INTERNATIONAL IP ENFORCEMENT: PROTECTING PATENTS, TRADE SECRETS AND MARKET ACCESS

HEARING

BEFORE THE

SUBCOMMITTEE ON
INTELLECTUAL PROPERTY,
COMPETITION, AND THE INTERNET

OF THE

COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

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JUNE 27, 2012

INTERNATIONAL IP ENFORCEMENT: PROTECTING PATENTS, TRADE SECRETS AND MARKET ACCESS

WEDNESDAY, JUNE 27, 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 10:06 a.m., in room 2141, Rayburn Office Building, the Honorable Bob Goodlatte (Chairman of the Subcommittee) presiding.

Present: Representatives Goodlatte, Quayle, Smith, Sensenbrenner, Coble, Chabot, Jordan, Marino, Adams, Watt, Berman, Deutch, Lofgren, and Waters.

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

Mr. GOODLATTE. Good morning. This hearing of the Subcommittee on Intellectual Property, Competition, and the Internet of the House Judiciary Committee will come to order. And I'll 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 raise the spotlight on the problems that American companies face when seeking, enforcing, and using patents overseas.

This Subcommittee held a hearing in April with industry stakeholders 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 innovators.

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.

When the latest patented chip design of a U.S. technology company is infringed, or a foreign government subjects an American patented pharmaceutical drug to a compulsory license or endless challenges to effectively block market access, the IP enforcement

issues implicated have a direct and negative impact on free markets and fair trade.

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.

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 a 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 the government authority, there is usually a lack of adequate safeguards to protect it. Some U.S. companies have decided to avoid the Chinese and Indian markets altogether, rather than lose their trade secrets.

Some countries, like South Korea, China, and India, are looking at using compulsory licensing in the trade secret space. The foreign regulators in these countries can potentially compel new licensing of a trade secret to 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.

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 for U.S. companies looking to compete.

Today, we will examine what the U.S. is doing to ensure this is indeed the case.

Some have argued that the Obama administration has taken a narrow approach when it comes to the concerns of the American innovative companies in the patents, trade secrets, and market-access space. They point to the Administration's lack of focus on international patent 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 Agreement, 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 context of the TPP negotiations could weaken, rather than strengthen, certain intellectual property laws abroad, whether it be requirements for plain packaging of certain products or pharmaceutical test data protection issues.

I look forward to continue to work to ensure that these negotiations result in stronger, not weaker, commitments by other countries to enhance their IP laws.

I want to commend the PTO for the work they have done in the context of their IP attaché program, their international policy advocacy, and the training and capacity-building programs they are conducting on the ground in targeted countries.

Today, I hope to hear more about the USPTO's plans to do more to expand the U.S. Government's efforts to find real solutions to these unfair trade practices that distort free market trade and, in the end, hinder American job creation.

I now am pleased to recognize the Ranking Member of the Subcommittee, the gentleman from North Carolina, Mr. Watt.

Mr. WATT. Thank you, Chairman Goodlatte. And I also thank you publicly for accommodating some schedules of some other witnesses who we wanted to testify. And I'm sure we'll get a chance to hear from them later on this important subject, which has continuing and important implications.

I want to welcome our witness, Deputy Under Secretary Rea, to her first appearance before this Subcommittee, and what I understand is her first her appearance before any Committee of Congress. She brings an impressive body of work prior to joining the U.S. Patent and Trademark Office and will, no doubt, share with us today additional achievements in her current capacity.

This hearing, as the Chairman has indicated, is a follow-up to a hearing we held in April, in which we heard from a number of witnesses from stakeholder industries and academia.

Today, we pivot to look at developments in enforcement in the increasingly relevant and sometimes complex international patent arena.

Just last month at the meeting of the G-8 at Camp David to address global, economic, and political challenges, the group emerged with a declaration that stated, in part, quote, "Given the importance of intellectual property rights to stimulating job and economic growth, we affirm the significance of high standards for intellectual property rights protection and enforcement," close quote.

While this commitment is welcomed, it must be embraced by the broader global community. And more importantly, it must be honored.

The U.S. takes pride in our IP-intensive industries, which collectively produce 27.1 million jobs for our citizens. But we continue to hear that, for some of those industries, barriers to access to some of the world's fastest growing markets is deliberately stymied by protectionist practices of foreign governments, lack of intellectual property enforcement, and other tactics that discourage and impede the ability of U.S. companies to compete on a level playing field.

These practices may affect entire industries, like the information technology sector, which, according to a recent report by the Business Software Alliance, called, "Lockout: How a New Wave of Trade Protectionism Is Spreading through the World's Fastest-Growing IT Markets—and What to Do about it," may be required to provide local licensing of its intellectual property as a condition to entering the market. Or they may deny a valid trademark of a U.S. company, like True Religion, whose largest supplier, Cone Mills, is in my congressional district, forcing them to instead litigate, which, although successful, quite often results in an unenforceable judgment of millions of dollars.

In addition to these policy challenges, there are also practical administrative hurdles for American companies. Small American businesses and startups are often saddled with high application fees for patent protection in other countries, as was noted in the PTO report earlier this year.

Although we provided some fee relief to micro-entities in the America Invents Act, lots of other countries do not have the same practices and policies.

Similarly, despite our efforts at global harmonization, the absence of a grace period in many other patent-issuing countries continues to place our inventors at a disadvantage. Because the laws of many foreign countries prohibit the grant of a patent where an invention was disclosed prior to the date of the application, the grace period effectively limits the patent to within the borders of the United States.

Finally, we must remain ever vigilant in our efforts to enhance America's standing in the competitive international market and to guard against unfair foreign encroachments on our intellectual property rights. But we also have an obligation to be good global citizens, particularly where health and safety concerns are concerned, so that our enforcement policies do not unfairly disrupt, exploit, or decimate the economies of developing countries.

Our colleague, Mr. Berman, has worked tirelessly over the years in his capacities both on the Judiciary Committee and on the Foreign Affairs Committee to promote and support a dynamic and nimble IP attaché corps, which through diplomacy, negotiation, and relationship-building may well be suited to helping achieve those dual goals.

This is an important hearing, Mr. Chairman. I thank the Chairman for convening it. And again, I thank him for accommodating our other witnesses. That means we'll be having some more hearings on this issue, so I appreciate it and yield back.

Mr. GOODLATTE. I thank the gentleman.

And it's now my pleasure to recognize the Chairman of the Judiciary Committee, the gentleman from Texas, Mr. Smith.

Mr. SMITH. Thank you, Mr. Chairman.

America's economic success has been built on innovation. But as we develop new technologies and products, foreign governments have disadvantaged American companies by imposing barriers to market access.

During the Bush administration, intellectual property enforcement involved patents, trademarks, copyrights, trade secrets, and market access.

The Bush administration established an IP attaché program in 2006 and a Global IP Academy at the Patent and Trademark Office. These work directly with trading partners to promote IP protection and enforcement, and to advance U.S. economic and political interests.

It elevated important IP enforcement cases, so that they could be raised at the Cabinet level with foreign governments. And President Bush appointed the first IP coordinator, which was housed at the Department of Commerce.

During those years, China joined the World Trade Organization, India passed a patent law, and other countries in Asia and Latin

America began to modernize their IP systems. Many of the IP enforcement issues of today were just starting to arise back then.

The Bush administration had the foresight to establish new programs, hold our trading partners accountable by filing IP cases at the WTO, and use all of our trade tools to promote effective IP enforcement in all areas of intellectual property, including patents and trade secrets.

So it is disappointing that the IP enforcement coordinator is not here today, even though we had informed her office of this hearing in early May.

I understand that the coordinator chose to travel to Oregon instead of appear before this Committee. I had hoped to get better cooperation from an office that this Committee established 4 years ago.

This Administration's approach to international IP enforcement issues has been too weak. But it is not too late for it to take a more comprehensive approach to IP enforcement.

As the Administration develops their next joint strategic plan, they must expand their approach. The Administration should ensure that a significant part of IP enforcement includes the issues around patents, trade secrets, and market access.

When foreign governments engage in practices that devalue the IP of American innovators, Federal officials need to respond strongly and swiftly. Appropriate responses should include filing IP cases at the WTO, something that we haven't seen in the last 3 years.

Under President Bush, the U.S. filed 24 WTO cases, which included two IP cases. Under President Obama, the U.S. has filed eight cases and none on IP.

In the absence of WTO IP enforcement actions, many foreign countries will continue to ignore legal reforms and create major barriers to trade for U.S. companies. Many of these patent-specific problems have intensified over the past 3 years.

