

**Responses to Questions for the Record for
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Questions from Sen. Grassley (R-IA)

- 1. Could you please elaborate on how the tactics of counterfeiters are evolving, and how you are keeping up with these criminals?**

One evolving tactic employed by criminal counterfeiters involves the mode of transport of fake goods. The use of container ships has typically been the common mode of transport of counterfeit goods. However, criminals are now increasingly using express mail delivery services to ship their goods internationally in small consignments. This mode is frequently used in the trafficking of counterfeit pharmaceuticals.

In fact, the Organization for Economic Co-operation and Development (OECD) recently confirmed this trend in a study on trade in counterfeit goods, which included input from the World Customs Organization (WCO), the European Union, and the U.S. Department of Homeland Security. To address this growing trend, U.S. Patent and Trademark Office's Global Intellectual Property Academy is addressing this transport issue in its technical assistance trainings for foreign officials on customs and border enforcement. For example, in May 2016, the U.S. Patent and Trademark Office in coordination with the IPR Center, U.S. Immigration and Customs Enforcement's Homeland Security Investigations (ICE/HSI), and U.S. Postal Inspection Service, conducted two (2) week-long trainings for Brazilian law enforcement, specifically focused on the trafficking of counterfeit goods via express mail delivery services. Colombian and Chinese law enforcement officials also participated.

- 2. Are foreign countries recognizing that the trafficking of counterfeit medicines is a problem, and are they working with us to address it? Can you tell us about your experience with foreign law enforcement and legislators? Are you seeing progress in this area?**

Foreign countries do recognize that the trafficking of counterfeit medicines is a problem, and the successful investigation, interdiction and prosecution of criminals engaged in this trade depends on the strength of a country's enforcement resources and its consumer health and safety laws. Foreign countries are working with us to address this issue. In our provision of technical assistance programs and capacity building training, USPTO collaborates with our domestic and foreign counterparts from the drug regulatory agencies, U.S. Customs and

Border Protection (CBP), the judiciary, pharmaceutical industry, enforcement agencies, and public awareness and consumer groups.

The USPTO incorporates discussion on combating counterfeit medicines in our technical assistance programs and capacity building trainings, as well as organizes workshops that focus on the topic of combating counterfeit medicines and products that impact health and safety. There has been some progress in this area, as countries work to protect the supply chain, and incorporate technology tools for customs, regulatory officials and consumers to determine the legitimacy of medicines.

3. Could you give us more information on what best practices you encourage or engage in to fight against the sale of counterfeit products?

A number of private sector voluntary best practice initiatives have been developed and are being implemented. These formalized best practices include initiatives from the Center for Safe Internet Pharmacies; the Center for Copyright Information's Copyright Alert System; the Ad Industry's Trustworthy Accountability Group Initiative; and the International Anti-Counterfeiting Coalition's Payment Processor Initiative, "RogueBlock." In particular, these efforts are aimed at decreasing the likelihood that a consumer will access and/or purchase counterfeit goods or copyright-infringing content online. The most effective initiatives employ various strategies that make it more difficult to access counterfeit and otherwise infringing products and content online, and they include both supply-side and demand-side initiatives.

4. Do you have best practices specifically designed to protect consumer health and safety?

USPTO collaborates closely with our interagency law enforcement partners, such as the U.S. Food and Drug Administration's Office of Criminal Investigations and DHS Immigration and Customs Enforcement, in providing training and exchanging best practices with foreign government officials as they relate to enforcing intellectual property rights in the field of health and safety. For instance, in 2015 USPTO organized a series of workshops for law enforcement officials and health regulators from ASEAN, South American, South Asian and Middle Eastern countries. These workshops included discussions on effective practices for combatting counterfeit agricultural chemicals, counterfeit pharmaceuticals, and other counterfeit products affecting health and safety.

5. What trends are you seeing in terms of the type of goods that are being counterfeited? Do the criminals have a preference for the type of products they like to counterfeit?

