

**INTERNATIONAL IP ENFORCEMENT:
OPENING MARKETS ABROAD AND
PROTECTING INNOVATION**

HEARING
BEFORE THE
SUBCOMMITTEE ON
INTELLECTUAL PROPERTY,
COMPETITION, AND THE INTERNET
OF THE
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INTERNATIONAL IP ENFORCEMENT: OPENING MARKETS ABROAD AND PROTECTING INNO- VATION

THURSDAY, SEPTEMBER 20, 2012

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON INTELLECTUAL PROPERTY,
COMPETITION, AND THE INTERNET,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to call, at 2:26 p.m., in room 2141, Rayburn Office Building, the Honorable Bob Goodlatte (Chairman of the Subcommittee) presiding.

Present: Representatives Goodlatte, Coble, Griffin, Marino, Watt, and Chu.

Staff present: (Majority) Vishal Amin, Counsel; Olivia Lee, Clerk; and (Minority) Stephanie Moore, Subcommittee Chief Counsel.

Mr. GOODLATTE. Good afternoon. The hearing of the Subcommittee on Intellectual Property, Competition, and the Internet will come to order. And I will recognize myself for an opening statement.

Today we are holding an oversight hearing on the Obama administration's international IP enforcement efforts, focusing specifically on international patent, trade secret, and market access issues to shine the spotlight on the problems that American companies face when seeking enforcement and using patents overseas.

This Subcommittee held hearings in April with industry stakeholders and in June with the Deputy Director of the USPTO to look at the patent systems in foreign countries and whether they meet global trading standards. The fundamental question we sought to answer was whether we have a level or an unlevel playing field abroad for American investors. What we learned is that much work needs to be done to level the playing field for American innovators.

When American businesses seek to sell their goods abroad, they must be able to compete fairly. Our trading partners must live up to their international obligations and not discriminate against U.S. companies or fields of technology when it comes to patentability and market access.

World Trade Organization members are required to make patents available for inventions in all fields of technology. However, many countries discriminate based on the place of invention, field of technology, or whether products are imported or locally produced. For example, countries like Brazil and India limit the scope

of patent eligible subject matter in a way that makes it difficult, if not impossible, for a U.S. innovator to get patent protection. Just as problematic is the flip side where a country grants many low quality or junk patents to local companies so that they can sue American companies and get rich quick. Many of these are utility model patents that go through minimal review and lack real inventiveness.

Recently we heard about the Goophone I5, a supposed iPhone 5 clone being manufactured by a Chinese company. This same company also sells a clone of the Samsung Galaxy smartphone. The issue here is that this company has filed for Chinese patents on innovations that were made by others, and this type of patent trolling can be used to threaten American companies and force monetary settlements.

For example, Bloomberg reported that in China, of the 530,000 patents granted during the first half of this year, only 107,000 were invention patents. The rest were for design or utility model patents, neither of which requires a rigorous examination process before being approved.

We have also seen a series of rulings in Canada that dramatically heightens utility requirements as to the usefulness of an invention, which will result in certain pharmaceutical patents being valid in the U.S., but not in Canada. This directly disadvantages American drug companies and could open the door to other countries that seek to further weaken protections for pharmaceutical patents.

Another field where foreign competitors have engaged in protectionist practices is trade secrets. Certain foreign governments have begun adopting policies that undermine trade secrets and disadvantage American companies. These policies include, one, requiring companies to provide trade secret information to a local partner or government agency as a condition of investment or market access, and two, testing or certification programs that require companies to disclose confidential information in order to sell their product in the foreign market.

When U.S. companies are forced to give their confidential business information to a government authority, there is usually a lack of adequate safeguards to protect it. U.S. companies should not have to choose between treating trade secret theft as simply a cost of doing business and avoiding certain markets in Asia all together. The issue of trade secret theft is not simply a business-to-business concern. Foreign governments must take these cases seriously and ensure that they have adequate remedies and laws in place.

Some countries, like South Korea, China, and India, are looking at using compulsory licensing in the trade secret space. The regulators in these countries can potentially compel new licensing of a trade secret by a third party. This is done to help a local competitor that claims that it needs access to the trade secret in order to compete. What makes this more troubling is that some of these third parties are State-owned enterprises.

All of these practices point to the fact that the U.S. needs to be more vigilant in ensuring an international market that is fair to U.S. companies looking to compete.

Today we will examine what the U.S. has and has not been doing to ensure this is indeed the case. Some have argued that the Obama administration has taken a narrow approach when it comes to concerns of American innovative companies in the patents, trade secrets, and market access space. They point to the Administration's lack of focus on international patent and trade secret issues generally, as well as the lack of a strong public response when in March the Indian government took the unprecedented step of issuing a compulsory license on a pharmaceutical patent.

Trade agreements, like the Trans Pacific Partnership Act, or TPP, provide platforms for the U.S. to exert pressure on other countries to level the playing field when it comes to these issues. It has come to our attention that some provisions being discussed in the TPP, like requirements for plain packaging of tobacco products and pharmaceutical test data protection issues, could weaken rather than strengthen global commitments to intellectual property rights.

I look forward to continuing to work to ensure that these negotiations result in stronger, not weaker, commitments by other countries to enhance their IP laws. Today I hope to hear more about the Administration's plans to do more to expand the U.S. government's efforts to find real solutions to these unfair trade practices which distort the free market and trade, and hinder American job creation.

And before we turn to our distinguished witness today, I would be pleased to recognize the Ranking Member of the Subcommittee, the gentleman from North Carolina, Mr. Watt.

Mr. WATT. Thank you, Chairman Goodlatte. And let me start by thanking you also for accommodating today's witness and me at our previous hearing on this topic in June. As we as Members all recognize, there are simply those occasions where you cannot be in two places at one time. And both our witness and I had that problem, as I recall, when the hearing was previously scheduled.

Be that as it may, I am happy that the Intellectual Property Enforcement Coordinator, Victor Espinel, is with us here today. Based upon her written submission, it is clear that she has been very busy working to fulfill the requirements of the position conceived by then Chairman Conyers and current Chairman Smith in the PRO-IP Act of 2008.

The Intellectual Property Enforcement Coordinator handles nationwide and international coordination of intellectual property enforcement efforts. The position has provided an institutional IP enforcement structure to help to ensure that the United States and our IP intensive industries have a solid economic base in the increasingly competitive global marketplace.

In April of this year, the Obama administration issued a report entitled "Intellectual Property and the U.S. Economy: Industries in Focus." The report makes plain the value of IP industries to the American economy. These industries produce 27.1 million jobs for our citizens.

But as we have seen over the course of this Congress, the foreign threat to American-generated intellectual property is real and ongoing, and in some cases is intensifying. Other countries and their citizens continue to profit from an immense world trade of illicit

goods, digital theft, and anti-competitive practices that violate the IP rights of U.S. rights holders.

Just this morning, the Congressional International Anti-Piracy Caucus, co-chaired by Chairman Goodlatte, released a report adding Switzerland and Italy to the list of countries that engage in piracy of American copyrights. So while today we focus on innovation and patent intensive industries, it is clear that foreign thieves do not discriminate with respect to the type of intellectual property they steal or misappropriate.

An emerging threat that I hope we will hear more about in this hearing is the theft of trade secrets of American businesses. In the 2011 annual report to Congress, the IPAC reported that, "The pace of foreign economic collection of information and industrial espionage activities against major U.S. corporations is accelerating. Foreign competitors of U.S. corporations with ties to companies owned by foreign governments have increased their efforts to steal trade secret information and intellectual property."

The theft trade secrets poses a substantial risk unlike that experienced in the production of low quality, substandard counterfeits. Trade secrets may enable foreign operatives to duplicate American products and undermine market access.

Earlier this year, I was happy to co-sponsor with Chairman Smith Foreign and Economic Espionage Penalty Enhancement Act of 2012, which I believe will send a clear message that those who dare to steal American trade secrets will pay a heavy price when caught. The bill passed the House in July and awaits action in the Senate.

Another area of interest is the impact on the U.S. pharmaceutical industry of the successful enforcement efforts noted in Ms. Espinel's written testimony. While our witness rightly emphasizes the public health and safety aspects of these efforts, it would be helpful to hear the impact both from an economic and reputational perspective on the companies whose drugs were copied.

Finally, Director Kappos, the Director of the Patent and Trademark Office, earlier this year testified in essence that litigation within and across American IP industries was a necessary and generally healthy aspect of IP enforcement. I am interested in the witness' perspective in her capacity as basically the one who herds the cats in how the U.S. IP industries cooperate or do not cooperate in the protection of each other's intellectual property abroad. Specifically, does IP litigation among U.S. companies have an adverse impact on whether they collaborate with government efforts to confront the global threat against intellectual property theft?

With that, Mr. Chairman, I will close. I thank you for holding this hearing again, and welcome our witness, and look forward to her testimony.

I yield back.

Mr. GOODLATTE. I thank the gentleman.

And without objection, and I do not believe there will be any objection, other Members' opening statements will be made a part of the record.

We have a very distinguished witness here today, and in light of the fact that we have just one witness here today, we will be more generous than the 5 minutes we ordinarily allow. But we will turn

the light on just so you know how the timing is going on that. And when it turns to red, that signals 5 minutes have expired, but we want to hear your report, Ms. Espinel.

And as I the custom of this Committee, we swear in our witnesses. So if you would like to stand and be sworn.

[Witness sworn.]

Mr. GOODLATTE. Thank you very much. And please join me in welcoming today the Honorable Victoria Espinel, the Intellectual Property Enforcement Coordinator at the Office of Management and Budget in the Executive Office of the President.

