2013 JOINT STRATEGIC PLAN ON INTELLECTUAL PROPERTY ENFORCEMENT

U.S. Intellectual Property Enforcement Coordinator

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Letter to the President of the United States and to the Congress

Dear Mr. President and Members of Congress,

I am pleased to transmit the 2013 Joint Strategic Plan on Intellectual Property Enforcement. This is the second Joint Strategic Plan and will guide our activities over the next three years. The Joint Strategic Plan also contains a report on the progress made since the Office of the U.S. Intellectual Property Enforcement Coordinator was established and the Administration's first Joint Strategic Plan was issued in June 2010.

Our Nation rightly prides itself on the innovation and creativity that has been the engine of our economy throughout our history. Predictable and effective enforcement of intellectual property rights supports jobs, maintains our global competiveness, and protects health and safety.

There have been a number of accomplishments since the first Joint Strategic Plan was released: significant increases in law enforcement; an innovative approach to Internet enforcement that includes law enforcement and voluntary initiatives by the private sector; improved efficiency and coordination in how agencies act together and how resources are deployed; and concrete progress by our trading partners abroad. Specifically, since the 2010 Joint Strategic Plan:

- U.S. law enforcement has significantly increased its enforcement against infringement that threatens the vitality of the U.S. economy and the health and safety of the American people. Since FY 2009:
  - U.S. Immigration and Customs Enforcement (ICE)-Homeland Security Investigations (HSI) new cases are up 71 percent, arrests are up 159 percent, convictions are up 103 percent, and indictments are up 264 percent.
  - Pending Federal Bureau of Investigation (FBI) health and safety-focused investigations are up 308 percent, FBI health and safety arrests are up 286 percent, and new trade secret theft cases are up 39 percent.
  - Customs and Border Protection (CBP) and ICE seizures of infringing imports have increased by 53 percent.
- Private sector companies have voluntarily agreed to adopt best practices aimed at curbing the sale of counterfeit goods and reducing online piracy. For example:
  - American Express, Discover, eNom, Facebook, Go Daddy, Google, MasterCard, Microsoft, Neustar, PayPal, Visa, and Yahoo! established the Center for Safe Internet Pharmacies—a new non-profit to combat fake online "pharmacies" selling dangerous illegal drugs over the Internet.
  - AT&T, Cablevision, Comcast, Time Warner Cable, Verizon, and major and independent music labels and movie studios entered into a voluntary agreement to reduce online piracy. Under the agreement, Internet Service Providers (ISPs) will notify subscribers, through a series of alerts,

when their Internet service accounts appear to be misused for infringement on peer-to-peer networks.

- American Express, Discover, MasterCard, PayPal, and Visa agreed to a set of best practices to withdraw payment services for online sales of counterfeit and pirated goods.
- The Association of National Advertisers and the American Association of Advertising Agencies issued a leadership pledge to not support online piracy and counterfeiting with advertising revenue.

- In March 2011, my office released the Administration's White Paper on Intellectual Property Enforcement Legislative Recommendations, setting out 20 legislative recommendations for Congress to strengthen intellectual property enforcement. To date, seven of the recommendations are now law. Congress has:
  - Increased penalties for counterfeit goods or services sold to, or for use by, the military or national security apparatus;
  - Bolstered criminal penalties for economic espionage and directed the U.S. Sentencing Commission (USSC) to consider increasing offense levels for trade secret crimes;
  - Granted CBP authority to share information regarding suspected counterfeit goods with trademark owners in order to assist CBP in making infringement determinations;
  - Increased penalties for trafficking in counterfeit drugs;
  - Directed USSC to review guidelines and policy statements related to offenses that involve counterfeit drugs;
  - Granted the U.S. Food and Drug Administration (FDA) authority to destroy, without the opportunity to export, counterfeit or adulterated drugs imported to the United States in small packages; and
  - Granted the FDA authority to require pharmaceutical manufacturers to report when a drug they manufacture has been found to be counterfeited or stolen.
  - It is also worth noting the enactment of Public Law 112-236 - *The Theft of Trade Secrets Clarification Act of 2012,* which closed a loophole by clarifying that the scope of the Economic Espionage Act protects trade secrets related to "a product or service used in or intended for use in" interstate or foreign commerce, is in line with the overall Administration priority of combatting theft of trade secrets.
- The Office of the U.S. Trade Representative (USTR) worked with Korea, Panama, and Colombia to bring our Free Trade Agreements into force, is negotiating a Trans-Pacific Partnership trade agreement that will include state-of the-art intellectual property protection and enforcement provisions, and is preparing to launch negotiation of a comprehensive Transatlantic Trade and Investment Partnership agreement with the European Union.
- In March 2012, Department of Commerce (DOC), in coordination with the Council of Economic Advisors and the chief economists of USTR, Department of Labor (DOL), and other Federal

agencies, released an economic report titled *Intellectual Property and the U.S. Economy: Industries in Focus*, detailing the breadth and depth of intellectual property industries and the jobs they support. The report concluded that, in 2010 alone:

- Intellectual property industries accounted for $5.06 trillion in value added, or 34.8 percent of U.S. gross domestic product;
- Intellectual property industries created 27.1 million jobs and indirectly supported another 12.9 million jobs;
- Intellectual property industries accounted for over 60 percent of all U.S. exports; and
- The average weekly wage in intellectual property industries overall was 42 percent higher in 2010 than in other industries. In patent and copyright industries, wages were 73 and 77 percent higher, respectively.

Moving forward, the Administration will continue to improve upon these efforts. We will focus on infringement that has a significant impact on the economy, the global economic competitiveness of the United States, the security of our Nation, and the health and safety of the American public.

We will increase efforts to improve enforcement of intellectual property rights here at home, improve cooperation with foreign governments, and use our trade tools to improve protection around the world. We will promote the use of private sector voluntary best practices to reduce infringement online and in conventional marketplaces. We will press vigorously for protection of trade secrets overseas and enforcement actions to address their theft or misappropriation.

I look forward to working with you to further enforce and protect American intellectual property rights. With continued leadership by the Administration and with the support of Congress, the American people will continue to lead the world in innovation and economic progress.



Victoria A. Espinel

U.S. Intellectual Property Enforcement Coordinator

Introduction

As President Obama has made clear, "[o]ur single greatest asset is the innovation and the ingenuity and creativity of the American people. It is essential to our prosperity and it will only become more so in this century." So it matters that we have the right approach to intellectual property enforcement; one that is forceful yet thoughtful, dedicated and effective, and that makes good and efficient use of our resources.

Ours is a Nation of entrepreneurs, inventors, innovators, and artists. The ideas that American citizens generate catalyze cutting edge research, ensure longer and healthier lives, and power the globe's most productive economy. Our ingenuity and entrepreneurial spirit make the United States great, and we must fiercely defend that competitive advantage. As President Obama has said, "if the playing field is level, I promise you—America will always win."

In June 2010, we issued the Administration's first Joint Strategic Plan for Intellectual Property Enforcement. Since then, we have made great progress: law enforcement operations have increased in scope and efficiency, and investigations, seizures, arrests, and convictions have increased significantly; several industry-led voluntary initiatives to reduce infringement online have been concluded and are in force; there is more efficiency and coordination among Federal agencies; the Federal government is now more aware of and active in eliminating counterfeits in its supply chain; and gains have been made in coordination and cooperation with our trading partners. We have worked cooperatively with Congress, and as a result of these efforts, seven Administration legislative recommendations to improve our enforcement system have become law.

Nonetheless, we know that infringement of intellectual property continues to pose significant risk to our economy and to our ability to compete globally. So we must continue to look forward, building on what has already been accomplished. On June 25, 2012, we asked the public for input in developing the Administration's second strategy. Incorporating this input, we worked with agencies from across the U.S. Government, including the Departments of Agriculture, Commerce (DOC), Defense (DOD), Health and Human Services (HHS), Homeland Security (DHS), Justice (DOJ), Labor (DOL), State (DOS), Treasury, and the Office of the United States Trade Representative (USTR) and other offices within the Executive Office of the President (EOP), as well as the U.S. Copyright Office to develop the strategy.

In this resultant Joint Strategic Plan, we seek to build upon ongoing work with an eye to increasing U.S. Government coordination and efficiency and to anticipating the challenges of the future. As with the original Joint Strategic Plan, we have set out a number of commitments by the Administration that we will undertake in order to improve enforcement.

Our primary concerns remain the same: creation of American jobs, promotion of the global competitiveness of American businesses and enterprises, protection of public health and safety, and preservation of the Constitutional rights of American citizens.

There are a number of issues that we anticipate will continue to be a focus of discussion. One of those issues is troubling patent litigation tactics that present a significant and growing challenge to innovation. President Obama recently identified this as an area to be addressed and on June 4, 2013, following a review by the White House Task Force on High-Tech Patent Issues, the Administration issued five

executive actions and seven legislative recommendations designed to curb abusive patent litigation and to ensure the highest-quality patents in our system. We believe it is in the country's best interest for companies involved in patent disputes to resolve them amicably so that they can get back to doing what they do best—creating innovative and useful products that spur the economy.

We are also concerned about efforts by foreign governments to condition market access or the ability to do business on the transfer of trade secrets or proprietary information. Forced technology transfer is not an acceptable tactic in the global trade environment.

As we move forward, we are aware that new technologies, evolving social norms, new business models, and novel global distribution mechanisms will present new challenges and opportunities to combat infringement of American intellectual property rights. Among these trends and innovations are increases in the power and prevalence of cloud computing, mobile computing, data storage, database management, information security, increased interoperability, and 3D printing.

Mobile devices will continue to increase in ubiquity, adding capabilities that will entrench such devices ever deeper into our daily lives and routines. There will be more connected devices than human beings by the end of this year. In 2012, average smartphone use grew 81 percent, mobile network connection speeds more than doubled, and video accounted for more than 50 percent of all mobile traffic for the first time.[1] In 2013, also for the first time, a majority of American adults now own smartphones.[2] Applications (apps) will grow in number, complexity, and usefulness as use of mobile devices increases. Some apps will be used to distribute infringing digital goods. Additionally, we are hearing reports that some apps themselves are being counterfeited by those seeking to unfairly capitalize on the success of others, and apps are being hacked to gain access to value-added services without payment.

3D printing has the capacity to revolutionize manufacturing and research and development capabilities for inventors, entrepreneurs, artists, academic researchers, and major global businesses. Much as the personal computer democratized computing power, 3D printing has the opportunity to enable greater market participation and innovation by reducing traditional barriers such as production, labor, and shipping costs. Whether it is the hobbyist in the garage coming up with a prototype for a new gadget to make our lives easier or the scientist producing life-saving medical devices, 3D printing brings with it a new set of opportunities for rapid and efficient trade, innovation, and creativity. And, just as 3D printing offers the opportunity to make meaningful contributions to our society, there also exists the opportunity for individuals who look to exploit others' hard work to abuse this technology by trading in counterfeit and pirated goods, of which we must be cognizant and diligent in our efforts to prevent.

We believe that technological developments present new and improved opportunities to help protect American intellectual property. We envision new technologies able to screen trucks and shipping containers at our borders faster, more efficiently, and more comprehensively than is possible at present. We hope to see increased engagement between technology experts and the U.S. Government, including the possible creation of advisory groups or other mechanisms for receiving input, and the placement of experts within certain relevant government agencies and departments. We will continue to encourage

1. Cisco Visual Networking Index: Global Mobile Data Traffic Forecast Update, 2012-2017; http://www.cisco.com/en/US/solutions/collateral/ns341/ns525/ns537/ns705/ns827/white_paper_c11-520862.pdf

2. Smartphone Ownership 2013; http://www.pewinternet.org/~/media//Files/Reports/2013/PIP_Smartphone_adoption_2013.pdf.

voluntary initiatives to reduce infringement online and in the physical world, and we hope to see technological solutions that facilitate better access to, and educate the public about, legitimate alternatives.

With respect to the online environment, the Administration believes that when Americans and people around the world are given real choices between legal and illegal options, the vast majority will want to choose the legal option. Accordingly, we encourage the further development and use of legitimate online services as an important part of an effective approach to reducing infringing activity. Today there are a myriad of legitimate ways to obtain music, video, books, games, software, and other entertainment and educational materials through a wide variety of business models. These include paying per use, paying per copy, and paying a fee for access to a collection of works; allowing customers to pay what they wish; and legitimate content that is available for free, including entertainment industry portals and artists and authors using systems to permit free distribution of their works under conditions that they choose.

We believe that legitimate goods, including digital goods, offer clear advantages over infringing ones regardless of price. Use of legitimate goods compensates artists, creators, and those who invest in bringing their works to the public, and provide incentives for future creation and distribution. In addition, legitimate goods are often of higher quality, come with express or implied warranties or guarantees of quality, offer customer services, and do not pose the same risk of viruses or malware. They may also include extra features not available with infringing content. And, increasingly, they may be more convenient and easier to find.

We support and will look for additional ways to encourage and facilitate efforts that will help expand the reach of legitimate alternatives to infringement, including through the development of copyright registries and online databases, micro-licensing arrangements, and other market-driven mechanisms to facilitate smooth and efficient access to content. We also encourage the work of the U.S. Copyright Office to update and improve the copyright registration and recordation system in ways that will facilitate licensing and encourage public-private partnerships.

We can best provide the legal, regulatory, and policy environment appropriate for a rapidly evolving intellectual property landscape through continued dialogue and discussion with industry, associations, labor unions, public interest groups, and academia, with the full range of interested stakeholders. Social media and networking tools allow consumers, employees, and members of the general public to make their views known in an increasing number of ways to influence companies' decisions as well as provide input to policymakers. Therefore, moving forward, IPEC and the wider Administration will remain committed to working with all stakeholders to learn about and take into account emerging trends, innovative ideas, and new technologies likely to affect American intellectual property rights in the future.

Building on the 2010 Joint Strategic Plan

The underlying approach and many of the specific action items from the original Joint Strategic Plan are continued in this strategy. In addition, we are expanding on several action items and adding entirely new action items including efforts to:

- *Facilitate voluntary initiatives to reduce online intellectual property infringement.* IPEC will reach out to additional sectors (which may include data storage services, domain name registrars, and

search engines) and will also encourage rightholders to adopt a set of best practices. USPTO will start a process to assess the voluntary initiatives;

- *Conduct a comprehensive review of domestic laws to determine needed legislative changes to improve enforcement*;
- *Support small and medium-size enterprises in foreign markets.* DOC will increase outreach and support to such enterprises through nationwide educational efforts;
- *Evaluate the enforcement process of exclusion orders issued by the U.S. International Trade Commission (ITC).* IPEC will chair an interagency working group to improve the process for enforcement of Section 337/ITC exclusion orders;
- *Coordinate international capacity-building and training.* IPEC will reorganize the interagency working group on capacity-building and training and embassies will follow up on a regular basis with governments that receive training to evaluate results;
- *Improve transparency in intellectual property policymaking.* IPEC will look for additional ways to hear concerns and gather input from a wide range of stakeholders;
- *Improve law enforcement communication with stakeholders.* DOJ and ICE will look for additional ways to engage a broad range of stakeholders in an effort to increase understanding of law enforcement operations and expand stakeholder relationships;
- *Assess the economic impact of intellectual property-intensive industries.* DOC will issue an annual report on the number of jobs and contribution to the GDP of such industries;
- *Use legal software.* IPEC, with the Federal Procurement Policy Administrator and the U.S. Chief Information Officer will review the mechanisms that agencies have in place in order to share best practices and ensure legal use;
- *Examine labor conditions.* DOS will examine the relationship between unacceptable labor conditions and the manufacture and distribution of counterfeits and take further action if necessary;
- *Improve IPR enforcement efficacy by leveraging advanced technology and expertise.* IPEC will chair an interagency working group to identify and advance new and innovative technologies to improve enforcement capabilities at the border. In addition, law enforcement agencies will look for ways to engage outside technology experts and Internet engineers to increase expertise on online enforcement approaches;
- *Increase focus on counterfeits shipped through international mail and work with express carriers.* CBP will work to obtain advance data from international post operators and express carrier companies to improve targeting;
- *Educate authors on "fair use" copyright doctrine.* The U.S. Copyright Office will summarize current law and provide general guidance targeted to artists seeking to apply the law to their own situations;
- *Protect intellectual property at the Internet Corporation for Assigned Names and Numbers (ICANN).* The National Telecommunications and Information Administration (NTIA) and the FBI will work

with ICANN, in collaboration with stakeholders, so that new top-level domains do not become new venues for infringement; and

- *Consider copyright and patent "small claims" courts.* The U.S. Copyright Office and USPTO are considering alternative adjudicatory processes for hearing "small claims" cases brought by copyright and patent holders.

Although we have made significant progress over the last three years, we still face many challenges. Infringement of intellectual property rights continues to harm U.S. businesses and unjustly usurps or undermines American innovation. More work must be done to ensure that counterfeits are eliminated from the government supply chain, especially in relation to the national security apparatus. We will continue to look for ways to improve efficiency and coordination; collaborate with the IPR Center to identify relevant criminal patterns and trends and develop solutions to address those threats; and encourage voluntary initiatives to reduce infringement in the online and physical world.

Addressing the theft and transfer of trade secrets overseas for innovative technology will continue to be a priority focus. Over the next three years, we will continue to work to ensure that standards, procurement, and regulatory policies of foreign countries do not unfairly exclude or prejudice innovative or creative American products and services. We hope that Congress acts on the Administration's remaining legislative recommendations from the 2011 White Paper on Intellectual Property Enforcement and on any further recommendations we deliver in the future.

As the United States powers the world out of the global recession with its innovative economic engine, intellectual property enforcement remains as essential as ever. As long as the intellectual property rights of Americans are protected and American workers, engineers, entrepreneurs, creators, and innovators are given a level playing field unhindered by infringement, we will continue to produce the technology and works of art that drive the world's economy and enable healthier, happier, and more prosperous lives.

	Action Item
Leading by Example	Secure the U.S. Government Supply Chain Against Counterfeits
	Use of Software by the Federal Government
Transparency and Public Outreach	Improve Transparency in Intellectual Property Policymaking and International Negotiations
	Improve Law Enforcement Communication with Stakeholders
	Evaluate Enforcement Process of Exclusion Orders Issued by the International Trade Commission
	Educate Authors on Fair Use
	Raise Public Awareness
Ensuring Efficiency and Coordination	Improve National Law Enforcement Efforts to Protect Intellectual Property Rights
	Improve Efficacy of Enforcement by Leveraging Advanced Technology and Expertise
	Improve Effectiveness of Personnel Stationed Abroad
	Coordination of International Capacity-Building and Training
	Consider Alternative Forums for Enforcement of Rights
Enforcing Our Rights Abroad	Enhance Foreign Law Enforcement Cooperation
	Strengthen Intellectual Property Enforcement through International Organizations
	Promote Enforcement of Intellectual Property Rights through Trade Policy Tools

	Action Item
Enforcing Our Rights Abroad (Continued)	Combat Foreign-Based and Foreign-Controlled Websites that Infringe American Intellectual Property Rights
	Protect Intellectual Property at ICANN
	Support U.S. Small and Medium-Size Enterprises (SMEs) in Foreign Markets
	Examine Labor Conditions Associated with Infringing Goods
Securing the Supply Chain	Expand Information-Sharing by DHS to Identify Counterfeit Goods at the Border
	Increase Focus on Counterfeits Shipped through International Mail and Express Carriers
	Facilitate Voluntary Initiatives to Reduce Online Intellectual Property Infringement and Illegal Internet Pharmacies
	Combat the Proliferation of Counterfeit Pharmaceuticals and Medical Devices
Data-Driven Government	Conduct Comprehensive Review of Domestic Laws to Determine Needed Legislative Changes to Improve Enforcement
	Assess the Economic Impact of Intellectual Property-Intensive Industries
	Monitor U.S. Government Resources Spent on Intellectual Property Enforcement

Administration Joint Strategic Plan

Action Items

I. LEADING BY EXAMPLE

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

Counterfeits entering the U.S. Government supply chain pose a particularly serious problem due to the damaging impact they can have on an agency's ability to accomplish its mission, the substantial waste of resources and taxpayer money, and the significant national security implications. For example, the inadvertent use of counterfeit parts within U.S. Government systems will increase the risk of equipment malfunctions, degrade operations and communications capabilities and performance, and further expose U.S. Government assets to security breaches from opportunistic actors. Further, the deliberate insertion of malware or spyware on counterfeit parts with the intent of selling them to, or installing them in, U.S. Government systems could increase the opportunity for unauthorized actors to gain access to U.S. Government networks. The Administration has two primary objectives: to reduce the incidence of counterfeits in the U.S. Government supply chain and to increase law enforcement efforts against those who knowingly sell counterfeits to the U.S. Government.

Since the June 2010 Joint Strategic Plan:

- IPEC established an interagency working group to develop a comprehensive strategy to avoid counterfeits entering the U.S. Government supply chain that is flexible enough to accommodate the broad set of missions across the U.S. Government and their respective levels of counterfeit risk. The interagency working group chaired by IPEC includes officials from: DOD, the Office of Federal Procurement Policy (OFPP), the National Aeronautics and Space Administration, DHS, DOJ, DOC, the Department of Energy, the Department of Transportation, the General Services Administration, the Small Business Administration, the Environmental Protection Agency, the National Reconnaissance Office, and the Nuclear Regulatory Commission.
- In 2011, the IPR Center launched Operation Chain Reaction to serve as a coordinated and comprehensive initiative directed at curtailing the flow of counterfeit items entering the U.S. Government supply chain. Today, with 15 Federal agencies participating in this initiative, Operation Chain Reaction has led to several criminal convictions and the recoupment of millions of dollars for Federal agencies that were supplied counterfeit goods.
- In March 2011, the Administration's White Paper on Intellectual Property Enforcement Legislative Recommendations recommended that Congress authorize strong anti-counterfeit measures and information sharing authorities as well as increase penalties for those selling counterfeits to the U.S. military.
- On December 31, 2011, President Obama signed *Public Law 112-81 - The National Defense Authorization Act for Fiscal Year 2012*, which provides for strong anti-counterfeit measures

within the defense supply chain. It also provides CBP with certain information sharing authority with regard to imports of goods suspected of being counterfeit and increases penalties for counterfeit goods or services sold to or for use by the military or national security applications.

- Pursuant to *Public Law 112-81 - The National Defense Authorization Act for Fiscal Year 2012*, DOD published a Counterfeit Prevention Guidance employing a risk-based approach to the detection, prevention, reporting and disposal of counterfeit parts and, is nearing completion of DOD-wide Counterfeit Prevention Policy to minimize the introduction of counterfeit parts into the DOD supply chain.
- At the conclusion of the Camp David G-8 meeting in May 2012, G-8 leaders issued a joint statement affirming the significance of strong IPR protection and enforcement in a number of priority areas including efforts to combat counterfeits entering government supply chains.

Going forward:
IPEC is working with the relevant Federal agencies and with other offices within the Executive Office of the President, including the National Security Staff, to develop a strategy coordinated with the ongoing efforts to secure the global supply chain and cybersecurity. It is intended that this Administration Strategy on Counterfeits in the U.S. Government Supply Chain will serve as a critical pillar to complement the security paradigm established by National Strategies for Global Supply Chain Security and Cybersecurity.

The Administration is working to finalize the Strategy on Counterfeits in the U.S. Government Supply Chain and expects to release it in 2013.

Simultaneously, Operation Chain Reaction will continue to be a focus for the IPR Center. DOS and IPEC will continue to work with the G-8 governments on implementation of their G-8 commitments on counterfeits in government supply chains.

2. Use of Software by the Federal Government

It is important that we take all necessary steps to ensure that the U.S. Government only uses legal software.

Since the June 2010 Joint Strategic Plan:

- IPEC has been working with Federal agencies to review the U.S. Government's practices and policies regarding the use of software by Federal agencies and contractors to promote the use of only legal software.
- On January 7, 2011, the U.S. Chief Information Officer, the Administrator for Federal Procurement Policy and the U.S. Intellectual Property Enforcement Coordinator issued a Joint Statement to Senior Procurement Executives and Chief Information Officers that highlighted the Administration's technology-neutral procurement policy and reiterated the Administration's policy that all technology used must be properly licensed in accordance with applicable law.

Going forward:
It is important for Federal agencies to ensure compliance with the terms of their licensing agreements both as a matter of law and as a strong example for our trading partners and the international community. In 1998, President Clinton issued Executive Order 13103 which requires that Federal agencies take steps to ensure against the acquisition or use of illegal software. The U.S. Chief Information Officer, the Administrator for Federal Procurement Policy, and IPEC will coordinate with departmental Chief Information Officers (CIOs) through the Federal CIO Council and review the measures Federal agencies have taken to implement Executive Order 13103. To the extent this review results in additional information about best practices for software acquisition and use, the Federal CIO Council will distribute this information and implement measures based on those best practices.

II. TRANSPARENCY AND PUBLIC OUTREACH

3. Improve Transparency in Intellectual Property Policymaking and International Negotiations

The Administration strongly supports improved transparency in intellectual property enforcement policy-making and international negotiations.