These global problems require real-world solutions that go beyond simply being listed in the annual United States Trade Representative's Special 301 watch list or a government report. They go to the very heart of our innovative companies' ability to compete on the global playing field.

The U.S. patent system is designed to be fair. It meets our international obligations and does not discriminate against any field of technology.

The same cannot be said of the patent systems around the world. When American companies seek protection in foreign markets, they see their patent applications being held up, as patent approval times approach a decade in some countries.

They see their patents subject to lengthy pre-grant and post-grant challenges that further reduce their patent term. And they continue to face obstruction by foreign courts and administrative agencies when trying to bring their product into the local market.

Those foreign countries not only violate their international commitments, but also create a significant negative economic impact that hits the U.S. economy and domestic jobs.

I plan to introduce the Promoting a Level Playing Field for American Industry, Innovators, and Job Creators Act. This IP

attaché training and capacity-building bill is based on concepts developed at the PTO.

It will improve the IP attaché program and U.S. Government IP training as it aligns policy priorities and brings them under the U.S. Patent and Trademark Office. It ensures that our IP efforts abroad are in line with compelling U.S. economic interests.

The goal is to focus our efforts to deal with IP issues at their source and use all of our trading tools as we work with other countries.

As the U.S. Government works with our trading partners to find solutions, we can ensure that the solutions reached are in line with compelling U.S. economic interests and job creation.

Thank you, Mr. Chairman. I yield back.

Mr. GOODLATTE. Thank you, Mr. Chairman.

Without objection, other Members' opening statements will be made a part of the record.

Ms. Rea, we are delighted to have you with us today as our distinguished witness, and your written statement will be entered into the record in its entirety. And we ask that you summarize your testimony in about 5 minutes.

As is the custom of this Committee, before we formally introduce you, we'd ask that you stand and be sworn.

[Witness sworn.]

Mr. GOODLATTE. Thank you very much.

Our witness today is the Honorable Teresa Stanek Rea, the Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the U.S. Patent and Trademark Office.

Deputy Under Secretary Rea joined the USPTO in 2011 and had previously served as a partner in Crowell & Moring's D.C. office, where she focused on IP and dispute resolution related to pharmaceutical, biotechnology, and other life-science issues. She also served as a past president of the American Intellectual Property Law Association.

Earlier in her career, she worked for Ethyl Corporation and at a boutique law firm in Alexandria, Virginia.

Ms. Rea received her law degree from Wayne State University and a Bachelor of Science Degree in Pharmacy from the University of Michigan.

Welcome, Deputy Director Rea.

Ms. REA. Thank you so much.

Mr. GOODLATTE. You may want to pull that microphone close to you.

TESTIMONY OF THE HONORABLE TERESA STANEK REA, DEPUTY UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DEPUTY DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, UNITED STATES DEPARTMENT OF COMMERCE

Ms. REA. Chairman Goodlatte, Ranking Member Watt, Chairman Smith, and distinguished Members of the Subcommittee, thank you so much for inviting me to be here with you today. And thank you for this opportunity to discuss the United States Patent and Trademark Office's efforts toward improving the international enforcement of intellectual property rights held by U.S. innovators.

Mr. Chairman, while I've been at the USPTO for just over 16 months, I have spent a good portion of my legal career, as you know, working in the field of biotechnology and pharmaceutical patents. I am a registered pharmacist in the State of Michigan, and I have worked for many years in a hospital setting. And this experience has provided me with a unique perspective from which I approach my job.

It is absolutely clear to me that we cannot overstate the importance of IP to our economy. The recent Department of Commerce report, as was indicated earlier, found that IP-intensive industries support at least 40 million jobs and contribute more than $5 trillion, or 35 percent of U.S. gross domestic product.

And as stated by the Commerce Department's Acting Secretary Blank, she indicated strong intellectual property protections encourage our businesses to pursue the next great idea, which is vital to maintaining America's competitive edge and driving overall prosperity.

Mr. Chairman, we are proud of the array of programs and initiatives we have at the USPTO that benefit American innovators doing business in the global marketplace.

A significant problem with overseas IP enforcement is the lack of training available to responsible foreign officials. Many foreign legal systems have minimal experience in enforcing IP laws and adjudicating IP disputes.

The U.S. Patent and Trademark Office has developed and conducted rigorous capacity-building programs in key countries and regions, focusing on training foreign enforcement officials, including police, prosecutors, customs officials, as well as the judiciary themselves. Also, we continue to provide training and resources that help guide U.S. companies as they enter into global markets, especially when they face particular challenges to enforcing their rights.

Through our Global Intellectual Property Academy, also known as GIPA, we have greatly expanded IP rights training, capacity-building, and technical assistance offerings to promote improved IP protection and enforcement.

Over the last year and a half, our Global Intellectual Property Academy has conducted almost 200 training programs, both domestically and abroad, reaching more than 6,000 foreign government officials, representing approximately 140 countries. Now, during that same period, we also trained more than 2,000 representatives of small- and medium-sized U.S. enterprises at programs throughout the United States to help them navigate that terrain.

GIPA has also produced seven e-learning modules on IP protection and enforcement, several of which are actually available in languages other than English. And those modules have received more than 20,000 hits since they were first placed on the USPTO website.

Now, Mr. Chairman, we are particularly proud of the important work done by our IP attachés, and they're stationed at U.S. Embassies and missions around the world. These IP experts are dedicated to promoting high standards of IP protection and enforcement internationally for the benefit of U.S. rights-holders.

They are frequently called on to play two significant roles. First, they coordinate and identify ways to effectively address the chal-

lenges faced by U.S. companies. And second, they work with the host government to consider changes that improve the effectiveness of their IP systems.

In addition to our attaché postings, we also have two USPTO employees on detail to the USTR and the U.S. Permanent Mission to the U.N. office in Geneva, supporting U.S. objectives relating to IP matters that arise in the course of the World Trade Organization, the World Intellectual Property Organization, and other international organizations.

Now, since entering this position, Mr. Chairman, I have had the opportunity to meet many of the USPTO IP attachés currently serving in our Embassies throughout the world, and I can attest to the valuable role that they play in facilitating informed discussions related to the creation of effective IP laws and the challenges U.S. companies face in enforcing their rights. I know that their work has also received very favorable reviews by the business community.

Mr. Chairman, in light of the increasing concerns by U.S. rightsholders on the importance of protecting their trade secrets from misappropriation, the USPTO is emphasizing this area in our domestic and foreign policy objectives, particularly as they relate to China. USPTO attorneys are undertaking a comprehensive study of Chinese laws and other legal measures governing trade secrets, and are discussing with Chinese Government officials changes that can facilitate a more effective protection regime in China.

Mr. Chairman, my written statement provides more detailed information on our initiatives and programs, all with the goal of achieving effective IP protection and enforcement for U.S. innovators doing business in the global marketplace.

Mr. Chairman, we look forward to continuing to work with the Committee, the leadership at the Department of Commerce, our colleagues within the Administration, and our stakeholders, toward that goal. And we do appreciate your continued support for all 10,000 employees at the U.S. Patent and Trademark Office. Thank you.

[The prepared statement of Ms. Rea follows:]

STATEMENT OF

TERESA STANEK REA

DEPUTY UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY
AND
DEPUTY DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE

SUBCOMMITTEE ON INTELLECTUAL PROPERTY,
COMPETITION AND THE INTERNET
COMMITTEE ON THE JUDICIARY
U.S. HOUSE OF REPRESENTATIVES

"International IP Enforcement: Protecting Patents, Trade Secrets and Market Access"

JUNE 27, 2012

Introduction

Chairman Goodlatte, Ranking Member Watt, and Members of the Subcommittee:

Thank you for this opportunity to discuss the United States Patent and Trademark Office's (USPTO) efforts toward improving the international enforcement of intellectual property rights held by U.S. innovators – particularly, in the areas of patents, trade secrets and market accessibility.

Mr. Chairman, we are pleased to work with the Congress, other Federal agencies, and our stakeholders in promoting effective enforcement of IP rights around the world. We are proud that the USPTO provides training and resources that can help guide U.S. companies as they enter into global markets and especially when they face particular challenges to enforcing their rights. Our IP attaches stationed in U.S. embassies around the world, to name one such resource in particular, are frequently called on to play two significant roles. First, coordinate and identify ways to effectively address the challenges faced by U.S. companies. And, second, work with the host government to consider changes that improve the effectiveness of their IP systems.