Ms. Espinel joined OMB in December 2009. Her responsibilities include developing the Obama administration's overall strategy for IP enforcement both at home and abroad. Earlier Ms. Espinel served in the Office of the U.S. Trade Representative as the Assistant U.S. Trade Representative for Intellectual Property and Innovation.

Ms. Espinel received her undergraduate degree from the Georgetown University School of Foreign Service, her law degree from Georgetown University Law School, and a master of law degree from the London School of Economics.

Welcome, and we are pleased to have your testimony.

TESTIMONY OF VICTORIA A. ESPINEL, U.S. INTELLECTUAL PROPERTY ENFORCEMENT COORDINATOR, OFFICE OF MANAGEMENT AND BUDGET, EXECUTIVE OFFICE OF THE PRESIDENT

Ms. ESPINEL. Thank you. Chairman Goodlatte, Ranking Member Watt, Members of the Subcommittee, thank you for your leadership on intellectual property enforcement and for the support that this Subcommittee has provided to the Administration's overall intellectual property enforcement efforts.

There are three areas that I will focus on in my remarks today: first, patent enforcement, second, counterfeit pharmaceuticals, and third, trade secret theft.

With respect to patents, last year in response to growing concerns over China's administrative and judicial systems of patent enforcement, we launched a new initiative to focus on patent enforcement in China. My office and the USPTO have conducted roundtables in Washington, Beijing, Shanghai, and Guangzhou to learn from U.S. companies directly about the specific challenges they face when trying to enforce their patents in China. The goal is to address the deficiencies in China's systems, including the lack of effective discovery, low damage awards, unexamined utility model patents, and the enforceability of judicial orders.

With respect to counterfeit pharmaceuticals, because of the very serious risk to health and safety that they pose, combatting counterfeit drugs is a critical priority for us. In March of last year, we sent to Congress a strategy that was specifically focused on how we will combat counterfeit drugs.

A few examples of our approach include a Customs and Border Protection pilot program that is focused on forming closer partnerships with the pharmaceutical companies to better understand their industry practices, and then to leverage that information into more effective and more efficient targeting and enforcement. The

effects of CBP's overall prioritization of health and safety is clear as seizures of counterfeit pharmaceuticals have increased in the last 2 years by nearly 600 percent.

There have been several notable law enforcement operations over the last year. In my written testimony, I highlight several instances of recent joint operations, many of them cross border operations, that resulted in the arrest of individuals that were selling counterfeit drugs and significant seizures.

In addition, we have worked with a number of companies from diverse sectors to form a non-profit group to combat illegal fake online pharmacies, criminals that are masquerading as legitimate pharmacies. The Center for Safe Internet Pharmacies was launched in July of 2012 and is now fully operational. And we hope and expect that CSIP will be particularly effective in reducing the prevalence of counterfeit and illegal pharmaceuticals.

On trade secret theft, we have very serious concerns related to the threat that is posed to U.S. innovation from economic espionage and trade secret theft. President Obama and senior Administration officials have expressly raised our concerns with China on trade secret theft, and we will continue to raise this as a priority issue and a grave concern.

In May at the most recent Strategic and Economic Dialogue, China agreed for the first time to include protection of trade secrets and agreed to intensify enforcement against trade secret theft. This past year, the Department of Justice and the FBI increased investigations of economic espionage and trade secret theft by 29 percent.

I want to thank Chairman Goodlatte, Chairman Smith, Ranking Member Watt, and many Members of the Subcommittee for the work that they did in sponsoring the Foreign and Economic Espionage Penalty Enhancement Act of 2012, which recently passed the House. Increasing penalties for economic espionage was one of the recommendations that we made to Congress to strengthen our ability to enforce against this crime, and I thank you for acting on this issue.

We are currently in the process of developing a strategy to officially coordinate the government's effort to mitigate the theft of trade secrets and economic espionage. We need to act aggressively to combat the theft of trade secrets, and I look forward to working with Members of this Committee as we develop the strategy.

Mr. Chairman, intellectual property is used throughout the U.S. economy, and intellectual property rights support innovation and creativity in virtually every sector and every U.S. industry. I look forward to working closely with this Subcommittee on improving protection of American intellectual property.

Now I am happy to take your questions.

[The prepared statement of Ms. Espinel follows:]

**EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20502**

**Testimony of Victoria A. Espinel
U.S. Intellectual Property Enforcement Coordinator
Office of Management and Budget
Before the U.S. House of Representatives'
Committee on the Judiciary -
Subcommittee on Intellectual Property, Competition, and the Internet
Washington, DC
September 20, 2012**

Chairman Goodlatte, Ranking Member Watt, members of the subcommittee on Intellectual Property, Competition, and the Internet, thank you for your continued leadership on intellectual property enforcement. I also want to thank you for the support that the Committee on the Judiciary and this subcommittee has provided to my office and the Administration's overall intellectual property enforcement efforts.

In June of 2010, we sent to you the Administration's Inaugural Joint Strategic Plan on Intellectual Property Enforcement. That Strategy was developed with significant input from the public and the coordinated efforts of Federal agencies, including the U.S. Departments of Commerce (DOC), Health and Human Services, Homeland Security (DHS), Justice (DOJ), State, and the Office of the U.S. Trade Representative (USTR). The overarching goal of the Strategy is to protect U.S. jobs, to increase exports of innovative technology and creative works and protect intellectual property rights, thereby allowing America's innovation to continue to drive our economic growth. A second overarching goal is to protect the health and safety of the public. In that Strategy, we set out six broad principles that we would follow to meet our goals and 33 specific actions that we would take to improve enforcement. We knew the Strategy would take time to implement fully, and we are making progress, including in areas involving international cooperation and improved protection for U.S. rightholders abroad.

Let me briefly mention the process my office is now conducting to review and revise the Administration's Strategy. When Congress passed the Pro-IP Act in

2008, it required the Intellectual Property Enforcement Coordinator to review and revise the Joint Strategic Plan to ensure we are addressing the latest challenges.

On June 26, 2012, my office published a notice in the *Federal Register* soliciting comments from the public on the new Joint Strategic Plan. The comment period closed on August 10, 2012. All the comments we received are available for review by the general public. Currently, my office is analyzing hundreds of comments submitted by companies, trade organizations, labor unions, academics, technology experts, and concerned citizens. There have been some excellent submissions with recommendations on ways to protect intellectual property rights both domestically and internationally, which will be helpful in shaping the next Strategy.

Let me shift to the subject of this hearing and the efforts we are making to ensure that American intellectual property is protected around the world. Today, I will be discussing partnerships with foreign law enforcement how we use trade policy tools, the use of U.S. personnel stationed overseas, international capacity building, the ongoing efforts with China, the development of a strategy to combat the theft of trade secrets and economic espionage, and the commitments made at the May 2012 G-8 Summit at Camp David.

Foreign Law Enforcement

Operating from abroad, often beyond the reach of U.S. law enforcement, today's criminals exploit technology and global distribution chains to develop increasingly sophisticated and diverse methods of infringement, such as the manufacture and sale of a wide range of counterfeit goods, including counterfeit pharmaceuticals; online infringement and theft of trade secrets. Enhanced international law enforcement cooperation is a critical component to combat the global nature of intellectual property infringement. Federal law enforcement agencies have strengthened ties with their foreign counterparts to: (1) enhance efforts to pursue domestic investigations of foreign intellectual property infringers; (2) encourage foreign law enforcement to pursue those targets themselves; and (3) increase the number of criminal enforcement actions against intellectual property infringers in foreign countries in general. To successfully reduce infringement overseas, we need the cooperation of other countries. Attorney General Eric Holder and U.S. Immigration and Customs Enforcement (ICE) Director John Morton have been pressing their foreign counterparts for better law enforcement cooperation in intellectual property crime investigations.

In addition, as described in more detail below, we are increasing the number of personnel overseas focused on intellectual property enforcement. The deployment of U.S. Government personnel abroad cultivates foreign law enforcement cooperation, expands the capabilities of foreign partners to enforce intellectual property rights, and further signals the commitment of the U.S. Government to protect intellectual property rights.

Cooperation between U.S. law enforcement and foreign counterparts in combating intellectual property crime has improved in recent years. For example, the National Intellectual Property Rights Coordination Center (IPR Center) has been able to expand its global membership. The IPR Center now has 17 domestic partner agencies and four international partners: Europol, INTERPOL, the Royal Canadian Mounted Police, and the Mexican Revenue Service. The IPR Center also has a partnership with multilateral organizations that has resulted in increased worldwide collaboration from international partners.

Counterfeit products that impact public health and safety remain a top priority for the IPR Center and the global law enforcement community—particularly regarding the escalating problem of foreign-based counterfeit pharmaceutical merchants. Toward that end, I am pleased to report that in January 2011, a Belgian national pleaded guilty to operating an illegal Internet pharmacy that sold \$1.4 million worth of counterfeit and misbranded drugs (along with controlled substances). The defendant used multiple websites to sell more than 40 types of prescription drugs. He operated a customer call center in the Philippines, received payments from customers using a credit card processor in the Netherlands, and paid employees using Western Union in the Philippines, Costa Rica, and the U.S. The defendant was arrested in Costa Rica and extradited to the U.S. under an agreement with that country. As part of his plea, the defendant agreed to pay a judgment of \$1.4 million.

Last fall, Operation Pangea IV, involving 81 participating countries, was launched by INTERPOL and the World Customs Organization (WCO) in a global law enforcement effort focused on websites supplying illegal and dangerous medicines. As a result, 2.4 million illicit and counterfeit pills worth \$6.3 million were confiscated, 13,495 websites were shut down, and 55 individuals are currently under investigation or under arrest, according to INTERPOL.