Since the June 2010 Joint Strategic Plan:

- IPEC has maintained an open door policy, meeting with hundreds of stakeholders, large and small, across a broad range of sectors in developing and implementing the Administration's strategy for intellectual property enforcement.
- The Administration has solicited and received public input through formal mechanisms such as Federal Register notices. For example, IPEC, USTR, and the U.S. Patent and Trademark Office (USPTO) have issued Federal Register notices seeking input and comments on a variety of intellectual property enforcement issues.
- IPEC issues periodic reports called the Intellectual Property Spotlight, highlighting the Administration's ongoing efforts to improve intellectual property enforcement. The Spotlight is available to any member of the public through an e-mail subscription and on the IPEC website.
- USPTO established and maintains a publicly-available database (www.usipr.gov) of intellectual property-related technical assistance and capacity-building programs delivered by U.S. Government agencies that increases transparency by allowing the public to see how the U.S. Government is allocating resources on intellectual property training.
- As part of FDA's implementation of *Public Law 112-144 - The Food and Drug Administration Safety and Innovation Act*, signed into law by President Obama on July 9, 2012, FDA established FDASIA-TRACK, a webpage dedicated to providing the public with information detailing FDA's progress on implementing the new law, as well as identifying lead offices and associated points of contact responsible for driving FDA's implementation efforts.

Going forward:
IPEC will continue to maintain an open door policy and actively seek input from a wide range of stakeholders in developing and implementing the Administration's strategy for intellectual property enforcement. This will include Federal Register notices, for example, as appropriate for the relevant process. IPEC will continue to issue the *Spotlight* to keep the public informed of the Administration's intellectual property enforcement efforts.

IPEC will consider additional means to receive input from a broad range of stakeholders and to effectively disseminate information to the public, including the possible establishment of an advisory group of stakeholders, as well as working more closely with existing advisory groups.

4. Improve Law Enforcement Communication with Stakeholders

Federal law enforcement must maintain communication with a broad range of stakeholders in order to gain an understanding of the issues these groups face. Additionally, as the quality of counterfeit products improves, trademark owners are best positioned to provide law enforcement assistance in identifying counterfeit products.

Since the June 2010 Joint Strategic Plan:

- The IPR Center has increased its outreach efforts 65 percent through Operation Joint Venture.
- Over 50,000 representatives from the private sector, foreign law enforcement and domestic law enforcement have participated in more than 600 Joint Venture training events.
- In FY 2012, Operation Joint Venture conducted 370 trainings for more than 20,000 individuals.

Going forward:
Federal law enforcement responsible for the investigation and prosecution of intellectual property crimes will continue to carry on regular contact with rightholders and victims of infringement. This will also include improved communication on mitigating the theft of U.S. trade secrets by foreign competitors and foreign governments.

Federal law enforcement will continue to identify opportunities to hear directly from stakeholders that have an interest in enforcement of intellectual property.

With respect to trade secret theft, the Office of the Director of National Intelligence (ODNI) will coordinate within the intelligence community to inform the private sector about ways to identify and prevent the theft of trade secrets. The ODNI will coordinate expanded discussions between the intelligence community and the private sector on the threat posed by trade secret theft.

The FBI will continue its outreach and education efforts with the private sector through various local, regional and national initiatives. At the local level, each of the FBI's 56 field offices will continue to work with academic institutions, manufacturers, laboratories and other entities that are located within the field office's area of responsibility and are perceived as being potentially at risk for trade secret theft. At the regional level, the FBI will continue to meet regularly with other government agencies, industry, and academia to share information about insider threats, economic espionage and trade secret theft.

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

Under Section 337 of the Tariff Act of 1930, the U.S. International Trade Commission (ITC) investigates allegations regarding unfair practices in import trade, including allegations related to intellectual property infringement, as well as other forms of unfair competition. Once the ITC finds a violation of Section 337 and issues an exclusion order barring the importation of infringing goods, CBP and the ITC are responsible for determining whether imported articles fall within the scope of the exclusion order. Because of these shared responsibilities, it is critical that the ITC and CBP have clear communication on what the order means to improve the order's enforcement and prevent importation of infringing product. Moreover, this determination can often be challenging, particularly in cases in which a technologically sophisticated product such as a smartphone has been successfully redesigned to not fall within the scope of the exclusion order.

Since the June 2010 Joint Strategic Plan:

- ITC began immediately sharing draft language for potential exclusion orders with CBP so that if ITC issued an exclusion order, CBP would be better prepared to enforce the order.
- ITC has developed a way to electronically transmit exclusion orders and the many confidential documents associated with the investigation for streamlined and more efficient review of Section 337 cases.

Going forward:
The ITC and CBP will continue using the more effective mechanisms for communication that have been put in place.

In addition, IPEC will chair a new interagency effort directed at strengthening the processes that CBP uses with regard to enforcement of ITC exclusion orders pertaining to intellectual property. The working group will be comprised of representatives from the ITC; DHS, DOC, Treasury, and DOJ; offices within the Executive Office of the President including USTR, OSTP, NEC; and other relevant agencies as necessary.

The interagency working group will review existing procedures that CBP and the ITC use to evaluate the scope of ITC exclusion orders and work to ensure the process and standards utilized during exclusion order enforcement activities are transparent, effective, and efficient. To help inform its review, IPEC will seek public input through issuance of a Federal Register Notice.

Among others, one focus of the interagency review will be on ensuring that CBP uses transparent and accurate procedures for determining whether an article is covered by the ITC exclusion order. Further, the working group will evaluate opportunities to improve the effectiveness of directions provided by the ITC to assist CBP with the challenges of enforcement.

Within six months of the issuance of the Administration's 2013 Joint Strategic Plan on Intellectual Property Enforcement, the interagency working group will prepare recommendations.

6. Educate Authors on Fair Use

Effective enforcement is critical to providing meaningful protection of intellectual property rights, but enforcement approaches should not discourage authors from building appropriately upon the works of others. We recognize the work that agencies across the U.S. Government are doing in the area of intellectual property education, and their efforts to increase and improve this work in the digital environment. This work includes efforts at the USPTO and the U.S. Copyright Office to help the general public better understand the Constitutional purpose and value of intellectual property laws, and the scope of both protections and exceptions in such laws.

The Administration believes, and the U.S. Copyright Office agrees, that authors (including visual artists, songwriters, filmmakers, and writers) would benefit from more guidance on the fair use doctrine. Fair use is a core principle of American copyright law. The Supreme Court has repeatedly underscored fair use provisions in the Copyright Act as a key means of protecting free speech, and many courts across the land have upheld the application of fair use as an affirmative defense to infringement, in a wide variety of circumstances.

In order to make fair use more accessible to the authors of the 21st century, ease confusion about permissible uses, and thereby encourage the production of a greater variety of creative works, the U.S. Copyright Office, working in consultation with the Administration, will publish and maintain an index of major fair use decisions, including a summary of the holdings and some general questions and observations that may in turn guide those seeking to apply the decisions to their own situations.

7. Raise Public Awareness

A significant component of an effective intellectual property enforcement strategy is to change public attitudes toward infringing activities.

Since the June 2010 Joint Strategic Plan:

- The Administration has worked with Federal agencies and a broad set of stakeholders to bring greater attention to the implications that counterfeiting and other intellectual property crimes have on jobs, the economy and the health and safety of consumers.
- On November 29, 2011, Attorney General Eric Holder, IPEC Victoria Espinel, Acting Secretary of Commerce Rebecca Blank, ICE Director John Morton, and President/CEO of the National Crime Prevention Council Ann Harkins unveiled the first comprehensive public awareness campaign to inform the public about the dangers of counterfeits and piracy. The campaign, funded through DOJ's Office of Justice Programs, includes television advertisements, print media advertisements, radio advertisements, Internet videos, and posters. Information about the campaign can be found at: http://www.ncpc.org/topics/intellectual-property-theft.
- The State Department has allocated public diplomacy funds to increase respect for intellectual property rights through public outreach. During FY 2010-2012, DOS, in partnership with host country public and/or private sector institutions, supported a total of 75 IPR public outreach campaigns across 51 countries to raise public awareness of the dangers surrounding counterfeit products, including counterfeit medicines and Internet piracy.

- On May 11, 2012, the FBI unveiled a public education campaign aimed at raising awareness of trade secret theft and the harm that could result from it.
- On September 28, 2012, FDA launched BeSafeRx, a national campaign to educate consumers about the dangers of buying medicine from fake online pharmacies and help people safely buy medicine online. Information and resources for consumers and health professionals are available through FDA's BeSafeRx website.

Going forward:
Federal agencies will continue to look for opportunities to raise awareness and increase understanding of the risks from intellectual property infringement.

III. ENSURING EFFICIENCY AND COORDINATION

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

Numerous Federal law enforcement agencies investigate criminal intellectual property violations. To avoid duplication and waste and to benefit from the specialized expertise of particular agencies, it is critical that Federal law enforcement work together in an effective, efficient, and coordinated manner, that they coordinate and support state and local law enforcement, and that they track and report law enforcement activities.

Since the June 2010 Joint Strategic Plan:

- The IPR Center, which brings together law enforcement from across the U.S. Government and international partners to create greater coordination, improved use of resources and more effective enforcement, increased the number of law enforcement partners from 11 to 21 and now includes four international partners—Europol, INTERPOL, the Royal Canadian Mounted Police, and the Mexican Revenue Service (a list of current IPR Center partner agencies can be found on page 63). IPR Center partner agencies have participated in joint operations and investigations which has resulted in:
  - The de-confliction of 4,704 investigations.
  - Operation Network Raider, a joint initiative by DOJ, ICE-HSI, CBP, and the FBI, resulting in more than 30 felony convictions nationwide in cases involving the sale of counterfeit Cisco products imported from China and sold to the U.S. military for use in Iraq.
  - DOJ, ICE-HSI, CBP, the Naval Criminal Investigative Service (NCIS), and the U.S. Postal Inspection Service (USPIS), investigated and successfully prosecuted an employee of an integrated circuit importer for selling counterfeit circuits to the U.S. military. The counterfeit circuits were imported from China and intended for use in missile and antennae technologies.
  - DOJ, ICE-HSI, FDA-Office of Criminal Investigations (OCI), and USPIS obtained the convictions of defendants who manufactured and trafficked in a counterfeit version of the diet drug Alli. After a number of consumers who purchased from these defendants reported

adverse side effects, FDA issued a warning stating that the counterfeit product "posed a very serious health risk."

- In June 2010, the IPR Center initiated Operation In Our Sites, the first coordinated and sustained law enforcement effort to target websites that distribute counterfeit merchandise and pirated works. Since the operation's inception, Federal law enforcement agencies, in conjunction with DOJ, have conducted 13 operations targeting sites focused on particular subject matter such as sports apparel or luxury goods and resulting in the seizure of more than 1,700 domain names of infringing websites and monetary seizures of over $3 million.
- In April and May 2012, as a result of investigations generated by the IPR Center led Operation In Our Sites, in two separate cases ICE-HSI, working with DOJ, seized over $2 million in proceeds from online sales of counterfeit goods by Chinese perpetrators. The funds were seized from correspondent bank accounts located at the Bank of China in New York under 18 U.S.C. § 981(k), which permits the U.S. Government to seize funds from a foreign institution's interbank accounts in the United States for forfeiture to the Treasury. This was ICE-HSI's first use of section 981(k) to seize illicitly-derived proceeds identified as part of an intellectual property rights criminal investigation deposited in a Chinese bank.
- In November, the IPR Center issued its first international intelligence bulletin to INTERPOL, Europol, and the World Customs Organization reporting the dangers of counterfeit airbags. ICE-HSI and the National Traffic Highway Safety Administration (NHTSA) issued a safety advisory to U.S. consumers in October. The advisory was as a result of testing conducted by the NHTSA of airbags purchased online by ICE-HSI agents during the course of criminal investigations into the distribution of counterfeit airbags through online sales. The airbags were ordered online directly from China or from foreign-based wholesale business to wholesale business websites and were represented as the genuine manufacturer's part. In an effort to share information with international partners, the IPR Center transmitted an international intelligence bulletin to consumers outside the U.S. who could be at risk if these airbags are installed in their vehicles.

- DHS has continued to dedicate more law enforcement resources towards protecting intellectual property:
  - ICE-HSI has increased the number of its Intellectual Property Theft Enforcement Teams (IPTET) from 22 to 26. ICE-HSI has conducted 40 state and local trainings nationwide.
  - ICE-HSI increased IPR investigations initiated by 71 percent since FY 2009 and increased arrests by 159 percent since FY 2009. In FY 2012, ICE-HSI initiated 1,251 IPR investigations and made 691 arrests.
  - ICE-HSI and CBP have combined to seize 47,640 counterfeit and pirated items. The combined Manufacturer's Suggested Retail Price (MSRP) value of these seizures was $2.37 billion.
  - CBP began reporting on enforcement activities related to circumvention devices. Since 2010, when recordkeeping on such seizures began, CBP has seized 75 shipments of circumvention devices.

- DOJ has continued its focus on intellectual property enforcement:
  - The FBI has placed and trained 51 agents dedicated to intellectual property enforcement in 21 major U.S. cities and established an IPR Unit which is embedded at the IPR Center. Enhanced intellectual property investigative squads are located in four of those cities.
  - The FBI has increased arrests by 68 percent since 2010. In FY 2012, the FBI initiated 170 IPR investigations and made 111 arrests.
  - DOJ Bureau of Justice Assistance (BJA) program grantees have seized approximately $220 million worth of infringing goods and currency. This is approximately 22 times the value of the grants awarded.
  - DOJ through the National White Collar Crime Center and the National Association of Attorneys General has held 33 training events for state and local law enforcement personnel seminars nationwide.
  - In 2012, DOJ created a network of Federal prosecutors with special training in computer crimes and national security to support law enforcement agencies in the investigation of, among other things, economic espionage and trade secret theft perpetrated by national security threat actors.
  - Since FY 2009, the US Attorney's Offices filed 178 intellectual property cases against 254 defendants, representing a 2 percent increase in cases filed and a 14 percent increase in defendants charged compared to the prior year.

Going forward:
IPEC will continue to work with Federal agencies to ensure that there is cooperation and coordination among agencies at the Federal, state, and local level. DOJ and DHS will continue to track and report their enforcement activities as well as activities that support state and local law enforcement.

CBP will increase analysis of enforcement, investigative and trade data to proactively target shipments of pharmaceuticals, electronics, and textiles.

The IPR Center will also expand its partnerships with state and local agencies to develop solution-oriented approaches to address distribution of counterfeit and pirated products. Federal law enforcement will continue efforts to disrupt the capabilities of large-scale intellectual property crime by a variety of means, including seeking seizure and forfeiture of facilitating property and illicit proceeds.

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

Developments in technology can improve IPR enforcement. For example, deployment of additional mobile tools to personnel in the field such as CBP's Enforcement Link to Mobile Operations could decrease the cycle time for inspection and infringement determination. The development of intellectual property protection technologies is an important anti-counterfeiting objective to further Federal agency efforts, particularly those with national security or intelligence functions, to guard against counterfeits entering the U.S. Government supply chain.

Going forward:
IPEC will bring together an interagency working group to help identify new and innovative technologies to improve our IPR enforcement capabilities. One area of focus will be on identifying new technologies to enhance the ability of border enforcement agencies such as CBP to identify shipments of authentic goods without inspection, enabling inspection resources to be more effectively deployed to shipments that pose a higher risk of containing counterfeit goods.

Further, we will work to provide opportunities for experts to assist agencies engaged in IPR enforcement better navigate highly technical areas such as Internet architecture.

10. Improve Effectiveness of Personnel Stationed Abroad

Combating intellectual property infringement overseas is a priority for the Administration, and it is critical that U.S. Government personnel covering intellectual property issues on the ground in key countries are well-coordinated, both within the Embassy, and also with home agencies, to ensure their effectiveness with regard to addressing intellectual property protection and enforcement.

Since the June 2010 Joint Strategic Plan:

- IPEC established an interagency working group that is led by IPEC and DOS's Bureau of Economic and Business Affairs (EB) and consists of representatives from the DOS's Bureau of International Narcotics and Law Enforcement Affairs (INL), the U.S. Agency for International Development, the Department of the Treasury, DOJ (CCIPS and FBI), DHS (CBP and ICE-HSI), DOC (USPTO, ITA, and the Commercial Law Development Program (CLDP)), USTR, and the U.S. Copyright Office.
- The working group identified 17 key countries—Brazil, Russia, India, China, Canada, Chile, Colombia, Egypt, Israel, Mexico, Nigeria, Peru, Saudi Arabia, Spain, Thailand, Turkey, and Ukraine—where intellectual property protection and enforcement is a priority.
- The U.S. Embassies in the17 key countries established senior-level internal IP Working Groups bringing together all embassy personnel who play a role in IPR enforcement.
- The 17 embassies developed country-specific internal Embassy IP Work Plans with short-term (achievable within 12 months and less), and long-term goals (over 12 months to accomplish). The Embassy IP Working Groups meet regularly to discuss the Embassy IP Work Plans, to share information, and to collaborate on activities under the Plans.
- IPEC regularly communicates with these posts to ensure the effectiveness and efficiency of U.S. Government-wide engagement on international IPR issues, and the 17 key U.S. Embassies report to the interagency working group in Washington on a regular basis regarding their progress on implementing the Embassy IP Work Plans.
- IPEC and the interagency working group meet with stakeholders on an annual basis to gather country-specific suggestions for possible inclusion in the Embassy IP Work Plans.
- USPTO has placed IPR Attachés in seven countries, including the deployment of two new Attachés: one in Shanghai, China and one in Mexico City, Mexico. Their mission is to promote high standards of IP protection and enforcement internationally. The FBI posted an intellectual

property-trained agent in Beijing, China in September 2011 to work full time on intellectual property crime for a year. As a result of the promise shown, the FBI has renewed this effort and deployed a replacement in February 2013 with a focused emphasis on joint investigations.

Going forward:
The 17 key U.S. Embassies will continue to report regularly to the interagency working group regarding their progress on implementing the Embassy IP Work Plans. USPTO will continue to post IPR Attachés in high-priority countries, including Brazil, India, and Russia, three postings in China, Egypt, Mexico, and Thailand, and will examine the feasibility of including other key countries. The IPR Attaches will continue to participate actively in and contribute to the U.S. Embassies' IP Working Groups on enforcement related issues. Law enforcement agencies will leverage their internationally-located officials to increase focus on intellectual property crime. DOJ would deploy up to four ICHIP attorneys, cross-designated as DOJ Attachés, if funded as called for in the President's FY 2014 Budget, to strategic locations to strengthen international cooperation on enforcement, to address threats at the source, and to enhance international cooperation and capacity-building efforts.

11. Coordination of International Capacity-Building and Training

The U.S. Government has engaged in a range of training and capacity-building programs to strengthen intellectual property protection and enforcement internationally. IPEC has established processes to facilitate interagency coordination in the delivery of international enforcement-related capacity-building and training, and to ensure the most efficient use of limited training resources.

Since the June 2010 Joint Strategic Plan:

- IPEC established and leads an interagency working group, comprised of representatives from DOC (USPTO, ITA, and CLDP), DOS (EB and INL), and USAID, the Department of the Treasury, DOJ (CCIPS, FBI, and the Office of Overseas Prosecutorial Development, Assistance and Training (OPDAT)), DHS (CBP and ICE), USTR, and the U.S. Copyright Office, to ensure efficiency and coordination in the design and delivery of international technical assistance and capacity-building programs. The interagency working group regularly meets to share information on past and upcoming programs and works together to prioritize countries and topics for training.
- USPTO established and administers a searchable database website entitled the Global Intellectual Property Education Database (www.usipr.gov) of intellectual property-related technical assistance and capacity-building programs delivered by U.S. Government agencies. The website is designed to prevent duplication of programming and resources and to improve efficiency and programming results by building upon past programs and targeting U.S. Government efforts on countries and topics of highest priority.
- DHS, DOC, DOJ, and DOS have collaborated on and delivered intellectual property capacity-building and enforcement programs, including those on civil and criminal aspects of online enforcement and border enforcement, as well as combating counterfeit drugs, among many others. For examples, please see agency reports.

Going forward:

- IPEC and DOS will organize the interagency working group on U.S. Government personnel overseas on a regional basis to better coordinate on IP enforcement-focused region-wide issues and best practices.
- All agencies delivering IP-related training and capacity-building programs will provide quarterly submissions of accurate and up-to-date data through the Global Intellectual Property Education Database.
- DOJ, USPTO, and DOS will continue to focus efforts on building awareness and understanding of intellectual property among foreign judges, particularly with respect to technological trends in infringement and technological advances in investigations of infringement. Agencies will also continue to use opportunities and encounters with judicial authorities to share information on their agencies' work.
- USPTO and DOJ will continue to include in training and capacity-building programs, discussions of alternative dispute resolution and other ways to resolve appropriate intellectual property cases fairly and efficiently, particularly in countries where heavy judicial backlogs are preventing intellectual property cases from being heard in a timely manner and options are being considered to increase the efficiency of the judicial system.
- USPTO, DOJ, ITA, and DOS will include trade secret theft among potential topics for programming, particularly in countries that are known to present high-risk conditions for trade secret theft.
- USPTO, DOS, and the U.S. Copyright Office will continue to provide technical assistance and capacity-building programs on the U.S. copyright system, including, as appropriate, its strong incentives for authors and creators, the role of limitations and exceptions, and effective enforcement measures.
- Appropriate members of the relevant Embassy IP Working Group will follow-up with technical assistance/capacity-building program recipients on an ongoing basis—for example, at the two-month, six-month, and one-year mark—following a U.S. Government sponsored IPR enforcement-related program to assess local actions, if any, that resulted since the program.

12. Consider Alternative Forums for Enforcement of Rights

Photographers, illustrators, inventors, and others have expressed frustration that the current Federal court litigation framework for pursuing civil enforcement of their intellectual property rights is time consuming and prohibitively expensive, effectively impacting their ability to pursue infringement claims that have a relatively small economic value.

With respect to copyright claims, over the past year, the U.S. Copyright Office has been examining the feasibility of a copyright small claims adjudicatory process through extensive public outreach, including soliciting written comments through notices in the *Federal Register*, and holding public meetings to obtain input from interested parties. The U.S. Copyright Office has commenced its study at the request

of Congress and expects to deliver recommendations regarding the feasibility of a copyright small claims system in the fall of 2013. This is an issue the Administration is watching with great interest.

With respect to patent claims, USPTO is examining closely, with the American Bar Association (ABA), the Federal judiciary, and others, the concept of a patent small claims court proceeding. USPTO has organized public outreach, will continue to solicit public comments, and will provide recommendations regarding the concept in due course thereafter, in consultation with the ABA, the Federal judiciary, and other stakeholders.

IV. ENFORCING OUR RIGHTS ABROAD

13. Enhance Foreign Law Enforcement Cooperation

International law enforcement cooperation is a critical element to achieving the overall goal of combating counterfeiting, piracy, and trade secret theft. The global nature of these crimes demands that U.S. law enforcement agencies develop relationships with international counterparts.

Since the June 2010 Joint Strategic Plan:

- The IPR Center has added four international law enforcement partners to the center.
  - The Royal Canadian Mounted Police
  - The Mexico Revenue Service
  - INTERPOL
  - Europol
- For the first time, a joint customs enforcement operation was conducted through the auspices of the Asia-Pacific Economic Cooperation (APEC) that led to over 1,200 enforcement actions against substandard, spurious, falsely-labeled, falsified, or counterfeit pharmaceutical shipments.
- Operation Pangea, an annual World Customs Organization operation to combat counterfeit pharmaceuticals, has expanded from 45 countries to 100 participating countries.
- In March 2011, Operation Short Circuit was initiated across 43 participating countries to increase their targeting, inspection, interdiction, and investigation of imports containing substandard and counterfeit electrical items such as power supplies, power adaptors, chargers, surge protectors, extension cords, holiday lights, and batteries. This global operation resulted in the seizure of over 4,000 boxes of extension cords and surge protectors, 791,936 individual batteries, over 75,000 power supplies and power adaptors, 115,117 chargers, and 4,760 boxes of holiday lights.
- DOJ has secured the extradition of several individuals indicted for Federal IPR violations and has received international cooperation on numerous others.
  - In 2010, Rodolfo Rodriguez Cabrera and Henry Mantilla were extradited to the U.S. from Latvia. Both men were convicted of producing and trafficking in counterfeit slot machines.

- In 2010, Manuel Calvelo was extradited from Costa Rica to face charges of operating an illegal online pharmacy that was distributing counterfeit drugs. Calvelo was convicted and sentenced to 48 months in Federal prison.
- In 2011, Ali Moussa Hamdan was extradited from Paraguay to face charges of distributing counterfeit goods and providing material support to Hezbollah.
- In January 2012, the FBI and DOJ collaborated with law enforcement in Australia, Canada, Germany, Hong Kong, the Netherlands, New Zealand, and the United Kingdom to arrest five individuals who were charged with operating an international organized criminal enterprise allegedly responsible for massive worldwide online piracy through Megaupload.com and other related sites. Through the assistance of international counterparts, the FBI and cooperating agencies executed more than 15 search warrants and seized approximately $50 million in assets in the U.S. and abroad.

Going forward:
Federal law enforcement will continue to pursue cooperation and assistance from foreign counterparts through the training of foreign counterparts. Federal law enforcement personnel deployed abroad will continue to cultivate relationships that lead to investigative assistance and cooperative efforts to address IPR infringement outside the territorial boundaries of the United States. Additionally, the President's 2014 Budget called for four International Computer Hacking and Intellectual Property (ICHIP) attorneys, cross-designated as DOJ Attachés, to address threats at the source and to enhance international cooperation and capacity-building efforts. The IPR Center will continue its efforts to expand its international partnerships, and will also continue to coordinate large scale global enforcement operations that target counterfeit goods and pirated works.