Counterfeiters gravitate toward any product in which the counterfeiter can profit from the stolen IP. Accordingly, counterfeit products range from luxury goods, such as fashion apparel and watches, industrial products, such as machines, spare parts and chemicals, and consumer goods, such as pharmaceuticals, food, toys and cosmetics. Moreover,

counterfeiters have exploited growing market openings, globalization of value chains and the increase of e-commerce in the furtherance of their illicit activities, which has contributed to a proliferation of various counterfeit products.

6. From which countries are you seeing an increase of exports of counterfeit products?

According to U.S. Customs and Border Protection (CBP) FY 2015 seizure statistics, the number of IPR seizures increased nearly 25% to 28,865 from 23,140 in FY 2014. The top sources for seized counterfeit products were China (49 %) and Hong Kong (34 %).

7. What can we do better here in the United States to protect consumer health and safety, given the realities of counterfeiting you and your colleagues at USPTO have observed in foreign markets?

In large part, thanks to our stricter regulatory framework governing the production of medicines and the distribution chain, counterfeit drugs are a lower threat in the U.S. than in many other countries. We note that Congress has taken some very positive steps to protect consumer health and safety in recent years. For example, the Food and Drug Administration Safety and Innovation Act (Pub. Law 112-144) provided the FDA with new authorities that will help to secure the safety and integrity of prescription drugs in the United States. Additionally, the FDA's recently began implementing its administrative authority to destroy certain drugs refused admission to the U.S., which is a good approach. As stated by the FDA, its implementation of this regulatory action serves to reduce the likelihood of drugs being refused admission and subsequently offered for re-importation into the domestic market.

Demand also needs to be addressed by supporting the FDA's efforts to educate the public on the dangers of purchasing prescription drugs from online pharmacies.

8. Is there anything that Congress should consider in terms of legislation to help address the counterfeiting problem and specifically counterfeits that directly impact the health and safety of consumers?

Current statutory provisions are working as intended to effectively provide parties with the tools they need to combat counterfeiting. The United States has a strong history of protecting intellectual property rights, specifically fighting the introduction of counterfeit goods into the stream of commerce. Our robust legal regime has evolved over time in response to increasing threats to the public and new technologies that challenge earlier iterations of laws. And, with the ability to point to U.S. law as an effective model, U.S. negotiators are better positioned to encourage other countries to adopt similar laws. A timely example of updating U.S. IP laws to address new challenges is the recent passage of the *Defend Trade Secrets Act of 2016*, signed into law by President Obama on May 11, 2016.

Congressional approval of the Trans-Pacific Partnership, which includes countries that today account for nearly 40 percent of the world's GDP, would also advance our efforts to set high intellectual property protection and enforcement standards. TPP establishes strong and balanced protections for patents, trademarks and copyrights, and closes loopholes that let dangerous counterfeits come across borders and get into the supply chain. Strong and fair enforcement rules to protect against trademark counterfeiting allow for increased penalties in cases where counterfeit or pirated goods threaten consumer health or safety.

9. What do you see is the value of building relationships with foreign legislators, judges, and law enforcement? What kind of results are we seeing from those efforts?

Creating a framework that provides effective protection and enforcement of intellectual property rights requires sustained efforts in reaching out to all branches of governments of U.S. trading partners. A key component is sustained engagement on relevant and emerging protection and enforcement issues. Building relationships with foreign legislators, judges and law enforcement through policy discussions and capacity building is instrumental in effecting positive change in combatting counterfeit medicines, enforcement in the digital environment, and a focus on deterrent penalties. The 2016 Special 301 Report issued by USTR illustrates results that we are seeing from these types of efforts. For example, we have been working closely with Pakistan, which has taken significant steps to improve IPR protection. As a result, Pakistan was upgraded from the Priority Watch List to the Watch List with an Out of Cycle Review to monitor ongoing progress. Also, Tajikistan, Belarus and Trinidad & Tobago are removed from the Watch List this year for improvements to enforcement of IPR, including in the areas of customs enforcement, criminal prosecutions, and broadcast piracy, respectively.

10. Does the USPTO program have any special initiatives to deal with counterfeits that impact consumer health and safety?

