europe and were approved for sale by the FDA. The drugs were shipped by Diwan to customers in numerous countries. Diwan did not sell misbranded and mislabeled drugs in the United States.

Diwan passed away in August 2016 prior to the scheduled September 2016 sentencing date.

This case was investigated by FDA-Office of Criminal Investigations (FDA-OCI), the United States Department of State, Internal Revenue Service-Criminal Investigation, Interpol, Europol and the Belgian Federal Judicial Police.

http://www.fda.gov/ICECI/CriminalInvestigations/ucm507624.htm

4. Counterfeit Cigarette Smuggler Receives Jail Sentence

On January 22, 2016, Gaurav Joseph Jayaseelan, 25, a citizen of India, was sentenced to 16 months in prison, to be followed by one year of supervised release, for trafficking in counterfeit cigarettes.

The investigation began in 2013, when an undercover agent from FDA-Office of Criminal Investigations (FDA-OCI) met and discussed the sale of counterfeit cigarettes with a middle-man. Thereafter, negotiating by email, a deal to sell and ship counterfeit cigarettes for a total cost of $377,300.00 was reached.

In August 2013, undercover agents met with Jayaseelan, who travelled to Miami, FL to discuss the pending sale. Following the meeting, Jayaseelan emailed that they would send 1,030 master cases of counterfeit cigarettes for a total wholesale price of $450,625. In May 2014 the shipment was seized by Customs and Border Protection Officers at Port Everglades, in coordination with the FDA-OCI and agents of ICE Homeland Security Investigations. The counterfeit cigarettes had an estimated street value in the United States exceeding $5.6 million. Jayaseelan was subsequently arrested in August 2015.

http://www.fda.gov/ICECI/CriminalInvestigations/ucm484450.htm