14. Strengthen Intellectual Property Enforcement through International Organizations

International organizations can and should play a positive role in improving enforcement of intellectual property.

Since the June 2010 Joint Strategic Plan:

- As part of the 2011 G-8 summit in France, G-8 leaders expressed strong support for intellectual property protections as a key principle, particularly as a component of the Internet economy and as a system to incentivize innovation and growth. The G-8 Declaration further articulated that:

  "With regard to the protection of intellectual property, in particular copyright, trademarks, trade secrets and patents, we recognize the need to have national laws and frameworks for improved enforcement. We are thus renewing our commitment to ensuring effective action against violations of intellectual property rights in the digital arena, including action that addresses present and future infringements. We recognize that the effective implementation of intellectual property rules requires suitable international cooperation of relevant stakeholders, including with the private sector. We are committed to identifying ways of facilitating greater access and openness to knowledge, education and culture, including by encouraging continued innovation in legal online trade in goods and content that are respectful of intellectual property rights."

- During the Camp David G-8 meeting on May 18-19, 2012, G-8 leaders again affirmed the significance of IPR protection and enforcement through a spectrum of approaches, including private-sector led voluntary codes of best practices to address online IPR infringement in the digital environment, implementing government procurement processes to combat counterfeits entering supply chains, and exchanging best practices on combating counterfeit pharmaceuticals and information on fake Internet pharmacies.
- In 2011, CBP led an enforcement partnership in the APEC forum targeting counterfeit pharmaceuticals shipped via mail and express carrier services that led to more than 1,200 enforcement actions against shipments containing more than 7 million fake or suspect pills and development of model effective practices for enforcing IPR in mail and express carrier facilities.
- The APEC 2011 Leaders Agreement on Promoting Effective, Non-Discriminatory, and Market-driven Innovation Policy included commitments by APEC member economies to: "provide effective protection and enforcement of IPR, refrain from local research and development requirements related to government procurement preferences, and ensure terms and conditions for technology transfer are voluntary and mutually agreed between individual enterprises." These commitments are expected to be implemented by November 2013 and should improve the environment for exports and direct foreign investment in the APEC region.
- In 2011 and 2012, U.S. law enforcement and Federal agencies, including DHS through ICE-HSI and CBP, DOJ, and FDA, participated in Operation Pangea IV and V, a global enforcement effort led by INTERPOL and the WCO that is aimed at disrupting organized crime networks behind the illicit online sale of fake drugs. In 2011, Operation Pangea IV resulted in the seizure of 7,901 packages with a value of $6.3 million in countries around the world. In 2012, Operation Pangea V resulted in 79 arrests and the seizure of 3.7 million doses of potentially life-threatening substandard, spurious, falsely-labeled, falsified, or counterfeit medicines worth an estimated value of $10.5 million, and approximately 18,000 websites engaged in the sale of counterfeit drugs being taken down.

Going forward:

CBP and DOS will continue to support the World Customs Organization's development of a Cargo Targeting System (CTS) that can be integrated into existing import and export operations management systems maintained by partner foreign governments. Successful deployment of CTS will support foreign partner governments' capabilities to curb illicit trade practices, including the flow of counterfeit goods prior to their attempted importation into the United States.

CBP will work to build upon the successes realized in 2011, particularly during the APEC Operation to expand enforcement efforts to cover counterfeit pharmaceuticals and electronic components shipped through the express carrier and international mail environments.

Federal agencies will continue to look for opportunities to further effective enforcement through the G-8, APEC, and other intergovernmental forums.

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

The U.S. Government leverages a range of trade policy tools to promote strong intellectual property rights protection and enforcement, including the annual Special 301 review of intellectual property protection and market access practices in foreign countries, trade agreements, and high-level bilateral engagement.

Since the June 2010 Joint Strategic Plan:

- USTR conducted annual Special 301 reviews, most recently in May 2013, examining intellectual property protection and enforcement in 95 trading partners—resulting in the listing of 41 trading partners as Watch List, Priority Watch List, or Section 306 Monitoring status. The 2013 Special 301 Report praised positive steps by eleven countries to address issues cited in previous reports; of these, one was removed from the Watch List and two others were downgraded from the Priority Watch List to the Watch List. Ukraine was designated as a Priority Foreign Country. USTR also reports on best practices by trading partners in the area of intellectual property enforcement in a special section of the annual Special 301 Report.
- Several trading partners, including Russia, are working with the United States to develop or implement action plans designed to positively impact future Special 301 reviews.
- In February 2011, USTR issued the first standalone Notorious Market List drawing special attention to particular online and physical foreign markets that deal with infringing products. In November 2011, USTR released the results of its second review, and on December 13, 2012, USTR released the results of its third review, listing over 30 Internet and physical markets that deal in infringing goods and services, facilitating and sustaining global piracy and counterfeiting. Following their inclusion on the Notorious Markets List, several markets have taken action to address the widespread availability of pirated or counterfeit goods. For example, Chinese search engine Baidu reached an agreement with global record companies, Russia's Savelovskiy Market adopted and implemented an action plan, and Chinese online shopping platform Taobao and search engine Sogou have both made notable efforts to work with copyright and trademark owners to address the availability of infringing goods and content on their sites.
- The Anti-Counterfeiting Trade Agreement (ACTA) was signed on October 1, 2011, by the United States and seven other countries.
- On October 21, 2011, President Obama signed legislation approving and implementing for the United States free trade agreements (FTAs) with Colombia, Panama, and South Korea; each contained strong provisions on IPR enforcement. USTR subsequently worked with these partners to bring all three agreements into force in 2012.
- USTR, working with other Federal agencies, is negotiating a Trans-Pacific Partnership (TPP) trade agreement with Australia, Brunei Darussalam, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam, which includes proposals for state-of-the-art provisions on civil, criminal, and border enforcement similar to the recent FTAs noted above. USTR is also seeking possible enhancements in certain areas, such as: provisions related to trade secret theft; provisions calling for enhanced penalties for counterfeiting offenses that threaten health and safety;

and a commitment by parties to seek to achieve an appropriate balance in their copyright systems in providing copyright exceptions and limitations for purposes such as criticism, comment, news reporting, teaching, scholarship, and research.

- On February 28, 2012, President Obama signed Executive Order 13601 creating the Interagency Trade Enforcement Center (ITEC) to investigate foreign trade barriers or unfair trading practices that harm the competitiveness of U.S. industries and cost American jobs. The ITEC will be focusing its efforts in several areas, including on foreign barriers and practices that interfere with the protection and enforcement of intellectual property rights.
- During the May 2012 U.S.-China Strategic and Economic Dialogue (S&ED), co-led by DOS and Treasury, China committed to creating an environment that would result in the increase in the sales of legitimate IP-intensive products and services within its borders, and agreed to intensify enforcement against trade secrets misappropriation. China also committed to continue promoting the use of legal software by Chinese enterprises, and to treat intellectual property owned or developed in other countries the same as that developed in China.
- The 22nd session of the US-China Joint Commission on Commerce and Trade (JCCT), co-led by DOC and USTR, was held in November 2011 in China, where China agreed to make a significant systemic change in its enforcement of intellectual property rights—namely the creation of a new high-level central government leading group on enforcement led by Vice Premier Wang Qishan. The State Council Leading Group on IP facilitates continued high-level government supervision and involvement in IP enforcement matters, and will enhance the Chinese Government's ability to coordinate Chinese government enforcement of intellectual property rights. In addition, China's leadership is committed to increased political accountability—a performance criterion of provincial level officials will be their enforcement of intellectual property rights in their regions. China also announced a new high-level central government mandate from the State Council requiring provincial and local governments—by December 1st 2011—to eliminate any policies that are not consistent with President Hu's commitment to sever the link between China's innovation policies and government procurement.
- At the 23rd session of the JCCT held in December 2012 in the United States, China confirmed that it requires state-owned enterprises to purchase and use legitimate software. In addition, China fulfilled a commitment made at the December 2012 JCCT when the Supreme People's Court released a Judicial Interpretation on Internet Intermediary Liability on December 17, 2012 (effective January 1, 2013), making clear that those who assist online infringement will be jointly liable for such infringement. China also reaffirmed that technology transfer and technology cooperation will be independent decisions made by businesses and will not be a precondition for market access.
- In February 2012, China agreed to significantly increase market access for U.S. movies in order to resolve outstanding issues related to films after the United States' victory in a World Trade Organization (WTO) dispute.

Going forward:
USTR, working with the Federal agencies, will continue to utilize the full range of trade policy tools, including those identified above. USTR will work with other signatories to bring ACTA into force, and will also continue working with all FTA partners to ensure full implementation of the commitments under the FTAs. DOS and Treasury, working with all relevant Federal agencies, including USTR, will continue their high-level engagement with China through the S&ED, and USTR and DOC (USPTO and ITA) will continue to use the JCCT to address key intellectual property priorities, such as trade secret theft and the need for stronger rule of law in litigation, and systemic IP-related concerns, such as market access tied to technology transfer and indigenous innovation policies.

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

The U.S. Government is pursuing an innovative and multi-pronged strategy to combat infringing foreign-based and foreign-controlled websites by encouraging cooperation by law enforcement, development of voluntary best practices, and international leadership.

Since the June 2010 Joint Strategic Plan:

- Operation Pangea is a joint global operation focused on targeting websites offering illicit and potentially dangerous substances to consumers in the United States and abroad. In 2012, Operation Pangea V resulted in the shutdown of more than 18,000 illegal pharmacy websites and the seizure of about $10.5 million worth of pharmaceuticals worldwide.
- In the fall of 2011, the co-founders and other top administrators of NinjaVideo.net, a website offering pirated movies and television programs to millions of users, which is hosted on servers located in the Netherlands and France, pleaded guilty to criminal copyright infringement and were later sentenced to Federal prison. In April and May 2012, in two separate cases generated from Operation In Our Sites investigations, ICE-HSI seized over $2 million in proceeds from online sales of counterfeit goods from the Bank of China in New York.
- Voluntary initiatives by the private sector are intended to help reduce the ability of foreign and domestic websites to target U.S. consumers. IPEC has worked closely with Internet service providers (ISPs), advertisers, credit card companies, payment processors, search engines, domain name registrars, and registries to encourage voluntary steps to reduce infringement. See **Facilitate Voluntary Initiatives to Reduce Online Intellectual Property Infringement and Illegal Internet Pharmacies**.
- USTR has issued three Notorious Markets Lists, which identify foreign websites offering pirated and counterfeit products as part of its annual review of physical and online markets that deal in copyright and trademark infringing goods. As noted, several markets included on those lists have taken action to address concerns. See **Promote Enforcement of U.S. Intellectual Property Rights through Trade Policy Tools.**
- Law enforcement officials from ICE-HSI and FBI are stationed overseas and facilitate cooperation with foreign law enforcement to target intellectual property infringement occurring within

their jurisdictions. This cooperation has resulted in foreign law enforcement taking investigative action and seizing servers that host illegal content in the countries in which they are located.

- International leadership by the United States and its allies has raised the international standard for intellectual property protection in the online environment. For example, the G-8 Declaration in May 2011 specifically highlights the "digital arena" as an area for "effective action against violations of intellectual property rights" and the G-8 Declaration in May 2012 contains a strong expression of support for high standards for IPR protection and enforcement and for voluntary best practices to reduce infringement online.
- During FY 2011-2012, DOS supported 33 public outreach campaigns that focused on the cost of Internet piracy. The campaigns were designed and driven by embassy staff in partnership with host country public and/or private sector institutions and leveraged seed money from DOS with significant financial and in-kind contributions from partners, covering diverse geographical areas including Asia, the Middle East, Europe, and South America.

Going forward:
We recognize that no single approach will solve the problem of intellectual property infringement online. As a result, we will continue to simultaneously pursue a variety of tactics as laid out above.

17. Protect Intellectual Property at ICANN

The expansion of the domain name system (DNS) through the implementation of ICANN's new generic top-level domains (gTLDs) is an important evolution in the administration of the DNS, which brings with it the need to ensure the new gTLDs take into account and provide for meaningful intellectual property and other safeguards and support the type of innovation and competition that has led to the success of the modern Internet.

Going forward:
Coordinated via the NTIA-administered DNS Interagency Working Group, NTIA will continue to lead the U.S. Government's engagement with ICANN's multi-stakeholder processes to further improve the new gTLD program, including through mechanisms for intellectual property protection, and to mitigate abuses of the domain name registration system. Specifically, NTIA will collaborate with all U.S. stakeholders, including intellectual property stakeholders, as well as other Federal agencies, such as USPTO, and FBI and other law enforcement agencies, to develop positions within ICANN's Governmental Advisory Committee (GAC) to advance access to accurate, complete, and publicly available WHOIS data, improvements to the Registrar Accreditation Agreement (RAA) between Registrars and ICANN, effective contract compliance by ICANN, and appropriate consideration of intellectual property issues in the context of gTLDs.

In this regard, NTIA will closely monitor the effectiveness of the Rights Protection Mechanisms (RPMs), such as the Trademark Clearinghouse and Trademark Claims Service, and the Uniform Rapid Suspension System (URS), that have been developed in conjunction with the new gTLD program to ensure they provide meaningful and effective remedies so that new gTLDs do not become avenues for cybersquatting and infringing activities. NTIA will work through all appropriate mechanisms within the ICANN multi-stakeholder process, and particularly the GAC, to review the effectiveness of the new RPMs, and

to seek necessary course corrections as affected U.S. stakeholders gain experience with the new DNS environment. In addition, NTIA will closely monitor adoption and implementation by Registrars of the revised Registrar Accreditation Agreement (RAA), which will include a specific focus on ICANN's contract compliance capabilities and results to ensure that ICANN holds its accredited Registrars to all of the new commitments included in the RAA.

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

American exporters face various barriers to entry into overseas markets, including barriers relating to inadequate protection and enforcement of intellectual property rights. Small businesses can be particularly vulnerable to intellectual property theft, simply because many small businesses may not be aware of the need, or may not have the information and resources available to them, to take the steps necessary to protect their intellectual property. Our review of existing U.S. Government efforts to educate, guide and provide resources to U.S. businesses shows that agencies have done good work to fill this need. However, these efforts could be more effective if existing coordination is strengthened, if the resources developed are targeted more narrowly to better address the unique needs of small and medium size enterprises (SMEs), and if the tools that have been developed and options for assistance are more accessible to the public.

Since the June 2010 Joint Strategic Plan:

- STOPfakes.gov was re-launched in March 2012 in a new format that will be particularly helpful to SMEs. Improvements include a focus on practical tools and resources for businesses, an expansion of the American Bar Association (ABA) International IP Advisory Program to include National Export Initiative countries and African countries, and the addition of closed-captioning for all China IP webinars. In conjunction with the re-launch, a joint Transatlantic IPR portal was created, giving Americans access to all of the EU's IPR resources worldwide. STOPfakes.gov is also expanding resources for consumers, including providing links to infringement reporting mechanisms at a number of popular online retailers and marketplaces and links to public awareness efforts, such as the Center for Safe Internet Pharmacies.
- USPTO, in partnership with the National Institute of Standards and Technology Hollings Manufacturing Extension Partnership program, launched an IP Awareness Assessment Tool in spring 2012, which assists small businesses and inventors with assessing their intellectual property needs and learning what steps they should take to protect and enforce these valuable assets. Go to www.uspto.gov/inventors/assessment or www.stopfakes.gov/business-tools.
- ITA partnered with U.S. Export Assistance Centers (USEAC), the Small Business Administration (SBA), USPTO, and the IPR Center on a new outreach program. The STOPfakes.gov road show traveled to eight U.S. cities to raise SME awareness about working with law enforcement and avoiding pitfalls when exporting to foreign markets. The road shows also provided opportunities for SMEs to receive individualized attention from IPR and trade experts.
- In addition to the road shows, USPTO has also continued to partner with ITA and other U.S. Government agencies to conduct Intellectual Property Awareness Campaign events for SMEs in cities throughout the United States. These "IP Basics" events included presentations on pat-

ents, trade secrets, trademarks, domain names, copyright protection, and enforcement, both domestic and overseas. At the conclusion of the programs, USPTO and other USG presenters also held one-on-one meetings with SMEs to discuss specific issues in more detail.

- As part of the DOC's overall IPR-outreach related activities, ITA continued its highly successful China Webinar Series. These webinars, conducted by the Office of China and Mongolia, offer U.S. SMEs doing business in China the opportunity to discuss current IPR issues with attorneys practicing in China. The entire webinar series is available free of charge on STOPfakes.gov.
- USPTO initiated a comprehensive "train-the-trainer" program for SBA Small Business Development Center (SBDC) employees, who provide a wide array of technical assistance to small businesses and aspiring entrepreneurs nationwide, through a series of webinars on patents, trademarks, copyright, enforcement, and China-related IP issues.

Going forward:

- DOC will reach out to U.S. SMEs through its existing and extensive network of offices and partners to ensure that SMEs throughout the United States, particularly those businesses contemplating exporting, have an opportunity to learn why protecting and enforcing their intellectual property rights is an essential consideration in their business planning. DOC (including ITA and USPTO) will gather input on how existing IP-related educational efforts could be improved and/or expanded. For example, USTR and DOC's Industry Trade Advisory Committee (ITAC-11) for Small and Minority Business have made recommendations on improving intellectual property educational efforts for SMEs, which agencies should take under consideration when planning educational efforts.
- DOC (including ITA and USPTO), DOJ, DOS, and the U.S. Copyright Office will review the current state of "IPR Toolkits", developed by U.S. Embassies to help companies navigate the intellectual property rights protection and enforcement regimes of nearly 20 countries, to ensure that those materials are SME-friendly and provide points of contact for questions.
- ITA, with the USEACs, SBA, USPTO, and the IPR Center, will continue its STOPfakes.gov road shows throughout the United States to increase IPR awareness among SMEs. For FY 2013, the STOPfakes.gov road shows are planned for 18 cities in the United States. ITA and USPTO also will continue to educate SMEs on the benefits of protecting their IPRs at the border.
- ITA will continue to use its China Webinar Series to explore issues of concern. USPTO and ITA will continue to expand their outreach efforts including continuing to partner with USEACs across the United States with the goal of holding at least one "live" full-day comprehensive program per month and follow-up webinars, expanding the SBA train-the-trainer program to include USEACs and other Federal employees who are counseling SMEs about protecting and enforcing IP and exporting IP-intensive products to foreign markets, expanding outreach to include relevant state authorities, such as state offices responsible for registering trade names, and conducting China road show events to better inform U.S. SMEs on how to protect and enforce intellectual property rights in China.

19. Examine Labor Conditions Associated with Infringing Goods

There have been anecdotal reports that poor and dangerous working conditions, sometimes involving child labor, are found to exist in facilities where counterfeit and pirated goods are being manufactured overseas or in illicit distribution networks. A deeper analysis of the issue would shed greater light on the problem and provide an opportunity to strengthen our engagement with foreign governments and improve efforts to combat manufacturing and distribution of illicit counterfeit and pirated goods. In addition, the resulting information could enhance public awareness of the direct connection between purchasing infringing goods, supporting illicit businesses, and the impact on working men and women across the globe.

Going forward:
DOS will begin an examination of the nexus between unacceptable working conditions and the production and distribution of counterfeit goods in certain countries. Further actions will be considered depending upon the outcome of that examination.

V. SECURING THE SUPPLY CHAIN

In his 2012 State of the Union address, President Obama stated that "[t]here will be more inspections to prevent counterfeit or unsafe goods from crossing our borders." Our Federal agencies will continue to build upon this national priority through a variety of initiatives.

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

Since the first Joint Strategic Plan, the Administration has pursued and delivered important new authorities and tools that enhance the enforcement capabilities of the U.S. Government agencies charged with protecting intellectual property rights. However, there remain agencies whose legal authorities do not provide them with all of the tools necessary to combat increasingly sophisticated counterfeit and pirated goods, which the Administration will continue to vigorously pursue.

Since the June 2010 Joint Strategic Plan:

- As part of the Administration's March 2011 White Paper on Intellectual Property Enforcement Legislative Recommendations, IPEC recommended legislation to provide DHS with authority to share information about and samples of suspected infringing imports and circumvention devices capable of circumventing technological measures that control access to and copying of copyrighted works with affected rightholders to assist CBP with infringement determinations. In July 2011, CBP submitted a legislative proposal to Congress reflecting the White Paper's recommendation.
- On December 31, 2011, President Obama signed *Public Law 112-81 - The National Defense Authorization Act for Fiscal Year 2012*, which gave CBP authority to share information about and samples of suspected counterfeit imports with trademark owners in order to assist CBP with making an infringement determination.

Going forward:
In line with the Administration's 2011 White Paper on Intellectual Property Enforcement Legislative Recommendations, we will continue to support Congressional efforts to provide DHS with information-sharing authority, including concerning copyright infringement, export violations, and circumvention devices.

At the same time, CBP will move forward to propose regulations to expand the agency's authority to share information concerning circumvention devices with affected companies. The regulation would authorize CBP to share information about and samples of potential circumvention devices to aid CBP in making a seizure determination. Under the new regulation CBP personnel would also be able to provide affected companies with post-seizure samples of circumvention devices and importer information under streamlined bonding requirements.

21. Increase Focus on Working with Express Carriers and on Counterfeits Shipped through International Mail

Shipments of counterfeit goods sent through international mail and express carriers have increased significantly in large part due to online sales by commercial counterfeiters directly to consumers and businesses.

Going forward:
CBP, ICE-HSI, FDA, and USPIS will continue Operation Safeguard in 2013 with a series of joint special operations focused on international mail and express carrier facilities.

CBP and FDA will work with private sector stakeholders, including the express carriers, and CBP's advisory committee, to identify efforts that could be undertaken between the U.S. Government and the private sector to improve enforcement efforts in express carrier facilities, including working collaboratively on enforcement operations and having express carriers provide advance data to CBP to improve targeting. CBP will work to leverage the success of and lessons learned from its existing Air Cargo Advanced Screening program in which express carriers provide advanced data to CBP to improve counterterrorism targeting of shipments.

In addition, CBP and DHS policy offices, in collaboration with FDA and USPS, will develop and implement a program to obtain advance data from international postal operators in order to better segment high risk shipments and importers from known low risk shipments and importers. CBP is currently engaged in a pilot program to obtain advance data from international postal operators focused on security. If successful, this may provide a model for extending to trade enforcement, including better targeting of counterfeits.

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

As an Administration, we have adopted the approach of encouraging the private sector to develop and implement cooperative voluntary initiatives to reduce infringement that are practical and effective. It is critical that such efforts be undertaken in a manner that is consistent with all applicable laws and with the Administration's broader Internet policy principles emphasizing privacy, free speech, competition, and

due process. Together with law enforcement efforts, private sector voluntary actions can dramatically reduce online infringement and change the enforcement paradigm. We encourage all participants to continue to work with all interested stakeholders, including consumer advocacy groups, to ensure that voluntary initiatives are as effective and transparent as possible.

Since the June 2010 Joint Strategic Plan:

- In December 2010, technology companies announced that they would form a non-profit group—now known as the Center for Safe Internet Pharmacies (CSIP)—to combat illegal online "pharmacies," criminals masquerading as legitimate pharmacies. In 2011, CSIP filed for non-profit status and established leadership positions, and it formally launched on July 23, 2012. CSIP will educate the public about the risks of illegal online pharmacies, while CSIP members can take voluntary steps to stop providing services to illegal Internet pharmacies. Today, the CSIP members are American Express, Discover, eNom, Facebook, Go Daddy, Google, MasterCard, Microsoft, Neustar, PayPal, Visa, and Yahoo!.
- In June 2011, American Express, Discover, MasterCard, PayPal, and Visa developed voluntary best practices to withdraw payment services for sites selling counterfeit and pirated goods. The International AntiCounterfeiting Coalition, a trade association representing brand owners, has established a portal to provide an efficient mechanism for brand owners to work with credit card companies.
- In July 2011, a memorandum of understanding was finalized among several ISPs—AT&T, Comcast, Cablevision, Verizon, and Time Warner Cable—and major and independent music labels and movie studios to reduce online P2P piracy.
- In May 2012, the Association of National Advertisers and the American Association of Advertising Agencies issued a leadership pledge to not support online piracy and counterfeiting with advertising revenue.
- Also in May 2012 at the Camp David G-8, President Obama and the other members of the G-8 leadership expressed support for voluntary best practices to reduce infringement, specifically highlighting counterfeit drugs.

Going forward:
IPEC will continue its ongoing work with advertising networks, encouraging them to establish best practices in order to reduce advertising revenue that supports online infringement. We will continue to facilitate and encourage dialogue among different private sector entities that make the Internet function, which may include domain name registries and registrars; search engines; and cyberlockers and other types of storage services.

Rightholders have a critical role to play. Voluntary initiatives will be most effective and efficient if all stakeholders are working together cooperatively. Consequently, we will pursue a set of best practices for rightholders that are using the voluntary initiatives created by service providers.

We believe that this Administration's voluntary, non-regulatory approach to combating online infringement may serve as a positive example to other countries as they contemplate their own Internet poli-

cies. We will work with other countries on voluntary approaches, consistent with our commitment to privacy, free speech, competition, and fair process, including on implementation of the Camp David G-8 commitments.

We remain optimistic that voluntary initiatives will be an effective tool in our multi-faceted approach to fight infringement. IPEC will be vigilant and revisit voluntary measures to make sure that they are working and that they are effective. As 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.