We cannot overstate the importance of IP rights to our economy. The recent Department of Commerce report titled "Intellectual Property and the U.S. economy: Industries in Focus" found that IP-intensive industries support at least 40 million jobs and contribute more than $5 trillion dollars to, or 35 percent of, U.S. gross domestic product (GDP). As stated by the Commerce Department's Acting Secretary Blank, "Strong intellectual property protections encourage our businesses to pursue the next great idea, which is vital to maintaining America's competitive edge and driving our overall prosperity."

The USPTO's IP-focused efforts include proactively facilitating a number of programs and initiatives detailed below.

Technical Assistance/Capacity Building

A significant problem with overseas IP enforcement is the lack of training available to foreign officials. The USPTO has developed rigorous capacity-building programs in key countries and regions targeting foreign enforcement officials, such as police, prosecutors, customs officials, as well as the judiciary. Recent technical assistance/capacity building activities include:

- In coordination with the Jordan Food and Drug Administration, the USPTO conducted a workshop on combating counterfeit medicines in Amman, Jordan, on April 23-24. The program was attended by Jordanian regulatory and law enforcement officials and included participation from The U.S. Food and Drug Administration, U.S. Department of Justice and the U.S. Immigration and Customs Enforcement, Homeland Security Investigations participated in the workshop.

- The USPTO organized a three-day symposium from April 18-20 in Jakarta, Indonesia for Association of Southeast Asian Nations (ASEAN) IP and law enforcement officials on "Enforcement of Intellectual Property Rights against the Trade in Counterfeit Goods."

- The USPTO organized a series of seminars in five different cities in Indonesia from April 10-17 focusing on enforcement against trade in counterfeit medicines. More than 200 enforcement officials, including local police, prosecutors, and customs officials, participated in these seminars.

- The USPTO organized a week long seminar at its Global IP Academy from March 12-16 on "Investigating and Prosecuting IP Crimes" for a group of police, investigators, and prosecutors from the Association of Southeast Asian Nations (ASEAN).

- The USPTO helped organize and participated in a symposium March 8-9 on the use of alternative dispute resolution in intellectual property disputes at California Western School of Law in San Diego, California. The symposium brought together experts in the field from Brazil, Finland, Canada, the United Arab Emirates, Switzerland, Paraguay, and the United States.

Working with Judicial Officials Around the World

- An ongoing challenge for U.S. businesses looking to protect their valuable intellectual property rights internationally are foreign judicial systems with little to no experience in adjudicating IP cases. It impossible to have an effective enforcement regime without an effective court system. Transparency, fairness, and an understanding of the legal issues are all hallmarks of an effective judicial system.

- To quote a recent study on intellectual property and the judiciary, conducted by the USPTO: "The laws that govern IP are complex, and the technologies protected by those laws can be even more complex. Due to these intricacies, highly experienced judges are often needed to assure timely adjudication and accurate, consistent case outcomes."

- In this respect, U.S. companies are at a great disadvantage when they face a court system which does not recognize the importance of IP and its integral role in a business' success and local economic development. Similarly, prosecutors inexperienced in IP issues and the technical nature of such cases, many times do not, or are reluctant, to take on IP cases, important to U.S. companies who depend on their IP.

- Accordingly, USPTO has taken an active role in working with the foreign judiciary and prosecutors to understand IP issues, through direct training and interchanges with U.S. officials, both judges and prosecutors who are experts in handling IP cases. Our judicial outreach and programs helps develop expertise of our foreign participants. In doing so, they also create consistency and predictability for rights holders and can lower litigation costs by speeding up the adjudication process.

Some noteworthy examples of our efforts include:

- On May 22-24, the USPTO held a Judicial Colloquium on Intellectual Property Rights in Algiers, Algeria for the Algerian judiciary.

- On May 10-11, the USPTO held a program on Judicial and Prosecutorial Best Practices in Riga, Latvia for judges and prosecutors from throughout the Baltic region, including Latvia, Lithuania, Estonia, Finland, and Sweden. This program was particularly well-received, and the Lithuanian prosecutors have requested a similar program in Lithuania, for the country's police, prosecutors and judges.

- On May 8-10, the USPTO and the World Intellectual Property Organization (WIPO) held a Judicial Colloquium on Intellectual Property Rights at USPTO. The Colloquium brought together senior WIPO officials and judges from a number of different countries to learn about court administration and IP.

- On April 24, the USPTO, in association with the International Judicial Academy, hosted a visit by a delegation of Brazilian judges and provided training on patent, trademark, and copyright law, IP enforcement mechanisms, and the impact of IP protection on public health. The judiciary is singled out as the main stumbling block in enforcing IP laws for reasons such as lack of training, lack of expertise, and overall lack of knowledge regarding IP issues. This program focused on the US approach to IP enforcement and included topics such as general knowledge of international IP laws and their related US interpretation, criminal enforcement of trademarks and copyrights, internet service provider liability, evidentiary standards in IP case.

- On April 16-18, the USPTO, in conjunction with Georgetown University, held a Workshop for Judges on Intellectual Property Law and Strategic Management for Sustainable Economic Development. The Workshop was held in Rio de Janeiro, Brazil and was designed to provide a forum for Brazilian judges to discuss how IP law and strategic management can contribute to economic growth.

- On April 2-6, the USPTO hosted a visit of twenty Sri Lankan judges, including one Supreme Court Justice and three High Court Judges, and briefed them on IP enforcement in the United States and the critical role of the judiciary.

- On January 17-19, in coordination with the International Intellectual Property Institute (IIPI), the USPTO held a symposium on Intellectual Property Rights Courts at USPTO's Global Intellectual Property Academy (GIPA), which brought together judges, attorneys, and IP officials from countries throughout the world. Feedback from the symposium fed into a survey conducted by USPTO and IIPI on the growing use and best practices of specialized IP courts throughout the world.

Global Intellectual Property Academy

Through our Global Intellectual Property Academy (GIPA), we have greatly expanded IP rights training, capacity building and technical assistance offerings to promote improved IP protection and enforcement.

- In FY 2011, GIPA conducted 141 training programs on intellectual property protection and enforcement topics both domestically and abroad for 4,338 foreign government officials representing 137 countries. During that period, GIPA trained 964 representatives of U.S. small or medium sized enterprises (SMEs) on intellectual property and enforcement at eight programs offered at locations around the United States.

- In the first half of FY 2012, GIPA conducted 54 training programs on intellectual property protection and enforcement topics both domestically and abroad for 2,021 foreign government officials representing 78 countries. During this period, GIPA trained 2,018 people employed at U.S. small or medium sized enterprises (SMEs) on intellectual property and enforcement at 16 programs offered in the United States.

- GIPA has produced seven e-learning modules on intellectual property protection and enforcement, six of which are available in languages other than English.. Topics include all areas of intellectual property: Patent Protection, Overview of Trademarks, Copyright: Encouraging and Protecting Creativity, Geographical Indications, International Standards for the Enforcement of IP, Trade and IP, and Introduction to the Patent Cooperation Treaty. The free e-learning modules have received more than 20,000 visits since they were first placed on the USPTO website.

IP Attaché Program

USPTO's overseas IP Attachés support many of the efforts already described and facilitate IP activities in their host country. The program was formally instituted in 2006 to promote high standards of IP protection and enforcement internationally for the benefit of U.S. economic and political interests abroad. Since its creation, the IP Attaché Program has placed individuals in seven countries: Thailand; China; Russia; India; Brazil; and Egypt.

Our attachés promote U.S. government IP policy internationally; help to secure strong IP provisions in international agreements and host country laws; and encourage strong IP protection and enforcement by U.S. trading partners for the benefit of U.S. rights holders. More specifically, the attachés advocate U.S. Government IP policy, interests and initiatives; assist U.S. businesses on IP protection and enforcement; conduct training activities with host governments; advise representatives of the host government or region on U.S. intellectual property law and policy; help to secure strong IP provisions in international agreements and host country laws, and monitor the implementation of these provisions; and advise officials at the USPTO, Department of Commerce, USTR and the Departments of State, Treasury and Justice, on the host government's IP system.

In addition to our attaché postings, we have two USPTO employees on detail to the Office of the United States Trade Representative (USTR) and U.S. Permanent Mission to the United Nations Office in Geneva, Switzerland supporting U.S. objectives related to IP matters that arise in the World Trade Organization, World Intellectual Property Organization and other international organizations.

TRIPS Agreement

The USPTO has worked closely with the USTR in ongoing IP discussions in the WTO regarding the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement). The USPTO also

advised USTR during the WTO accession process of several countries by evaluating IP laws, regulations and practices of countries in the process of accession, and advising USTR as to TRIPS Agreement obligations.