Operation APEC was a U.S. Customs and Border Protection (CBP)-led Asia Pacific Economic Cooperation (APEC) Mutual IPR Enforcement Operation. The operation targeted counterfeit pharmaceuticals by developing model practices for intellectual property enforcement in international postal and express courier

facilities. This is the first time a joint law enforcement operation has ever been conducted through the auspices of APEC. The United States and ten other countries participated in the operation which had enforcement actions ranging from detentions to seizures of over 1,200 shipments.

This year, CBP apprehended a notorious counterfeit pharmaceutical offender. A New Zealand physician (based in China) now faces up to 30 years in prison and \$6 million in fines after pleading guilty in July 2012 to supplying counterfeit erectile dysfunction pills. Robert Han was originally indicted in December 2007, but remained at large until March 29, 2012. He was taken into custody at San Francisco International Airport by CBP officers following his arrival on a flight from Hong Kong. The original investigation was spearheaded by ICE, in conjunction with the Food & Drug Administration.

In addition to counterfeit pharmaceuticals, the law enforcement community continues to target a wide variety of infringing products through joint operations and providing strategic training programs for our overseas counterparts. In February 2011, Paraguayan law enforcement authorities cooperated with DOJ, the U.S. Marshal Service and the FBI Joint Terrorism Task Force in Philadelphia to extradite a fugitive who had been identified as providing material support to Hizballah through the sale of counterfeit goods and other illegal activities. At the time of the indictment, the defendant had fled to the Tri-Border Area of Paraguay. This area includes Ciudad del Este, which has been identified in USTR's Special Out-of-Cycle Review of Notorious Markets as a haven for purveyors of counterfeit hard goods.

In June 2011, ICE-HSI Attaché special agents in Brasilia participated with Brazilian authorities in operations against several complexes near a shopping district that led to the seizure of 10 million counterfeit items estimated to be worth the equivalent of approximately \$255 million. The Sao Paulo Mayor's office initiated the program and invited the ICE-HSI Brasilia special agents to participate in the operation which included 400 Brazilian national, state, and city officials.

Operation Short Circuit was a three-month operation concluded in October 2011 and conducted by 43 countries that led to the seizure of more than one million counterfeit electrical goods that posed a significant risk to public safety. This operation was spearheaded by the IPR Center and conducted on an international level in coordination with the WCO.

During the six-week Holiday Hoax II Operation in November and December 2011, the IPR Center coordinated with several federal agencies, state and local law enforcement, and the Government of Mexico to seize over 327,000 counterfeit items worth an estimated \$76.8 million, nearly 300 percent greater than the first Holiday Hoax operation in 2009 (\$26 million). The 2011 operation spread across 66 U.S. cities; 55 cities in Mexico; and Seoul, South Korea. Local authorities also arrested 33 people connected to the violations.

While there is still much work to be done to foster cooperation internationally, these cases demonstrate a trend towards increased cooperation. In addition to coordinated law enforcement operations, the Administration continues to pursue improved international law enforcement cooperation through continued diplomatic engagement by the State Department, enforcement activities by DOJ and DHS, and trade agreements and reporting mechanisms at USTR.

Trade Policy Tools

The Administration has also been utilizing trade policy tools to press foreign governments to do more to protect American rightholders. In April, USTR issued the 2012 Special 301 Report. The report, which USTR issues pursuant to Section 182 of the Trade Act of 1974, as amended by the Omnibus Trade and Competitiveness Act of 1988 and the Uruguay Round Agreements Act (enacted in 1994), represents the result of an intensive review of our trading partners efforts to provide adequate and effective protection and enforcement of intellectual property rights (IPR) and market access for U.S. industries that rely on IPR.

This year's Special 301 Report highlights progress made in Spain, which after years of placement on the Watch List, was removed from the list because of steps made to address piracy over the Internet, including the recent adoption of regulations to implement a law regarding this issue. Malaysia was also removed from the Watch List after passing significant copyright amendments to strengthen its protection and enforcement against copyright piracy and promulgating regulations to protect pharmaceutical test data. The United States will continue to monitor their progress and work with these trading partners to address other areas of concern. In addition, Ukraine was moved to the Priority Watch List in this year's Special 301 Report because of its failure to effectively implement its 2010 IPR action plan and in light of serious concerns relating to counterfeiting and rampant piracy, including piracy over the Internet.

In addition to the removal of Spain and Malaysia from the Watch List and placement of Ukraine on the Priority Watch List, the 2012 Special 301 Report noted significant new laws, rules, and/or leadership structures in Israel, the Philippines, Russia, and China, among other countries. Significant trends noted in the report included growth in the online sale of pirated products and counterfeit hard goods; a surge in the use of legitimate courier services to deliver infringing goods; an increase in the practice of shipping of counterfeit products separately from labels and packaging in order to evade enforcement efforts; and growing challenges facing rightholders seeking to collect royalties that are legally owed for the public performance of their musical works in certain regions.

The report also noted the need for stronger and more effective criminal and border enforcement to stop the manufacture, import, export, transit, and distribution of pirated and counterfeit goods, including, counterfeit pharmaceuticals and bulk active pharmaceutical ingredients (API) used to manufacture counterfeit pharmaceuticals.

In 2012, the Special 301 Report contained a section highlighting best practices by trading partners in the area of intellectual property enforcement, including:

- Efforts by several trading partners that participated or supported innovative mechanisms, such as the Medicines Patent Pool, that enable government and the private sector to voluntarily donate or license intellectual property on mutually-agreed terms and conditions; and
- Positive reports regarding Russia's efforts to combat counterfeit medicines through a Memorandum of Understanding between the Ministry of Health and the Federal Service for Intellectual Property.

In February 2011, USTR released its first-ever Special 301 Out-of-Cycle Review of Notorious Markets (Notorious Markets List), following a separate request for comments and review of online and physical foreign markets that deal in infringing products. As a standalone report published separately from USTR's annual Special 301 report, the February 2011 Notorious Markets List increased public awareness of, and guided trade-related enforcement actions against, markets that exemplify the problem of global piracy and counterfeiting. As a result of the increased attention to these markets, Baidu, a leading Chinese search engine listed in the report, signed a music licensing agreement with One-Stop China, a joint venture between the Universal Music Group, the Warner Music Group, and Sony BMG.

In December 2011, USTR released its second Notorious Markets List following another request for comments published in September 22, 2011. In addition to listing markets that are reportedly engaged in piracy and counterfeiting, the Notorious Markets List also highlighted positive developments since the previous review. For example, the December 2011 Notorious Markets List noted Baidu's landmark licensing agreement mentioned above, as well as action taken by Hong Kong's local customs officials at the Ladies Market to remove allegedly infringing goods from the premises. These authorities reported a commitment to continue to undertake enforcement actions at the market. In addition, the Notorious Markets List noted that at the Savelovsky Market in Russia, management implemented an action plan to stop the distribution of infringing goods. Accordingly, Baidu, the Ladies Market, and the Savelovsky Market—which had been listed previously in February 2011—were removed from the Notorious Markets List in December 2011.

In October 2011, the United States and seven other countries signed the Anti-Counterfeiting Trade Agreement (ACTA). ACTA provides for enhanced international cooperation, promotion of sound enforcement practices, and a strengthened legal framework for IPR enforcement. We are currently working with our partners to bring the agreement into force. In October, Congress overwhelmingly approved and President Obama signed legislation approving bilateral Free Trade Agreements with Colombia, Panama, and South Korea. Each of these trade agreements contains a chapter dedicated to intellectual property rights, with requirements for protection spanning all types of intellectual property and commitments to join key multilateral intellectual property rights agreements. They also contain strong provisions to ensure that intellectual property rights are efficiently and effectively enforced in those countries.

The United States is also participating in the Trans-Pacific Partnership (TPP) negotiations with eight partner countries (Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam) to conclude an ambitious, next-generation Asia-Pacific trade agreement that reflects U.S. priorities and values, including with respect to intellectual property and enforcement. All the TPP countries have agreed to reinforce and develop existing World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) rights and obligations to ensure an effective and balanced approach to intellectual property rights among the TPP countries. Proposals are under discussion on many forms of intellectual property, including trademarks, geographical indications, copyright and related rights, patents, trade secrets, data required for the approval of certain regulated products, as well as intellectual

property enforcement. In June 2012, the TPP negotiating countries extended an invitation to Canada and Mexico to join the negotiations, pending successful conclusion of domestic procedures.

Overseas Personnel & International Capacity Building and Training

U.S. personnel stationed overseas play an important role in combatting intellectual property infringement.

In 2010, as part of the Joint Strategic Plan, IPEC established an interagency working group to improve the effectiveness and efficiency of overseas personnel involved in the effort to combat intellectual property infringement in priority locations around the world. It includes representatives from the State Department (Bureau of Economic and Business Affairs and Bureau of International Narcotics and Law Enforcement Affairs); the U.S. Agency for International Development; Treasury Department; DOJ (Computer Crime & Intellectual Property Section and the FBI); DHS (CBP and ICE); DOC (U.S. Patent and Trademark Office (USPTO), International Trade Administration (ITA), and Commercial Law Development Program (CLDP)); USTR; and the Copyright Office. The group identified 17 key countries – Brazil, Canada, Chile, China, Colombia, Egypt, India, Israel, Mexico, Nigeria, Peru, Russia, Saudi Arabia, Spain, Thailand, Turkey, and Ukraine. Each embassy in those 17 countries established a senior-level interagency team to bring together U.S. personnel stationed there to improve enforcement of intellectual property. In 2011, those 17 embassies drafted their first annual interagency work plans that set out objectives and activities to address the host country's critical intellectual property issues identified by the United States. These embassy work plans were developed with the input of outside stakeholders and in coordination with an IPEC interagency working group. The embassies report on a quarterly basis to the IPEC on the status of the implementation of the work plans.