23. Combat the Proliferation of Counterfeit Pharmaceuticals and Medical Devices

The Administration has taken action on several fronts to implement the pharmaceutical strategy and combat the proliferation of counterfeit pharmaceuticals and medical devices.

Since the June 2010 Joint Strategic Plan:

- In 2010, IPEC established an interagency working group on counterfeit pharmaceuticals to bring together the expertise of numerous Federal agencies whose authorities deeply impact pharmaceutical enforcement. The working group was convened by IPEC and includes DOC, DHS (CBP and ICE-HSI), DOJ, DOS, FDA, and USAID.
- Based on the efforts of that interagency working group, IPEC issued a strategy to Vice President Biden and Congress in March 2011 that described in detail how the U.S. Government will work to fight counterfeit drugs sold on the Internet, smuggled into the United States, and sold in cities nationwide.
- Federal law enforcement has met with great success in fighting counterfeit pharmaceuticals, as the number of counterfeit pharmaceuticals seizures by DHS has risen steadily in the past few years, with a nearly 600 percent increase in counterfeit pharmaceutical seizures from FY 2009 to FY 2011.[3]
- There have been three Operation Pangea global sweeps with the IPR Center working with INTERPOL and the WCO. Operation Pangea V—operated between September 25 and October 2, 2012—involved a record 100 participating countries and led to the shutdown of more than 18,000 illegal pharmacy websites and the seizure of about $10.5 million worth of pharmaceuticals worldwide. On October 3, 2012, in conjunction with Operation Pangea, HSI Baltimore, in coordination with the IPR Center, executed seizure warrants for 686 U.S.-based websites linked to the sale of substandard, spurious, falsely-labeled, falsified, or counterfeit pharmaceutical drugs as part of an international effort to dismantle the global online counterfeit drug trade. The seizures of domain names were a result of an In Our Sites Operation dubbed "Project Bitter Pill."
- In 2011 and 2012, CBP in collaboration with ICE-HSI, FDA, and USPIS conducted Operation Safeguard, a series of joint special operations at international mail and express carrier facilities focused on counterfeit, unapproved, and/or adulterated pharmaceuticals. In addition to the

3. FY 2011 was the last year that CBP reported data on counterfeit pharmaceuticals.

direct enforcement activities carried out as part of Safeguard, the joint operation identifies, measures, and attacks potential vulnerabilities in the entry process that might permit the smuggling of commercial quantities of counterfeit, unapproved, and/or adulterated pharmaceuticals.

- In 2011, Operation APEC was a year-long CBP-led APEC Mutual IPR Enforcement Operation that targeted counterfeit pharmaceuticals which resulted in developing model practices for intellectual property enforcement in international postal and express courier facilities. See **Strengthen Intellectual Property Enforcement through International Organizations**.
- In December 2010, eleven market leaders committed to form a non-profit group to combat illegal fake online "pharmacies." The Center for Safe Internet Pharmacies formally launched in July 2012. See **Facilitate Voluntary Initiatives to Reduce Online Intellectual Property Infringement and Illegal Internet Pharmacies**.
- In 2011, CBP instituted a pilot program—the Centers for Excellence and Expertise (CEE) — that focused on forming closer partnerships with pharmaceutical companies to better understand industry practices and leverage this information into more efficient and effective enforcement. To build upon these successes, CBP permanently established the Pharmaceutical CEE in New York City in November 2011.
- In the White Paper on Intellectual Property Enforcement Legislative Recommendations submitted to Congress in March 2011, the Administration recommended that Congress adopt a track-and-trace system for pharmaceuticals and related products.
- In July 2012, President Obama signed into law *Public Law 112-144 - The Food and Drug Administration Safety and Innovation Act*, which incorporates several of the IPR enforcement recommendations contained in the March 2011 Administration White Paper on Intellectual Property Enforcement Legislative Recommendations. The Act:
  - Enhances penalties for trafficking in counterfeit drugs and directs USSC to review and amend, if appropriate, its guidelines and policy statements related to counterfeit drugs.
  - Allows FDA, after issuing implementing guidance or regulations, to require that companies notify FDA if their drug has been counterfeited or stolen, and;
  - Granted FDA authority to destroy, without the opportunity to export, counterfeit, misbranded or adulterated drugs imported to the United States that are valued at $2,500 or less.
- In 2011 and 2012, DOS renewed its focus on combating counterfeit pharmaceuticals and devoted one third of its international intellectual property training funds to help other countries build capacity to combat counterfeit drugs, funding training conducted by DOJ, DHS, and USPTO.
- During FY 2010-2012, DOS supported 33 public outreach campaigns focused exclusively on the dangers of counterfeit pharmaceuticals. The campaigns were done in partnership with host country public and/or private sector institutions and leveraged seed money from DOS with significant financial and in-kind contributions from partners, covering a diverse geographical area including Africa, Asia, the Middle East, Europe, and South America.

- In February 2012, FDA warned health care professionals and the public about a counterfeit version of the injectable cancer drug Avastin, which may have been purchased and used by some medical practices in the United States. The counterfeit version of Avastin did not contain the active ingredient, bevacizumab. FDA also issued letters to 19 U.S. medical practices that purchased unapproved cancer medicines that potentially included the counterfeit version of Avastin.
- In April 2012, FDA informed the healthcare community and the public that another cancer medicine had been determined to be counterfeit. Specifically, a counterfeit version of Roche's Altuzan 400mg/16ml (bevacizumab), originating from a foreign source and purchased by U.S. medical practices, contained no active ingredient. FDA further informed the healthcare community that medical practices that purchase and administer illegal and unapproved foreign medications are putting patients at risk of exposure to drugs that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous.
- In September 2012, FDA unveiled a handheld Counterfeit Detection (CD3) device, developed by FDA scientists, which can be used to rapidly screen and detect suspect products and packaging such as in the case of counterfeits. Light of selected wavelengths emitted by the CD3 enables users to visualize differences between suspect products and authentic products and provides preliminary findings in the field in real-time.

Going forward:
The Administration recognizes the significant threat of dangerous counterfeit, unapproved, or illegally prescribed pharmaceuticals, and we will continue to employ a wide range of responses to tackle this problem.

FDA will expeditiously develop and issue regulations necessary to implement the destruction authority provided for under FDASIA for counterfeit, misbranded or adulterated drugs imported to the United States that are valued at $2,500 or less.

Further, with respect to notification by companies to the FDA when a drug has been counterfeited or stolen, FDA will ensure that guidance or regulations associated with this authority are implemented as expeditiously as possible.

The Administration remains supportive of track-and-trace systems as an effective tool against counterfeit pharmaceuticals and related products. We will continue to encourage efforts by FDA, Congress, and stakeholders to pursue a national approach to implementation of track-and-trace systems for pharmaceuticals and medical products.

VI. DATA DRIVEN GOVERNMENT

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

The changing nature of infringement and the increasing sophistication of intellectual property violators highlight the importance of maintaining laws that effectively and comprehensively combat infringement.

Since the June 2010 Joint Strategic Plan:

- IPEC worked with the Federal agencies to conduct a review of domestic legislation to determine if there were deficiencies. At the conclusion of that review, in March 2011, the Administration made 20 recommendations to Congress to strengthen IPR enforcement in the White Paper on Intellectual Property Enforcement Legislative Recommendations.
- Since the release of the White Paper, IPEC and relevant agencies have been working with Congress on legislative proposals that reflect the White Paper recommendations.
- Seven of the recommendations are now law. Respectively, the enacted bills have:
  - Increased penalties for counterfeit goods or services sold to, or for use by, the military or national security apparatus.
  - Bolstered criminal penalties for economic espionage and directed USSC to consider increasing offense levels for trade secret crimes.
  - Granted CBP authority to share information regarding suspected counterfeit goods with trademark owners in order to assist CBP in making infringement determinations.
  - Increased penalties for trafficking in counterfeit drugs.
  - Directed USSC to review guidelines and policy statements related to offenses that involve counterfeit drugs.
  - Allowed FDA to require pharmaceutical manufacturers to notify the FDA when a drug they manufacture has been found to be counterfeited or stolen.
  - Granted FDA the authority to destroy, without the opportunity to export, counterfeit, misbranded, or adulterated drugs imported to the United States that are valued at $2,500 or less.

It is also worth noting the enactment of Public Law112-236 - *The Theft of Trade Secrets Clarification Act of 2012,* which closed a loophole by clarifying that the scope of the Economic Espionage Act protects trade secrets related to "a product or service used in or intended for use in" interstate or foreign commerce, and is in line with the overall Administration priority of protecting trade secrets from misappropriation.

Further information on enacted legislation can be found in the Annex of this strategy.

Going forward:
IPEC will initiate and coordinate a process, working with Federal agencies and the U.S. Copyright Office, to review existing intellectual property laws to improve enforcement. This review will examine potential shortfalls in existing laws, gaps created by advances in technology, and limitations placed on agencies by outdated language, taking into account all relevant sections of the Green Paper on Copyright Policy, Creativity, and Innovation in the Internet Economy currently being developed by USPTO. The initial review process will be completed within 120 days from the date of the submission of this Joint Strategic Plan to Congress. The Administration, coordinated through IPEC, will recommend to Congress any proposed legislative changes to improve enforcement resulting from this review process.

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

The Administration undertook an economic analysis to identify the industries that most intensively produce intellectual property and to measure the importance of those industries to the U.S. economy.

Since the June 2010 Joint Strategic Plan:

- On April 11, 2012, DOC, working with the President's Council of Economic Advisors and the chief economists of the USTR, the Department of Labor, and other Federal agencies, released a report identifying the sectors that generate intellectual property, as well as the jobs, exports, and wage premiums those sectors support.
- The report, titled *Intellectual Property and the U.S. Economy: Industries in Focus*, was the first of its kind and makes clear that intellectual property is a key driver of our economy.

Going forward:
The Administration will make this an annual report. DOC, working with other relevant Federal agencies, will calculate the number of jobs and the contribution to the GDP on an annual basis and release those figures in an updated report at the end of the following calendar year. The next updated report will be released in December 2013.

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

Several agencies devote resources toward intellectual property enforcement, and IPEC collects information annually in order to better track baselines and resource allocations.

Since the June 2010 Joint Strategic Plan:

- IPEC collects this information through a Budget Data Request (BDR), whereby agencies report the amount of resources they dedicated to human capital and programs and planned and estimated expenditures for future years.

Going forward:
IPEC will continue to coordinate this BDR annually and will request the same data and metrics to allow for cross and multi-year comparisons.

Performance Data

Law Enforcement Investigations and Prosecutions

ICE- Homeland Security Investigations (ICE/HSI)

- In FY 2012, ICE/HSI initiated 1,251 intellectual property investigations and had 691 arrests, 423 indictments, and 334 convictions.
  - In FY 2011 ICE/HSI opened 1,212 intellectual property investigations and had 574 arrests, 355 indictments, and 291 convictions.
  - In FY 2010, ICE/HSI opened 1,033 intellectual property investigations and had 365 arrests, 216 indictments, and 170 convictions.
  - In FY 2009, ICE/HSI opened 730 intellectual property investigations and had 266 arrests, 116 indictments, and 164 convictions.

Since FY 2009, ICE/HSI has significantly increased its enforcement activities, including a 71 percent increase in opened intellectual property cases, a 159 percent increase in arrests, a 264 percent increase in indictments, and a 103 percent increase in convictions.

Federal Bureau of Investigation (FBI)

- In FY 2012, the FBI initiated 170 intellectual property investigations, made 111 arrests, secured 66 indictments/informations, and obtained 74 convictions.
  - In FY 2011, the FBI initiated 235 investigations, made 93 arrests, secured 79 indictments/informations, and obtained 79 convictions.
  - In FY 2010, the FBI opened 218 investigations and had 66 arrests, 73 indictments/informations, and 79 convictions.
  - In FY 2009, the FBI opened 151 investigations and had 96 arrests, 127 indictments/informations, and 76 convictions.

Since FY 2009, the FBI has reported a 39 percent increase in its number of new trade secrets cases, a 221 percent increase in new health and safety intellectual property investigations, a 286 percent increase in health and safety-related arrests, and a 308 percent increase in pending health and safety intellectual property cases.

Since FY 2009, pending IPR investigations have decreased by 22 percent and arrests have increased by 15 percent.

National Intellectual Property Rights Coordination Center (IPR Center)

- In FY 2012, the IPR Center vetted 283 investigative leads directly referred to it and de-conflicted 4,704 investigative leads submitted by field offices and partner agencies.

- In FY 2011, the IPR Center vetted 178 leads directly referred to it and de-conflicted 2,877 investigative leads submitted by field offices of partner agencies.
- In FY 2010, the IPR Center vetted 240 leads directly referred to and de-conflicted 544 investigative leads submitted by field offices of partner agencies.
- In addition, the IPR Center, in coordination with INTERPOL, the World Customs Organization and law enforcement authorities in 100 countries successfully carried out *Operation Pangea V*, focusing on websites supplying illegal and dangerous medicines to consumers in the U.S. and abroad.

Since FY 2010, when data first became available, the IPR Center's number of de-conflicted investigative leads submitted by field offices and partner agencies increased by 764 percent.

Department of Justice Prosecutions

- **Charges:** In FY 2012, Assistant U.S. Attorneys (AUSAs) received 390 intellectual property referrals, and they charged 178 cases involving 254 defendants.
  - In FY 2011, AUSAs received 387 intellectual property referrals, and they charged 168 cases with 215 defendants.
  - In FY 2010, AUSAs received 402 intellectual property referrals, and they charged 177 cases with 259 defendants.
  - In FY 2009 AUSAs received 285 intellectual property referrals, and they charged 173 cases with 235 defendants.
- **Sentencing:** In FY 2012, courts sentenced 202 intellectual property defendants. 95 received no prison term, 46 received sentences of 1-12 months in prison, 26 received sentences of 13-24 months in prison, 15 received sentences of 25-36 months in prison, 17 received sentences of 37-60 months and 3 received sentences of more than 60 months in prison.
  - In FY 2011, courts sentenced 208 intellectual property defendants, 102 received no prison term, 27 received sentences of 1-12 months in prison, 33 received sentences of 13-24 months in prison, 17 received sentences of 25-36 months in prison, 21 received sentences of 37-60 months and 8 received sentences of more than 60 months in prison.
  - In FY 2010, courts sentenced 207 intellectual property defendants. 121 received no prison term, 38 received sentences of 1-12 months in prison, 27 received sentences of 13-24 months in prison, 10 received sentences of 25-36 months in prison, 7 received sentences of 37-60 months and 4 received sentences of more than 60 months in prison.
  - In FY 2009, courts sentenced 233 intellectual property defendants. 126 received no prison term, 35 received sentences of 1-12 months in prison, 29 received sentences of 13-24 months in prison, 6 received sentences of 25-36 months in prison, 18 received sentences of 37-60 months and 9 received sentences of more than 60 months in prison.

District Totals	FY 2009	FY 2010	FY 2011	FY 2012
Investigative Matters Received by AUSAs	285	402	387	390
Defendants Charged	235	259	215	254
Cases Charged	173	177	168	178
Defendants Sentenced	223	207	208	202
No Prison Term	126	121	102	95
1-12 Months	35	38	27	46
13-24 Months	29	27	33	26
25-36 Months	6	10	17	15
37-60 Months	18	7	21	17
60 + Months	9	4	8	3

For more detailed information on the DOJ and FBI's overall efforts to combat intellectual property crime, see the respective PRO IP Act Reports for 2012 submitted to Congress. The reports are available at http://www.justice.gov/dag/iptaskforce/proipact/.

Department of Homeland Security Intellectual Property Seizures

Since FY 2009, CBP and ICE-HSI intellectual property seizures have increased by 53 percent, with 24,792 seizures carried out in FY 2011 representing the highest total number of seizures to date.

- In FY 2012, CBP and ICE-HSI effectuated 22,848 intellectual property seizures representing a 7.8 percent decrease in seizures compared to FY 2011, but a 14.5 percent increase in seizures over FY 2010.
- The MSRP of infringing goods seized, *i.e.*, the retail price infringing goods would have had if they were genuine, increased by 11.9 percent from $1.11 billion in FY 2011 to $1.26 billion in FY 2012, with an average seizure value of approximately $10,450.
- At international mail facilities, IPR seizures both by number and by MSRP increased over FY 2011. The number of IPR seizures increased by18 percent, while the MSRP of these seizures increased by 7.1 percent.

Consumer Safety and Critical Technology

- In FY 2012, seizures of counterfeit consumer safety and critical technology products totaled 3,402 reflecting a 22.2 percent decrease in seizures as compared to FY 2011, but an 11.5 percent increase in seizures over FY 2010.

- The MSRP of counterfeit consumer safety and critical technology products seized in FY 2012 was $146.4 million, reflecting a 25 percent decrease in MSRP value as compared to FY 2011.
- The top three categories of consumer safety and critical technology products seized in both FY 2012 and FY 2011 were pharmaceuticals/Personal Care, Consumer Electronics, and Critical Technology Components.

Shipping Methods

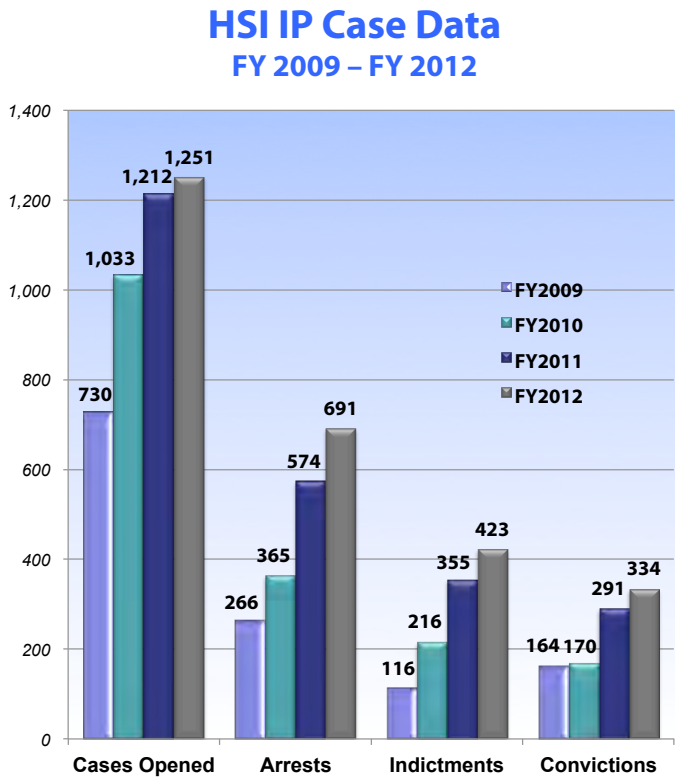
- In FY 2012, as in previous years, the overwhelming majority of intellectual property seizures occurred in the international mail and express carrier shipping environments. Representing 80 percent of all intellectual property seizures for FY 2012, a total of 8,490 seizures occurred in the express carrier shipping environment and 9,852 seizures occurred in the international mail shipping environment.

Circumvention Devices

- In FY 2012, CBP seized 25 circumvention devices, a technology that works to bypass technological measures intended to protect copyrighted works such as videogame software and DVDs.
- In FY 2011, CBP seized 29 circumvention devices.

ITC Exclusion Order Enforcement

In FY 2012, CBP carried out 68 enforcement actions against IPR infringing imports covered by an ITC exclusion order.



Agencies' 2013 Major Intellectual Property Enforcement Activities to Date

Department of Commerce

United States Patent and Trademark Office (DOC/USPTO)

The sections below highlight the many USPTO initiatives that support IPEC's enforcement mission. In addition to these initiatives, the USPTO also undertakes a wide range of substantive policy, legal, operational and regulatory efforts that positively impact the intellectual property regime. For example, the USPTO this year actively promoted the development of intellectual property law through the courts by participating in a variety of significant intellectual property lawsuits both in defense of USPTO decisions and as an *amicus curiae* — including an *amicus* brief on behalf of the United States in an *en banc* Federal Circuit case, and assisting the Solicitor General with *amicus* briefs to the Supreme Court in its cases raising intellectual property issues.

Policy

Through policy leadership, advocacy, and technical expertise, USPTO promotes effective intellectual property rights enforcement both at home and abroad. USPTO contributes policy and technical expertise in the analysis of countries' IP laws pertaining to civil, criminal, and border enforcement. USPTO provided technical assistance to USTR in connection with ensuring that Colombia, Korea, and Panama implemented the IPR enforcement provisions contained in the U.S. Free Trade Agreements with these countries. As technical advisors to USTR, USPTO participated in negotiations on the TPP framework, which includes provisions on enforcement. USPTO played a prominent role in interagency policy formulation regarding China's IPR enforcement efforts. As a co-chair of the IPR Working Group under the U.S.-China Joint Commission on Commerce and Trade (JCCT), USPTO, alongside USTR, plays a primary role in coordinating with U.S. industry representatives to understand and develop "deliverables" and cooperative engagement proposals to advance USG policy interests in improving China's IPR enforcement environment. USPTO participated in the "U.S.-China Legal Exchange" under the auspices of the JCCT Commercial Law Working Group by delivering presentations in China about the U.S. IPR enforcement system and how certain aspects of the civil, border, and criminal enforcement mechanisms operate together effectively. Chinese participants were encouraged to consider how these aspects could be incorporated into China's mechanisms to enhance the effectiveness of those mechanisms. In addition, through other bilateral cooperative mechanisms, the USPTO engaged directly with counterpart agencies at the central and sub-central levels of China's government to address specific technical and policy objectives.

The USPTO and the U.S. Copyright Office co-sponsored and convened a roundtable of experts at The George Washington University Law School to consider the possible introduction of small claims proceedings for patent and copyright claims. With regard to the patent claims roundtable discussion, experts considered previous proposals for small claims proceedings in light of constitutional constraints with

the hope of formulating a viable framework for small claims proceedings that could be utilized by patent owners. With regard to the copyright small claims roundtable, participants explored foreign small claims court models, U.S. constitutional issues, and alternative dispute resolution systems. Subsequent to the roundtable discussions, the USPTO hosted a *Patent Small Claims Proceeding* forum continuing the discussion on a patent small claims proceeding.

Reports and Initiatives

The USPTO together with the Economics and Statistics Administration published the *Intellectual Property and the U.S. Economy: Industries in Focus* report, identifying first-order market actors who are growing IP in the U.S. economy and protecting their innovations through patents, trademarks, or copyrights. For DOC's *Assessing Costs Everywhere* initiative to measure the impacts of offshore manufacturing, the USPTO provided content on the IP-related costs, risks, and legal considerations associated with offshoring. A joint study between the International Intellectual Property Institute (IIPI) and the USPTO produced the *Study on Specialized Intellectual Property Courts*. The report examined specialized intellectual property courts around the world, highlighting that a positive correlation exists between these courts and the resolution of cases involving intellectual property rights in an efficient and effective manner. Strategies to combat counterfeiting were examined in a USPTO supported study conducted by Dr. Michele Forzley titled *Counterfeit Hard Goods and the Public's Health and Safety: A Study of Interventions*.

Global Intellectual Property Academy

The USPTO's Global Intellectual Property Academy (GIPA) provided capacity-building and technical assistance programs in the United States and around the world on intellectual property protection, enforcement, and commercialization. GIPA conducted seven Intellectual Property Awareness Campaign (IPAC) or "IP Basics" events for small- to medium-sized enterprises (SMEs) in cities throughout the United States. These events included presentations on patents, trade secrets, trademarks, domain names, copyright, and enforcement, both domestic and abroad. GIPA conducted a U.S. - China Road Show event in Denver, Colorado, targeted at SMEs who operate in or are considering doing business in China. GIPA partnered with ITA to conduct eight STOPFakes.gov Road Show events across the U.S. that were designed to educate SMEs about IPR issues related to exporting and working with law enforcement to protect the U.S. market. GIPA also developed a comprehensive educational outreach plan for helping American Indian and Alaska Native businesses to better protect and enforce their intellectual property.

USPTO Attaché Program

USPTO's IP attachés actively worked to improve the protection of U.S. intellectual property rights overseas. Their IP-related expertise is a key asset in their work. USPTO currently has IP attachés in Rio de Janeiro, covering South America; in Moscow, covering Eastern Europe; in Delhi, covering South Asia; in Shanghai, covering China; in Bangkok, covering South East Asia; and in Mexico City, covering Latin America and the Caribbean. Additionally, USPTO has an IP attaché in Geneva covering IP issues arising under the WTO and an attaché covering IP issues arising under WIPO and the other UN Agencies.

Combating Counterfeit Medicines

In coordination with the Jordan Food and Drug Administration, USPTO conducted a workshop in Jordan on combating counterfeit medicines. The program was attended by Jordanian regulatory and

law enforcement officials and included discussions on the impact of counterfeit medicines, combating counterfeit medicines and the role of drug regulatory agencies. The discussion also focused on education and awareness, border enforcement, investigation, and criminal prosecution. The FDA, DOJ and ICE-HSI participated in the workshop.

USPTO's regional IP attaché for Southeast Asia co-organized with Embassy Jakarta a series of one-day workshops on *Effective Practices Against the Trade in Counterfeit Medicines* in the cities of Batam, Bandung, Jakarta, Makassar, and Surabaya, Indonesia, with each workshop drawing the attendance of 40-50 local officials, including police and other enforcement personnel, customs officials, judges, academics, public health officials, and consumer protection advocates. These workshops were co-sponsored by the Indonesian Directorate General for Intellectual Property Rights and the Indonesian Food and Drug Administration, the Indonesian Judicial Commission, and supported by the ICITAP Indonesian Project of DOJ, the International Pharmaceutical Manufacturers Group, and the Indonesian Anti-Counterfeiting Association.

