UNITED STATES OF AMERICA

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

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SPECIAL 301 REVIEW PUBLIC HEARING

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February 24, 2014
10:00 a.m.

Office of the U.S. Trade Representative
1724 F Street, NW
Washington, D.C. 20508

COMMITTEE MEMBERS:

SUSAN WILSON	Chair, Special 301 Committee, Office of the United States Trade Representative
DAMON DuBORD	U.S. Department of State
WON CHANG	U.S. Department of the Treasury
MATTHEW LAMBERTI	U.S. Department of Justice
OMAR KARAWA	U.S. Department of Agriculture
ANDREA CORNWELL	U.S. Department of Commerce/ International Trade Administration
JoELLEN URBAN	U.S. Department of Commerce/ U.S. Patent and Trademark Office
MAUREEN M. PETTIS	U.S. Department of Labor
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NOTE ON THE TRANSCRIPT: At various points in the transcript the Chair refers to the Committee's intention to provide follow-up questions to parties who testified at the hearing. The Committee subsequently decided not to submit additional questions, but to rely instead on information submitted by interested parties during the post-hearing comment period.

P R O C E E D I N G S

(10:00 a.m.)

CHAIR WILSON: Good morning, everyone. Welcome to the offices of the United States Trade Representative for the 2014 Special 301 Public Hearing. My name is Susan Wilson. I am Director for Intellectual Property and Innovation here at USTR, and I am also the chair, not chairman, chair, just chair of the Special 301 Subcommittee of the Trade Policy Staff Committee. It is the Special 301 Subcommittee, or Committee as I'll refer to it going forward, that actually conducts the Special 301 Annual Review.

As I said, today is Monday, February 24, 2014. The hearing today is scheduled to go until 1:10 p.m. I understand we can't hear. Is that better? Can you hear in the back? No, no hearing in the back. What about this, a little bit better? I love technical difficulties. Okay, raise your hand if you can hear. Can you hear? Okay, all right, good. This is the first time in my life I have needed two microphones, just so everybody

knows. I have three, okay, in stereo. Interpretive dance to come later.

So we will do our best to stay on time. As you can imagine with things like this, things happen, so I'm going to ask for the support and cooperation of my co-panelists and for the presenters today to help us end as near to 1:10 as possible.

As I mentioned, the hearing is taking place at the offices of the United States Trade Representative. Both a transcript and a videotape are being prepared of today's proceedings. Both of those will be available free of charge at USTR.gov within two weeks of today's date.

Before I go any further, I'd like to ask my co-panelists and committee members to introduce themselves, please. And speak up.

MR. DuBORD: I'm Damon DuBord. I'm with Intellectual Property Enforcement Office of the State Department.

MR. LAMBERTI: Good morning, everyone. My name is Matt Lamberti. I'm with the U.S. Department

of Justice.

MS. BLEIMUND: Good morning. My name is Emily Bleimund. I'm in the Office of Global Affairs of the Department of Health and Human Services.

MR. KARAWA: Good morning. My name is Omar Karawa, from the Department of Agriculture.

MS. CORNWELL: Good morning, Andrea Cornwell with the U.S. Department of Commerce.

MS. URBAN: JoEllen Urban with the U.S. Patent and Trademark Office.

MS. PETTIS: Hi, good morning, Maureen Pettis from the Department of Labor, Bureau of International Labor Affairs.

MS. STRONG: Good morning, Maria Strong with the U.S. Copyright Office.

CHAIR WILSON: Great, thank you, everyone. A bit of a logistical note before we begin, it appears that we have reached maximum capacity for fire code purposes and are at risk of being shut down by the D.C. Fire Department -- no, that's an exaggeration. But I would like to invite my U.S.

government colleagues who are not on the panel, panelists you have to stay, to please make room available for our private sector and other guests. So, if you are with the U.S. government, I would like to ask that you please step outside until -- unless and until some of our guests leave the room, please. Thank you. I apologize for that.

So today's hearing, so today you'll hear from interested parties, private sector, civil society, and foreign governments who responded to USTR's January 3, 2014 Special 301 *Federal Register* notice requesting public comments for the Special 301 process this year. All of those public filings are available at regulations.gov, Docket Number USTR-2013-0040.

The purpose of today's hearing is to provide the Committee with additional information that we can use in our deliberations. Those deliberations will lead to the publication of a report to Congress, and that report will be provided to Congress and the public on or about April 30th of this year. This year, we received filings covering

over 90 countries and addressing the usual dozen or so issues.