We continue to provide expert technical advice on the full range of substantive IP protection and enforcement issues to the USTR in connection with on-going trade negotiations. The USPTO plays an active role in the ongoing Trans-Pacific Partnership negotiations, and the implementation and monitoring for compliance of other bilateral and free trade agreements.

Bilateral Engagement with China

The USPTO continues to engage with China on a variety of fronts to improve IP enforcement:

- On March 19-21, the USPTO and USTR co-led the U.S. delegation for a meeting of the IP Working Group under the U.S.-China Joint Commission on Commerce and Trade. The meeting included a number of enforcement-focused discussions, including trade secrets issues and enforcing trademarks in the online environment.

- On April 11 and 12, USPTO participated in the Ambassador's IP Roundtable in Beijing. This annual event this year focused on the Information Communication Technology (ICT) sector and the online environment. We discussed the importance of IP protection and enforcement and highlighted the role the USPTO team plays in the mission in working with rights holders to enforce their rights in China.

- On April 27, attorneys from the USPTO presented on protecting and enforcing intellectual property rights in China during the U.S.-China People's Friendship Association's bi-annual meeting in Washington, DC.

- On May 28-30, the USPTO and the U.S. Court of Appeals for the Federal Circuit co-sponsored an intellectual property adjudication program with Renmin University of China, the China Law Society, the Bar, and others. More than 1,200 people attended the three-day program, including nearly three hundred judges from China's judiciary; hundreds of lawyers and business people from the United States and China; several hundred Chinese academics; and, most importantly, seven judges from the Federal Circuit, as well as a like number of judges from the Supreme People's Court. There was an "en banc" Q-and-A session between the Federal Circuit and China's Supreme People's Court, a moot court involving a common fact pattern that resulted in a nearly identical adjudication on the same set of facts, and breakout sessions on such topics as pharmaceutical patent adjudication, copyright (including online infringements) and trademark developments (including "squatting"). The program was a milestone in bilateral judicial, intellectual property and rule of law exchanges.

In early June, USPTO attorneys met with several Chinese administrative enforcement agencies to discuss concerns raised by U.S. right holders and reached agreement with several of these agencies to work with such right holders to develop new measures and enforcement practices to better facilitate the protection and enforcement of IP in China.

Patents in China

In 2011, the USPTO convened four roundtables (three in China and one in the U.S.) with U.S. industry representatives and published a *Federal Register* notice to solicit input on their experiences enforcing

patents in China. The input received will be compiled into a report which will be published and made available on our website. The report will help guide USPTO's engagement with China on patent enforcement.

Trade Secrets Protection

In light of the recent and increasing concerns by U.S. right holders on the importance of having effective mechanisms to protect their trade secrets from misappropriation, the USPTO is emphasizing this area in our domestic and foreign policy objectives, particularly as they relate to China. USPTO attorneys are undertaking a comprehensive study of Chinese laws and other legal measures governing trade secrets and are discussing with Chinese government officials changes that can facilitate a more effective protection regime in China. We are also using this information to update the "China IP Toolkit" on Stopfakes.gov with a section dedicated to trade secret protection and enforcement. This component of the Toolkit will provide an overview of China's major laws and other measures affecting trade secrets and include basic steps a company can consider to protect its trade secrets in China, including not only information on judicial and administrative enforcement mechanisms but also basic strategies companies can employ to help prevent misappropriation from occurring.

Also, the USPTO is currently developing training modules on trade secrets for SMEs and enforcement officials. These modules will include an overview of trade secret law in the United States, measures to protect trade secrets, criminal and civil enforcement procedures and international trade secret protection and enforcement.

IP Small Claims

On May 10, 2012, a roundtable of intellectual property experts convened at the George Washington University Law School. Co-sponsored by the USPTO and the U.S. Copyright Office, the purpose of this roundtable meeting was to consider the possible introduction of small claims proceedings for patent and/or copyright claims.

The day began with framing of the challenge: offering access to IP justice to creators least resourced but often most in need, in an age in which creative works (both in the copyright and patent domain) are more subject to disputes, of all magnitude, than ever before. Presentations followed on the small claims system in the UK, and the U.S. Constitutional limitations on the nature of such procedures, including the Seventh Amendment right to a jury, Article III judicial power, and due process.

In breakout sessions on patents and copyrights, attendees discussed the need for and ways to structure a small claims system in both areas.

This productive session was a first step in determining whether and how it makes sense for the government to help set new parameters for the resolution of small claims in the patent and copyright areas. The USPTO will continue to work with the Copyright Office on taking these ideas forward.

International Copyright Leadership

While outside the scope of this current hearing, I would like to note that the USPTO has also demonstrated key leadership in the copyright arena. Internationally, we have worked within WIPO to reconvene a Diplomatic Conference to conclude action on the WIPO Audiovisual Performances Treaty. A Diplomatic conference on this treaty concluded yesterday in Beijing, China. We have also engaged other WIPO Member States to address copyright exceptions for the benefit of blind persons. Finally, we

have worked with our partners at the Department of Commerce to continue to address leading-edge policy issues at the intersection of copyright, creativity, and innovation in the Internet economy.

Korea-U.S. and Colombia-U.S. Free Trade Agreement Implementation

Free trade agreements have played an increasingly important role in promoting modern IP enforcement legislation with our trading partners. USTR together with the USPTO, worked with Korean and Colombian officials to guide implementation of the intellectual property enforcement provisions of the free trade agreements with the United States. That implementation was completed this year. Among other things, our efforts helped secure improved legislation on IP enforcement for U.S. and foreign right-holders. These include improved ability to collect damages for infringement, destruction of materials and implements used in infringement, and securing evidence on counterfeiting distribution channels. In the end, these provisions will help U.S. companies to more effectively enforce their IP rights in these important markets.

Chief Economist

The USPTO's Office of Chief Economist (OCE) advises the Under Secretary and senior USPTO management on the economic implications of policies and programs affecting intellectual property protection and enforcement in the United States.

Most recently, the OCE hosted a major international conference in November titled "Patent Statistics for Decision Makers" in collaboration with the Organization for Economic Co-operation and Development (OECD), the European Patent Office, and the World Intellectual Property Organization. The OECD is also supporting efforts leading to the publication of special issues on "intellectual property and innovation" in three major economics journals – the International Journal of Industrial Economics; the Journal of Industrial Economics; and the Journal of Economics, Management, and Strategy.

In April, the Secretary of Commerce released a report written by the OCE in partnership with the Economics and Statistics Administration. Titled "Intellectual Property and the Economy: Industries in Focus," this report showed the 75 most IP-intensive industries in the U.S. accounted in 2010 for 40 million jobs, 35.5% of overall GDP, and 61% of all merchandize exports. This report has had a large impact, being downloaded from the USPTO website more than 82,000 times in the first month after its release.

Conclusion

Mr. Chairman, we look forward to continuing to work closely with the Committee, our colleagues within the Administration and our stakeholders to improve the resources available to help U.S. companies succeed in global markets and to work with our foreign counterparts to promote the protection of IP rights.

We appreciate your continued support for the employees and operations of the USPTO.

# # #

Mr. GOODLATTE. Well, thank you, Deputy Director Rea. I'll begin the questioning.

In the patent world, there are many hurdles that a foreign country can raise to prevent a company from selling a product based on a lawfully granted patent. But in recent years, we've seen countries

like Brazil, Thailand, and India using the threat of a compulsory license as a negotiating strategy to those American companies to manufacture or license their products to local companies at government-mandated prices.

Recently, 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.

What steps did the Administration take and should be doing now to ensure that countries think twice about using a compulsory license simply as a negotiating strategy or to facilitate their budget planning?

Ms. REA. Thank you, Mr. Chairman.

Actually, on that particular issue, I can pretty much speak from the heart.

As a pharmacist, as someone who has worked in both a drug store and a hospital setting, I can tell you that pharmaceuticals are something that we all need and that there is a global need for those. Unfortunately, compulsory licenses dissuade pharmaceutical and biotech companies from innovating or from bringing their product into countries that grant compulsory licenses.

In the case of India, I have to tell you, I was quite dismayed and surprised when they did indeed decide to grant that compulsory license for a reason that I think did not meet international standards and was not due to, for instance, a national crisis.

What we do at the USPTO, is we have somebody on the ground right now in India, in the Embassy in Delhi, who constantly engages with all of the respective offices in India to discuss with them the importance of not granting a compulsory license in a situation where it is not warranted.

Unfortunately, our education efforts on that issue to date have not yet been successful. I'm not sure if you were aware of it, but that compulsory license was granted by Commissioner Kurian on the very last day he left the Indian Patent Office as Commissioner.

Mr. GOODLATTE. Was that granting appealed?