Judicial and Alternative Dispute Resolution Colloquia

USPTO conducted several capacity building initiatives and training programs with the aim of facilitating a more effective IPR enforcement system in China. USPTO co-sponsored a three-day judicial conference on IPR adjudication. The conference—the first of its kind in China—involved judges from the Court of Appeals for the Federal Circuit (CAFC) and the Supreme People's Court (IPR Division), as well as academics, private sector lawyers, government representatives, and judges from throughout China. The program presented a valuable opportunity to highlight differences between the U.S. and Chinese IPR enforcement systems and how such differences impact the ability of rightholders to successfully protect their intellectual property.

USPTO, in coordination with the International Judicial Academy, held a seminar for a delegation of Brazilian judges at the Global Intellectual Property Academy. The program addressed legal issues related to patents, trademarks, copyrights, and IP enforcement. Participants also received an overview of the U.S. civil law court system as it relates to enforcement of patents and other IP rights. The session included a digital video conference with the office of the IPR attaché in Brazil, which involved discussions analyzing the U.S. and Brazilian legal systems for civil IP enforcement. USPTO hosted a visit of twenty Sri Lankan judges, including one Supreme Court Justice and three High Court Judges. The delegation was briefed on IP enforcement in the United States and the critical role of the judiciary. The program also included visits to the CAFC, and the Court of Federal Claims. The Sri Lankan judges also had an opportunity to attend a briefing on Alternative Dispute Resolution for IPR Cases at the Federal Judicial Center, and observed proceedings at the U.S. District Court for the Eastern District of Virginia.

USPTO organized an IPR program for judges of the Supreme Arbitration Court of Russia. The Russian judges consulted on civil, criminal, and administrative IPR enforcement issues with Federal judges at the U.S. Court of Appeals for the Federal Circuit, the Southern District of New York, and the Court of International Trade, and also administrative law judges at ITC and USPTO. The United Nations Economic Commission for Europe in partnership with USPTO held a sub-regional conference for judges and prosecutors on *Selected Intellectual Property Issues: Valuation, Competition and Anti-trust* in the Former Yugoslav Republic of Macedonia. Judges, prosecutors and attorneys from the Albania, Croatia, and

Macedonia attended. The program included discussion of the assessment of damages in intellectual property infringement cases and intellectual property valuation in litigation.

USPTO, in coordination with U.S. Embassy Riga, organized a two-day capacity building workshop on *Judicial and Prosecutorial Best Practices in Intellectual Property Rights Enforcement* in Riga, Latvia. Forty-nine prosecutors and judges from Latvia, Estonia, Finland, Lithuania, and Sweden participated in panels moderated by attorneys from the U.S. Department of Justice and USPTO, as well as a member of the U.S. Federal Judiciary. The program included separate sessions for prosecutors and judges to allow a deeper interchange on shared challenges and best practices in applying and enforcing intellectual property laws. The program also served as a mode to increase regional cooperation in combating the increasing transnational nature of IPR crime.

In coordination with the World Intellectual Property Organization, USPTO hosted the *WIPO-USPTO Judicial Colloquium on Intellectual Property Rights*, which focused on trademark and copyright infringement determination, remedies and court administration. Judges from Cameroon, Egypt, Ghana, Guyana, Liberia, Malawi, Malaysia, Namibia, Philippines, the United States, and Zimbabwe participated in the program. A regional workshop on the enforcement of intellectual property rights for the judiciary and law enforcement officials was held in Zambia. Topics included the value of intellectual property protection and enforcement, border enforcement sentencing, disposal and destruction of infringing goods. With the cooperation of the Algerian Ministry of Justice, USPTO coordinated a judicial colloquium on the adjudication of intellectual property issues involving counterfeiting and piracy in civil and criminal cases. Infringement analysis was discussed along with civil remedies, commercial arbitration and mediation, judicial administration, and criminal cases.

In coordination with IIPI, USPTO held a symposium titled *Seminar on Specialized Intellectual Property Courts*. The symposium, which took place at USPTO's Global Intellectual Property Academy, brought together judges, attorneys, and intellectual property officials from countries throughout the world. The symposium focused on the role that specialized courts play in adjudicating intellectual property rights cases. Feedback from the symposium informed the survey conducted by USPTO and IIPI on the growing use and best practices of specialized intellectual property courts throughout the world. With regard to alternative dispute mechanisms, USPTO assisted in organizing and presenting at a symposium on the use of alternative dispute resolution in intellectual property disputes at California Western School of Law in San Diego, California. The symposium brought together experts in the field from Brazil, Canada, Finland, Paraguay, Switzerland, the United Arab Emirates, and the United States.

Law Enforcement Capacity Building Programs

China:

The USPTO co-convened two separate programs in China on combating IPR infringement that takes place through the Internet. The first of these programs was held in collaboration with USTR and provided an opportunity for U.S. companies to share experiences with Chinese government and industry representatives regarding best practices for combating the online sale of counterfeit goods. Additional meetings will be planned where government and industry representatives will discuss additional ways that all parties can work together to further improve efforts in this area within China. USPTO, in conjunction with the National Copyright Administration of China, organized a two-day conference focusing on

capacity-building on copyright enforcement on the Internet. In addition, throughout the year USPTO officials engaged with various IPR enforcement officials at various levels of government to promote more robust enforcement efforts throughout China.

Southeast Asia:

USPTO organized a week-long seminar at its Global IP Academy on *Investigating and Prosecuting IP Crimes* for a group of police, investigators, and prosecutors from the Association of Southeast Asian Nations (ASEAN). This program hosted more than 30 IP enforcement officials representing all of the ASEAN countries, except for Burma. The USPTO regional IP attaché for Southeast Asia organized and participated in a three-day ASEAN-USPTO *Advanced Workshop on IP Enforcement Against Trade in Counterfeit Hard Goods*, in Jakarta, Indonesia, with more than 80 government officials and speakers from the ASEAN region attending, including speakers representing the Partnership for Safe Medicines, the ASEAN Intellectual Property Law Association, the Indonesian Anti-Counterfeiting Association, the IPR Business Partnership, and the World Intellectual Property Organization. The attaché also coordinated a capacity-building program on IP administrative and criminal investigation and enforcement for Vietnamese law enforcement officials and judges in Ho Chi Minh City, Vietnam, and IP border enforcement for Vietnamese customs officials in Hanoi and Ho Chi Minh City, Vietnam. The attaché also organized and spoke at four different regional seminars on criminal intellectual property investigation and prosecution for local public prosecutors on IP criminal prosecutions of pirate and counterfeit goods, with an emphasis on transnational border and online piracy and counterfeit cases. In addition, in each region where such training programs were held, the attaché organized and hosted a local roundtable on *Changing Attitudes About IPR in High Density Tourist Destinations*.

India:

A U.S. team comprised of USPTO, CBP, and ICE traveled to five ports throughout the country to exchange best practices on border enforcement of IPR, and to discuss a range of related topics, including counterfeiting of technology products and why they present a threat to governments, business, military/national security, and health care infrastructures; trends in IPR criminal investigations in the technology sector; risk analysis and targeting of incoming shipments; and counterfeit determinations by Customs. The USPTO IP attaché in India, in cooperation with Confederation of Indian Industries (CII), organized an *Interactive Session with Police Officials on IPR Enforcement—Best Practices* at the Punjab Police Academy. A similar program was held with the Delhi Police Academy. In collaboration with the USPTO attaché, CII and the Karnataka State Government launched the Model IP State Initiative in Bangalore, Karnataka. The first event in the Initiative was a customs roundtable, which included 20 participants from State government and industry. The USPTO IP attaché in India, in collaboration with CII, organized the two-day *6th International Conference on Anti-Counterfeiting & Anti- Piracy* in Mumbai. The USPTO IP Attaché spoke about the importance of public-private cooperation to protect public health and safety.

Brazil:

The USPTO IP attaché in Brazil office assisted in organizing and participated in enforcement training conferences co-sponsored with the Instituto Brasiliero Direito Criminal (IBDC). Both the IBDC events were well attended by various levels of Brazilian law enforcement personnel and included attendance by DOS officers. The IBDC events both included participation by U.S. stakeholders and focused primarily

on hard goods and consumer products. The attaché's office also organized an enforcement seminar for Brazilian police, prosecutors and judges in Belo Horizonte, Brazil.

Africa:

In conjunction with WIPO, USPTO held a two-day program for sub-Saharan IP enforcement officials in Lusaka, Zambia. The program focused on the benefits of IP protection and enforcement to developing countries and offered presentations and case studies highlighting the enforcement provisions of the WTO TRIPs Agreement. Approximately 75 persons attended the program and participated in the various activities and presentations from both government and industry groups. USPTO participated in a program organized by the Commercial Law Development Program on implementing an interagency approach to IP protection and enforcement for Kenya and the East African Community.

INTERPOL:

USPTO participated in the INTERPOL *International Law Enforcement IP Crime Conference* held in Panama. More than 500 police, prosecutors, customs officials and rights-holders from 58 countries participated in the three-day conference. The program, with a theme of *East Meets West: Working with the Americas to Combat Counterfeiting*, addressed issues such as the nature and extent of transnational organized intellectual property crime, integrating and enhancing regional and international cooperation, disrupting counterfeit supply chains, and operational planning of enforcement activities. USPTO supported INTERPOL's Illicit Goods Sub-directorate and participated in a series of regional IP enforcement training programs in Ecuador, Hong Kong, India, Panama, and Tanzania.. The programs, which included participation of police, prosecutors, customs, and regulatory authorities, were designed to ensure that enforcement officials were equipped with the tools needed to identify and dismantle transnational organized crime groups involved in the manufacture and smuggling of counterfeit and pirated products.

International Trade Administration (DOC/ITA)

Policy

Transatlantic IPR Working Group: Established in 2005, the Transatlantic Intellectual Property Rights (IPR) Working Group (previously known as the U.S.-EU IPR Working Group) met most recently in Brussels, Belgium in July 2012 to conduct government-to-government talks and consult with transatlantic stakeholders from both the business and NGO communities on a wide range of IPR-related issues. The U.S. delegation is co-chaired by DOC's ITA and USTR. The EU delegation is chaired by the Directorate General for Trade. The Working Group coordinates in three areas under the U.S.-EU IPR Action Strategy: engagement on IPR issues in third-country markets and multilateral organizations, customs cooperation, and public-private partnerships.

In 2012, the Working Group coordinated efforts to resolve issues in third-countries, with a primary focus on China, Russia, Brazil, Turkey, Ukraine, and India. Both the United States and the European Union were alarmed by developments within third country markets that have contributed to an erosion of IPR protection and enforcement around the globe. IPR developments in China and India were of particular concern. In 2013, both governments will continue to work together to address China's poor protection

and enforcement of IPR. Both governments will also work together to encourage India to adopt policies that encourage innovation and respect IPR.

- In FY2013, the U.S. and the EU will also continue to work cooperatively to advance common objectives within multilateral forums such as the World Trade Organization (WTO), the Organisation for Economic Co-operation and Development (OECD), and the United Nations (UN).
- ITA's Office of Intellectual Property Rights (OIPR) and the IPR Center co-sponsored a series of roundtables of U.S. Government officials and experts to discuss the issue of trade secret theft and its impact on U.S. industry. The roundtables brought together for the first time a wide array of agencies to discuss the problem from several perspectives—trade, law enforcement, military, policy, and intelligence angles. The roundtables helped launch an interagency discussion on how to add a trade policy angle to the USG's existing law enforcement and intelligence responses.

Enforcement

Overcoming Trade Barriers through the Trade Agreements Compliance Program: To improve the overall trade environment for U.S. businesses, ITA monitors foreign governments' compliance with international trade agreement obligations and actively engages with trading partners bilaterally and multilaterally in support of this effort. ITA provides individualized assistance to U.S. businesses that face IPR-related barriers. Within ITA, the Office of Intellectual Property Rights works closely with regional and country experts to assess the problem, assemble a team of experts from across DOC and other Federal agencies, and develop a strategy for resolving the barrier. Washington-based teams rely on the expertise of U.S. Government personnel at embassies and missions to fully understand the particular issue and to develop and deploy a USG response.

Outreach

ITA is committed to increasing public awareness of intellectual property rights and the enforcement of these rights in the global marketplace. ITA/OIPR partnered with USPTO and the NIPRCC for a series of outreach events, entitled the "STOPfakes.gov Road Shows," around the country to increase SMEs' awareness of IPR issues from both law enforcement and trade perspectives. This is the first time that USPTO and ITA have partnered with Federal and state law enforcement officials to conduct IPR outreach. Law enforcement mechanisms are often a mystery to SMEs, and this series was critical in breaking down that barrier. The programs featured half- or full-day presentations by IPR, trade and law enforcement officials, followed by individual client counseling sessions. Some sessions had an industry and/or geographic focus, such as on China or Brazil. The STOPfakes.gov Road Shows were well-received in eight U.S. cities. ITA/OIPR will continue working with the U.S. Export Assistance Centers, USPTO and the NIPRCC to identify opportunities for additional programs.

ITA's OIPR continues working to ensure that U.S. businesses, particularly U.S. SMEs, understand how to protect and enforce their IPR internationally, so that exporting is a sustainable activity. OIPR participated in 68 outreach/education/capacity building meetings and events focusing on intellectual property rights, reaching over 1,000 U.S. and foreign industry representatives, government representatives, and

consumers. Training is conducted in person, through webinars, by digital video conference, and by telephone, both as stand-alone trainings or on the margins of larger events.

IPR Webinars: ITA has developed several IPR webinars featured in ITA's U.S. Export Assistant Center (USEAC) organized programs focusing on trade missions to China. ITA's webinars provide SMEs with practical advice on how to protect and enforce their IPR in China as well as inform them of U.S. government resources. Since January 2012, ITA's webinars have provided IPR training to more than 150 U.S. SMEs.

STOPfakes.gov Re-launch: In March 2012, ITA helped enhance the public's access to USG IPR-related tools and services be redesigning and re-launching www.STOPfakes.gov. Since 2006, STOPfakes.gov has served as the USG portal for all things IPR. The redesign provides the following enhancements:

- Content on the site has been arranged to make it easier and faster for U.S. businesses and consumers to navigate and use the USG's IPR resources.
- The redesigned website is compatible with both Macs and PCs and viewable on mobile platforms including smart phones and tablets.
- The tools available on STOPfakes.gov have been enhanced, including the addition of links to infringement reporting mechanisms at a number of popular online retailers and marketplaces, including Chinese-run Alibaba and Taobao.

ITA plans to continue partnering with other U.S. agencies to offer additional resources on STOPfakes.gov. For instance, the development of an educational resource page, with links to partner agency IPR resources for educators and students, is currently underway. ITA continues to work with the USPTO and U.S. embassy staff to expand and streamline the IPR country toolkits that are currently offered on STOPfakes.gov.

ITA's China Webinars: ITA continued its highly successful China Webinar Series. These webinars, conducted by the Office of China and Mongolia, offer U.S. SMEs the opportunity to discuss current IPR issues with attorneys practicing in China. The webinars are designed to assist companies doing business in China by addressing a wide a variety of issues related to intellectual property protection and enforcement. The entire webinar series is available free of charge on STOPfakes.gov.

ITA and FDA co-lead an Anti-Counterfeiting Medical Products Task Force. This is a public-private task force that coordinates with stakeholders—multilateral organizations, governments, and private sector entities—to exchange information on activities to stop the spread of counterfeit and substandard medicines and medical products in an effort to better understand the scope and depth of this global threat to public health, and its impact on intellectual property rights.

ITA organized anti-counterfeit medical product detection technology workshops in China (September 2011) and India (September 2012), and is working with FDA in the JCCT Subgroup on Pharmaceuticals and Medical Devices on better regulation of active pharmaceutical ingredients (APIs) in China. China has become the world's largest producer of APIs and many of these APIs are counterfeit or end up being used in the production of counterfeit medicines.

Future Outreach:

ITA is working with the Drug information Association to organize a China API workshop to take place on May 12 in Beijing during the DIA Annual China Conference.

ITA and FDA have helped to develop an anti-counterfeit medical products initiative within the APEC Life Science Innovation Forum. The Anti-counterfeit Medicines Action Plan was adopted in 2010 and will include a May 2013 anti-counterfeit medical products workshop with a focus on public awareness and single point of contact, to take place in Korea.

Capacity Building Programs

Transatlantic IPR Resource Portal: Cooperation between OIPR and the European Union's Directorate General for Enterprise continued to be strong in 2012. The two agencies continue to expand the resources found on the Transatlantic IPR Resource Portal, which was launched in December 2010. The Portal is an ongoing cooperative effort to build the awareness and capacity of transatlantic businesses to protect and enforce their intellectual property rights when exporting to foreign markets. The goal of the Portal is to help companies and small business owners on both sides of the Atlantic fully utilize all the intellectual property-related resources and tools developed by both governments. The Portal is accessible through www STOPfakes.gov.

U.S.-Peru Free Trade Agreement (FTA): In partnership with the American Chamber of Commerce, ITA led a four-day IPR mission of 30 public and private sector representatives to Washington, D.C. The objectives were to improve the implementation of the U.S.-Peru FTA's IPR Chapter, incorporate IPR protection into Peru's economic development strategy, and create a better IPR institutional framework to strengthen U.S.-Peruvian commercial ties.

Latin America IP Program: ITA partnered with the Association of American Chambers of Commerce in Latin America (AACCLA) to host a half day IP seminar at the AACCLA conference in early October 2012 to promote broader understanding of and respect for IP in Latin American communities. The seminar drew on the IP expertise of U.S. government officials, academics and leaders of international organizations to provide information and training on the importance of intellectual property rights to business growth and development.

Implementation of a Mexican Customs Trademark Registration System: OIPR partnered with the USPTO and CBP to encourage U.S. businesses to participate in the Mexican Customs trademark registration system which was launched on January 2, 2012. Since its inception, twelve U.S. companies have participated in the Mexican Customs trademark registration system. The new system will improve the ability of Mexico's Customs to identify counterfeits and prevent entry of counterfeits into the Mexican market.

Commercial Law Development Program (DOC/CLDP)

Technical Assistance Programs

Kenya: The Enforcement of Intellectual Property Rights: An Interagency Approach with Private Sector Coordination (May 2011)

CLDP, with International Trade Administration (ITA), the Office of Intellectual Property Rights (OIPR), USPTO, DOJ, and the Kenyan Anti-Counterfeit Agency (ACA), conducted a workshop that exposed 80 IP

administrative and enforcement officials from Kenya, as well as private sector stakeholders, to best practices in interagency collaboration on IP enforcement. Officials from the governments of Burundi, Rwanda, Tanzania, Uganda, and the East African Community also participated in the program as observers.

Kenya and East African Countries: Workshop on the Implementation of an Interagency Approach to IP Protection and Enforcement (August 2012)

CLDP and the Kenya Anti-Counterfeit Agency (ACA), in collaboration with USPTO, DOJ, DHS, organized a three-day regional workshop to facilitate the determination, by approximately 80 officials from Kenya and across the East Africa region, of the best way to implement an interagency approach to intellectual property protection and enforcement.

By promoting an interagency approach among the key partner agencies and the private sector, the workshop contributed to increased efficiency, consistency, and effectiveness in the protection and enforcement of IP rights in Kenya and the EAC region.

Mali: CLDP Exposes Key Malian Decision Makers to Importance of Intellectual Property Rights (March 2012)

CLDP, with the support of the USAID mission in Bamako and in partnership with the African Organization for Intellectual Property (OAPI), and the Malian Government (GOM) organized a workshop to introduce and familiarize members of the Malian executive, legislative and judicial branches with the benefits of Intellectual Property (IP). The workshop focused on creating a commercial environment in Mali that protects IP rights by addressing the strengths and weaknesses of the Malian economy, the socio-economic issues at stake and strategies for incorporating IP in development programs and policies in Mali.

Mali: CLDP trains Mali Customs on Preventing Counterfeit Medicines and Health-Related Products (October 2011)

CLDP, in partnership with the USAID Mission in Mali, French Customs and the International Institute for Counterfeit Medicines and the Malian Government (GOM) organized a workshop to improve the skills and effectiveness of the Malian Customs Service for better enforcement of Intellectual Property (IP) rights. The workshop focused on specialized targeting techniques designed to identify counterfeit shipments at the border and within the Malian territory and emphasized the devastating public health and environmental effects of trade in counterfeit products.

Ghana, Liberia, Nigeria and Kenya: Developing Regional IP Task Force Coordination Action Plans (August 2011)

CLDP worked with USPTO and DOS on a program for four African countries to develop interagency task forces for the coordination of IP enforcement. The week-long consultations in D.C. helped officials from different agencies enforcing IP rights in Ghana, Kenya, Liberia, and Nigeria to develop interagency IP enforcement action plans, with a goal of facilitating an improved IP interagency approach, and thus a more effective protection and enforcement of IP in their respective countries.

Mali: Workshop on Intellectual Property Issues Related to Food Safety, Health and the Environment (May 2011)

CLDP was joined by several US, European and West African experts in organizing this workshop in Bamako, Mali. The program for 175 enforcement officials and private sector participants addressed the scope of the challenges in combating trade in counterfeit products such as medicines, vaccines and pesticides; their impact on public health and the environment; the social and economic impact counterfeits are having on the country; and the role of regulatory agencies in inspection, regulation and enforcement of intellectual property crime.

EUROPE/EURASIA

Bosnia and Herzegovina (BiH): CLDP Assists BiH in Development of First Judicial IP Benchbook (September 2011)

CLDP, in coordination with the High Judicial and Prosecutorial Council of Bosnia and Herzegovina and the U.S. Federal Judicial Center, developed a BiH Judicial Intellectual Property Benchbook. This manual will be a practical guide for judges as well as prosecutors in IP cases and will be used for training purposes by the Judicial and Prosecutorial Training Centers in FBiH, Republika Srpska and Brčko District.

Georgia: U.S. Consultations on Collective Management of Copyright and Related Rights (March 2012)
CLDP and USPTO hosted a delegation from the Georgian Copyright Association (GCA) and Sakpatenti (National Intellectual Property Center of Georgia) for consultations in Washington, D.C. and New York City. The program instructed GCA and Sakpatenti on how to effectively and efficiently manage a collective copyright agency and raise public awareness of the importance of intellectual property protection.

Pakistan: Judicial Capacity Building (April 2011)

CLDP, in close coordination with USPTO, conducted a Judicial Enforcement of Intellectual Property Rights and International Commercial Arbitration Program at Pakistan's Federal Judicial Academy in Islamabad, Pakistan. Topics included Patents, Copyright and Trademark Infringement, Economic and Health/Safety Risks of Counterfeiting, Civil Remedies, Compensation and Remedies in Civil Cases, and Deterrent Value of Civil and Criminal Penalties.

Egypt: Cybercrime and Electronic Evidence (November 2011)

CLDP in cooperation with the National Center for Judicial Studies (NCJS) and the Ministry of Justice held a conference in Cairo for 230 Egyptian Economic Court judges and prosecutors from all of the Economic Court jurisdictions in Egypt on Cybercrime and Electronic Evidence.

Iraq: Judicial Training Workshop on Intellectual Property (September 2011)

As part of CLDP's and the Iraqi judiciary's joint capacity building efforts in the area of commercial law, CLDP and the Iraqi Judicial Development Institute organized a workshop on the enforcement of intellectual property rights. The workshop focused on common disputes relating to trademarks, copyrights, trade secrets and other forms of IP.

Iraq: Developing the Ministry of Planning's Patent Examination System (May 2012)

CLDP, in concert with USPTO, provided consultations on 'Effective Patent Examination' to a delegation of patent examiners, lawyers, and administrators from Iraq's Central Organization for Standardization

& Quality Control (COSQC). The program provided specialized training in the patent application filing and review process from private and public sector perspectives.

Iraq: Consultations for the Development of a National Database of Iraqi Research & Development projects (May 2012)

CLDP, in close coordination with USDOC's National Technical Information Service (NTIS), is assisting Iraq's Ministry of Science and Technology (MoST) with the development of a national repository of Iraqi science and technology information.

Department of Health and Human Services

Food and Drug Administration

New Legislation

In July 2012, President Obama signed into law *Public Law 112-144 - The Food and Drug Administration Safety and Innovation Act* (FDASIA), which incorporates several of the IPR enforcement recommendations contained in the March 2011 Administration White Paper. FDASIA provided for enhanced penalties for trafficking in counterfeit drugs, and it directs USSC to review and amend, if appropriate, its guidelines and policy statements related to counterfeit drugs. Further, FDASIA authorized FDA, upon issuance of regulations, to destroy, without the opportunity to export, counterfeit, misbranded or adulterated drugs imported to the United States that are valued at $2,500 or less. The Act also allows FDA, upon issuance of guidance or regulation, to require that companies notify FDA if their drug has been counterfeited or stolen FDA is actively engaged in developing the statutorily-required regulations and guidance necessary to implement this important new law, and has established FDASIA-TRACK, a webpage dedicated to providing the public with information detailing FDA's progress on implementation.