We are also increasing the number of personnel overseas in key countries. The USPTO is adding two more intellectual property attachés to assist U.S. businesses in foreign countries by creating new posts in Mexico City, Mexico and Shanghai, China. In September 2011, the FBI posted an intellectual property-trained agent in Beijing, China to work full time on intellectual property crime. In the President's 2013 budget, DOJ requested funds to place six International Computer Hacking and Intellectual Property (ICHIP) Coordinators in strategic global locations to strengthen international intellectual property enforcement. . In 2010, ICE-HSI designated its Assistant Attaché in Guangzhou to be its first "IP

Attaché” and point of contact for all intellectual property matters involving China. In addition, ICE-HSI has added a liaison to the European Union in Brussels, Belgium.

In 2010, IPEC also established an interagency working group to improve the efficiency and coordination of international intellectual property enforcement capacity building and training, and to ensure the U.S. Government makes the best possible use of its training resources by focusing on priorities, such as training foreign law enforcement officials to tackle counterfeit drugs and developing new techniques to combat intellectual property crime.

To help facilitate the group’s coordination and oversight of training activities, USPTO launched a searchable database (<http://www.usipr.gov>) where relevant U.S. Government agencies now post information on the intellectual property enforcement trainings they conduct. The publicly available database is intended to: (1) use resources more efficiently by sharing training materials between U.S. Government agencies and avoiding duplicative programs; (2) improve results by building on past programs and targeting U.S. Government efforts on countries and topics where more training is needed; (3) increase transparency by allowing the public to see how the U.S. Government is allocating resources on intellectual property training; and (4) increase public participation by identifying upcoming training events that are open to the public. Notable training programs conducted in 2011 include:

- Philippines: The IPR Center and ICE-HSI Attaché special agents in Manila organized an IPR Criminal Enforcement Symposium in Manila on July 18-20, 2011 for law enforcement officers, customs officials, and prosecutors. Within two months of receiving this training, Philippine authorities conducted two highly successful enforcement operations, resulting in the seizure of counterfeit goods worth over \$18 million.
- Ukraine: CLDP and U.S. Embassy Kyiv conducted a workshop on counterfeit medicines for Ukraine’s health and safety enforcement agencies in May 2011, where U.S. officials put forward a key legislative recommendation for Ukraine to make the manufacture or distribution of counterfeit medicines a crime. This legislative recommendation was adopted by the Government of Ukraine in October 2011.
- Mexico: DOJ worked with several other groups, including the WCO, U.S. and Mexican rightholders, and customs and intellectual property-

related agencies within the Mexican government to provide a new generation of Mexican officials with the skills necessary to identify counterfeit products, refer cases for criminal prosecution, and continue to establish prosecutors at the major ports in Mexico. Based on the success of previous joint programs, the Mexican Navy requested to participate in the program to increase interagency cooperation on enforcement. This training resulted in the identification of containers of counterfeit products and the initiation of new criminal prosecutions.

Intellectual Property Enforcement in China

President Obama, Vice President Biden, and other senior Administration officials have directly and frequently engaged with Chinese officials and conveyed that they have much more to do to combat intellectual property theft.

President Obama has repeatedly raised intellectual property enforcement with China's president, Hu Jintao, including during his State Visit to Washington D.C. in January 2011. The engagement resulted in a commitment that "China will continue to strengthen its efforts to protect IPR, including by conducting audits to ensure that government agencies at all levels use legitimate software" and that "China will not link its innovation policies to the provision of government procurement preferences." In November 2011, President Obama continued the Administration's press for more American jobs at the Asia Pacific Economic Cooperation (APEC) leader's summit, by calling attention to China's record on intellectual property.

Vice President Biden also continued the Administration's engagement on intellectual property rights as part of his August 2011 trip to China, pressing for better enforcement in several forums, including in his meetings with China's leaders. In February 2012, during Vice President Xi's visit to the United States, Vice President Biden announced an agreement with China 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 WTO dispute in 2011. The agreement allows for more U.S. film exports to China and provides fairer compensation to U.S. film producers for the movies being shown there. Among other things, the agreement allows more American exports to China of 3D, IMAX, and similar enhanced format movies on favorable commercial terms, strengthens the opportunities to distribute films through private enterprises rather than the state film monopoly, and ensures fairer compensation levels for U.S. blockbuster films distributed by Chinese state-owned enterprises.

Secretary of State Hillary Clinton, Treasury Secretary Timothy Geithner, Acting Commerce Secretary Rebecca Blank, Attorney General Eric Holder, U.S. Trade Representative Ron Kirk, Ambassador Gary Locke, ICE Director John Morton, Under Secretaries Robert Hormats, David Kappos, and Francisco Sanchez, DHS Assistant Secretary and Chief Diplomatic Officer Alan Bersin, and other senior Administration officials have directly and repeatedly pressed China to do much more to combat intellectual property theft. China has made several important commitments as part of our ongoing bilateral trade dialogues.

Following closely on the President's engagement at the APEC in November 2011, USTR and DOC secured important commitments from China on key intellectual property issues during the 22nd Joint Commission on Commerce and Trade (JCCT) in Chengdu, China. These included the following: the establishment of a State Council-level leadership structure to lead and coordinate intellectual property rights enforcement across China; the completion dates for the legalization of software at the provincial, municipal, and county level governments; and the elimination of any catalogues or other measures linking innovation policies to government procurement preferences at the provincial, municipality, and autonomous region levels.

In May 2012, at this year's Strategic & Economic Dialogue (S&ED), the United States and China committed to intensive, ongoing discussions of the implementation of China's February 2012 commitment that technology transfer and technology cooperation shall be decided by businesses independently and will not be used by the Chinese government as a pre-condition for market access. Both countries will ensure the full participation and timely cooperation of all relevant agencies and authorities.

Also during the S&ED, the United States and China affirmed that the protection of trade secrets is an important part of the protection of intellectual property rights and agreed to intensify enforcement against trade secret misappropriation. China agreed that enforcement against trade secret misappropriation would be included in the 2012 Annual Work Plan of the State Council Leading Group on Intellectual Property Enforcement.

During the S&ED, China also, for the first time, committed to creating an environment where sales of legitimate intellectual property-intensive products and services within its border will increase, in line with its status as a globally significant economy. This commitment is significant, as one goal of enforcement is

to take back the marketplace from counterfeiters so that our businesses can compete on fair terms and legitimate sales can flourish.

As previously mentioned, the Notorious Markets Lists published in February 2011 and December 2011 noted progress and the need for additional work in China. The December report documented that some sites have taken positive steps in obtaining licensing agreements and were removed from the list.

The Administration has attempted to forge better partnerships with Chinese law enforcement. In May 2011, ICE Director Morton signed a Memorandum of Understanding (MOU) with China's General Administration of Customs (GACC) to enhance cooperation on law enforcement, including intellectual property theft. This agreement followed Director Morton's trip to China that resulted in a Letter of Intent with China's Ministry of Public Security (MPS) to cooperate on joint intellectual property investigations signed in 2010. Also in May 2011, CBP signed an MOU with China's MPS to increase information sharing and enforcement.

As noted earlier, the Administration has placed more U.S. personnel in China dedicated to intellectual property enforcement. In 2010, ICE designated its Assistant Attaché in Guangzhou to be its first "IP Attaché" and point of contact for all intellectual property matters involving China. In September 2011, the FBI posted an intellectual property trained agent in Beijing to work full time on intellectual property crime. USPTO, adding to its two Intellectual Property Attaches in Beijing and Guangzhou, has stationed a third in Shanghai.

Lastly, in response to growing concerns over China's administrative and judicial systems of patent enforcement, we launched an initiative to focus on China's patent enforcement system. The goal is to address the deficiencies in China's system, including the lack of effective discovery, low damages awards, unexamined utility model patents, and enforceability of judicial orders. In 2011, IPEC and USPTO conducted roundtables in Washington, Beijing, Shanghai, and Guangzhou to learn from U.S. companies about challenges they have faced when enforcing their patents in China.

Trade Secret Theft

The Administration has serious concerns related to the threat posed to U.S. innovation from economic espionage and trade secret theft by persons on behalf of Chinese companies. Economic espionage and the theft of trade secrets represent significant costs to victim companies. These include loss of unique intellectual

property, loss of expenditures related to research and development, and loss of future revenues and profits. Many companies are unaware when their sensitive data is pilfered, and those that find out are often reluctant to report the loss, fearing potential damage to their reputation with investors, customers, and employees.

The pace of foreign economic collection of information and industrial espionage activities against major U.S. corporations is accelerating. Foreign competitors of U.S. corporations, including competitors with ties to companies owned by foreign governments, have increased their efforts to steal trade secret information and intellectual property. The loss of this information and intellectual property can have serious repercussions for the victim company.

In FY 2011, DOJ and the FBI increased investigations of economic espionage and trade secret theft by 29 percent compared to FY 2010. Since the passage of the Economic Espionage Act, nine cases have been prosecuted pursuant to 18 U.S.C. § 1831 – economic espionage to benefit a foreign agent. Seven of those cases have involved a link to China.

We are currently developing a strategy to more efficiently coordinate the government's efforts to mitigate the theft of trade secret misappropriation and economic espionage. We need to act aggressively to combat the theft of trade secrets, whether state sponsors, those that are supported by state actors, or those that are acting for their own commercial gain. I look forward to working with the members of this subcommittee as the Administration continues to develop the strategy.