Ms. REA. I'm sorry?

Mr. GOODLATTE. Was it appealed?

Ms. REA. Yes. It's currently being ongoing discussed and appealed at this time legally. But we're also working with trying to continue our discussions with their equivalent of the U.S. FDA and their regulatory authorities.

We're engaging in as many discussions as we can with them, outside of just the Indian Patent Office context. But we are doing everything we can to respect the rights of U.S. innovators.

Unfortunately, from my perspective, I think that perhaps the loser in all of this will actually be the Indian people, the Indian patients, where major pharmaceutical companies will actually delay bringing pharmaceuticals into those countries.

Mr. GOODLATTE. Well, let me just say that I appreciate that concern, but here's the problem: Whenever you have a country that doesn't treat our pharmaceutical manufacturers fairly in the process and they both issue compulsory licenses or threaten to do so, and have mandated prices—price controls, if you will—that's an untenable combination, because the fact of the matter is, if the

company refuses to offer the drug in India, they simply acquire the drug, reverse engineer it, and compulsory license it to a local Indian company. How do we stop that?

Ms. REA. I can tell you that reverse-engineering some of these very sophisticated anti-cancer or chemotherapy drugs is actually exceedingly complex. If it was a small molecule or something that someone took orally, those can be more easily reverse-engineered and identified.

For the country of India to gear up and to make some of these very sophisticated biotech molecules, it takes really quite a long time.

Mr. GOODLATTE. But they've done it in this instance?

Ms. REA. That's what I understand. But perhaps they started a bit earlier than I would've anticipated, but it takes a very long time for them to gear up and do that.

From the USPTO perspective, education, IP awareness, teaming with them, constantly being there on the ground, is perhaps the best weapon that we have. Because we think that, in the long term, they do indeed want to be a good player in the international community. And so I think education and our efforts out front in trying to stop this in the future——

Mr. GOODLATTE. Let me ask you another question before my time expires.

As opposed to criminal activity, these international patent and trade secret problems in the civil law space seem to be driven directly by foreign governments to benefit their domestic industries. And it seems like they've been getting a free pass as they devalue the patented innovations of American companies. If there was one thing that we could do immediately to improve this global situation, what would it be?

Ms. REA. I think get a little bit more on track, both procedurally and substantively, with patent harmonization issues.

As you know, because of your great efforts——

Mr. GOODLATTE. And I would think that making the compulsory license issue a part of those international intellectual property negotiations would be critical part of that.

In other words, I understand why countries want to have a compulsory license. If they have a life-saving drug and a company chooses not to sell it in a particular market, they're going to use their compulsory license.

On the other hand, if they're going to make it unattractive to sell the drug in the market by forcing the company to manufacture it locally or by mandating price controls that are unfair—and unfair, by the way, to U.S. consumers, who wind up subsidizing the cost of developing the drug at the same time that the country that compulsory licenses it gets to not only do that, but also sell it at a lower price, again, unfair to U.S. consumers.

So, to me, this needs to be front and center a priority issue. It's not new to the current Administration. It's been a problem for quite awhile now. That needs to be injected into that process, and I hope very aggressively.

Ms. REA. We do. I, personally, have engaged in discussions with various agencies of the Indian Government on this issue. And it continues to be part of the ongoing effort within the U.S. Patent

and Trademark Office with our external affairs division, which sort of oversees our IP attachés.

So this is front and center, and we are consistent in trying to stop those efforts and in trying to stop the granting of further compulsory licenses.

Mr. GOODLATTE. Can a WTO case be brought on this dispute with India if the appeal does not succeed?

Ms. REA. That is actually an appropriate question. Since I work with a different agency, based on my limited knowledge, I think that that would be one of the tools in our toolkit that perhaps should be considered.

Mr. GOODLATTE. Thank you very much.

The gentleman from North Carolina, Mr. Watt, is recognized.

Mr. WATT. Thank you, Mr. Chairman.

And I'm happy to see that the Chairman is coming to our position that a number of issues need to be included in discussions in these trade agreements. Not only does not negotiating about compulsory licenses have an adverse impact on businesses, but not negotiating about labor conditions and employment conditions in those countries have an adverse impact on our workers.

So we seem to be coming closer together on some of these issues. And I'm happy to see that.

Mr. GOODLATTE. If the gentleman would yield?

Mr. WATT. Yes, sir.

Mr. GOODLATTE. I'd say that the former is true, but not the latter, I think the compulsory license used in conjunction with other issues directly related to trade.

But I certainly appreciate the gentleman——

Mr. WATT. And employment conditions is directly related to trade, I would assure the gentleman.

But, you know, I thought that we were getting closer together, but maybe I misread what the Chairman was saying.

But there are some interesting challenges in negotiating, formally or informally, respect for intellectual property in developing countries.

And, Ms. Rea, maybe you could tell us or just list some of those challenges that the United States encounters in these negotiations.

Ms. REA. Culturally, a lot of countries come from a different perspective from what we do. They have different legal systems. They have different issues that they're struggling with.

One thing that we all have in common is we all have the need for vibrant economies, and we all have the need for jobs. So when we discuss with people, even with individuals from other countries, even on intellectual property issues, we try and establish things as if they're a global playing field and that we all have the very same interests and concerns.

Some countries have not had an intellectual property system or a patent system in place for very long, so they're getting familiar with how things are working. Their judiciary sometimes needs to be brought up to speed.

So with our educational efforts through that Global Intellectual Property Academy of ours, we actually also train judges from various countries. Director Kappos, about 3 or 4 weeks ago, attended a program in Beijing that brought together, I believe it was eight

of the judges from our Court of Appeals for the Federal Circuit, which we think of as our own patent court. And he brought together individuals from the supreme court of China. There were over 1,000 attendees, and they were able to observe the interaction between the judiciary in contrasting things in the context of IP.

So I think that getting everyone, when we sit down at these negotiations, down to actually making positive progress, we've got to realize what our differences are, try and develop more similarities, and then negotiations get a little bit more efficient.

Mr. WATT. I thank you for that response. And that leads me actually to a second question that I had, because some people have raised questions about whether our officials should be talking to the whole range of players in these discussions.

I presume that Director Kappos met with stakeholders in the tech and pharmaceutical industries to discuss the impact of various proposals on these sectors domestically and internationally during the America Invents Act. Is that the case, that you're aware of?

Ms. REA. Most of our interaction that I'm aware of occurred after the America Invents Act actually went into place.

We do reach out to our stakeholders. We do have ongoing discussions, but it's important for them to align us with their industries to make sure that, for instance, our implementing legislation for the America Invents Act, that we are on target and that it is going to work as intended.

So having discussions with stakeholders—whether they're small, medium, large corporations; whether they're universities; whether they're the independent inventor community—it is essential that we speak to our constituencies so we do not remain out of touch.

So we do have discussions. I wouldn't say they're ongoing discussions. But from time-to-time, we do discuss with them.

Whenever we publish something in the Federal Register, we have a Notice of Proposed Rulemaking, we do get a vibrant variety of responses from small, medium, large businesses; universities; and independent inventors.

Mr. WATT. All right, thank you.

I see my time has expired, Mr. Chairman. I yield back.

Mr. GOODLATTE. I thank the gentleman.

The Chair is now pleased to recognize the gentleman from Arizona, Mr. Quayle, the Vice Chairwman of the Subcommittee.

Mr. QUAYLE. Thank you, Mr. Chairman.

Thank you, Ms. Rea, for being here today.

China has indicated that they plan to increase the amount that they spend on R&D to about 2.5 percent of their GDP and double the number of patents that they grant by 2015. And they'll expect that their patents will be enforced around the world, yet they fail to protect the patents of U.S. researchers that they have spent years developing.

To what extent do you think it is a problem for the U.S. and global economy if countries like China don't reciprocate in protecting our IP and the jobs, exports, and other contributions they create?

Ms. REA. Thank you. That's a good question.

I actually am pleased that China is going to spend that much effort in innovating, because I think getting everybody to innovate is exactly what we want to do.

And you're correct that, in the coming years ahead, there will be a surge of patents that will go through every country of the world, including the United States.

Now enforcement of those patents is indeed critical. And seeing how their legal system handles them, it has to be done correctly.

Right now, China's legal system, with respect to IP, doesn't yet have the years of experience that our country has had, because patents and copyrights were the foundation of this country. So we have a lot more experience in how to handle them.

I can tell you from personal on-the-ground experience, I met with stakeholders in three different cities in China in 2011, and I got to hear the on-the-ground frustrations and difficulties that companies were having in China. And the judicial system was frequently mentioned.