The USPTO, through its Global Intellectual Property Academy, conducts IP training and education programs, including programs with emphasis on IP counterfeits that impact consumer health and safety. As noted in the U.S. Intellectual Property Enforcement Coordinator's FY 2015 Annual Report¹, the USPTO conducted five programs that included a focus on the impact of IP counterfeits on consumer health and safety. These programs included: a "Workshop on Effective Practices in Transnational Cooperation in the Border Enforcement of Intellectual Property Rights" in March 2015 for customs, border, regulatory and enforcement officials from the ministries of food, health, environment and agriculture from the ASEAN region; an "ASEAN-USPTO Roundtable for the ASEAN Judiciary on Intellectual Property Rights Issues" in October 2014; a "Philippines Roundtable Discussion on Issues and Concerns Relating to Intellectual Property Rights Enforcement" in October 2014 for officials from the Philippines Department of Justice and the Philippines Intellectual

¹ See, Annual Report of the Intellectual Property Enforcement Coordinator for Fiscal Year 2015 Under Section 304 of the Pro IP Act of 2008 (15 U.S.C. § 8114) (April 29, 2016), at pp. 28, 29, 31, 59, 60.

Property Office; an “Inter-regional (MENA and South Asia) Counterfeit Medicines Program” in April 2015 in Bahrain; and a March 2015 workshop on “Combatting Counterfeit Pharmaceutical Sales on the Internet” held at the USPTO for officials from Brazil, Paraguay, Uruguay, Chile, Panama and Mexico.

11. What can you tell us about the experiences of American companies enforcing rights abroad? How does the USPTO Intellectual Property Attaché Program help American companies in problem countries?

U.S. companies have a range of experiences working overseas in trying to protect and enforce their IP rights. In several countries, there are problems with “local protectionism” where IP enforcement officials are often reluctant to take action against local domestic companies that infringe against a U.S. company’s IP interests. The USPTO’s IP attachés regularly meet with representatives from U.S. businesses to learn from them about the situation on the ground in their various areas affecting IP protection and enforcement.

The IP attaché can also raise specific cases with host government officials where those cases demonstrate a systemic flaw in the host country’s IP protection and enforcement regime. The IP attaché can take a local problem and elevate discussion of the matter to the next higher level. For example, in the case of China, they could elevate a municipal level problem to an engagement with provincial level officials. If the problem persists, then it can also be elevated to the national level where officials from the central government are then able to investigate and determine whether there are any instances of undue local influence. This type of interaction is also very useful in informing USPTO Headquarters in its bilateral negotiations within the U.S.–China Joint Commission on Commerce and Trade or the U.S.–China Strategic and Economic Dialogue framework.

12. How do foreign law enforcement and other authorities deal with dangerous counterfeits? Are counterfeits a priority for foreign law enforcement and other authorities?

There is a great disparity amongst the many nations on their prioritization and approach to dealing with dangerous counterfeits. Undoubtedly, most developed countries with an effective regulatory system and market control (e.g., Australia, the European Union, and Japan to name a few) are more effective in addressing the problem. However, according to a 2015 analysis by the Pharmaceutical Security Institute, geographical regions:

“[t]hat are more frequently linked to incidents are not necessarily those with weak enforcement and inspection programs. . . Those regions with seemingly low incident totals are not necessarily unaffected by or at a lower risk of pharmaceutical crime. Due to competing law enforcement priorities, lack of funding or inadequate regulatory structures, in certain regions of the world, counterfeit medicines often go undetected. It is important to recognize these facts, since they complicate region to region comparisons.”²

² See, <http://www.psi-inc.org/geographicdistributions.cfm>

According to a 2004 report issued by the World Health Organization, “[m]ost countries have a medicines regulatory authority and formal requirements for registering medicines. However, medicines regulatory authorities differ substantially in their human and financial resources, and in their overall effectiveness. Fewer than one in six WHO Member States have well-developed drug regulation and two in six have no or very little drug regulatory capacity....” These figures are still accurate today.