For the benefit of those who are here today and those who may be watching the video at a later date who are not familiar with the 301 process, I'd like to take a few moments to go into some background.

The Special 301 Report that I mentioned is a result of a congressionally mandated annual review of the state of intellectual property rights protection and enforcement and trading partners around the world. USTR conducts this review pursuant to Section 182 of the Trade Act of 1974, as amended by the Omnibus Trade and Competitiveness Act of 1988 and the Uruguay Round Agreements Act. And if anyone can say that three times really quickly correctly, I will give you a quarter.

The provisions of Section 182 are commonly referred to as the Special 301 provisions of the Trade Act and, hence, the Special 301 Report. Specifically, Section 182 requires USTR, through the Committee, to identify countries that deny adequate

and effective protection of intellectual property rights or deny fair and equitable market access to U.S. persons who rely on intellectual property protection.

The statute requires USTR, through the Committee, to determine which, if any, countries should be identified as priority foreign countries. The acts, policies or practices that are the basis of a country's identification as a Priority Foreign Country can be subject to the procedures set forth in Sections 301 through 308 of the Trade Act.

In addition to the statutory designation PFC, USTR created the Priority Watch List and Watch List categories to assist the Administration in pursuing the goals of the Special 301 Provisions.

The review is conducted each year by a USTR-chaired interagency Special 301 Subcommittee of the Trade Policy Staff Committee. The review is driven by stakeholder contributions and the contributions of Washington-based agencies and our Embassy personnel overseas.

So, if anyone is interested in reading

more about what I have just said or about any trade issues in general, you can visit the USTR website, USTR.gov.

The format of today's hearing will be as follows. Each party has been allotted no more than 10 minutes. We have asked them to spend seven minutes on prepared statements and allow the Committee to ask questions for three. However, as you can imagine, in a setting like this, there has to be some flexibility in there.

I will be watching the clock and will interrupt speakers with different time cues. However, the panel will hold all questions until the presenters conclude their prepared statements.

In some cases, we have prepared questions based on the written submissions that preceded today's hearing. In other cases, we'll be responding to the verbal testimony today.

I would like to note that there is a post-hearing comment period that is available to the people who are testifying today. If you would like to provide additional information in response to

some of our questions, or somehow supplement the answers that you have given, or if you cannot address a particular question today but would like to do so after, you have until 5:00 p.m., on March 7th to file the additional information. I would, however, encourage you to file that information as quickly as possible so that we have an opportunity to review it and follow up in advance of the beginning of our deliberations.

As I said, we are scheduled to go to 1:10. We will have a short break at 11:00 a.m. to allow the transition between the government speakers and our private sector and NGO presenters for the afternoon.

So, without further delay, I would like to recognize the Government of Bulgaria. Thank you for being here today. We look forward to your testimony. Please get us started.

Yes, so the transcriber has requested that each person who sits at the table please identify yourself and spell your name before you begin. Thank you.

DEPUTY MINISTER DIMITROV: Thank you, Madam Chairperson, the Committee. My name is Krassin Dimitrov – K-R-A-S-S-I-N, D-I-M-I-T-R-O-V. And I am a Deputy Minister of Economy and Energy of Republic of Bulgaria. Thank you once again for the opportunity to present my country in front of this hearing.

Bulgaria appreciates the United States' recognition of the positive steps that our country has taken to address the IPR infringement in its domestic market. This is a continuous process, and we invested serious interest in improving respectful legislation and enhance the framework for enforcing judicial adjudication.

The USTR Special 301 for 2013 identifies four areas of U.S. concerns regarding the intellectual property rights infringement for which Bulgaria is on the Watch List in 2013.

The first area of concern is the Internet piracy, which is a global issue and threat to global prosperity. It needs systematic solution through collective coordinated actions of all countries.

Bulgaria will seriously consider joint actions and better IPR protection in this regard.

During 2013, our attention was focused on enhancing control over many online services potentially infringing intellectual property rights, enlarging the number of stakeholders on the Council on Intellectual Property Protection, and improving coordination of activities amongst individual institutions, tightening penalty measures for Internet piracy.