I must tell you that within certain courts, in certain areas of China, there are some what I consider best practices. And so what we're trying to do is to identify where there's a best practice, where is the introduction of evidence, for instance, being done in what we consider to be a fair and proper manner, and to get those best practices and to piecemeal come up with the best way for the judiciary to handle these enforcement issues.

I think that Chief Judge Rader of the Court of Appeals for the Federal Circuit, the program that he had in Beijing last month, getting judges together to talk about common issues and how IP should be handled, and for the judges to understand how our judges think about IP and how they approach it, helps.

Mr. QUAYLE. But one of the things that I'm just worried about is that, as they continue to grow and expand the number of patents that they provide, and there's no reciprocity with the patents that our inventors and our innovators are developing, the danger that it poses to people and companies here in the United States, when they have patents that are violated on a regular basis by China, and if they're increasing the number of patents, how are we going to be able to best protect our own IP from the United States in China, whether they're going through the patent process there and violating a patent that is already in place in the United States?

Ms. REA. Just as China is new and has put an increased emphasis on innovation, China's patent office—it's called SIPO—is also undergoing dramatic change with how they're handling patent applications. And we have one-on-one discussions—I have one-on-one discussions with individuals in the Chinese intellectual property office, talking about the patent procedure and any frustrations that U.S. innovators have felt.

I can also tell you, on the judicial side, their courts are dramatically changing. So with our on-the-ground attachés, our constant communication with our counterparts in China, the increase in innovation, the increased number of Chinese patents will change their system to the benefit of not just U.S. innovators but also Chinese innovators.

Mr. QUAYLE. Okay.

Ms. REA. Because much to your surprise, you're probably going to find that Chinese innovators themselves do occasionally have frustrations with their legal system, and so that this is a common problem. And I think that we are in a dramatic place of change right now.

Mr. QUAYLE. Okay, thank you.

Now the Administration is currently negotiating a wide-range trade agreement with 10 other countries in the Asia Pacific known as the Trans-Pacific Partnership. This agreement will serve as a docking station for other countries to join in the future, including possibly China.

To that point, just last week, Canada and Mexico were invited to join.

Given the scale of this agreement, it is critical that we propose and secure IP protections that reflect U.S. law. With respect to pharmaceutical IP protections, is the Administration doing everything it can to ensure the strongest protections, including 12 years of data protection for biologics?

Ms. REA. We are. We are doing exactly that right now. We view that the Trans-Pacific Partnership provides a good venue to make sure that we get appropriate data protection, and that that 12 years of data exclusivity is something that we are definitely trying to negotiate for right now.

I understand that the TPP will be meeting in San Diego next week. It is indeed one of their issues.

Now, I don't know if that specific issue is on their agenda for next week, because there are many issues that are being gone through with the TPP, the Trans-Pacific Partnership, but it is on their agenda.

We are constantly pushing to make sure that data protection remains as high on their list as possible.

We don't just use TPP as the venue. We approach data protection from a wide variety of directions to make sure we have a consistent story, and everybody understands our position and the needs of U.S. innovators.

Mr. QUAYLE. Okay, great. Thank you.

Thank you, Mr. Chairman. I yield back.

Mr. GOODLATTE. I thank the gentleman.

The gentleman from California, Mr. Berman, is recognized for 5 minutes.

Mr. BERMAN. Well, thank you very much, Mr. Chairman.

And I take it, Ms. Rea, from your answer to the Ranking Member's questions, that, in fact, you and other PTO officials meet regularly with high-tech companies that hold patents and trademarks and otherwise utilize PTO services. And that these meetings not only occur in PTO offices in Virginia, but at the headquarters of these companies. I think that makes sense. I think that's the smart and the right thing to do.

And just to add to this, if you could just quickly tell me whether you think you could do the job, and the office could do the job it has to do, without such meetings?

Ms. REA. We need input from the user and shareholder and innovator community. And in order to best serve the American public,

we have to know how business operates and what they need. So communicating with them is critical.

I wouldn't say we talk to them a lot, because we are really busy in the USPTO. But we talk to them when appropriate.

It is actually rare when we actually have the luxury of time to go visit somebody directly. Usually, we try and get groups of people together, if convenient, for very brief meetings. And sometimes it's a spinoff from another meeting.

But I think that to maintain the best system that we can—and right now we are in the midst of an awful lot of rulemaking with the America Invents Act. And in particular, with that new interparties review, post-grant review, where we've issued a U.S. patent that comes back to us, we want to make sure we're designing that as good as possible.

Mr. BERMAN. Great. Let me turn to a different subject.

You mentioned WIPO at the end of your testimony. Actually, in large part, because of my colleague Ms. Lofgren I have been closely following reports that WIPO officials have been transferring computers, firewalls, and other technological devices to the governments of North Korea and Iran.

Needless to say, we find this highly distressing, not only because it potentially violates a slew of U.N. Security Council resolutions, and, very possibly, our country's policies on internet freedom, but also because these technology transfers were carried out by an organization largely funded by U.S. inventors.

What actions is the PTO taking to ensure an independent external investigation into why and how this happened? And has the WIPO director general agreed to requests by the U.S. for such an investigation?

Ms. REA. I have to tell you that the leadership that the U.S. Patent and Trademark Office was disappointed when they got, to say the least, that information.

We are not taking the lead in the investigation right now. There is an active, ongoing investigation. The Department of State is handling that at this time.

From what I understand, Director General Francis Gurry has not yet been fully open as to all of the issues and that more information will likely be forthcoming.

So we are processing and handling all of our clients' PCT applications as usual. The World Intellectual Property Organization is operating in our U.S. innovators' and stakeholders' best interest.

But this issue is something that's particularly distressing to us at the U.S. Patent and Trademark Office. And then, in collaboration with other U.S. Government agencies, we will do and handle it in the way that's appropriate.

Mr. BERMAN. Well, and I certainly think particularly the State Department has to be aggressive in getting to the bottom of this and making sure it doesn't recur.

Thank you. I yield back, Mr. Chairman.

Mr. GOODLATTE. I thank the gentleman.

The gentleman from Pennsylvania, Mr. Marino, is recognized for 5 minutes.

Mr. MARINO. Thank you, Chairman.

Good morning.

Ms. REA. Good morning.

Mr. MARINO. It's a pleasure to talk with you.

You touched on this issue a little bit, but perhaps you can expand on it a little more for me.

China, the most blatant IP thief, along with Russia, has implemented barriers that have a severe negative impact on U.S. trade and patent protections. Can you explain what and how these barriers or compulsory licenses negatively impact our economy?

And equally important, what are we doing to seriously address and counter—other than meetings—what I consider criminal activity on the Chinese part?

Ms. REA. Thank you, Congressman Marino. That's actually a good question.

The U.S. Patent and Trademark Office is collaborating with other U.S. Government agencies to try and minimize or totally remove these biases that occur right now with certain countries.

China is just a very large country undergoing a great deal of change right now, so it is truly taking a lot of our resources in external affairs right now.

What we're doing is we're collaborating with other U.S. Government agencies. Having our IP attachés on the ground in seven different countries has been actually—or six different countries—has been very efficient. And we're able to talk one-on-one having boots on the ground to try and move things along.

I do think that there has been positive movement and that communicating and having discussions works. And our training and education programs are also very good.

Participating and making sure the right language is in these international trade agreements is also something that's first and foremost.

Mr. MARINO. May I stop you there, please.

Are we collaborating with any other countries in conjunction?

Ms. REA. Well, that's actually a good question, because we do collaborate with other countries in what I consider the most productive sense—is that the five biggest patent offices in the world, where I believe 74 percent of all patent applications are filed, is the USPTO, the European Patent Office, Japan, Korea, and China.

And these five patent offices, we all get together and we talk about practices, problems, issues. It's existed for 5 years so far. And we are making what I consider to be significant progress.

Mr. MARINO. One of my areas of study is China, in general. I've been studying China for 20 years. And China reminds me a little bit like my 8-year-old, who, when dad says, "Don't do this." He says, "Okay, dad, I won't," and then continues to do it.

Is China taking us seriously? And are we doing anything to, I guess for a lack of a better term, threaten China to the extent that we're going to have a negative impact on your trade with the United States?

Ms. REA. I do think China does take us seriously. They have modified some things, how they're handled, and what their behavior is.

I think China is trying to be a proper global player right now. So I do think that we are in the middle of a lot of change right

now with China. I hope that they continue in this positive direction.

And so, actually, communicating with them has been effective so far.

Mr. MARINO. Thank you, Madam Secretary. Good answers.

And I yield back my time.

Ms. REA. Thank you so much.