Global Engagement

FDA's work with other Federal agencies and G-8 member countries led to G-8 leaders' affirmation of the "grave threat that counterfeit and falsified medical products pose to public health" at the Camp David G-8 meeting on May 18-19, 2012. G-8 leaders affirmed the significance of increasing public awareness of counterfeit and falsified medicines, combating rogue internet sites selling medical products, and sharing best practices on combating counterfeit and falsified drugs. FDA will continue to look for opportunities to further develop effective enforcement and communication through the G-8, APEC, and other intergovernmental organizations.

In April 2012, FDA released its "Global Engagement" report detailing the many activities and strategies FDA is using to transform from a domestic to a global public health agency. Recognizing the risks to pharmaceuticals posed by economic adulteration and substandard, counterfeit and falsified products, the report describes the steps the agency is taking to ensure that imported food, drugs, medical devices and other regulated products meet the same rigorous standards for safety and quality as those manufactured domestically. The efforts outlined in the report further the FDA's implementation of its global strategy, set forth in the agency's special report "Pathway to Global Product Safety and Quality" released last year. The Agency is also furthering its work in import risk analytics, detection technologies,

and in building global coalitions of regulators to help combat counterfeit drugs and other substandard medical products.

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

In September 2012, FDA, along with a dozen pilot countries, participated in training for the newly established WHO Global Surveillance and Monitoring System for SSFFC Medical Products. The purpose of this project is to establish: 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.

BeSafeRx

On September 28, 2012, FDA launched a new national campaign, "BeSafeRx—Know Your Online Pharmacy," (www.fda.gov/BeSafeRx) designed to educate consumers about the risks of purchasing prescription medicine through fraudulent, illegal online pharmacies. The campaign also provides resources to help consumers make informed decisions when considering buying medicines online. Many fraudulent online pharmacies use sophisticated marketing methods and fake "store fronts" to appear legitimate, and may entice consumers with deep discounts that appear too good to be true. The reality is that drugs purchased from illegal online pharmacies may be counterfeit, contaminated, or not approved by FDA. They may be expired, improperly stored, or contain the wrong ingredients—or contain too little, too much, or no active ingredient at all. Such products are a health risk and may also be deadly. In addition to tips for patients and caregivers, FDA has developed BeSafeRx campaign materials for other Federal agencies, and nonprofit and private organizations to use for their own educational efforts.

Counterfeit Drug Public Health Alerts

In 2012, FDA issued three public health alerts warning consumers and health care professionals about counterfeit drugs. On February 14, 2012, FDA warned consumers and healthcare professionals about a counterfeit version of Roche's Avastin 400 mg/16mL, an injectable medicine used to treat cancer. The counterfeit version of Avastin did not contain the medicine's active ingredient, bevacizumab. In a related action, FDA issued letters to medical practices in the United States that purchased unapproved cancer medications that may include the counterfeit version of Avastin.

On April 3, 2012, FDA warned consumers and health care professionals about a counterfeit version of Roche's Altuzan 400 mg/16ml, a foreign injectable cancer medication that was obtained from a foreign source. The counterfeit contained no active ingredient. Altuzan is not approved by FDA for use in the United States (although it is an approved drug in Turkey). In related actions, FDA issued letters to medical practices in the United States that purchased unapproved cancer medications that may include counterfeit versions of Altuzan.

On May 29, 2012, FDA warned consumers about a counterfeit version of Teva Pharmaceutical Industry's Adderall, which treats attention deficit hyperactivity disorders and narcolepsy. Adderall is a prescription drug classified as a controlled substance, a class of drugs for which special controls are required for dispensing by pharmacists. The counterfeit version of Adderall contained the wrong active ingredients. Adderall contains four active ingredients: dextroamphetamine saccharate, amphetamine aspartate,

dextroamphetamine sulfate, and amphetamine sulfate. Instead of these active ingredients, the counterfeit product contained tramadol and acetaminophen, which are ingredients in medicines used to treat acute pain.

Stakeholder Outreach

FDA has conducted outreach activities on counterfeiting by presenting and participating at various stakeholder meetings such as the Partnership for Safe Medicines 2012 Interchange; the Food and Drug Law Institute (FDLI) Annual Conference; SSFFC WHO Workshop; the Partnership for Safe Medicine's Congressional Briefing on Counterfeit Drugs; the Healthcare Distribution Management Association's Track and Trace Technology Seminar; the Global GS1 Healthcare Conference; the American Pharmacists Association Annual Meeting; the Drug Information Association (DIA) Annual Meeting; the USP Workshop on Supply Chain Integrity; the Parenteral Drug Association/FDA Pharmaceutical Supply Chain Conference; the FDA Health Professional Organizations Conference; National Association of Boards of Pharmacy, Federation of State Medical Boards, National Council of State Boards of Nursing Tri-Regulator Symposium; the U.S. Public Health Service Scientific and Training Symposium; California State Board of Pharmacy Public Meeting; International Drug Regulatory Authorities Meeting; FDLI's U.S. & Brazil: Navigating New Frontiers in Pharmaceutical, Medical Device and Food Law Regulation Meeting; and the DIA Latin American Regulatory Conference.

Counterfeit Technology

FDA continues to expand the use of the handheld Counterfeit Detection (CD3) units to field staff so that the units can be utilized at the port of entry during the admissibility process. The device, developed by FDA scientists, can be used to rapidly screen and detect suspect problem products and packaging, like counterfeits. Light of selected wavelengths emitted by the CD3 enables users to visualize differences between suspect products and authentic products, and provides preliminary findings in the field in real-time. FDA has been using this new technology in FDA labs and at international mail facilities. FDA initiated an assessment of the public health value of this new technology in detecting suspect drugs of significant public health concern such as counterfeit anti-malarial drugs. Validation of the new technology is on going.

Enforcement Actions

International Internet Week of Action: In 2012, FDA contributed to the success of efforts under INTERPOL's Operation Pangea initiative. Operation Pangea is a concentrated global effort at stemming the online sale and importation of counterfeit and illicit drugs. Personnel from across FDA teamed up to identify and disrupt the financial systems and Internet infrastructure of more than 4,100 Internet pharmacies that illegally sell potentially counterfeit, dangerous and unapproved drugs to U.S. consumers. FDA worked collaboratively with international and domestic law enforcement and regulatory partners as well as the private sector through the companies that participate in the Center for Safe Internet Pharmacies.

RAM Medical, Inc.: On May 8, 2012, RAM Medical, Inc.—a distributor of medical devices, pharmaceuticals, food, cosmetics, and miscellaneous commodities—was sentenced to three years of probation and ordered to pay a $100,000 fine and $72,922.43 in restitution for importing and selling counterfeit and contaminated surgical hernia mesh stemming from an investigation by FDA's Office of Criminal

Investigations (OCI). The company admitted that numerous boxes sold between December 2008 and June 2009 included adulterated mesh which contained numerous microorganisms. Also, RAM Medical acknowledged that boxes the company distributed between October 2008 and January 2010 contained misbranded, counterfeit mesh. In March 2010, the FDA issued a warning concerning the counterfeit surgical mesh products. FDA's warning was of particular significance to health care professionals and their patients with surgical mesh implants as well as hospitals and surgical centers, operating room medical professionals and staff, and purchasing and risk managers.

Andrew Strempler/RX North: On October 4, 2012, Andrew Strempler, a Canadian citizen, pleaded guilty in the Southern District of Florida for his role in a scheme to defraud consumers purchasing pharmaceuticals online. Strempler pleaded guilty to conspiracy to commit mail fraud in connection with his role as owner and president of Mediplan Health Consulting Inc., a Canadian company that also operated under the name RxNorth.com. RxNorth was an Internet, mail and telephone order pharmacy, through which Strempler and others marketed and sold prescription drugs to residents of the United States. The FDA advised Strempler in a 2001 letter that his prescription drug sales would be illegal in the United States if the drugs were not FDA approved. The FDA letter explained that the FDA approves drugs based on evidence that they are safe and effective, and that the quality of drugs from foreign sources could not be assured. Strempler and his co-conspirators unlawfully enriched themselves by selling prescription drugs to individuals in the United States, falsely representing that RxNorth was selling safe prescription drugs in compliance with regulations in Canada, the United Kingdom and the United States. Strempler obtained the prescription drugs from various other source countries without properly ensuring the safety or authenticity of the drugs. In fact, some of the drugs sold by Strempler included counterfeit drugs. Strempler caused prescription drugs from foreign countries to be shipped to a facility that Strempler operated in the Bahamas. Prescription orders made through RxNorth were then filled at the Bahamas facility, with labels on the vials and drug cartons stating they had been filled by RxNorth in Canada. Strempler then used indirect routes involving multiple countries to ship packages with prescription drugs from the Bahamas to individuals in the United States.

Francis Ortiz Gonzalez and Edward Alarcon: FDA-OCI collaborated with the U.S. Postal Inspection Service and ICE-HSI in an investigation that culminated in the convictions of two men for distribution of counterfeit drugs. Francis Ortiz Gonzalez and Edward Alarcon were separately convicted in a scheme to distribute counterfeit brand name products such as Lipitor, Viagra, Xanax, and Cialis obtained from China. Evidence showed that the scheme resulted in the shipment of more than 140,000 tablets to individuals throughout the United States. If the drugs had been authentic, the retail value would have been more than $1 million.

Tobacco Investigations: In 2012, FDA's Office of Criminal Investigations (OCI) Tobacco Enforcement Program initiated more than 30 criminal cases with the majority of the investigations involving the manufacturing and/or distribution of counterfeit tobacco products. These investigations have resulted in twelve criminal arrests involving the distribution of counterfeit tobacco products. OCI efforts have led to the recovery and seizure of more than 1000 master cases of counterfeit cigarettes, which amount to more than 10 million counterfeit cigarettes that never made it to U.S. consumers.

International Training and Outreach: Since 2011, FDA-Office of Criminal Investigations has conducted training seminars with foreign law enforcement and health and safety regulators concerning the investigation of illegal online pharmacies. These seminars have been conducted in Australia, Belgium, Italy, Mexico, and Singapore. International outreach continues from FDA's membership in the Permanent Forum on International Pharmaceutical Crime.

Department of Homeland Security

DHS, through its component agencies U.S. Customs and Border Protection (CBP) and U.S. Immigration and Customs Enforcement (ICE), conducted a number of noteworthy intellectual property enforcement activities in FY 2012.

U.S. Customs and Border Protection (CBP)

- **Border Enforcement of Intellectual Property Rights (IPR):** The total number of IPR seizures in FY 2012 decreased by 7.8 percent compared to FY 2011. The total MSRP for IPR seizures increased from $1.11 billion in FY 2011 to $1.26 billion in FY 2012, averaging more than $10,450 per seizure. The domestic value of all IPR seizures in FY 2012 decreased by 12.2 percent compared to FY 2011.
  - Handbags/wallets was the top commodity category for IPR seizures in FY 2012, with the MSRP of seizures increasing 142.2 percent compared to FY 2011. This was followed by watches/jewelry, which grew 8.3 percent in MSRP from FY 2011 to FY 2012.
  - At international mail facilities, IPR seizures both by number and by MSRP increased over FY 2011. The number of IPR seizures increased 18 percent, while the MSRP of these seizures increased 7.1 percent.
  - CBP, in collaboration with ICE-HSI, increased the number of counterfeit airbags seized by 1026 percent from FY 2011; and counterfeit contact lenses emerged as a new commodity trend, with seizures increasing 800 percent from FY 2011.
  - CBP deployed a number of new authentication devices to streamline infringement determinations and expedite release of authentic shipments.
  - CBP launched Intellectual Property Rights Strike Units to increase the deterrent effect of enforcement process.
- **Spotlight on Counterfeit Pharmaceuticals:** CBP established the Pharmaceutical, Health and Chemical Center of Excellence and Expertise (CEE) after completing a one-year pilot, providing the opportunity to not only facilitate trade for trusted partners, but also to more effectively enforce IPR through increased industry knowledge.
  - Issued 177 lab reports where 1,094 pharmaceutical products were analyzed to verify their authenticity as part of Operation Safeguard.
  - Seized 5,319 parcels containing counterfeit, substandard or unapproved pharmaceuticals in the international mail system.

- Implemented the White House-initiated Strategic Threats Operation, with a particular focus on the pharmaceuticals, wearing apparel and consumer electronics industries. Over 1,800 examinations were conducted, resulting in a number of seizures, exclusions and referrals for investigation.
- Seized 8,912 counterfeit pills, 88 counterfeit labels, various counterfeit packaging materials, computers and smartphones, and $41,080 from a single suspect.
- Finished a year-long initiative in the Asia Pacific Economic Cooperation venue targeting counterfeit pharmaceuticals shipped via international mail and express courier services with more than 1,200 enforcement actions against shipments containing more than 7 million fake or suspect pills.

U.S. Immigration and Customs Enforcement (ICE)

- **Expansion of Partnerships at the National Intellectual Property Rights Coordination Center (IPR Center):** During 2012, the IPR Center increased its partnerships with two additional partners to include the Europol and the U.S. Nuclear Regulatory Commission. To date, 21 agencies have partnered together through the IPR Center to leverage their combined resources, skills, and authorities to better combat intellectual property theft and dismantle the criminal organizations seeking to profit from the manufacturing, importation, and sale of counterfeit merchandise and pirated works. IPR Center partner agencies include: ICE; CBP; FBI; USDA's Office of Criminal Investigations; U.S. Consumer Product Safety Commission; USPIS; Naval Criminal Investigative Service; Defense Criminal Investigative Service; U.S. Army Criminal Investigative Command, Major Procurement Fraud Unit; U.S. Air Force Office of Special Investigations; Defense Logistics Agency, Office of Inspector General; General Services Administration, Office of Inspector General; National Aeronautics and Space Administration, Office of Inspector General; U.S. Nuclear Regulatory Commission; Department of Commerce, U.S. Patent and U.S. Patent and Trademark Office and International Trade Administration; DOS, Office of International Intellectual Property Enforcement; Royal Canadian Mounted Police; Mexican Revenue Service; INTERPOL; and Europol.
- **ICE-HSI IPR Enforcement Increases:** In FY2012, HSI achieved 691 arrests, 423 indictments, and 334 convictions. These enforcement results represent a 20 percent increase in arrests, a 19 percent increase in indictments, and a 15 percent increase in convictions from FY2011.
- **New Anti-Piracy Warning:** On May 8, 2012, HSI and the Federal Bureau of Investigation (FBI) joined with several major American movie studios to launch an updated anti-piracy warning to be displayed on new releases and on DVDs and Blu-ray discs. The movie studios, all members of the Motion Picture Association of America, have agreed to utilize this joint anti-piracy warning which displays, for the first time, the ICE HSI badge alongside the FBI anti-piracy warning seal and the IPR Center logo. Since the introduction of this new warning, the number of actionable leads to the IPR Center mailbox increased by more than 450 percent from an average of 10 leads per month to 55 leads per month.

- **Intellectual Property Theft Enforcement Teams (IPTETs):** In 2010, HSI created IPTETs in each of the 26 HSI Special Agent in Charge (SAC) Offices around the country. The IPTETs employ an informal task force approach, through which the IPR Center, its partner agencies and industry representatives provide training and share investigative and enforcement best practices in combating IP theft with state and local law enforcement agencies and prosecutors. The IPR Center coordinated more than 72 IPTET and state and local training events in 2012. The efforts of the IPTET program have produced numerous investigations, arrests, convictions and seizures stemming from IP violations at the Federal, state and local levels. In FY12, cases initiated have increased by more than 215 percent from 33 to 104; arrests by 46 percent from 84 to 123; indictments by 12 percent from 64 to 72; and seizure incidents by 147 percent from 190 to 469.

Intellectual Property Enforcement Operations

- **Operation Chain Reaction:** In June 2011, the IPR Center launched Operation Chain Reaction, a comprehensive initiative targeting counterfeit and substandard items entering the supply chains of U.S. Government agencies. In 2012, 15 Federal law enforcement agencies involved in overseeing fraud-related matters relating to procurement and acquisitions performed on behalf of U.S. Government entities signed a strategy to jointly cooperate and target suspects. By partnering together, the participants in Operation Chain Reaction have agreed to take a strong stance against the sale of counterfeit goods. To date, Operation Chain Reaction has resulted in 24 arrests, 39 indictments, and 26 convictions, as well as the seizure of over $9.8 million in counterfeit merchandise, as well as currency and vehicles.
- Participated in an international operation that included 43 countries and seized 388 shipments of over a million dangerous products, with the U.S. making 80 seizures to stop $5.8 million of potentially harmful counterfeit electronics.
- Disrupted massive international conspiracies to import and distribute approximately $300 million worth of counterfeit goods into the United States, through methods to compromise port security and import more than 135 containers of counterfeit, fraudulent and stolen materials.
- Investigation done with assistance from FBI, targeted an organization which utilized stolen corporate identities and fraudulent personal identities to facilitate the smuggling of counterfeit merchandise from China into the United States, resulted in the seizure of over $300 million in goods, $3 million U.S. currency, 75 shipping containers containing counterfeit merchandise and the arrests of 28 subjects, including two in Germany.
- **Operation Market Day**: Targeted a large scale retail outlet for counterfeit goods, including clothing, shoes, jewelry, handbags, and personal care items, and revealed the owners of the market had deposited approximately $70,000 cash into one bank account every week for the past 15 years. DHS, in cooperation with FDA and state and local law enforcement agencies, executed several Federal search warrants which resulted in the seizure of over 220,000 counterfeit items with an estimated MSRP of $47 million. The operation also seized $1.4 million in suspected criminal proceeds and made four arrests for trafficking in counterfeit goods.

- **Project Fake Sweep:** From October 1, 2011 - February 6, 2012, HSI, CBP, the U.S. Postal Inspection Service (USPIS), and other law enforcement agencies partnered with the National Football League (NFL) to establish enforcement teams in a nationwide effort to identify vendors selling counterfeit NFL trademarked merchandise. The Operation seized approximately 50,703 items of counterfeit NFL merchandise with an estimated MSRP of $5.12 million and an additional 22,570 non-NFL sport affiliated items with an estimated MSRP of $1.57 million. The operation also seized more than 22,000 additional pieces of merchandise infringing the trademarks of other major sports leagues, such as Major League Baseball, the National Basketball Association, and the National Hockey League. In addition, the operation executed warrants to seize over 300 websites engaged in selling counterfeit merchandise and distributing pirated works, such as copyrighted telecasts of these sports leagues.
- **Operation In Our Sites (OIOS):** Initiated in June 2010 in coordination with the National IPR Coordination Center (IPR Center) to target the illicit online sale of counterfeit goods and pirated media, IOS has resulted in the shutdown of more than 1,700 websites following seizure by the Federal government. Visitors to the websites will find a seizure banner that notifies them that the domain name has been seized by Federal authorities and educates them about the Federal crime of trafficking in counterfeit goods. After the domain names have been seized, they are processed for forfeiture to the United States. The Operation has resulted in 14 arrests and over $3 million seized.
- **Operation Guardian:** Initiated in FY 2008 in response to an Administration effort to address incidents of hazardous importations into the United States with public safety implications, Operation Guardian combines the expertise of IPR Center partners to include HSI and seven Federal law enforcement agencies to target, interdict, and investigate substandard, tainted, and counterfeit products being imported into the United States that pose a health and safety risk to consumers. During FY 2012, HSI enforcement efforts resulted in 35 arrests, 62 indictments, and 51 convictions. FY 2012 indictments and convictions increased by 82 percent and 50 percent respectively.
  - **Operation Safeguard,** formerly Operation Apothecary, is a 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 pharmaceuticals through international mail facilities, express courier hubs, and land borders. In 2012, Operation Safeguard investigations have resulted in the examination of more than 3,000 parcels and the seizure or detention of 246 parcels.
- **Operation Pangea V:** From September 25 to October 2, 2012, CBP and HSI personnel from the IPR Center participated in an INTERPOL-led international pharmaceutical "week of action" targeting the sale of unapproved and counterfeit pharmaceuticals. In the largest operation of its kind, 100 countries took part in Pangea V. Pangea V was coordinated by INTERPOL, the World Customs Organization, the Permanent Forum of International Pharmaceutical Crime, the Heads of Medicines Agencies Working Group of Enforcement Officers, Pharmaceutical Security Institute, and Europol. For the first time, Pangea V was also supported by the Center for Safe

Internet Pharmacies, which brings together 12 of the world's leading Internet and e-commerce companies.

  - A global enforcement effort, Pangea is an annual operation aimed at disrupting the organized crime networks behind the illicit online sale of unapproved or counterfeit drugs. Worldwide, preliminary results show Pangea V has accounted for 79 arrests and the seizure of 3.7 million doses of potentially life-threatening counterfeit medicines worth an estimated value of $10.5 million. Additionally, approximately 18,000 websites engaged in the illegal sale of counterfeit drugs were taken down by U.S. and foreign law enforcement agencies.
  - During Pangea V, operations were conducted in Europe and throughout the United States and targeted websites involved in supplying unapproved and counterfeit pharmaceuticals. CBP intercepted packages that were believed to contain counterfeit pharmaceuticals. Various payment processing companies supported Pangea V by identifying and blocking payments connected to illicit online pharmacies, identifying individuals responsible for sending spam emails and identifying abuse of electronic payment systems.

- **Project Bitter Pill:** Bitter Pill was initiated by the IPR Center in conjunction with IOS and Pangea V and concluded in October 2012. Bitter Pill targeted and seized more than 680 websites selling counterfeit, substandard, and falsified pharmaceuticals.

Significant Intellectual Property Seizures

- Seized a total of five shipments arriving from China containing 20,457 pairs of ladies footwear with trademark violations covering an estimated MSRP of $18 million.
- Seized a commercial shipment of counterfeit watches and commingled watches used to facilitate their importation with a retail value of $28.7 million.
- Seized a shipment of 25,822 counterfeit purses worth more than $8.4 million.
- Led Operation Long Distance Haul which resulted in the seizure of 32,000 counterfeit phones and safety deposit boxes containing nearly $500,000 as well as the issuance of warrants.
- Seized 14,900 counterfeit children's sleepwear worth $537,000.
- Seized 30,300 pairs of counterfeit sunglasses worth $4.5 million.
- Issued 162 lab reports involving the analysis of 1,070 items suspected of intellectual property infringement, resulting in seizures of multiple products.

Significant Intellectual Property Enforcement Cases

- **Counterfeit Airbags:** In October 2012, a North Carolina man pleaded guilty at the U.S. District Court for the Western District of North Carolina to trafficking in counterfeit airbags, following an investigation by HSI and the U.S. Department of Transportation's National Highway Traffic Safety Administration. The individual also pleaded guilty to delivering and causing to be delivered hazardous material, the airbags, by air commerce in violation of rules and regulations prescribed by the Secretary of Transportation. A Federal criminal indictment charged him with one count of trafficking and attempting to traffic in counterfeit airbags bearing the registered trademarks

of automobile manufacturers, and one count of delivering and causing to be delivered hazardous materials to air carriers for transportation in air commerce. The indictment also contained a notice of forfeiture covering all of the seized counterfeit airbags, $60,000 in funds seized during the investigation, and real estate in North Carolina.

  - According to information presented at court, the individual is a part-owner of Krugger Auto, located in Charlotte. On Aug. 16, 2012, HSI and the DOT Office of Inspector General (OIG) executed Federal search warrants at Krugger Auto and his residence. While executing the search warrants, HSI Special Agents seized 99 counterfeit airbags from the suspect's business and 1,514 counterfeit airbags from his residence. The individual under investigation also had purchased counterfeit airbags from China, which he then resold through eBay. According to filed documents and court proceedings, the counterfeit airbag shipments ordered by him did not display the legally-required hazardous material warnings when the shipments were transported in air commerce from China to the United States.
  - The individual sold at least 7,000 counterfeit airbags online, and between February 2011 and May 2012 he earned at least $1.4 million in revenue from eBay sales of counterfeit airbags.
  - To date, HSI has conducted numerous counterfeit airbag investigations, resulting in 6 criminal arrests, 6 indictments and 2 convictions. HSI and CBP have seized approximately 2,511 counterfeit airbags

- **Patapsco Flea Market** - On Sunday, April 22, 2012, HSI Baltimore special agents, in cooperation with the IPR Center, executed a Federal search warrant at the Patapsco Flea Market in Baltimore, MD as part of an ongoing criminal investigation. The enforcement operation was based on specific information developed during a two and a half year investigation by ICE HSI involving violations of intellectual property rights law. Over the course of numerous days, HSI Baltimore special agents, with assistance from Federal, state and local law enforcement and industry partners, seized nearly 220,000 counterfeit items including clothing, shoes, jewelry, handbags, DVDs, CDs, perfume, make-up and other personal care items. If those items were legitimate, the total MSRP would be approximately $47.3 million.
- **Operation Yao Biao:** The IPR Center routinely works with brand owners both in the United States and around the world. In one of the most sophisticated examples dubbed Operation Yao Biao (YOW-BOW), HSI special agents and CBP Officers at Port Elizabeth in Newark discovered more than 70 shipping containers filled with fake Nike sneakers, Ugg boots, Gucci and Luis Vuitton handbags as well as numerous other items. The lead was generated from a Customs Broker who did the necessary due diligence and verified a power of attorney prior to filing entry on a container.
  - The Yao Biao organization, using stolen corporate identities and false personal identification documents, imported or attempted to import more than 135 containers of counterfeit goods into the United States. Specifically, principals of this organization obtained the information of legitimate companies and used that information to complete false entry documents. Conspirators managed the flow of false paperwork between China and the United States and supervised the importation of the counterfeit goods. Conspirators created

and used fraudulent personal identification documents, such as Social Security cards, to facilitate the scheme. Upon entry of the counterfeit goods into the United States, conspirators managed the distribution of the counterfeit goods; delivering them to warehouses and distributing them throughout New Jersey, New York, and other locations in the United States. The criminal organization concealed the counterfeit goods utilizing various methods, including using generic outer lids on boxes and generic labels on products to hide the brand name labels beneath. Once the counterfeit goods cleared the ports, the conspirators removed the outer lids and cut off the generic labels. This organization laundered millions of dollars in illicit profits to China without filing Currency Transaction Reports as required by Federal law. The profits of their crimes were used to maintain lavish lifestyles, which included purchasing luxury automobiles and tens of thousands of dollars in jewelry.