Counterfeit Drugs

Because of serious risks to health and safety, combating counterfeit drugs is a critical priority. In March 2011, we sent to Congress a strategy focused on how we will combat counterfeit drugs sold on the Internet and smuggled into the U.S. A few examples of our approach include a CBP pilot program—the Centers for Excellence and Expertise (CEE)—instituted in 2011 that focused on forming closer partnerships with pharmaceutical companies to better understand industry practices and leverage this information into more efficient and effective enforcement. The effect of CBP's prioritization of health and safety is clear as seizures of counterfeit pharmaceutical have increased by nearly 600 percent over the last two years.

In December 2010, American Express, Discover, eNom, GoDaddy, Google, MasterCard, Microsoft (Bing), Neustar, PayPal, Visa, and Yahoo! committed to form a non-profit group to combat illegal fake online “pharmacies” - criminals masquerading as legitimate pharmacies. The Center for Safe Internet Pharmacies (CSIP) was officially launched in July 2012 and is now operational. We are pleased to note that on September 1st, Facebook joined as a member of the group as well.

G-8 Commitments

We know that effective enforcement must involve private sector stakeholder efforts such as the Center for Safe Internet Pharmacies described above. The G-8 Leaders Camp David Declaration contains a strong expression of support for voluntary best practices to reduce infringement, specifically highlighting counterfeit drugs. Our embassies will conduct formal outreach to the G-8 member countries – Canada, France, Germany, Italy, Japan, Russia, and the United Kingdom – to foster cooperation on these efforts and turn the statement into action.

These voluntary best practices must be practical and effective, must respect privacy, due process, competition, free speech, and must protect legitimate uses of the Internet. In 2011, my office worked closely with Internet Service Providers, advertisers, industry associations, credit card companies, payment processors, search engines, and domain name registrars and registries to develop effective ways to take voluntary action to avoid supporting infringing activity.

Closing

Mr. Chairman, in closing, I commend this subcommittee’s leadership on intellectual property enforcement. Intellectual property is used throughout the U.S. economy and intellectual property rights support innovation and creativity in virtually every U.S. industry.

I look forward to working closely with this subcommittee on improving our protection of American intellectual property. Now, I would be happy to take any questions.

Mr. GOODLATTE. And in less than 5 minutes, too. My goodness. Well, thank you very much for that report, and we do have a number of questions. And Mr. Watt and I may go back and forth here in terms of the opportunity to ask lots of questions without going too far. And I hope we are joined by some of our other Members of the Committee because this is a very important issue.

The Administration is currently negotiating a Trans-Pacific Partnership Trade Agreement that includes provisions dealing directly with the issue of regulatory test data protection and how it should be protected. I understand that although trade promotion authority has expired, the Administration continues to negotiate agreements in line with TPA standards, which require the U.S. when in negotiations for a trade agreement to advocate for standards that are in line with existing U.S. law, which would mean a 12-year term of protection for biologic test data as provided for in the Affordable Care Act.

But it appears that when it comes to regulatory test data protection, the Administration has instead been working off of a suggestion from the President's budget that calls for a 7-year term. I also understand that as part of the United States-China Joint Commission on Commerce and Trade Meetings, the issue of a 12-year data protection term was planned on being raised, but then taken out and watered down during interagency review to simply push for a generic "new protections" for biologics.

There seems to be a real disconnect here. Regulatory test data is valuable IP, and when countries provide limited or no protection, it would make sense for our negotiators to at least start their negotiations with U.S. law rather than a suggestion made in the President's budget proposal.

Can you explain to the Committee the importance of data protection, the markets that lack adequate protection, and how you believe it should be protected as a part of the TPP?

Ms. ESPINEL. So with respect to data protection, this Administration, like prior Administrations, has made that a priority issue in our trade negotiations.

With respect to the specific issue you raise and the term of years, I know that Ambassador Kirk has spoken on that in previous hearings, and I will just repeat that he, the USTR, and the Administration as a whole, we stand by U.S. existing law. We also stand by the President's budget.

My understanding on this specific issue of the difference of term is that that USTR has not, in fact, tabled text on that particular issue yet, and is in the process now of talking to a range of stakeholders about the right path there.

So I am happy to take that back to them, but that is my current understanding of the status of that.

Mr. GOODLATTE. Let me interrupt there. If you stand by both U.S. law and the proposal in the President's budget, there seems to be a conflict between the two. Is there a way to reconcile that?

Ms. ESPINEL. So as I said, my understanding is that the USTR has not tabled text on that because I believe them to be in discussion with the various stakeholders right now about that very issue.

On the JCCT and the agenda in the JCCT, that I am not aware of, but I can certainly look into that and take that back to them.

Mr. GOODLATTE. Thank you. It is crystal clear that many countries have de facto TRIPS violations. And although the President announced a subsidies case while in Ohio on Monday, the Administration has failed to bring a single IP case at the WTO in 4 years. The Bush administration filed 24 WTO cases overall, including 2 IP cases, and 7 cases against China, despite having a limited

amount of time to file since China joined the WTO in 2001 and China's WTO commitment did not become fully operative until 2006.

One incredibly powerful tool to help address serious challenges to the economic value of U.S. companies' IPR would be to make use of non-violation nullification and impairment disputes at the WTO. NVNI disputes relate to measures that may not on their face clearly violate any specific TRIPS or other WTO rule, but that nonetheless prevent a member from enjoying the benefits that should accrue to it under the relevant agreement.

NVNI measures that harm the economic interests of creative and innovative U.S. companies are prevalent, especially in the area of IP, and they result in significant economic harm to U.S. companies and exporters. And yet there is currently a moratorium on the use of NVNI disputes, and the Administration recently agreed to an extension of this moratorium, essentially giving a free pass to China, Indian, and Brazil on measures that impair U.S. IP interests.

Examples of subsidies that could be targeted include preferential or IP free procurement or subsidy programs that programs such as China have in place, and technical standards that discriminate in favor of a locally owned IPR, as well as a range of other preferences accorded to indigenous IPR owners and assets. They could also be used to deal with inadequate enforcement regimes that may implement TRIPS in a manner that impairs the economic interests of right holders.

Why has this been allowed to continue, and why has the United States not been more aggressive in investigating and in bringing IP cases at the WTO and making use of all of our international trade tools?

Ms. ESPINEL. So I was at USTR as the Assistant USTR for Intellectual Property and Innovation during the Bush administration when the two intellectual property cases were brought against China. So I am personally aware of how much of a priority intellectual property was for the former Administration, and I hope it is evident from the work that we have been doing that it is very much a priority for this Administration as well.

There are a variety of trade tools that we use, and I am happy to speak to those. But since you really focused on WTO dispute resolution in your remarks, I will focus on that. And one thing that I want to make sure that you are aware of, in case you are not, is that the President announced in his State of the Union, and it is now up and running, to form something called the ITEC, the Interagency Trade and Enforcement Committee. And the ITEC is charged with aggressively investigating potential trade barriers and looking for ways to resolve them using a variety of trade tools, as you said, to bring all of our trade tools to bear. And that includes using our domestic trade law and using WTO dispute resolution.

We are very interested in looking for more aggressive ways to resolve the trade barriers that remain. You mentioned, at least in general terms, what might be some specific suggestions for cases that could be brought. I think we would be very interested in that. And if there is a way for us to have a follow-up conversation—prob-

ably best not in an open hearing—about specific suggestions, we would really welcome that.

Mr. GOODLATTE. Thank you. And can you shed any light on the Administration's apparent recent agreement for an extension of the moratorium on NVNI disputes?

Ms. ESPINEL. That is not an issue that I have been close to. I am familiar with nullification and impairment cases as a concept for the USTR, but I was not aware of the moratorium or the recent extension on that. But that is certainly something that I can look into further.

Mr. GOODLATTE. Yes, if you would and report back to the Committee your thoughts on that and where that is headed, that would be helpful.

Next, I would like to ask about two significant problems that American companies face abroad that center on trade secret theft and patent quality, including weak utility model patents, particularly in foreign markets in Asia, I mentioned in my opening statement.

The trade secret theft issue becomes even more troubling when the companies involved may be State-owned enterprises or share significant links with their home government. Trade secret theft is not simply a business-to-business concern, but one that requires real governmental action and legal reform.

American companies operating overseas should not have to view this kind of theft as simply a cost of doing business. As part of the Strategic and Economic Dialogue, and the U.S.-China Joint Commission on Commerce and Trade, what are the types of commitments that the Administration is pushing for to address these pressing problems?

Ms. ESPINEL. So first let me say, I absolutely agree with you that this should not be a cost of doing business. It should absolutely not be occurring. And I think we need to move very aggressively to try to stop it as I referred to in my opening remarks.

With respect to trade secrets, I think there are a number of things that we can do. You mentioned the Strategic and Economic Dialogue. I will talk about that specifically, but I think there are a few other things that we can do as well.

First, this is a critical issue for us. I think the theft of trade secrets, economic espionage, and the potential impact that it could have on our economy, on our ability to stay competitive globally, is a critical one. So it is very much a front and center issue for us.

The President and a range of other very senior Administration officials have been raising this with China very directly and very forcefully. And coming out of the most recent Strategic and Economic Dialogue, which was held in May, China for the first time made a commitment to include trade secret theft and to increase enforcement against trade secret theft. So obviously now our job is to make sure, having had China make that commitment—agree to make that commitment for the first time—to have them actually follow through on that commitment.

There are other things that we can do here at home. One of those is to increase our own domestic law enforcement investigation of trade secret theft to try to stop it before it happens, and then prosecution of trade secret theft after it has happened.

In that regard, I want to note again the Foreign Economic Espionage Penalty Enhancement Act. We think that will be very valuable to us in terms of enforcing, so I thank you and other Members of this Subcommittee that worked on that piece of legislation.