- 13. I understand that the illegal production and trade of counterfeit crop protection is a major problem in the global agricultural industry, causing dangerous consequences that affect the entire agricultural production chain and jobs in the United States. Over \$1 billion of the \$58 billion international trade in crop protection chemicals is estimated to be produced illegally, either by counterfeited patented and branded chemicals or by illegally producing chemicals legally registered by other parties that may not be intended for these uses. What role can the USPTO play to combat this issue?**

Combatting the illegal trade and production of counterfeit crop protection products requires the participation and coordination of national governments, health and regulatory agencies, law enforcement as well as agricultural producers and the food and pesticide industries.

The USPTO meets with stakeholders and manufacturers of agricultural products to receive insight as to the nature, scope and extent of the counterfeiting problem. We also, through capacity building training and technical assistance programs, as well as our intellectual property attachés, engage legislators, regulatory officials, intellectual property law officials, customs, police, prosecutors, and the judiciary to highlight the nature of the problem, discuss laws available to protect consumers, delineate the agency charged with enforcement, and review strategies and best practices for ensuring a coordinated approach to combat this growing problem.

In March 2015, the USPTO organized an ASEAN-USPTO Workshop on Effective Practices in Transnational Cooperation in The Border Enforcement of Intellectual Property Rights. Regulatory and enforcement officials from the food and health ministries, environmental regulators, agricultural officials, as well as customs and border officials from Brunei, Malaysia, Laos, Cambodia, Vietnam, Singapore, Indonesia, Philippines and Thailand all participated in the workshop. The workshop focused on the problem of adulterated, substandard and counterfeit agricultural chemicals in the ASEAN region. One of the many goals of the workshop was to open discussion on the issue of counterfeit agricultural chemicals, introduce the officials to their counterparts in other countries, and to facilitate dialogue among the participants to improve the skills and knowledge of customs and border officials to better analyze, target and interdict IP counterfeit and pirated goods, especially those that affect health and safety.

Questions from Sen. Leahy (D-VT)

- 1. The IP attachés do important work advocating for strong intellectual property protections in other countries. One step that could make them more effective in their advocacy is to elevate their rank, to improve their diplomatic stature with other governments and give them greater access to resources. Do you agree this would be a helpful step? What actions, if any, is the Commerce Department taking to achieve this goal?**

The Commerce Department has been in discussions with the State Department on this issue.

- 2. In his testimony, Mr. Maguire recommended that Customs & Border Protection (CBP) should enable the recording of design patents to facilitate CBP's seizure of counterfeit products. What views does the U.S. Patent & Trademark Office (USPTO) have of that recommendation? Is the USPTO willing to facilitate a conversation to explore whether this would be an effective tool?**

USPTO is prepared to engage CBP in conversations on the feasibility and effectiveness of design patent enforcement.

- 3. Mr. Maguire testified about how Revision Eyewear lost a contract in the Ukraine to a competitor that was providing counterfeit versions of Revision's product. The competitor even submitted Revision's own test data with its replicas. What is the United States government doing to educate other governments about the safety risks and broader economic effects of purchasing counterfeits of American goods?**

Part of the training conducted by the USPTO's Global Intellectual Property Academy educates foreign governments on the health and safety risks of counterfeit goods, as well as the economic harm they cause. These critical issues play a prominent role in our capacity-building programs. For example, these issues are raised in the outreach conducted by our IP attachés in their bilateral engagements with foreign governments and industry, as well as by the USPTO when hosting foreign officials.

Question from Sen. Klobuchar (D-MN)

Question for Mr. Foucart and Mr. Wong:

There are many ways to get counterfeit products into the market, but third party websites are one of the most widespread and flagrant. We have seen some websites shut down, but it is still too easy to find online sources for counterfeit products.