Mr. GOODLATTE. I thank the gentleman.

The gentlewoman from California, Ms. Lofgren, is recognized for 5 minutes.

Ms. LOFGREN. Thank you, Mr. Chairman.

And before asking my questions, since I represent Silicon Valley, it would not be right for me to address anybody from the PTO without saying: How's it going on the selection of our next patent office?

Ms. REA. We are actively working on the identification of our additional satellite offices.

Ms. LOFGREN. As you know, a quarter of all the patents in the country come from Silicon Valley.

Ms. REA. And they have great weather.

Ms. LOFGREN. They do have. It's 71 degrees in San Jose today.

I just wanted to, first, thank you for being here, and express a couple of concerns and then really get into a question.

We've seen ACTA kind of explode over in Europe. I don't think it's going to go anywhere. And I think one of the reasons why is the perceived lack of transparency in the negotiation of that matter. Whether or not that's correct, that's the perception.

And I think the TPP is also being negotiated confidentially. And my belief is that because of the lack of transparency, TPP is quite likely to suffer the same fate as ACTA.

And so here's the question: We have a leaked version of the TPP in May. And it seemed to indicate, if that was accurate, I don't know; I really should sit down in a closed session and find out that the U.S. is really seeking to transport enforcement of our IP laws. But I didn't find the exceptions and safeguard, like fair use, that we enjoy in this country.

So the concern and question is whether, under the treaty, people would have the same freedom as they would in the United States vis-à-vis copyright.

And going to the WIPO issue, and I know that you've taken an important role. And that's proper that the U.S. should play an important role with WIPO. The moral rights issue that has been extended does not appear to have the same kind of fair use exceptions that we find in U.S. Copyright Law. And as you're aware, it's quite common now, especially for young people, to do mashups and other manipulations of other documents that has generally been seen as protected under U.S. law.

So here's the question: In both the TPP as well as the WIPO provisions, are we just exporting enforcement and not rights?

And what can we do to make this a more transparent process? Because to work hard, and I know you do work hard, and have a measure that may have merit in some regards absolutely just blow up because of suspicion is really not a positive thing.

Ms. REA. Okay, thank you.

I can tell you I have not seen the most recent TPP draft, because I do a great deal of reading. But that one didn't make it to the top of my pile.

Ms. LOFGREN. Okay.

Ms. REA. But I can tell you that we do look at rights, as well as enforcement. And as to the transparency issue, I can get back to my colleagues and get back to you on that, because I don't know why things mechanistically or procedurally were handled that way, if it's just tradition or in the past. Maybe we should reconsider or relook at it. I'm not familiar with why it's handled in a certain way. So maybe we can get back to you on that issue.

Ms. LOFGREN. Could we do that? And maybe I could make an appointment with you offline and talk about this issue. I know it's not entirely up to you. It's the trade representative. Maybe we should pull him into this discussion as well, because I think it's a severe concern in the United States and, really, internationally.

Just a final note on the issue raised by Mr. Berman, I want to give him tremendous credit for his position, not only in this Committee, but also Foreign Affairs, for leading up an investigation on the WIPO. I just think it's an outrage. Really, it's an outrage that WIPO would be transferring material, violating the sanctions that we have, to North Korea and Iran.

And this stuff, I mean, basically, it's funded by U.S. inventors. So, yes, you're right. It's the State Department, but I think if American inventors knew that their funding was being used to send firewalls and other material to Iran and to North Korea, they'd be furious. And I'd like to say I'm furious.

So I hope that the PTO will be more vigorous publicly in the concern about this. Certainly, I intend to be. And Mr. Berman has shown tremendous leadership in this.

But I think it's something that merits our loud objection and insistence on correction.

With that, my time is up. And I yield back, Mr. Chairman.

Mr. GOODLATTE. I thank the gentlewoman.

The gentlewoman from Florida, Ms. Adams, is recognized for 5 minutes.

Ms. ADAMS. Thank you, Mr. Chairman. I've been sitting here, and I've heard a lot about a lot of talking, significant progress.

Can you expound on that just a little bit? Like what kind of progress?

Ms. REA. How about if I take it down to a very granular level?

Ms. ADAMS. Okay.

Ms. REA. We have an IP attaché in Guangzhou in southern China. And there was a U.S. rights-holder that had a lot of difficulties with somebody allegedly infringing his patents in China. And there's something that I've never been to, but it's huge and so I'd like to go there someday, it's called the Canton trade fair or trade show. It's like the biggest in the world. Perhaps Congressman Marino is aware of it.

But it's huge. It's supposed to be a giant event.

Ms. ADAMS. Can we kind of——

Ms. REA. An individual at a booth who actually was the culprit who was infringing a U.S. company, our IP attaché from Guangzhou brought the U.S. rights-holder there, along with en-

forcement personnel, and that individual who was doing the infringement was kicked out of the Canton trade show.

So that was one very granular detail on something that we did.

Ms. ADAMS. So he was kicked out?

Ms. REA. Pardon me?

Ms. ADAMS. He was kicked out?

Ms. REA. Yes.

Ms. ADAMS. Any other enforcement action taken on this person or just allowed to leave?

Ms. REA. You know, I don't know about the follow-up.

Ms. ADAMS. Okay.

Ms. REA. I just happened to hear it, because it had just happened when I had been there.

Ms. ADAMS. All right. Well, that's what I'm trying to get to, is what kind of follow-up do we have. And I'd be interested in hearing that.

You know, foreign countries have already used compulsory licensing in the pharmaceutical space, but what about clean energy technologies? Do you know if any foreign governments are raising this as an option instead of paying for environmental technologies?

Ms. REA. Off the top of my head, I'm not aware of anything in the green technology area, but I know that that's a very sensitive area at this time. Perhaps some of my colleagues back at the PTO are working on that. But that has——

Ms. ADAMS. Can you get us the answer to that question?

Ms. REA. Yes. We'll get back to you.

Ms. ADAMS. All countries that have signed onto the TRIPS Agreement have committed to not discriminate against any field of technology when it comes to patenting. What types of restrictions have you seen in some of these foreign markets that go directly against this commitment?

Ms. REA. I think that the compulsory license that was recently granted in India on the anti-cancer drug I think was anti-TRIPS type behavior. Some of the behaviors in patent offices, even with getting patents granted, the requirements, some of that could be considered to be anti-TRIPS, but I'm not certain.

But I think the compulsory license, unfortunately, does not comply with the TRIPS Agreement. That's probably the most egregious that I could think about right now.

Ms. ADAMS. In tying patent rights to domestic manufacture and 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 made a "Made in China" requirement, requiring inventions that have a tangential link—I hate that word—to China to 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 coming up on the horizon?

Ms. REA. I can't think of anything new that I've seen recently. I think that we've just made progress on some well-identified issues. I can't think of anything I've seen recently.

Ms. ADAMS. And progress, can you give us some of that progress? You say you've made progress. What type of progress?

Ms. REA. Actually, if I can digress one moment to our IP attachés on the ground in China. They actually attend court hearings. They actually participate. They actually provide input. I think of it as handholding the U.S. innovator, if they're having difficulty in China.

They will take them to agencies and navigate things. There have been positive outcomes.

I can't name one specifically right now. I can't think of a name of a company, so I do apologize.

Ms. ADAMS. Well, I like the fact that you're giving us some kind of, you know——

Ms. REA. Something tangible.

Ms. ADAMS. Yes.

Ms. REA. Okay.

Ms. ADAMS. Because, you know, we keep talking and talking and talking. What I'd like to hear is what you just said, is that you do have your attachés working with our patent-holders when the infringements happen in the courts in these other countries.

And I yield back.

Ms. REA. Thank you.

Mr. GOODLATTE. I thank the gentlewoman.

The gentlewoman from California, Ms. Waters, is recognized for 5 minutes.

Ms. WATERS. Thank you very much, Mr. Chairman and Members.

A lot of the questions today have centered around the same kind of issues that I am concerned with. The scope of the IP theft in China imposes massive harm on U.S. companies and the U.S. economy. China is not only a worldwide leader in piracy, but it is also a worldwide leader in creating IP-related market barriers for foreign countries.

Losses to IP-intensive industries from IP infringement in China was estimated at about $48 billion in 2009.

And even though, Ms. Rea, you have indicated steps that are being taken, one of the reasons I suppose so many Members of this Committee are concerned about the IP theft is that China's reputation, not only in the IP area but in pharmaceuticals and other areas does not appear to have improved substantially, that we have pharmaceutical products that are still coming out that are fake. And I have been concerned for a long time about baby food that's coming out of China.