And then the last thing that I want to note is that we are right now working internally on developing a strategy focused on trade secret theft and economic espionage specifically to try to make sure that we are as coordinated as possible and that we are acting as aggressively as we can. And I would very much look forward to working with this Committee as we develop that strategy.

Mr. GOODLATTE. Thank you. And one final question. Tying patent rights to domestic manufacturing, or actual use in country appears to be the new trick that countries are employing to nullify legally-granted patent rights. Brazil and India are countries that require a patentee to “make use of” a patent in the country, basically forcing a domestic manufacturing requirement on foreign companies.

The Chinese patent office has a made in China requirement requiring inventions that have a tangential link to China be filed in China first or risk losing patent protection.

What is the next threat or legal trick that you are just starting to see come up on the horizon, and what can we do about these?

Ms. ESPINEL. So as you know, there have been a number of things that other countries, including China, have done to try to undermine our innovation in ways that go beyond simply infringement of intellectual property, and you mentioned a few of them. Indigenous innovation was something that we were very concerned about, I believe Members of this Committee were very concerned about. And China did take steps back from that when it was raised as an issue of serious concern by the Administration.

But it is, I think, inevitable that other countries will try to gain an unfair advantage in gaming their system in various ways. And for us, anything that means that our companies have a less stable and predictable environment overseas is an issue of real concern. So whether it is tying things to local manufacture, whether it is, as you said, other tricks that countries are using to try to undermine our innovation in different ways, whatever those issues are, we will continue to try to combat them.

Let me take this opportunity, though, to mention one other new commitment that came out of the S&ED, which I think is very relevant to this conversation. In the most recent S&ED, China made a commitment to increase sales of legitimate IP intensive products in accordance with its status as a global leader and the economy. And I think that is worth spending a little bit time on it because of the significance of having China agree to a commitment in those terms.

One of the reasons, one of the primary reasons that we are concerned about piracy and counterfeiting, that we are concerned about infringement, that we are concerned about other countries gaming their system to undermine innovation is because we truly believe—we collectively truly believe—that if our companies have a level and fair playing field, if they have the ability to compete on fair terms, that they will do very well. And so having China make a commitment that will focus and that will lead to increased ex-

ports of U.S. product, that will lead to increased sales of legitimate products.

So having China agree to a commitment that is focused on that for a practical outcome of what we are trying to achieve I think is very significant, and I wanted to highlight it. That is basically a different way, in addition to the all the other things we were doing, to try to combat unfair practices that China and other countries raise. It is another way of us going at this issue and trying to make sure that our companies have the ability to compete on fair terms.

Mr. GOODLATTE. Well, given the substantial trade deficit that the United States has with China, if we were to impose a make use of or made in China requirement on the protection of property manufactured in China, and essentially force a domestic manufacture in the United States, it would have an enormous impact on the Chinese economy, would it not?

Ms. ESPINEL. I believe it would. I think there are—

Mr. GOODLATTE. I am not necessarily advocating that. I would rather see the Chinese back away. But sometimes when you get overwhelmed, the pressure builds on people like Members of Congress who if you cannot beat them, join them.

Ms. ESPINEL. Really what we are all looking for are ways to get China's attention and make sure that they are taking this seriously. And they have made progress in some areas, but I do not want to overstate that because there is still an enormous problem.

What we are looking at doing is looking basically at every point of leverage that we have and trade policy tool that we have and seeing how we can use it most effectively against China. But then also as I mentioned, in the most recent S&ED, looking to see if there are other ways to address this rather than just going trade barrier by trade barrier by China and having them step back and make improvements in one area, but then raise new trade barriers in other areas. Get at the core of the problem, which is trying to make sure that our companies have the ability to compete fairly and that we are seeing exports and sales of legitimate goods go up in those markets. And that is really one of our primary goals. That is really at the core of what we are trying to get at.

Mr. GOODLATTE. Thank you. We will now turn to the gentleman from North Carolina, Mr. Watt, and he will enjoy the same latitude that he afforded me.

Mr. WATT. Mr. Chairman, I am going to exercise my latitude to let Ms. Chu go before me, if it is all right.

Mr. GOODLATTE. The gentlewoman from California is recognized for 5 minutes.

Ms. CHU. Thank you. I actually wanted to follow up on a question that Congressman Goodlatte asked, and ask about the issue of compulsory licenses because some countries have been able to use their ability to demand compulsory licenses in ways that I find alarming.

For instance, on March 12, 2012, India gave a license to an Indian company to sell a generic version of a patented Bayer drug, even though Bayer had a valid and enforceable Indian patent for the drug. The Indian government justified the compulsory license by stating that the cost was too high and the drug was imported into India as opposed to being manufactured in the country.

Some people have opined that compulsory licensing has weakened an intellectual property owner's use of the property. How do you respond to that statement, and what impact do you believe that compulsory licenses have on the effectiveness of international agreements?

Ms. ESPINEL. So I am not familiar with the details of that particular case, so I cannot speak to that particular case. I can say as a general matter that I believe that countries can and should be able to address the public health situations that they face without taking measures that are going to undermine American intellectual property and American innovation. And that whatever steps they take they do working closely with U.S. industry. It sounds like U.S. industry was not necessarily involved in that case, but that they work with our stakeholders, they work with our companies in a co-operative way.

Ms. CHU. Okay. Well, let me also ask about the Special 301 report. This identifies foreign policies that may unfairly disadvantage U.S. rights holders in other countries. It lists those countries that are deemed to have inadequate intellectual property right protections. What is the significance of this report, and how can it be used to incentivize countries to harmonize their laws to conform to international agreements to which they are a party?

Ms. ESPINEL. Many countries are unhappy with being listed on the Special 301 list, so it does serve as an incentive for countries to make changes to increase enforcement, or there are other reasons beyond enforcement that countries end up on the Special 301 list. And so it has been a useful tool.

I believe in order for it to be effective, it needs to be clear to countries exactly what they need to do to get off of the Special 301 list, or exactly what will place on the Special 301 list. So one of the things that we have been working with the USTR on, and the USTR could of course speak to this in more detail, is working with countries that are on the Special 301 list to come up with action plans that make it very clear to them what steps they would need to take to come off of the Special 301 list.

I fear that at least in the past, countries either felt that they did not know enough of why they were there, or they knew why they were there, but they were not sure exactly what steps they needed to take to get off. And so I think whether or not that was true or that was simply an excuse they made, I think steps that USTR has been taking to negotiate action plans with countries to make it very clear to them the kinds of improvement the United States would like to see will go far in making the Special 301 list even more effective than it has been. And I think there are a number of instances where it has been quite effective in getting countries to bring their practices more in line with protection of American intellectual property.

Ms. CHU. In fact, in your testimony you mentioned that Spain was removed this year after years of placement on that list. What specifically did Spain do to get themselves off the list? What got them on the list, and then what steps did they take to get off?

Ms. ESPINEL. So I believe Spain was put on the list after my tenure at USTR, so with your permission I would like to go back to

them so I can get more details from them about Spain's placement on the list. And I would be happy to come back to you on that.

Ms. CHU. Well, in general, how about the kind of trading best practices that might be able to ensure that people get off the list, that these countries get off the list?

Ms. ESPINEL. Right, absolutely. So I think there are a number of things that we as government can do to try to help countries get off the list. Part of that is being clear about what our expectations are. Part of that, as you alluded to, is training and capacity building, and there is a lot that we do now to try to make sure that our training and capability building is as effective as it can be and is focused on the priorities that we have.

I would be happy to talk more about sort of the specifics, and USTR can certainly speak to this as well, the specifics of how action plans are negotiated.

I know this past year when they put the list out at the end of April, they made an open offer for the first time to any country that was on the list to negotiate an action plan with the United States to try to set up concrete deliverables so that country would see a path forward to getting off the list. Obviously our goal is not to have countries on the list. Our goal is to use the list as a way to encourage countries to make improvements in their system.

Ms. CHU. Like are there any one or two or concrete examples that you have?

Ms. ESPINEL. In terms of countries making improvements to come off the list?

Ms. CHU. Yeah.

Ms. ESPINEL. So I am going to reach back to my time at USTR. So just as one example that is relevant to the subject matter of this hearing, we worked with the government of Hungary because of concerns that we had with their data protection legislation. And they made changes to their data protection legislation, and I understand that the reason why they did that was because of their concern of being placed on the list.

I know we have listed in the Special 301 report and the Notorious Markets list particular markets in China and Russia, and sort of highlighted the level of concern we have about counterfeit and pirated goods being sold in those markets. And that has also apparently motivated increased enforcement against those markets.

So those are a couple of specific examples off the top of my head. And again, I would be happy to go back to the USTR and give you a more thorough debrief.

Ms. CHU. Okay, thank you. I yield back.

Mr. COBLE [presiding]. I apologize to the Subcommittee for my delay. I had two other hearings to attend to simultaneously. Good to have you with us.

What are the three key problems that American companies face in China and India regarding patent and trade secret protection? And are they in compliance with their international obligations under the TRIPS agreement?

Ms. ESPINEL. What are the key problems, and are they in compliance with the TRIPS Agreement?

Mr. COBLE. Correct.

Ms. ESPINEL. So let me speak to the key problems. I am not the right person to speak to compliance of the TRIPS Agreement, so I will put that aside, although I will, as I noted earlier, mention that USTR and the President's Interagency Trade Enforcement Committee is looking at investigating whether or not there are new ways that we can resolve trade barriers.

But putting aside WTO consistency for the moment, certainly patent enforcement or the deficiencies in patent enforcement in China and trade secret theft are, I believe, a real issue of concern to our companies. And in the last year, on patent enforcement, as I mentioned, we actually mid-strategy launched a new initiative specifically focused on patent enforcement in China because of concerns that we were hearing from our industry that our companies had been having in trying to enforce their patents in China. They have met with a significant amount of difficulty.