By doing this, we have achieved the following results, identified and sanctioned any infringements of IPR in 2013, registered positive trend of successful operations of organized Cyber Crime Unit under the State Agency for National Security in the fight against cyber crime and software piracy. And, in that regard, we have over 40,000 Bulgarian legal entities which were given warning to discontinue Internet access to websites which provided unlimited access of Internet users to protected music, and identified location among the net website which was cited in the report in

Switzerland, and the administrators of the websites were ordered to immediately stop access to torrent files that were infringing IPR.

Currently, our government further took steps for resolving Internet piracy by proposing new penal codes and increasing of sanctions. We propose new Chapter 9(a), computer crimes, engaging criminal liability for the providers of Internet connectivity in the cases of illegal instigation and supporting the exchange of illegal content via Internet.

The amendments also include changes in the penal procedure code and to facilitate and accelerate investigation of crimes against IPR over the Internet and improve legal procedures in full compliance with the industry requirements for a better and wider scope of application, and stricter sanctions and higher fines.

The second area of concern is bad faith trademark registrations. Here, it is important to know that as regards prevention of false trademark registration in the Bulgarian and other markets for the purpose of subsequent extortion of the true

holder of the trademark, the patent office -- Bulgarian Patent Office is not the competent body that could prevent such a practice. The holders of rights are the persons that should take care for the protection of their rights and follow policies in registration of trademarks on the territories of all countries where they have business interest.

Bad faith trademark claim can be proved only by a court procedure where court order can ask patent office to delete bad faith trademark registration. The country cannot create legislative or other conditions to prevent or eliminate such unfair practices.

The third area of concern is the court case examinations. In the first half of 2013, for which we have contemporaneous statistics, were examined in total 110 cases, of which 85 cases were closed, where 15 cases by conviction and 7 case by agreement. The Supreme Prosecutor's Office of Cassation, in first half of 2013, in regards intellectual property rights protection, convicted 99 persons, of which 5 person for infringement of

copyright and enabling rights and 94 persons for piece infringements of industry or property.

And the last, fourth area of concern, difficulties in enforcing collective rights through administrative or judicial action, no more different from any other debt collection in the country, especially after the global financial economic crisis that resulted in filing of multiple enforcement cases in court system which caused delays in all proceedings.

We attach utmost importance to increase of the capacity of prosecutors, investigating magistrates, and panel judges on proceedings against intellectual property crimes by providing adequate knowledge transfer and best practice exchange programs with U.S. magistrates. It is important that priority's assigned to IPR case proceedings. Bulgaria recognized certain weaknesses in the existing legislation, both procedural and panel, and in this regard, as I said, we have submitted in parliament, on January 31, 2014, the new penal code for public discussion dialogue with business and

consumers.

And my final statement here, members of the hearing Committee, this past year, Bulgaria worked on implementing the specific recommendations of the U.S. government highlighted in the 2013 Special Report. All stakeholders focused their efforts on Internet piracy, bad faith registrations of trademarks, and difficulties with collecting royalties by companies conducting collective management of rights.

During 2013, the Bulgarian government paid special attention to protection of intellectual property rights, copyright and industry property. We feel strongly that increasing the public awareness, changing public attitudes, and stepping up the efforts to enforce the intellectual property protection will enhance the country's international reputation, and will provide the basis for increase of investments, and will help improve Bulgaria's strained relations with the EU member states and the U.S.

We want further to strengthen our growing

political and economic cooperation with the U.S. We appreciate the U.S. continuous support to our efforts for better protection of IPR, and we hope to see Bulgaria taken off from the Watch List. Thank you very much.

CHAIR WILSON: Thank you very much, Deputy Minister. Thank you for joining us today, and thank you for your testimony. Obviously, there is a lot there to be encouraged by. We are particularly encouraged by your willingness to continue the dialogue with us.

In particular, we are interested in exploring the idea of an action plan with Bulgaria going forward to address some of the remaining issues. I know that my colleagues have questions, so why don't I turn it over to them.

MS. STRONG: Thank you. We commend the Bulgarian Ministry of Culture and the Ministry of Interior for the government-led mass software compliance campaign in early 2013. We understand that both ministries sent a joint letter to approximately 20,000 local businesses informing them

of the risks of software piracy and encouraging auditing and compliance programs.

We understand, however, that the planned intensive follow-up by the authorities with enforcement capacity has not yet happened. Would you please let us know if and when the Bulgarian government plans to resume this important campaign by engaging in follow-up activities that were planned for last year?