So you're in a position where, you know, you're trying to explain the improvements that you're making, but because we hold such suspicion about China in so many other areas, it does not help you in talking about improvement.

And while I appreciate the discussion that you had about having kicked out this particular business from the Canton Trade Fair, that's one instance of what appears to be an effort to clean this piracy up.

I'm really looking for substantial public policy. I'm really, you know, wondering what our trade office is doing. And I'm looking

for, I guess, significant changes or improvements or ways by which we can penalize.

So aside from what you have described, can you think of anything else that would make us feel better about China and this IP theft?

Ms. REA. Congresswoman Waters, China is undergoing so much change right now, that this communication, education, and training that we provide to China I happen to think is invaluable. Right now, they are in the midst of a major change to their copyright law, as well as a major change to their trademark law.

We are constantly providing input and discussing with them at different agencies, different levels, what changes we would like to see. Because especially in the area of counterfeiting, when it comes to trademarks, we want to make sure that the U.S. consumer and the U.S. innovator is adequately protected. I believe in the Trademark Act, they're in their third draft right now. They make substantive changes to their draft trademark law based on input that they have received from the United States and perhaps other countries.

So those communications and talk and change actually are beneficial, because that's the foundation for how they're going to handle things.

In terms of any substantive change, I don't have anything more specific than that at this time. And if we think of something, I will get back to you.

Ms. WATERS. Thank you very much. I yield back.

Mr. GOODLATTE. I thank the gentlewoman.

And I have an additional question, which may prompt an additional question by the Ranking Member or Ms. Waters, if they would like to pursue further questions.

Ms. Rea, the U.S. Government used to have in place a China case referral mechanism process, whereby companies could bring specific issues or cases to the Commerce Department. And after an interagency review, particularly egregious or unique cases would be raised to the Cabinet level for direct engagement with their Chinese counterparts.

Do you think that a case referral mechanism process should be reestablished and possibly expanded beyond just China to include other key countries in Asia and Latin America as well?

Ms. REA. It's hard, Chairman Goodlatte, for me to address that, because we get so many of our stakeholders and so many individuals in our user community already come to the USPTO with what their issues are, and so we are already holding their banner and being their advocate. And we are working with countries such as China with the JCCT, the Joint Commission on Commerce and Trade. And we're going through these issues right now.

I think that perhaps a mechanism such as that would be helpful. I just need a clearer idea of how it would operate, because right now I think that the business community might be frustrated with how business is oftentimes handled in countries such as China.

But I think that we try and balance things out and get our user community, our stakeholders, what they need, so they can get efficient operation of business.

So I'm not familiar with the earlier program that the U.S. Government had. And I can't envision how it would operate. If it goes up to the Cabinet level, they're pretty busy right now.

Mr. GOODLATTE. I have no doubt they're busy. But certainly raising trade issues to the highest level possible would be, certainly, an important undertaking for job creation in the United States.

And I would ask that you take that back and discuss that with Director Kappos. And maybe you could respond or he could respond, either one, to the Committee and let us know whether you think this is something that you could recommend that the Administration take to a higher level.

Ms. REA. We would be pleased to do that. Thank you.

Mr. GOODLATTE. Thank you.

Does the gentleman from North Carolina have any additional questions?

Mr. WATT. No, Mr. Chairman. I appreciate it.

Ms. REA. Thank you.

Mr. GOODLATTE. I thank you.

And, Ms. Rea, this has been a very helpful hearing, and we appreciate your participation today. And we thank you very much for that.

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 her answers may be made a part of the record.

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

And with that, I would like to, again, thank Deputy Director Rea. And this hearing is adjourned.

[Whereupon, at 11:15 a.m., the Subcommittee was adjourned.]

APPENDIX

Material Submitted for the Hearing Record

Prepared Statement of the Biotechnology Industry Organization

Biotechnology Industry Organization

By electronic submission:

Written Testimony of the Biotechnology Industry Organization

Submitted to the

UNITED STATES HOUSE OF REPRESENTATIVES

COMMITTEE ON THE JUDICIARY

SUBCOMMITTEE ON INTELLECTUAL PROPERTY, COMPETITION

AND THE INTERNET

Hearing on: International IP Enforcement: Protecting Patents, Trade Secrets and Market Access

June 28, 2012

The Biotechnology Industry Organization (BIO) is a non-profit organization with a membership of more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 States and a number of foreign countries. BIO's members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. The U.S. life sciences industry, fueled by the strength of the U.S. patent system, supports more than 7.5 million jobs in the United States, and has generated hundreds of drug products, medical diagnostic tests, biotech crops, and other environmentally-beneficial products such as renewable fuels and bio-based plastics. These products are literally helping to feed, fuel and heal the world.

The majority of BIO's members are small companies that currently do not have products on the market. As such, BIO's members rely heavily on the strength and scope of their patents, both domestically and internationally, to generate the investment necessary to sustain their long product development cycle. On average, it takes more than 10 years to develop a biotech medicine or a plant improved through agricultural biotechnology from its inception to regulatory approval and finally to market launch. The average, fully capitalized cost of developing a new medicine has been estimated at $1.2 billion and a new biotechnology derived plant product at approximately $136 million.

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To fully understand what is needed to level the playing field for the biotechnology sector in international markets, one must understand the intellectual property (IP) needs of the biotechnology sector. Biotechnology innovation requires predictable and effective upstream (early stage) and downstream (product) IP protection. Biotechnology innovation generally starts with an early laboratory discovery, and thus upstream protection helps to generate investment and interest in the further, applied research and development of the invention. Upstream protection includes broad patent eligibility for biotech innovations, consistent patent term, flexible licensing practices, and effective patent enforcement.

Downstream protection is just as important. As mentioned above, the research and development of a biological product can take decades and cost more than a billion dollars to complete. A significant portion of this time and money goes towards developing the regulatory data package that is required by the FDA, USDA, or similar foreign regulatory offices to approve the biotech product. Therefore, downstream protection for biotech products must include sufficient protection against foreign and domestic competitors relying on the innovator's data package to secure abbreviated approval of competitive products in such markets.

IP Attaché Program

The U.S. Intellectual Property Rights Attaché Program has had significant success and holds immense promise in helping to enhance IP protection abroad for U.S. interests. This international focus is imperative, given that that more than 60% of U.S. merchandise exports are from IP-intensive industries.[1] IP Attachés located in America's most important trading markets are crucial for the continued vitality of the U.S. economy and to preserve America's global competitive advantage.

For example, BIO has worked with IP Attachés to organize roundtable discussions and other meetings with officials and examiners in foreign patent offices, during which our member company IP experts can educate on biotechnology patenting and can raise general technical or policy challenges in securing sufficient IP protection for biotechnology-related inventions in those countries. Such opportunities are incredibly valuable in fostering greater understanding and awareness amongst both parties.

While the IP Attaché Program has been beneficial to date, several enhancements are necessary for the program to fully achieve its critical mission. First, more resources are needed to hire additional IP Attachés to serve in key export markets around the world. Such

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[1] *Intellectual property and the U.S. Economy: Industries in Focus*. Prepared by the Economics and Statistics Administration and the United States Patent and Trademark Office (2012). Accessed at http://www.uspto.gov/news/publications/IP_Report_March_2012.pdf

an expansion would serve as a powerful signal to these foreign nations that the United States government considers protecting the intellectual property and economic interests of American inventors a major economic priority.

Second, the U.S. government needs to broaden its international IP focus from "enforcement" to include the scope of current and future protection. Put more simply, patent infringement and "knock offs" can become problems only if American inventions are granted patents by these countries in the first instance. Protecting U.S. technology in its early stages will help to ensure that Americans can reap the rewards of their massive investments in research and development. Furthermore, plants and seeds are often denied patent protection by statute in many foreign countries and the Plant Variety Protection laws are often adverse to innovators. There is a critical need for broadening the scope of patent protection in many foreign countries where BIO member products are not patent eligible, to expand U.S. market access and avoid the legal piracy created when products are not patent eligible. The U.S. IP Attachés should be on the front lines advocating with our trading partners that America's current and future economic interests should be more greatly protected.

Finally, the IP Attaché Program would benefit from greater coordination with the United States Patent & Trademark Office's other international IP programs and offices, consistent with this agency's stated mission of "... guiding domestic and international intellectual property policy, and delivering intellectual property information and education worldwide."

BIO thanks the Subcommittee Chairman and Ranking Member for the opportunity to submit this written testimony for the record. BIO urges that this Subcommittee and the United States Congress as a whole continue its efforts to improve IP protection abroad for American innovation, and to encourage greater predictability of patent rights across multiple foreign jurisdictions.

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