- During the investigation, HSI Newark, in conjunction with CBP, targeted inbound containers being imported utilizing stolen corporate identities. In addition, HSI coordinated with the FBI on a parallel investigation into the narcotics smuggling activities of the Yao Biao Organization; resulting in coordinated enforcement actions. In 2012, HSI seized the counterfeit contents of seventy-five (75) shipping containers with a Manufacturer's Suggested Retail Price of over $300 million dollars. HSI and the FBI have arrested 28 subjects, seized vehicles and more than $3 million dollars, and filed a *lis pendens* on one residence.

Training and Outreach

- In FY2012, HSI conducted 406 outreach and training events that focused on IPR and commercial fraud. This was a 15 percent increase in events, which targeted 21,377 participants. This participation rate increased by more than 25 percent over FY2011 and included 137 international events.
  - Since 2009, the IPR Center has participated in 1,231 domestic and international outreach and training events, speaking to over 64,868 individuals.
- In 2012, CBP launched the Integrated Intellectual Property Rights Field Training program to improve enforcement capabilities at high risk ports of entry.
- For the first time, in 2012, the International Law Enforcement Academy in Budapest hosted an IPR theft enforcement training program for national police and customs officers. Organized by HSI and the IPR Center, the training included participants from Bulgaria, Hungary, Romania, and Slovakia, who learned about the economic and public safety threats from IPR theft as well as best practices in investigations over a four-day course, funded through DOS's Bureau of International Narcotics and Law Enforcement Affairs. Instruction was conducted by HSI, FBI, the U.S. Department of Justice, and CBP.
  - During 2012, the IPR Center's Global Outreach and Training Unit participated in numerous international trainings to include several in South America. HSI Attaché Offices in Buenos Aires and Brasilia have subsequently assisted authorities in Brazil, Argentina, Paraguay, Chile, and, Uruguay in numerous enforcement actions that have resulted significant seizures. In September 2012, a representative from the IPR Center participated in seven-day training with Brazilian authorities. As part of the training, a two-day enforcement operation was con-

ducted in the tri-border region, where Brazilian authorities seized approximately $500,000 dollars in counterfeit merchandise, 1,385 kilograms of marijuana, 1.5 kilograms of cocaine paste, 3 guns, and 15 vehicles. In November 2012, HSI Brasilia and Brazilian authorities seized $1,400,000, 134.5 kilograms of marijuana 20.5 kilograms of cocaine paste, four firearms, and 20 vehicles. Future enforcement operations are being coordinated by HSI Brasilia.

- In September 2012, Argentinian authorities seized 5,626 counterfeit Hewlett Packard toner cartridges, 3,050 counterfeit HP ink cartridges, 500 counterfeit toner security labels, 420 counterfeit toner boxes, and 140 counterfeit in boxes. The estimated MSRP value exceeded $500,000 dollars. In October 2012, HSI Buenos Aires and Paraguayan customs officers and other Paraguayan authorities seized counterfeit merchandise with an MSRP of $34 million. Also seized were approximately 12, 500 counterfeit Samsung cellular phones. In October 2012, Chilean Customs identified an express parcel that contained counterfeit merchandise valued at approximately $20,000 MSRP.

In 2012, in an effort to support State and Local law enforcement efforts directed at intellectual property, the IPR Center hosted temporary assignments from the Los Angeles Sheriff Department and the New Hampshire State Police at the IPR Center.

Department of Justice

Significant recent accomplishments of the Department of Justice in combating intellectual property crime and achievements in IP policy are detailed in the Department's 2012 PRO-IP Report to Congress, http://www.justice.gov/dag/iptaskforce/proipact/, and in the Department's Annual Performance and Accountability Report—Intellectual Property Appendix. Under the leadership of the Department's Intellectual Property Task Force, the FBI, and Justice Department components including the Criminal, Civil and Antitrust Divisions and the Bureau of Justice Affairs worked in FY 2012 to improve the protection of intellectual property, both in the U.S. and abroad.

IP Prosecutions in Priority Areas

- The Department, through the U.S. Attorneys' Offices (USAOs), the Computer Crime & Intellectual Property Section (CCIPS) in the Criminal Division and the Consumer Protection Branch (CPB) in the Civil Division, has continued to prioritize and pursue investigations and prosecutions in every priority area identified by the Department of Justice Task Force on Intellectual Property ("IP Task Force" or "IPTF"), including cases involving health and safety, trade secret theft and economic espionage, large-scale online piracy and counterfeiting, and links to organized criminal enterprises.

Ongoing Enforcement Initiatives

- **Operation Chain Reaction**. The National Intellectual Property Rights Coordination Center (IPR Center), with assistance from the Criminal Division, has developed a strategy to increase the investigation and prosecution of counterfeit goods entering the government supply chain.

- **Operation In Our Sites.** The Department, through USAOs and CCIPS, continues to support Operation In Our Sites (OIOS), an initiative spearheaded by ICE-HSI through the IPR Center that uses domain name seizures as a means to disrupt infringing sites and to educate and protect consumers. Since its inception OIOS has resulted in over 2000 seizures and the law enforcement banner to which site visitors have been redirected has been viewed over 110 million times.
- **Project Sustained Effort.** The Asset Forfeiture and Money Laundering Section (AFMLS), CCIPS, and USAOs are working with ICE-HSI to build on OIOS by seizing proceeds of online counterfeiting sites. For example, in two separate cases, the Department seized over $2.4 million in proceeds from the distribution of counterfeit sports apparel and jerseys as the result of investigations into the sale of counterfeit goods on commercial websites. The investigations also resulted in the collective seizure of 10 domain names associated with websites engaged in the sale of counterfeit goods. The funds were seized from correspondent bank accounts in China as well as PayPal accounts. Significantly, the domain names seized in these two investigations were new versions of domain names seized in an early iteration of OIOS in November 2010 and used by the same subjects.
- **Engine-Newity**. The FBI is leading a joint initiative to address counterfeit automotive parts, equipment, and accessories in the supply chain.
- **IPR Center Pharmaceutical/Health & Safety Working Group**. The IPR Center has started a pharmaceutical/health and safety working group in which CCIPS and the Civil Division's CPB are participating. The group is focused on information-sharing and coordinating efforts targeting counterfeit medicines and medical devices.

Media Strategy

- The IPTF worked with the Office of Public Affairs to develop the following IPTF message that has been disseminated to USAOs for incorporation into press releases involving IP prosecutions:

  "This case is part of efforts being undertaken by the Department of Justice Task Force on Intellectual Property (IP Task Force) to stop the theft of intellectual property. Attorney General Eric Holder created the IP Task Force, which is led by the Deputy Attorney General, to combat the growing number of domestic and international intellectual property crimes, protect the health and safety of American consumers, and safeguard the nation's economic security against those who seek to profit illegally from American creativity, innovation and hard work. The IP Task Force seeks to strengthen intellectual property rights protection through heightened criminal and civil enforcement, greater coordination among Federal, state and local law enforcement partners, and increased focus on international enforcement efforts, including reinforcing relationships with key foreign partners and U.S. industry leaders. To learn more about the IP Task Force, go to www.justice.gov/dag/iptaskforce."

Federal Bureau of Investigation Intellectual Property Program

- The FBI aggressively pursues intellectual property rights enforcement through its role as a primary partner at the IPR Center, investigations, intelligence driven initiatives, and coordinated efforts with both private industry and domestic and foreign law enforcement partners. It disrupts and dismantles international and domestic organizations and individuals that manufacture or traffic in counterfeit and pirated goods and/or steal, distribute, or otherwise profit from the theft of intellectual property.
- Three divisions at FBI Headquarters investigate intellectual property violations. The Criminal Investigative Division focuses on the theft of trade secrets, counterfeit goods that pose a threat to health and safety, and copyright and trademark infringement cases with a national security, organized crime, or significant economic impact. It has placed IPR-dedicated Special Agents around the country in field offices with US Attorney's Office Computer Hacking and Intellectual Property units. The Counterintelligence Division and its field office agents investigate economic espionage and the theft of trade secrets. The Cyber Division and its field agents address the theft of intellectual property through national security and criminal cyber intrusions.

Engagement with the Government and Victim Industries

The FBI recognizes the importance of engaging with rightholders, victim companies, and their representative organizations to identify investigative opportunities, to better address the IPR threat and emerging trends, and to improve awareness of IP theft. At the local level, each of the FBI's 56 field offices work with academic institutions, manufacturers, laboratories and other entities that are located within the field office's region and are perceived as being potentially at risk for trade secret theft. At the regional level, the FBI meets regularly with other government agencies, industry and academia to share information about insider threats, economic espionage and trade secret theft. At the national level, the FBI reviews the effectiveness of its local and regional efforts with a focus on the extent of outreach to companies and entities such as security-cleared defense contractors, universities, hospitals, high science companies, and emergent technology firms. It engages with stakeholders through several national outreach organizations, including the Domestic Security Alliance Council (DSAC), the National Security Business Alliance Council (NSBAC), and InfraGard, and works closely with various Information Sharing and Analysis Centers (ISACs).

In addition to ongoing interaction related to specific cases and initiatives, FBIHQ arranged, contributed to, or participated in numerous events. In partnership with ICE HSI and other IPR Center partners, FBI regularly met with rightholders and their representatives. These productive meetings facilitated communication about initiatives, emerging IPR threats, and yielded new investigations. The FBI provided presentations, served on panels of subject matter experts, and attended meetings and conferences associated with IPR related organizations, government agencies, and rightholders nationally and internationally.

FBIHQ also participated in working groups, briefings, joint strategic plan development, international capacity building/training initiatives, and provided FBI-specific information for inclusion in the IPEC's bi-monthly newsletter. During FY 2012, the FBI actively participated with the IPEC in the development

of the Administration's Strategy on Mitigating the Theft of U.S. Trade Secrets. The FBI also actively participated and contributed to several other U.S. Government working groups on IP enforcement and training, including the DOJ's IP Task Force and DOJ's Joint Liaison Group with China. In addition, the FBI worked closely with DOC and USTR on several IP issues and initiatives.

Supporting International Enforcement

In September 2011, an FBI Agent dedicated to the IPR program and joint investigations was deployed to the U.S. Embassy in Beijing, China for a tour of one year. The agent contributed to the FBI's IPR mission on several levels including meeting with a large number of rightholders, law firms, USG entities, nonprofit organizations, and foreign government agencies in Beijing, Shanghai, and Mongolia about IPR issues in China. These meetings and relationships led to a number of IPR threat intelligence reports and investigative leads. In addition, the agent participated in joint interviews along with Chinese officials of subjects of a large copyright case. As a result of the promise shown, the FBI has renewed this effort and deployed a replacement in FY13 with a focused emphasis on joint investigations.

FBI IPR Program Changes

The IPR program focuses on the most significant and serious threats to the country's economy and national security. In FY2012, the FBI's IPR program was realigned from the Cyber Division to the Criminal Investigative Division. The realignment will facilitate improved cross-program coordination with other FBI criminal programs, both at FBIHQ and in the field. For example, IPR investigations frequently have an organized crime element. Placing the IPR program with traditional criminal programs such as Organized Crime will lead to more effective and broader IPR investigations. At the same time, the cyber expertise in the IPR program will carry over into the Criminal Investigative Division, and reinforce the collaboration between agents investigating traditional IP violations and agents investigating IP theft based on cyber intrusions.

The FBI will build on its momentum in the IP field through continuous and productive working relationships with its IPR Center partners, rightholders and groups, other government agencies, and foreign counterparts. The FBI will employ the resources provided by the PRO IP Act to initiate, advance and support cutting edge and significant IP investigations, initiatives, training, and projects.

Increasing Public Awareness and Education

During FY 2012, the FBI completed or initiated significant projects designed to increase public awareness of the harm and illegality of copyright infringement. A joint partnership with the DOJ included efforts to make the FBI's Anti-Piracy Warning (APW) Seal available to all copyright holders, subject to certain conditions. This new regulation permits broad use of the APW Seal for all copyrighted works and provides users with a simple and efficient means to download the APW Seal from the FBI's public website.

In addition, the FBI partnered with the ICE HSI to launch a joint FBI/HSI anti-piracy warning banner and a companion IPR Center banner. This joint banner program was designed to reinvigorate the APW program and replace the traditional FBI warning which had appeared at the beginning of movies. Through close collaboration and with the outstanding support of the Motion Picture Association of America, the FBI and ICE HSI succeeded in securing the placement of the joint APW banner and the IPR Center page at

the beginning of most newly released movies as of May 2012. As a result, IPR case referrals through the IPR Center website have increased substantially.

In May, the FBI launched a media campaign highlighting the insider threat relating to economic espionage. This campaign included print and television interviews, billboards along busy commuter corridors in nine leading research areas nationwide, and public information on the FBI website. Through this campaign, the FBI reached out to the public and business communities, explaining how the insider threat affects company operations and educating them on how to detect, prevent, and respond to threats to their organizations' proprietary information. Perhaps the most important among these is identifying and taking defensive measures to reduce or eliminate employee theft of trade secrets.

Notable Civil Division Litigation Efforts

The Civil Division participated in a variety of significant intellectual property lawsuits and, in so doing, advocated for vigorous protections under IP law.

The following constitutes a non-exhaustive list of such efforts and includes instances where the United States participated as *amicus curiae* in private intellectual property disputes so as to promote the vigorous civil enforcement of U.S. intellectual property law. This list includes instances in which the Civil Division assisted the Office of the Solicitor General in the preparation of U.S. Supreme Court filings:

- *Golan v. Holder* [Sup. Ct.]: The United States defended the constitutionality of a statute that restored copyright protection to certain foreign works that had fallen into the public domain.
- *Mayo Collaborative Services v. Prometheus Laboratories* [Sup. Ct.]: The United States submitted an *amicus curiae* brief arguing, *inter alia*, that an improved method of treating a patient with a man-made drug may be eligible for patent protection even if the therapeutic efficacy of the drug depends on the natural metabolic processes of the human body.
- *St. Gobain Ceramics & Plastics v. Siemens Medical Solutions USA* [Sup. Ct.]: The United States submitted an *amicus* brief opposing a petition for a writ of certiorari, and arguing that an improvement may be deemed non-obvious, and thus, eligible for patent protection, even if a jury finds that the improvement is the equivalent of something claimed in an earlier patent.
- *Already, LLC v. Nike Corp*. [Sup. Ct.]: The Civil Division prepared an *amicus* brief arguing that a trademark owner's covenant not to sue an accused infringer over particular articles does not moot the infringer's challenge to the validity of the trademark unless the trademark holder demonstrates that it is absolutely clear that the dispute between the parties is not reasonably likely to recur.
- *Association for Molecular Pathology v. Myriad Genetics* [Fed. Cir.]: The Civil Division submitted an *amicus curiae* brief arguing, *inter alia*, for the patent-eligibility of man-made nucleotide sequences that do not exist in nature. The United States also argued against the patent eligibility of human DNA sequences that are isolated, but otherwise unmodified, from nature.

Intercollegiate Broadcasting System, Inc. v. Copyright Royalty Board [D.C. Cir.]: The Civil Division filed a brief defending the constitutionality of the provisions of the Copyright Act governing the appointment of Copyright Royalty Judges.

Antitrust Division IP Efforts

The Antitrust Division of the Department of Justice is mindful that the successful promotion of innovation requires both competitive markets and the protection of intellectual property, as each drives innovation in complementary ways. Over the past year, the Division has played an active role in issues involving IP, cognizant of the need to balance competition and patent rights—both pillars of our innovation economy.

- On December 10, 2012, the Division and the Federal Trade Commission (FTC) held a joint public workshop to explore the impact of patent assertion entities (PAE) on innovation and competition, and the implications for antitrust enforcement and policy. The workshop consisted of a series of panels examining, among other topics, the legal treatment of PAE activity, economic theories of potential efficiencies and harms concerning PAE activity, and industry experiences.
- In February 2012, the Division closed its investigations of the acquisition of two very significant patent portfolios—each of which included patents that the selling company had declared essential to telecommunications and/or wireless standards and committed to license on fair, reasonable and nondiscriminatory (FRAND) terms. The Division's investigations focused on whether the acquiring firms would have the incentive and ability to exploit ambiguities in commitments sellers made to license their patents on FRAND terms and thereby raise rivals' costs or foreclose competition. (*See* ***Statement of the Department of Justice's Antitrust Division on its Decision to Close its Investigations of Google Inc.'s Acquisition of Motorola Mobility Holdings Inc. and the Acquisitions of Certain Patents by Apple Inc., Microsoft Corp. and Research in Motion Ltd.*****, February 13, 2012, available*** at http://www.justice.gov/atr/public/press_releases/2012/280190.htm).
- On July 11, 2012, then Acting Assistant Attorney General Joe Wayland testified on factors the International Trade Commission might consider in deciding whether it was in the public interest to issue an exclusion order based on infringement of a standards essential patent, where the patent holder, or a predecessor owner, had committed to license on FRAND terms for implementation of the standard. (*See Statement of Joseph F. Wayland, Acting Assistant Attorney General, Antitrust Division, Regarding "Oversight on Competition of Exclusion Orders to Enforce Standards Essential Patents,"* July 11, 2012 available at http://www.justice.gov/atr/public/testimony/284982.pdf). Through speeches and meetings with leading organizations involved in standard setting, a number of Division officials have been actively encouraging procompetitive changes that Standard Setting Organizations should consider implementing in order to, among other things, clarify the meaning of FRAND in their IP policies. (*See* Renata Hesse, Deputy Assistant Attorney General, U.S. Dep't of Justice Antitrust Division, Remarks as Prepared for the ITU-T Patent Roundtable, *Six "Small" Proposals for SSOs Before Lunch*," available at http://www.justice.gov/atr/public/speeches/287855.pdf).
- The Division participated in DOJ's consideration of numerous potential court of appeals and Supreme Court amicus briefs (and occasional government merits briefs) related to IP, in order to bring competitive considerations to bear when appropriate.

- In May 2012, the Division and the FTC submitted an amicus brief to the Federal Circuit in *Ritz Camera & Image, LLC v. Sandisk Corp.* (*See Ritz Camera & Image, LLC v. Sandisk Corp., Brief for the United States and the Federal Trade Commission in Support of Appellee* available at http://www.justice.gov/atr/cases/f283500/283593.pdf). In the brief, the agencies argued that direct purchasers have standing to seek overcharge damages caused by an alleged antitrust violation involving enforcement of a patent procured by fraud.

The Division regularly advised foreign competition authorities and international organizations on issues involving the intersection of antitrust and IP, including a joint DOJ-FTC seminar for Chinese agencies that implement China's Antimonopoly Law.

OUTREACH, TRAINING AND EDUCATION

DOJ Leadership on IP

- The IPTF has looked for opportunities for senior Department officials and IPTF members to speak on IP enforcement as a means to raise awareness and also to publicly demonstrate the Department's commitment to IP enforcement. In the past two years, Attorney General Eric Holder, Deputy Attorney General Jim Cole, former Assistant Attorney General Lanny Breuer, Acting Associate Attorney General Tony West, former Deputy Assistant Attorney General Jason Weinstein, U.S. Attorney Jenny Durkan, and FBI Assistant Director Gordon Snow have all provided keynote and other remarks at widely attended events on IP enforcement.
- Deputy Attorney General Cole and other Department officials will continue to host a series of issue-oriented roundtable discussions with key stakeholders from a cross section of the IP industry. An upcoming roundtable is being planned for early 2013 in New Jersey and will focus on counterfeit pharmaceuticals. Other topics will include trade secret theft, online piracy, antitrust issues and hard goods counterfeiting.

Public Awareness: IP Theft Public Education Campaign Activities (Office of Justice Programs)

- The joint DOJ and National Crime Prevention Council IP Public Awareness campaign has garnered more than $45 million in donated media since its launch in November 2011. The campaign has received more than 52,952 total airings on TV in 208 of 210 markets and 26,830 airings on radio.

On-Going Federal, State, and Local IP Trainings

- *The Bureau of Justice Assistance (BJA) Supports Training for State and Local Law Enforcement on IP Theft.* BJA continues to support one-day training events on IP rights for state and local law enforcement agencies across the country through cooperative agreements with the National White Collar Crime Center (NW3C) and National Association of Attorneys General (NAAG). Since the Training and Technical Assistance (TTA) Program's inception, 33 trainings have been held, with 880 students representing 458 agencies participating in these sessions.

International Training and Outreach

As detailed in the PRO-IP Act Report, the Department continues to provide extensive training and technical assistance to countries around the world through programs funded by DOS's Bureau of International Narcotics and Law Enforcement (INL), through bi-lateral engagement, including the IP Working Group of the US-China Joint Liaison Group, and through the IP Law Enforcement Coordinator program.

Department of State

Foreign Government Enforcement Related Capacity Building:

Government-to-Government Enforcement Training: The DOS, using foreign assistance anti-crime funds managed by the Bureau of International Narcotics and Law Enforcement Affairs (INL), in collaboration with the Economic Bureau (EB), has a long-standing program to provide capacity-building training and technical assistance to foreign law enforcement partners to combat intellectual property rights crime. The DOS enables U.S. Government law enforcement interagency training teams to prioritize assistance to developing countries in Latin America, Africa and the Asia Pacific that are named in the Special 301 Report as countries of concern and that face human health and safety risks associated with counterfeit medicines as well as growing digital piracy. As an example of this government-to-government training, **Embassy Mexico** worked with the U.S. Department of Justice (DOJ) in 2012 to conduct trainings on IP-related computer forensics and digital evidence in order to address infringement in the digital environment. Training programs were conducted in cooperation with Mexican Customs, Revenue Service investigators, anti-trust officials, prosecutors, judges and the Mexican IP Office. DOJ and the Embassy also organized a conference on criminal enforcement at the border, and a series of train the trainers' workshops on IPR for Mexican technical and operational advisors. DOS/EB/INL funds also were allocated to train government law enforcement officials in West, East Central and Sub-Saharan Africa, ASEAN, Brazil, Chile, Colombia, South Asia, the Philippines, Thailand and Turkey on various topics such as (1) customs/border enforcement, (2) organized crime elements of trafficking in counterfeit medicines and gathering electronic evidence, (3) addressing Internet piracy, (4) judicial and prosecutorial management of IPR cases, and establishing special IPR courts.

Bilateral Engagement:

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

Multilateral Engagement:

In 2012, DOS continued its efforts to promote respect for IPR through international organizations and in other multilateral forums. Where relevant, DOS representatives requested that U.S. international development and trade agency partners actively educate their program recipients about the importance of intellectual property to support business development, entrepreneurship and innovation. These

efforts contributed to an increased focus on the role of intellectual property and development by the U. N. International Trade Centre (ITC) and the U.N. Conference on Trade and Development (UNCTAD). For example, ITC's Ethical Fashion Initiative matches artisans and micro-entrepreneurs in developing countries with representatives at high-end fashion brands that benefit from trademark protection and sell at a premium. This allows those artisans and micro-entrepreneurs to earn a higher wage. DOS's engagement with UNCTAD contributed to its issuance of a landmark Entrepreneurship Policy Framework in 2012 that supports developing country policymakers in the design of initiatives and institutions to promote entrepreneurship and included sound policy advice on the importance of registering, protecting and enforcing intellectual property rights.

DOS also contributed to U.S. Government efforts to advance trade policy goals in APEC, ASEAN, TPP negotiations and the G-8. DOS continued efforts to address counterfeit medicines in APEC and the G-8, including through inclusion of language in those forums' Leaders' Statements to encourage further collaboration on counterfeit medicines. DOS supported the IPEC on efforts to promote voluntary practices to address on-line piracy among G-8 members. In APEC and ASEAN, DOS used government-to-government law enforcement training funds to contribute to efforts to improve intellectual property systems in the region, to foster economic growth, and to encourage harmonization of IP systems. DOS assisted USTR in matters relating to the Anti-Counterfeiting Trade Agreement (ACTA). Finally, DOS participated in the US-EU IP Working Group to implement a number of key objectives, including those related to addressing key IP issues in 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.

World Intellectual Property Organization (WIPO) Standing Committee on Copyrights and Related Rights (SCCR):

DOS's Office of Intellectual Property Enforcement (IPE) is a member of the interagency WIPO SCCR team, led by USPTO, and sends a representative to SCCR meetings. On June 26, 2012, the United States signed the Audiovisual Performances Treaty (otherwise known as the "Beijing Treaty"), which is the first substantive multilateral copyright treaty since the 1996 WIPO Copyright Treaty and WIPO Performances and Phonograms Treaty. Once the Beijing Treaty enters into force, it will fill a gap in the international copyright system and make it easier for American actors to get paid for their work. DOS is also closely engaged on negotiations for an international copyright exceptions agreement that would benefit persons with print disabilities. A diplomatic conference is scheduled for **June 2013 in Morocco.**

DOS Public Diplomacy Counterfeit Medicines and Internet Piracy initiatives:

During FY 2012, DOS devoted over $200,000 in public diplomacy funds toward its international "Campaign against Counterfeit Medicines, Counterfeit Products and Internet Piracy." EB provided seed money to support public awareness campaigns developed by DOS' embassies and consulates in 27 countries in Africa, Asia, Europe, the Middle East and Latin America. All of the projects involved partnerships with the host governments and other public and private sector partners, whose contributions in many cases matched or exceeded that provided by DOS. Summaries of FY2012 public diplomacy programs are noted below.