- **What efforts are being taken to shut down websites selling counterfeit products?**
- **What are the biggest obstacles in the way, and how can we fix them?**

The U.S. Patent and Trademark Office (USPTO) is responsible for patent and trademark operations and examination in the United States, and maintaining the patent and trademark registry. It does not have enforcement authority over web sites which sell counterfeit products. However, the USPTO works closely with the National IPR Coordination Center, which U.S. Immigration and Customs Enforcement administers, as well as with prosecutors with the Computer Crime and Intellectual Property Section of the U.S. Department of Justice. When we learn of rogue web sites offering fake products for sale, through complaints submitted via the stopfakes.gov website or other sources, we collect as much information as possible, then refer it to our aforementioned colleagues. To collect this information, attorneys from the USPTO's Enforcement Team of the Office of Policy and International Affairs confer with the complainants themselves, requesting as much information as possible including the following: the alleged infringing activity; the suspect products; individuals or entities involved; how long the conduct has been occurring; contact information; the web address of the suspect website; and whether the individual or entity is active in other locales. We then forward all of this information to the National IPR Coordination Center, where officers of U.S. Immigration and Customs Enforcement commence their review and determine whether the information is sufficient and credible enough to open an investigation.

Regarding obstacles, even when suspect websites are shut down, they re-appear, sometimes in a matter of hours, under a different owner. Regardless of whether a suspicious website may have "re-appeared" after being shuttered, the USPTO will continue to collect as much information as possible, then refer it to our aforementioned colleagues.

Congressional approval of the Trans-Pacific Partnership, which includes countries that today account for nearly 40 percent of the world's GDP, would also advance our efforts to set high intellectual property protection and enforcement standards. TPP establishes strong and balanced protections for patents, trademarks and copyrights, and closes loopholes that let dangerous counterfeits come across borders and get into the supply chain. Strong and fair enforcement rules to protect against trademark counterfeiting allow for increased penalties in cases where counterfeit or pirated goods threaten consumer health or safety.

Question for Mr. Wong:

The Organization for Economic Cooperation and Development’s recent report “Trade in Counterfeit and Pirated Goods” identifies that goods originating in, or shipped through, China make up the bulk of seized counterfeited goods.

- **From your experience in your current position and previously as an IP attaché in China, has China’s enforcement against counterfeiting improved?**
- **What more could China do to address this problem?**

China is transitioning its economy from one based on low-cost manufacturing to an innovation and consumer-driven model. As such, it has undertaken efforts to improve IP protection, including against counterfeit goods. Nonetheless, serious systemic problems remain, including low civil damages, rapid growth in online sales, and non-deterrent administrative enforcement.

To address problems with counterfeits emanating from China at this time, we are working with the Chinese Government to improve enforcement remedies and transparency through outreach and information exchanges under the U.S./China Cooperative Framework Agreement (CFA), a commitment of the U.S./China Joint Commission on Commerce and Trade (JCCT). Under the CFA, the USPTO brings approximately fifteen to twenty Chinese officials from relevant IP agencies, the courts, and various ministries and legislative offices to the U.S. to study the various vehicles through which we protect IP and promote innovation.

In September 2014, the USPTO organized a program held in Washington, D.C. and Silicon Valley, California on how the U.S. promotes innovation through partnerships between government and research institutions, such as universities, as well as individual rights holders, such as companies. In April 2015, the USPTO facilitated a legislative study program in Washington, D.C., where the Chinese officials learned how the U.S. promulgated legislation that enables robust IP protection as well as maximizing IP’s commercial potential. In April 2016, the USPTO focused on judicial remedies for enforcing IP, arranging for appointments in Washington, D.C. and Madison, Wisconsin, to visit with federal and state jurists, federal prosecutors from the Department of Justice, and representatives from and the U.S. International Trade Commission. Participants also conferred with officials of the University of Wisconsin’s IP-licensing office to learn how to maximize the commercial potential of inventions emanating from the University’s laboratories.

The USPTO also currently is organizing a program, tentatively scheduled for the latter part of 2016 or the first half of 2017, to bring federal judges with IP trial and appellate experience to China, so that they may interact with their Chinese counterparts. China is just beginning to allow injunctive relief, evidentiary preservation, and redacted opinions, remedies that American courts and practitioners have extensive experience in smartly moving forward IP litigation towards resolution. The Chinese judicial system still has much to learn in handling complex litigation and sensitive information, such as proprietary intellectual property and trade secrets. This judge-to-judge interaction will promote greater understanding between China and the U.S., and foster greater exchange, as China’s judicial system evolves into one of greater efficiency, transparency, and ease of use.