There are a range of reasons why they have. So one of the things that we did when we launched this initiative is have a series of sit-downs with a wide range of companies in various industry sectors to find out exactly the problems that they were facing in China and which of those we could try to make progress on. That is an ongoing effort that we have, but it is coming directly because of our increasing concern about the ability to enforce our patents in China.

We also have concerns about the quality of patents in China, which I alluded to earlier. And then with respect to trade secret theft, I would just reiterate my remarks from before, but, yes, we are very concerned about trade secret theft. We are very concerned about economic espionage. We are concerned about the impact that it will have on our companies and our economy as a whole.

There is much that we are already doing to try to combat the theft of trade secrets, but because of the level of concern that we have on trade secret theft, we are at this moment engaged in a process of developing across agency administration strategy focused just on trade secret theft. And as we are in the process of developing it now, we would be very interested in working with Members of this Subcommittee as we come up with that strategy.

Mr. COBLE. Thank you. I appreciate your response. The distinguished gentleman from North Carolina, Mr. Watt.

Mr. WATT. Thank you, Mr. Chairman. I am glad to see you.

Let me deal with two questions that I kind of glossed over in my opening statement first, and then I will ask one final question. And then I will let you go, unless somebody else comes and demands your presence.

Your testimony talked some about the pharmaceutical industry and the public health and safety aspects of the efforts that we are undertaking. I just wanted to give you an opportunity to talk a little bit about the economic and reputational aspects or implications of the pharmaceutical efforts that we are taking in addition to the health and safety aspects of it.

Ms. ESPINEL. So perhaps I will open by saying when I took this job, and I tried not to have that many preconceived notions when I took it. But when I took this job, my assumption was going to be that there were almost no incidents of counterfeit or substandard drugs coming into the United States, and that the real problem—and it is an enormous problem—was in overseas markets, particu-

larly in Africa, which are really plagued by an incredibly high prevalence of counterfeit drugs, and that our efforts would be focused on trying to get more aid to those countries. And that is something that has happened, and we have increased the amount of the State Department budget for aid on those issues.

But what I also found out was that we recently have started seeing counterfeit and substandard drugs come into the United States—come to U.S. citizens—because of these fake pharmacies, which are pharmacies in no sense of the word. So we have worked very aggressively to try to combat those fake online pharmacies in a number of ways, which I am happy to talk about.

But I think, you know, to your question on economic impact, I think at least in the United States, given the levels we have seen, this is not an issue that I think is having, at least in terms of the U.S. market, a major economic impact on the pharmaceutical industries. What I think is happening, though, is that you have counterfeit drugs going to U.S. citizens. And even one instance of that happening is too much because of the health and safety risks that they pose.

In terms of reputational harm to the industry, that again is something that obviously we would like to avoid. But at bottom, our real concern, the real thing that is driving this, is the level of concern of having fake drugs coming into the United States, coming to our citizens, and the risk that that pose to people that are taking them unknowingly.

Mr. WATT. I also alluded to in my opening statement this question about what impact all of this litigation is having. I take it that to really be effective internationally, we need all hands on board, including the private sector. And one of the concerns a number of people have expressed is that these internal disputes, legal disputes, may be undermining the willingness and aggressiveness of private sector participants in supporting aggressive efforts internationally to protect somebody else's patent and intellectual property.

Can you give us some assurance that you are getting full cooperation from our private sector participants in protecting not only their own intellectual property, but protecting the intellectual property of other U.S. companies?

Ms. ESPINEL. So I heard that in your statement, and I thought it was interesting. So I will say two different things. One is in terms of the domestic situation, I am probably not the person best suited to speak to the domestic litigation that is going on. But I will say that we heard a lot when we asked people for input for the next strategy. We heard a lot about escalating litigation costs in the United States, and of course we want to have a patent system here that is working as efficiently as possible. And Director Kappos and others are trying to make sure that happens through implementation of the American Invents Act.

In terms of cooperation with other companies, I would say I think by and large we have had good cooperation with companies. We have tried to have an approach that is very inclusive and has as much input as possible from a whole range of companies.

And so what I have seen over the last couple of years is a real increase in cooperation. Now is it—there are clearly areas where I

feel like we could have more cooperation, we could have more effective cooperation. So I guess I would say I feel like there is a positive increasing trend, but we are by no means there.

Mr. WATT. Finally, in a report to Congress in October, there was a suggestion that U.S. technologies and trade secrets face heightened vulnerability to theft in cyberspace. Do you have any recommendations on how we should confront those increasing risks, or do you recognize that that is an increasing risk as the report seems to suggest?

Ms. ESPINEL. I think trade secret theft is definitely an increasing risk, whether it happens through cyber or not through cyber. And cyber itself I think is also an increasing risk, and our concern about increased risk is why, as I mentioned before, we are working on developing the strategy to try to make sure that we as a government are pulled together in as coordinated and as forceful as possible as we can be on that issue because, yes, we see it as an increasing concern.

Mr. WATT. Okay, Mr. Chairman, I think I will yield back.

Mr. COBLE. I thank the gentleman. I am told the gentleman from Pennsylvania has no questions. Is that accurate?

Mr. MARINO. That is accurate. I just apologize. I am trying to get to several Committee hearings today.

Mr. COBLE. I, too, was late as well, so you will not be punished.

Mr. MARINO. And I apologize to Ms. Espinel. I am very sorry that I was not here earlier.

Mr. COBLE. Well, I want to thank the witness for her testimony today. Good to have you with us.

Without objection, all Members will have 5 legislative days to submit to the Chair additional written questions for the witness, which we will forward and ask the witness to respond as promptly as she can so that their answers may be made a part of the record.

Without objection, all Members will have 5 legislative days to submit any additional materials for inclusion in the record.

With that, again I thank the witness. And this hearing is adjourned.

[Whereupon, at 3:16 p.m., the Subcommittee was adjourned.]

A P P E N D I X

MATERIAL SUBMITTED FOR THE HEARING RECORD

Response to Questions for the Record from Victoria A. Espinel, U.S. Intellectual Property Enforcement Coordinator, Office of Management and Budget, Executive Office of the President

**Chairman Lamar Smith
United States House of Representatives
Committee on the Judiciary
Subcommittee on Intellectual Property, Competition and the Internet
Questions for the Record Following the Hearing on the
“International IP Enforcement: Opening Markets Abroad and Protecting
Innovation”
September 20, 2012**

Question #1: Ms. Espinel, we have seen a series of troubling rulings in Canada that dramatically heighten utility requirements as to the “usefulness” of an invention, which will result in certain pharmaceutical patents being valid in the U.S., but not in Canada. So even if a company meets this new standard, the Canadians can still knock the patent out as being “obvious” – creating a catch-22. This directly disadvantages American drug companies, and could open the door to other countries that seek to further weaken protection for pharmaceutical patents. It appears that Canada is not meeting their WTO-TRIPS obligations. What has been the Administration’s response to these rulings, has your office, USTR or Commerce reached out to the Canadian government?

As you know, we have had longstanding concerns on IP issues with Canada, as well as some recent notable improvements. With respect to the emerging patent utility test that Canadian courts are adopting with respect to pharmaceuticals, I am troubled by the negative consequences this test will have on U.S. patent holders. I understand that the U.S. Trade Representative (USTR) is working with representatives of the affected companies and industries to ensure that we fully understand the problem and its possible solutions and to engage with the Government of Canada, as we regularly do, with a view to ensuring that U.S. inventors enjoy adequate and effective protection of patent rights in Canada in line with relevant international norms. The U.S. Patent and Trademark Office (USPTO) has engaged the Canadian government on this issue. Director Kappos has raised this issue with his counterpart in the Canadian Patent Office.

Question #2: Ms Espinel, until 2009 the U.S. government used to have in place a China case referral mechanism process, whereby companies could bring specific issues/cases to the Commerce department, and after an inter-agency review, particularly egregious or unique cases could be raised to the Cabinet level for direct engagement with their Chinese counterparts. Why was the case referral Mechanism process suspended under the Obama Administration and is there any plan to re-establish and expand the program beyond just China, to include other key countries, in Asia and latin America, as well?

The Administration, through USTR and the Department of Commerce (DOC), continually raises U.S. company cases involving intellectual property infringement in our bilateral engagements with China. We do this in an effort to assist companies facing

specific intellectual property issues and to illustrate systemic problems with China's intellectual property system.

The case referral mechanism mentioned in your question was established under the Joint Commission on Commerce and Trade (JCCT). In 2009, the JCCT was suspended by China as a consequence of the United States filing a dispute with the WTO regarding, among other things, audiovisual media piracy in China. China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights (WT/DS362). China suspended its participation in the JCCT's IP Working Group (IPWG) and was unwilling to discuss company issues raised as part of the Case Referral Mechanism (CRM). When the JCCT was reinstated, USTR and DOC did not reinstate CRM because it had become an ineffective mechanism to resolve company issues. Rather, USTR and DOC now have a more streamlined referral mechanism that achieves the same objective as the CRM. DOC's interagency program known as the Case Referral Process (CRP) effectively replaced the CRM process to help track company issues. This program is part of the International Trade Administration's (ITA) Trade Agreements Compliance Program.

The Administration also regularly handles basic intellectual property procedural issues raised by U.S. companies through the CRP. DOC assembles an interagency team of IP experts to provide advice to U.S. companies navigating China's intellectual property system. Companies can also receive basic resources and access to self-help through DOC's website www.STOPfakes.gov. DOC also coordinates with our embassies to facilitate meetings between U.S. companies and foreign government officials as appropriate. In certain circumstances, when warranted, DOC and USTR will weigh in with the Chinese government directly on company-specific issues, including raising specific cases during the JCCT IPWG and other meetings. Let me cite an example in which the CRP has had a success: the Zippo Manufacturing Company obtained well-known trademark status in China, allowing it to effectively enforce its trademark in China and curtail the counterfeiting of its lighters.