Africa

In **Cameroon**, Embassy Yaoundé conducted pharmaceutical IPR outreach in the Southwest region, particularly among rural communities, where HIV/AIDS prevalence is high and where there is a serious proliferation of counterfeit medicine. In **Guinea**, Embassy Conakry conducted a two-day public outreach seminar featuring presentations on counterfeit medicines from relevant Guinean ministries, NGOs, and the private sector. In **Kenya,** Embassy Nairobi extended its public awareness campaign on the dangers of counterfeit medicines and consumer products to rural areas.

Asia

In **China**, Consulate Guangzhou developed a mobile application targeting young adults through free job advice that featured the important role of intellectual property protection and enforcement to corporations. A regional campaign organized by Embassy Phnom Penh in collaboration with Embassies Hanoi, Vientiane, and Bangkok in **Cambodia, Laos, Thailand and Vietnam,** conducted a contest for a counterfeit medicines outreach campaign slogan and incorporated the slogan into print advertising, radio/ TV messages, and outreach events in the context of World Health Day on April 8 and World Intellectual Property Day on April 26. In **Nepal**, Embassy Katmandu organized five workshops to raise awareness among key stakeholders from the Government of Nepal, private sector, media, and consumers regarding Nepal's current IPR environment and needed reforms. In **New Zealand**, Embassy Wellington implemented a four-month educational campaign on IP infringement surrounding the December 2011 World Rugby Cup. The campaign featured a 30-second public service announcement in cinemas, TV networks, and online social networking. Embassy Colombo targeted the **Maldives** with a campaign against counterfeit drugs and copyright piracy. The American Institute in Taiwan (AIT Taipei) partnered with government officials and key local pharmaceutical industry stakeholders to conduct an infomercial video competition on the dangers of counterfeit drugs. And, in **Vietnam**, Embassy Hanoi launched "Deter, Detect, and Distinguish: Keeping Families Safe from Counterfeit Drugs" via a poster and Internet campaign.

Europe

In **Bosnia**, Embassy Sarajevo conducted a "Buy Smart, Buy Safe" multimedia campaign to alert the public to the dangers of counterfeit medicines using billboards, posters, leaflets, news articles, Facebook, radio, and TV spots. In **Bulgaria**, Embassy Sofia hosted a regional public diplomacy speaking tour in three major cities focusing on Internet piracy and targeting young up-and-coming entrepreneurs in the IT field. In **Estonia**, Embassy Tallinn's campaign targeted middle and high school students through seminars led by cadets from the Police and Border Guard School, accompanied by young stars and IPR experts. In **Finland,** Embassy Helsinki used social media to feature famous musicians and representatives from the creative industries as spokespersons. Embassy Helsinki held an online anti-piracy advertisement competition that culminated in a concert to raise awareness about the cost to society of illegal downloading and counterfeit medicines. In **Georgia**, Embassy Tbilisi targeted the business community to promote use of legitimate business software, and youth and the general public to encourage use of legal goods. In **Latvia**, Embassy Riga created a short documentary on the costs of producing records. In **Lithuania**, Embassy Vilnius worked with a partner to create a crowd-sourced platform enabling anonymous reporting of intellectual property rights violations. In **Portugal**, Embassy Lisbon used an Internet-based video

competition to promote the message that downloading unlicensed music or movies is stealing. In **Ukraine**, Embassy Kyiv partnered with the local music industry to conduct a high-profile public service video campaign with Ukrainian artists.

In **Morocco**, Embassy Rabat hosted a national public-private roundtable to promote public diplomacy outreach on counterfeit medicines and hygiene products. The roundtable launched a series of industry-funded public outreach events building on a FY2011 WIPO/DOS event that taught participants how to develop their own anti-counterfeiting public awareness campaigns.

Latin America

In **Brazil**, Consulate General Sao Paulo engaged students in the creative process of designing their own intellectual property through the production of short films using "flip cameras." In **Chile**, Embassy Santiago conducted a ten-day "computer game and application development" outreach campaign targeting Chilean high school students. The campaign emphasized the importance of intellectual property protection for innovation and fairness. In **Guatemala**, the embassy team conducted a national outreach campaign highlighting the dangers of purchasing counterfeit drugs. In **Peru**, Embassy Lima undertook a countrywide public outreach campaign focused on the cost of illegal downloads to the Peruvian economy. In **Venezuela**, Embassy Caracas hosted three IPR best practices workshops and initiated a series of public service announcements (PSAs) via radio and social media that focused on trademark counterfeiting, counterfeit medicines, and Internet/software piracy.

During FY 2013, DOS will use $342,000 to support 33 campaigns against counterfeit medicines, counterfeit products and Internet piracy in 30 countries. As of December 2012, four of those campaigns (Mauritius, Fiji, Bulgaria, and Croatia) were already completed. In **Mauritius**, Embassy Port Louis held a Counterfeit Medicines workshop for ministerial-level officials from the Government of Mauritius, private sector stakeholders, and U.S. officials. In **Fiji**, Embassy Suva held a Concert "Musicians against Pirates." In **Bulgaria,** Embassy Sofia developed a Bulgarian language music video that built upon the National Crime Prevention Center's Intellectual Property Theft Public Education Campaign. In **Croatia,** Embassy Zagreb held a two-day seminar to raise awareness of the link between IPR protection and a vibrant knowledge-based economy. Looking ahead, similar campaigns will be implemented during the remainder of FY2013 throughout Africa, Asia, Europe, and Latin America.

Training State Employees:

IPE, along with USPTO, held its annual IPR course at the Alexandria, Virginia-based Global Intellectual Property Academy (GIPA) for Foreign Service officers that will have intellectual property as part of their portfolio at an overseas post. The course equips Foreign Service Officers to actively engage their host governments to improve intellectual property-related legislation and enforcement and raise public awareness about the role of intellectual property rights in the economy and the danger of counterfeits. IPE also integrated a session on intellectual property rights into the economic and political tradecraft courses that are offered almost monthly at the Foreign Service Institute and improved its website to facilitate more work on IP issues at posts.

Special 301 and Notorious Markets Contributions:

DOS/IPE provided extensive support to USTR and the interagency team as part of 2012's Special 301 process. Seventy-four posts submitted detailed analysis on the state of intellectual property rights protection and enforcement as part of the 2011 review. The IPE office also coordinated post input for the Notorious Markets Report, with detailed input from 39 posts.

Supply Chain Integrity:

DOS began working with the Center for Responsible Enterprise and Trade (CREATe.org)—a private sector organization focused on supply chain integrity and related issues, including intellectual property protection—to promote policies among suppliers and business networks in global supply chains that ensure respect for intellectual property, put in place strong anti-corruption measures, and insist on transparency and accurate record-keeping. In May 2012 DOS and CREATe co-hosted a public-private sector event to increase awareness of the role of IP protection in supply chain integrity.

United States Copyright Office

The work of the U.S. Copyright Office touches a broad range of both administrative and policy functions, including copyright protection, exceptions and limitations to copyright, and effective enforcement of the exclusive rights of authors and other copyright owners. The Copyright Office administers the Copyright Act for the Nation and other major provisions of Title 17, including registering hundreds of thousands of copyrights a year and recording licenses and other transfers of copyright ownership. Together, these systems play an important role in both commerce and enforcement involving American authorship and innovation. On the one hand, they provide the world's largest database of copyright information for those seeking licenses to use copyrighted works, and on the other hand, they provide copyright owners with certain protections and benefits under the law, such as the availability of statutory damages in certain instances of infringement.

In addition to administering the registration and recordation systems of the United States, the U.S. Copyright Office provides leadership and impartial expertise on questions of copyright law and policy, advises Congress on national and international issues relating to copyright, and provides information and assistance to Federal departments and agencies and the judiciary on national and international issues relating to copyright. Congress has also directed the Office to participate in meetings of international intergovernmental organizations and meetings with foreign government officials on copyright matters.

In October 2011, Register of Copyrights Maria Pallante announced a two-year work plan for the Office, which will conclude in October 2013 and will serve as a basis for the Office's long term strategic plan. *See* www.copyright.gov. The Office's ambitious work plan includes a number of special projects designed to improve the quality and efficiency of the Office's public services in the 21st century. The Office is now one year into its work plan, and is undertaking a comprehensive review of its technical processing capabilities and related legal underpinnings. As part of this review, the Office is engaging in a robust discussion with a variety of interested stakeholders from both technical and legal communities on ways to upgrade the national database of copyright information in order to facilitate copyright transactions in the marketplace, and to assist the identification of works in the public domain.

Copyright Policy

In 2012, the Office requested written public comments on three important copyright policy issues: (1) legal remedies for small copyright claims (*i.e.,* copyright infringement claims that have a relatively small economic value); (2) proposed solutions for orphan works and mass digitization; and (3) a possible Federal resale royalty right. The Office is also actively engaged in reform of the library exceptions under Section 108 of the Copyright Act.

Small Claims Study

The Office's small claims study will assess how small copyright claims are handled under the current legal system and will recommend potential administrative, regulatory and/or statutory changes to improve their adjudication. In its notice of inquiry on this issue, the Office requested public comments on how parties—both copyright owners and those alleged to have infringed—view the current system, what their experiences with the current system have been, and what types of alternatives to the current legal system would be helpful and viable. Among the issues the Office is exploring are what may constitute a "small" copyright claim, the current difficulties in litigating small copyright claims, possible state court solutions, and alternative administrative legal procedures. In November 2012, the Office held a series of public roundtables on small claims in New York and Los Angeles. The Office will issue its report on small copyright claims in the fall of 2013.

Orphan Works

The Office is also reviewing the problem of orphan works (*i.e.,* works for which a copyright owner cannot be identified and/or located) under U.S. copyright law. The Office has long shared the concern with many in the copyright community that the uncertainty surrounding the ownership status of orphan works does not serve the objectives of the copyright system. For good faith users, orphan works are a frustration, a liability risk, and a major cause of gridlock in the digital marketplace. The Office's current request for public comments is a continuation of its previous work on the subject, and will assist the Office in its effort to advise Congress on possible next steps for the United States.

Resale Royalties

In the fall of 2012, the Copyright Office began its review of the feasibility and desirability of a Federal resale royalty right. As part of its review, the Office is considering how the current copyright legal system affects and supports visual artists, and how a Federal resale royalty right for visual artists would affect those involved in the creation and sale of works of visual art.

Library Exceptions and Limitations

The Office has also prioritized the goal of resolving problems related to library exceptions and limitations (17 U.S.C. § 108) in a manner that provides institutions with appropriate and meaningful guidance in the digital age. The Office is working with stakeholders to develop exceptions that allow libraries, archives, and museums to meet their responsibilities in a world of digital preservation, research, and scholarship, while not unduly affecting the incentives that copyright law provides to authors for the creation and dissemination of creative works. As with other projects, the Office is partnering with the private sector to encourage public discussion of potential solutions, and in February 2013, the Office

hosted a symposium on Section 108 reform in cooperation with the Kernochan Center for Law, Media and the Arts at Columbia Law School.

Section 1201 Rulemaking

In October 2012, the Office concluded the fifth triennial rulemaking proceeding pursuant to 17 U.S.C. § 1201. Section 1201 provides that, upon the recommendation of the Register of Copyrights, the Librarian of Congress may designate certain classes of works as exempt from the prohibition against circumvention of technological measures that control access to copyrighted works. The final rule, effective as of October 28, 2012, along with the analysis and recommendation of the Register, may be accessed on the Copyright Office website at www.copyright.gov/1201. The rule exempts certain categories of works to the benefit of documentary filmmakers, educators, researchers, and individuals with print disabilities.

International Activities

The Copyright Office supports a number of international copyright goals of the United States. The Office routinely analyzes pending and current copyright legislation of other countries, and participates in bilateral technical discussions with countries on their legal reform and enforcement efforts. The Register of Copyrights and other senior leaders in the Office also regularly participate in conferences and symposia sponsored by the World Intellectual Property Organization (WIPO) in Geneva and in other WIPO-sponsored meetings throughout the world.

In 2012, the Copyright Office participated on a number of U.S. delegations and continued to work with other agencies on various copyright issues at WIPO. The Office was part of the U.S. delegation to the June 2012 Diplomatic Conference on the Protection of Audiovisual Performances in Beijing, China, which resulted in the successful adoption of the "Beijing Treaty" harmonizing copyright protection for audiovisual performances on the international level. The Office also served on several United States delegations to the Standing Committee on Copyright and Related Rights (SCCR), including an October 2012 intercessional meeting focused on a possible international instrument(s) for copyright exceptions for blind, visually impaired, and print disabled persons.

In early 2012, the Office assisted the Library of Congress staff and U.S. publishers on U.S. participation in the WIPO Trusted Intermediary Global Accessible Resources Project (TIGAR), a voluntary pilot project involving cross-border licensing of accessible works for visually impaired persons. The Library of Congress/National Library Service for the Blind and Physically Handicapped (NLS) formally joined the project as a trusted intermediary in May 2012. Copyright Office experts also served on the United States delegation to the WIPO Intergovernmental Committee and participated in deliberations on possible international recognition of and protection for traditional cultural expressions (folklore).

The Office continued to provide advice and support to USTR in the context of trade negotiations and has been an active participant on official delegations and negotiating teams for the proposed TPP. The Office participated in many of the TPP negotiating rounds and intercessional negotiations held in 2012. The Office also continued its participation in the annual Special 301 process. The Office contributed to the development of U.S. government positions in other copyright- and enforcement-related activities of multilateral organizations such as the Organisation for Economic Co-operation and Development

(OECD), as well as ongoing trade policy reviews of countries' intellectual property laws at the World Trade Organization (WTO).

Training and Outreach

The Office receives funding from Congress to produce training and outreach programs for the benefit of users, stakeholders, and the general public as well as foreign government officials. Last year, the Office's training programs focused on the topic of emerging copyright issues in the digital age. The Office's notable training and outreach programs in 2012 included:

- In March 2012, the Copyright Office and WIPO co-sponsored a week-long training program for senior level government officials from developing countries entitled "Emerging Issues in Copyright and Related Rights for Developing Countries and Countries with Economies in Transition." The program brought together 21 senior-level copyright officials from 19 countries to discuss a host of important copyright issues, including, digital rights and technology, licensing, limitations and exceptions, cross border enforcement, and collective management. As part of the program, the Register of Copyrights and the Undersecretary of Commerce for Intellectual Property met with the heads of the copyright offices of eight different countries.
- In September 2012, the Copyright Office and the USPTO jointly organized a four-day training symposium for foreign copyright officials entitled "Copyright Law in the Digital Age." This program included government officials from 16 countries and addressed a wide array of copyright issues related to the digital environment, including online enforcement, exceptions and limitations, and the digital marketplace.
- The Office coordinated intensive training on the U.S. registration system for visiting government copyright officials and hosted international visitors to the Copyright Office to discuss and exchange information on the U.S. copyright system and international copyright issues.

Speaking Engagements

The Register and her senior staff regularly sponsor or participate in programs and conferences on issues relating to domestic and international copyright law, which often include significant discussion of enforcement issues. These programs have taken place within the United States and abroad and involve a diverse array of copyright constituencies, including private sector and government audiences.

United States Trade Representative

In 2012, USTR successfully advanced President Obama's National Export Initiative (NEI) and other global trade objectives by securing and maintaining markets for U.S. goods and services. U.S. Trade Representative Ron Kirk continued to lead USTR's comprehensive efforts to engage with trading partners, maximize market opportunities, and remove barriers to U.S. exports. In addition, USTR celebrated the fiftieth anniversary of President Kennedy's 1962 signature of legislation creating a Special Representative for Trade Negotiations.

Protection and enforcement of intellectual property rights is critical to the effort to benefit from increased exports. These rights protect the value added—the creativity, innovation and brand value—that helps

to make American goods and services competitive in global markets. To further U.S. interests in this area, USTR works with trading partners to promote adequate and effective protection and enforcement of intellectual property rights.

Increased U.S. exports continue to support American economic recovery and job growth. In coordination with Congress and agencies across the Administration, USTR actively pursued opportunities to enhance international trade and boost U.S. exports through dialogue and negotiations this year.

Intellectual property was the focus of several USTR initiatives in 2012, and was an important part of many broader efforts. For example:

- *Cracking Down on Theft of Intellectual Property.* In April, USTR issued its annual comprehensive "Special 301" report on intellectual property protection and enforcement by U.S. trading partners. Israel was removed from the Special 301 Priority Watch List based on its progress implementing a 2010 agreement on pharmaceutical intellectual property rights, while Ukraine was added to the Special 301 Priority Watch List based on its failure to implement a previously agreed action plan on intellectual property rights.
- *Spotlighting Notorious Markets.* In December, USTR issued a Special 301 Out-of-Cycle Review of Notorious Markets to continue shining a spotlight on marketplaces that facilitate and sustain global piracy and counterfeiting. Eight markets USTR identified one year ago were able to be removed from the 2012 list, thanks to significant law enforcement actions or significant voluntary actions aimed at addressing IP theft. USTR added several new sites in China and other parts of the world to encourage continued progress, and warned sites removed from the list that they could be listed again in the future if corrective actions prove inadequate or short-lived.
- *Entry into Force of New Trade Agreements with Korea, Colombia, and Panama.* USTR worked with Korea, Colombia, and Panama to begin implementing the trade agreements approved by Congress in 2011, including through enactment of IPR legislation necessary for each partner to implement its agreement with the United States. The U.S.-Korea trade agreement entered into force on March 15, followed by the U.S.-Colombia trade agreement on May 15 and the U.S.-Panama trade agreement on October 31. USTR is now using the consultative mechanisms set out in each agreement to ensure that all elements of the agreements continue to operate properly. Job-supporting U.S. exports to each market are anticipated to grow in the coming months and years.
- *Terminating the Jackson-Vanik Amendment and Extending PNTR to Russia to Secure the Full Benefits of Russia's WTO Commitments.* The passage of legislation terminating application of the Jackson-Vanik amendment and authorizing the President to extend permanent normal trade relations status (PNTR) to Russia and Moldova permitted the application of the WTO Agreement between the United States and both countries as of December 21, 2012. In particular, this action will ensure that American firms, exporters, farmers, ranchers, and workers enjoy the same benefits of Russia's WTO membership as their international competitors. It will also provide the trade tools necessary to hold Russia accountable for its commitments, including obligations concerning the protection of intellectual property. In December, USTR also announced that the United States and Russia reached a mutual understanding on an Action Plan to improve IPR protection and

enforcement in all spheres, including over the Internet. Increasing U.S. exports to Russia's large and growing market will support additional American jobs at home.

- *Advancing the Trans-Pacific Partnership Negotiations.* Through five formal negotiating rounds and numerous intercessional meetings this year, TPP partners together made meaningful progress in all areas of the agreement as outlined by TPP Leaders in late 2011. Work continued to move forward on strong commitments in the area of intellectual property, as well as other chapters of the agreement. Informed by input from a wide range of stakeholders, the United States complemented its strong intellectual property rights proposals in TPP with a new proposal that would, for the first time in any U.S. trade agreement, obligate Parties to seek to achieve an appropriate balance in their copyright systems in providing copyright exceptions and limitations for purposes such as criticism, comment, news reporting, teaching, scholarship, and research.
- *Securing a Better Deal for U.S. Film Exports to China.* In February in an agreement that followed USTR enforcement victories at the WTO, Vice President Joe Biden announced that China had agreed to increase market access significantly for U.S. movies being shown in China. The increased market access will enable more job-supporting U.S. film exports to China and provide fairer compensation to U.S. film producers for the movies being shown there. Specifically, the agreement allows significantly more exports of U.S. blockbuster films to China, ensures significantly higher revenue for American producers when their blockbuster films are distributed by Chinese state-owned enterprises, and strengthens the opportunities for independent American producers and small firms to have their films distributed in China on fair commercial terms.
- *Advancing U.S. Interests through Trade Dialogues.* USTR advanced discussions of intellectual property and innovation issues in diverse trade policy dialogues, forums and pending negotiations with partners around the world, including through the World Trade Organization (WTO), the Asia Pacific Economic Cooperation forum, and regional and bilateral initiatives with partners around the world including the EU, China, Russia, and many others, and also worked toward entry into force of the Anti-Counterfeiting Trade Agreement. Key issues in these dialogues included sustaining and modernizing measures for copyright, patent, and trademark protection and enforcement, as well as a growing emphasis on trade secret protection and other emerging issues affecting U.S. businesses and their workers. USTR also engaged on IPR issues with partners seeking accession to the WTO.
- *Advancing Key IPR and Innovation Issues in China.* U.S. Trade Representative Ron Kirk and Acting Secretary of Commerce Rebecca Blank, together with Chinese Vice Premier Wang Qishan, co-chaired the 23rd Joint Commission on Commerce and Trade (JCCT) in Washington, D.C., on December 18-19, 2012. Key results from this year's JCCT on intellectual property rights and localization of IPR and technology included commitments on: state-owned enterprise software legalization; a judicial interpretation on intermediary liability; technology transfer and technology cooperation; indigenous innovation requirements in China's Multi-level Protection Scheme; and concerns related to official use vehicles and high and new technology enterprises.
- *Upholding Commitments Required under the Generalized System of Preferences (GSP).* USTR led interagency reviews of country practices regarding several GSP beneficiary countries, and

launched new GSP reviews regarding protection of intellectual property rights in Indonesia and Ukraine.

- *Setting Up the Interagency Trade Enforcement Center (ITEC).* In his 2012 State of the Union Address, President Obama called for the creation of an interagency trade enforcement unit charged with investigating unfair trading practices. In February, the President established the Interagency Trade Enforcement Center (ITEC), bringing together resources and expertise from across the Federal government into one organization with a clear, "all hands on deck" commitment to strong trade enforcement. As Congress continues to provide valuable input, the ITEC is significantly enhancing the Administration's capability to investigate potentially unfair trade practices and enforce U.S. trade rights proactively.
- *Expanding Stakeholder Consultations as an Integral Element of Trade Negotiations.* USTR's extensive outreach to diverse stakeholders informed and improved many job-supporting trade initiatives this year. Creative new approaches enhanced USTR's public engagement and helped to address important issues appropriately with both trading partners and concerned citizens.

Together with Congress, partner agencies, and a wide range of stakeholders, USTR developed and deployed U.S. trade policy to support additional exports and jobs for American businesses, workers, and families.

"From day one, President Obama has pursued a thoughtful and comprehensive approach to trade that advances U.S. interests and reflects our values. We've used every means available—and created new tools as necessary—to secure a level playing field for American exporters to compete and win in world markets. In the process, we've proven that trade can be a balanced part of our economic portfolio, helping to increase exports and create jobs, and we look forward to doing even more in the future," said Ambassador Kirk.

Annex

Intellectual Property Enforcement Legislative Recommendations Enacted

In March 2011, the Administration undertook a review of existing laws to ensure that they were effective and to identify deficiencies that could hinder enforcement. Based on that review, the Administration sent to Congress 20 intellectual property enforcement legislative recommendations. These recommendations were designed to increase the effectiveness of U.S. enforcement efforts in areas related to protecting the U.S government supply chain, the sharing of information with rightholders, protecting consumers from counterfeit pharmaceuticals and increasing penalties for trade secret theft.

It is also worth noting the enactment of Public Law 112-236 - *The Theft of Trade Secrets Clarification Act of 2012,* which closed a loophole by clarifying that the scope of the Economic Espionage Act protects trade secrets related to "a product or service used in or intended for use in" interstate or foreign commerce. This legislation was introduced by Senate Judiciary Chairman Senator Patrick Leahy in response to the Second Circuit decision in *United States v. Aleynikov*, 676 F.3d 71 (2d Cir. 2012), which overturned a verdict that found that the defendant violated 18 U.S.C. §1832(a) by stealing proprietary computer code, a trade secret, from his employer. This legislation was in line with the overall IPEC objective of protecting trade secrets from misappropriation.

During the 112th Congress, seven Administration recommendations were enacted into law:

Public Law 112-81- *The National Defense Authorization Act of 2012*

- Increased Federal criminal penalties for counterfeit goods or services sold to, or for use by, the military of national security apparatus.
- Granted Customs and Border Protection (CBP) authority to share information regarding suspected counterfeit goods with trademark owners in order to assist CBP in making infringement determinations.

Public Law 112-144 - *The Food and Drug Administration Safety and Innovation Act*

- Allowed FDA to require pharmaceutical manufacturers to notify the FDA of the theft or counterfeiting of a drug they manufacture.
- Granted FDA the authority to destroy certain counterfeit or adulterated drugs with a value of less than $2500.
- Increased Federal criminal penalties for trafficking in counterfeit drugs.
- Directed USSC to review guidelines and policy statements related to offenses that involve counterfeit drugs.

Public Law 112-269 *- The Foreign and Economic Espionage Penalty Enhancement Act of 2012*

- Bolstered criminal penalties for economic espionage and directed USSC to consider increasing offense levels for trade secret crimes.