The Administration also responds to the needs of U.S. companies through a multi-faceted, interagency case management process that addresses both basic and complex intellectual property infringement cases. In China, U.S. companies can face a combination of complex market access barriers and intellectual property rights enforcement issues. For example, U.S. companies may experience shortcomings or irregularities in the Chinese government's enforcement mechanisms, including irregularities in judicial processes or decisions.

As noted above, the ITA's Trade Agreements Compliance Program works to break down barriers to market access abroad and proactively monitors and helps promote foreign government compliance with trade agreement obligations, such as those in the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The program provides a framework for proactive monitoring of trade agreements; a process for identification, investigation, and resolution of trade barriers for individual companies; and a strategy for conducting outreach to inform stakeholders of efforts and services in this area. For example, the ITA organizes regular webinars in which experts provide free advice to companies on recent developments in and strategies for protecting and enforcing their IP rights in China.

In addition, the USPTO's Office of Policy and External Affairs (OPEA) works to address intellectual property rights (IPR) protection and enforcement concerns on a case-by-case basis, as well as on a macro level. As part of OPEA's efforts, OPEA attorneys work with the interagency IP team to address issues raised by U.S. industry constituents who are experiencing problems with protecting and enforcing their IPR in China (or in any other foreign market) and can provide assistance, as appropriate, in addressing those problems. The USPTO also has established strong office-to-office relationships with Chinese IP agencies and engages directly with those agencies to institute a stronger IPR protection and enforcement regime in China.

The above-mentioned methods of engagement are fully integrated into a broader interagency process. This program and the types of assistance outlined above are available to U.S. companies of all sizes not only in China, but in all markets worldwide.

Question #3: The U.S. government's IP attaché program has been a key part of our IP efforts abroad. But we have seen one significant shift over the past couple years. In June, we heard from the Deputy Director of the PTO, and it appears that Administration policy is to not allow the IP attaches to deal with specific issues raised by an American company, and instead only allow them to engage if several companies face the same problem or more likely just have them deal with general policy concerns? Shouldn't our attaches be helping American companies directly in places like China, India, Brazil and Russia?

USPTO's IP Attachés can, and do, provide direct assistance to U.S. companies on the IP problems they face overseas (although such support does not include legal advice). IP Attachés work with individual companies, in a variety of ways, including providing information and insight on the intellectual property climate of foreign markets, helping companies understand how to navigate the challenges of regimes, and putting companies in touch with relevant government agencies or local trade associations. They also discuss problems directly with foreign governments.

DOC's Ethics Office recently clarified that there is no ethics problem with an IP Attaché advocating on behalf of specific companies as part of duties under the terms of a Memorandum of Understanding. It is worth noting that, to maximize efficiency and effectiveness, IP Attachés often address issues that relate to widespread or systemic problems with a foreign government's intellectual property regime, as many U.S. companies face similar types of challenges.

I would also like to mention the Administration's proposal contained in the President's budget for Fiscal Year 2013 to deploy six Department of Justice (DOJ) Attachés overseas to fight transnational crime, with particular emphasis on intellectual property crime. These DOJ Attachés, who will also serve as regional International Computer Hacking and Intellectual Property attorneys (ICHIPs), will be well-positioned to help American companies combat the increasing threat of transnational crime. The ICHIP Attachés would build on and expand the highly successful Intellectual Property Law Enforcement Coordinator ("IPLEC") program, through which DOJ placed two experienced federal

prosecutors in Asia and Eastern Europe to carry out DOJ's IP mission in those regions. The ICHIP program is modeled on the successful approach in Thailand where the incumbent serves as both DOJ Attaché and IPLEC. As a DOJ Attaché, the incumbent will be able to directly assist in the operational aspects of investigations and to participate in capacity-building and other outreach and training programs.

Question #4: When a decision is made by the ITC to ban foreign products infringing on U.S. intellectual property rights, it appears that Customs has been taking a more subjective approach as to which ITC orders it will enforce. Is there anything that your office can do to ensure that DHS enforces orders that are in place to prevent IP infringing goods from entering the United States?

Once the International Trade Commission (ITC) finds a violation of 19 U.S.C. § 1337 and issues an exclusion order barring the importation of infringing goods, U.S. Customs and Border Protection (CBP) is responsible for carrying out the enforcement of the ITC exclusion order. In carrying out this function, CBP is charged with making a determination as to whether an imported article falls within the scope of the ITC exclusion order. This determination can often be challenging, particularly in cases requiring a determination whether a technologically sophisticated product has been redesigned in such a way as to no longer infringe the intellectual property right addressed in the ITC exclusion order.

We take seriously any concerns over subjectivity or inequity in the Federal agencies' enforcement approach, and we would appreciate learning any further details you or your staff can provide.

When my office issued the Administration's first Joint Strategic Plan on Intellectual Property Enforcement in June 2010, we, as an Administration, committed to work towards improving the enforcement of Section 337 exclusion orders, including through enhanced communications between the ITC and CBP. In implementing this commitment, the ITC, CBP, and my office have worked together to establish a process for ITC staff to provide CBP with advanced draft exclusion order language prior to issuance. This approach provides CBP with the ability to discuss any questions of interpretation or scope prior to being called upon to enforce the exclusion order.

As you may be aware, my office is right now in the process of working with the Federal agencies to develop a new intellectual property enforcement strategy for submission to the President and Congress. In this regard, my office is evaluating opportunities to improve the Section 337 process. This could include CBP developing new regulations in 19 C.F.R. Part 177 that would create *inter partes* proceedings to either replace or supplement the current *ex parte* process for exclusion order-related rulings. Although the strategy is still being developed, I can tell you that the Administration is committed to ensuring that the processes and standards used during enforcement of exclusion orders are transparent, effective, and efficient for all parties involved.

I welcome the continued focus and attention of Congress on intellectual property enforcement, and I look forward to opportunities to continue to work with you and the

committee to ensure the effective and fair enforcement of U.S. intellectual property rights.

Question #5: Ms. Espinel, in recent years, we have seen countries like Brazil, Thailand and India using the threat of a compulsory license as a negotiating strategy, to force American companies to manufacture or license their products to local companies at government mandated prices. Earlier this year, India took the unprecedented step of issuing a compulsory license against a Bayer oncology drug, stating among other reasons, that the patented drug was not being sufficiently “worked” in India because it was not locally manufactured. In October, the Indian government went one step further and simply revoked a Pfizer patent on Sutent, a cancer therapeutic, that has been patented in over 90 countries. And, most recently, in November the Indian government revoked a Roche patent for drug treating liver disease. The denial of patent protection in India, for therapies that have been granted intellectual property rights elsewhere in the world is quite troubling. It appears that the Indian government is slowly creating a protectionist regime that harms U.S. job creators and violates their international commitments under TRIPS.

What steps have the Administration taken to ensure that India lives up to their WTO commitments and provide meaningful patent protection for innovative pharmaceuticals? Has the Administration considered raising these issues at the WTO? If not, why?

The Administration agrees that there are serious and growing concerns about the innovation climate in India. These problems span many fields of technology, including pharmaceuticals, green technology, information technology, and many others. They arise in connection with India's intellectual property system, its approach to international standards, its industrial policies, and in a variety of other ways.

These are high-priority issues for the Administration, and we are raising them in all appropriate fora. U.S. trade officials are closely monitoring the developments on pharmaceutical patents in particular. In the case of the Pfizer product Sutent, we understand that India's courts have, for the time being, stepped in to block the initial adverse decision. However, this is far from the only concern; continued engagement is needed to promote pro-innovation policies in India and in other countries.

For example, last month in Geneva, the United States partnered with other WTO Members to promote a broad-based exchange of national experiences on IP and innovation. There, the United States strongly encouraged constructive policies, like those reflected in the APEC innovation principles agreed to last year in Honolulu, and joined with others in firmly rejecting certain policies that India has recently pursued, like local working requirements. On December 7, 2012, Ambassador Marantis, the Deputy U.S. Trade Representative, highlighted our concerns with India's deteriorating innovation climate in a speech delivered in India. U.S. trade officials intend to continue that kind of pro-innovation advocacy in India and more broadly.

Question #6: As described in a recent report by the Business Software Alliance, China's Multi-Level Protection Scheme (MLPS) requires that products and software procured for "sensitive IT networks." Essentially, the definition covers a broad array of networks related to transportation, finance, telecommunications, health, education and others – basically, a large portion of the Chinese economy. This shuts out many U.S. companies, or forces them to transfer their IP to Chinese companies to qualify for these sales. What should the U.S. government be doing to combat this policy? Can you discuss how policies like this are beginning to spring-up in other countries as well?

The Administration has been working to combat China's framework regulations for information security in critical infrastructure known as the Multi-Level Protection Scheme (MLPS), first issued in June 2007 by the Ministry of Public Security (MPS) and Ministry of Industry and Information Technology (MIIT). The MLPS regulations put in place guidelines to categorize information systems by level, according to the extent of damage a breach in the system could pose to social order, public interest, and national security. The MLPS regulations bar foreign products from information systems graded level 3 and above, because all products deployed must be developed by Chinese information security companies and must bear Chinese intellectual property in their key components. The United States is raising the concerns posed by these regulations at the 2012 JCCT and will continue to urge China to refrain from adopting any measures that condition the receipt of government preferences on where intellectual property is owned or developed.