DEPUTY MINISTER DIMITROV: Thank you very much. In this year, we have four planned sessions of our intergovernmental committee which is chaired by the Minister of Culture. I am a member of that committee. We have enhanced this committee by introducing more regulators from the telecom and TV regulators, from customs office, and etc. And it will happen definitely this year.

And I would like also to state that in terms of software copyrights, our government looks on this area as a priority issue. We have already devoted 20 million leva for innovations, and most of them will go for software development. Currently,

my ministry has about 600 million for financial grants, for development of software applications. And European Union provides access to 88 billion euro francs in this regard.

So the ICT sector is a priority sector for Bulgaria. It is a sector where we have 30 percent growth on an annual basis and zero unemployment rate, and we will make anything to be sure that all copyrights, especially for produce sector, are maintained in the utmost possible way. Thank you.

MR. LAMBERTI: Dobar den.

DEPUTY MINISTER DIMITROV: Dobar den.

MR. LAMBERTI: We understand that during the summer of 2013, just last year, Bulgaria's new government moved the cyber crime unit from the Ministry of Interior's General Directorate to Combat Organized Crime, or GDBOP, to the Independent State Agency for National Security, or DANS, and then transferred the unit's cases to regional police forces.

As far as we can tell, as a result of this move, the cyber crime unit is now inactive. That is

truly unfortunate as the cyber crime unit, under the leadership of Yavor Kolev, was truly a bright spot of IPR enforcement in Bulgaria. In fact, with limited resources and personnel, the unit not only conducted some of the biggest and most successful enforcement operations within Bulgaria, but also the entire region.

We understand that the cyber crime unit may resume its activities this year in early 2014. Could you provide us with an update on whether the cyber crime unit is now active; and, if not, when it will resume its activities?

DEPUTY MINISTER DIMITROV: Thank you for the question. I will start backwards from your last question. Actually, this report that we filed with the USTR for the Special 301 was possible to be submitted by the help of Yavor Kolev and his institution from the cyber crime unit, and we are working closely with him. As I told you, we have now a new intergovernmental committee where we have a lot of institutions involved.

So, in particular, the alleviation and

movement of the General Directorate of Organized Crime to the National Security Agency was promotion of these special units, including in that regard the cyber crime unit, because now it is an independent agency with much more bigger budget and powers, and they can do a lot in order to improve the business environment in regard the IPR.

And, definitely, it will happen this year. Whether it will be the first quarter, next month, I don't know, but we would like to see it happening before the end of April. Thank you.

CHAIR WILSON: Okay. We're out of time, unfortunately, for the Bulgaria segment. We would, however -- we have two or three other questions that we would like to ask, so we will submit those to you in writing, and you'll have two weeks to respond.

So thank you very much for your time today; obviously, very important issues raised, and look forward to continued progress. And we really appreciate your coming today.

DEPUTY MINISTER DIMITROV: Thank you for giving me the floor. Thank you.

CHAIR WILSON: So our next presenter is the Government of Italy. Sir, welcome. May I ask you to please state your name and spell it for the transcriber?

MR. GALANTI: Yes, ladies and gentlemen, my name is Lorenzo Galanti. I am First Counselor at the Embassy of Italy. I am head of the Office for Economic and Scientific Affairs. And it is not without a certain degree of personal satisfaction that I testify here today before this panel in light of recent developments in Italy on IP protection, both on regulation and enforcement.

The Government of Italy welcomes today's public hearing as an opportunity to reaffirm its commitment to a constant and fruitful dialogue on intellectual property with the Government of the United States.

In this respect, let me first mention the visit paid to Italy on May 24th, last year, by Assistant United States Trade Representative for Intellectual Property and Innovation, Mr. Stanford McCoy, to attend the workshop organized by the

Italian Communications Regulatory Authority, during which we met with the Vice Minister of Economic Development, Mr. Carlo Calenda, and the then Deputy Director General for Global Affairs in the Italian Ministry of Foreign Affairs, Carlo Spunetti. The event was an opportunity to exchange views on the main intellectual property topics of mutual interest, including Italy's position in the Watch List, in the framework of USTR Special 301 Report.

I also wish to recall the visit of Italy's Vice Minister of Foreign Affairs, Marta Dassù, to Washington on April 10th, last year, and her meeting with the Deputy U.S. Trade Representative, Ambassador Miriam Sapiro, an opportunity again to discuss the expected approval on the anti-piracy regulation in Italy. This regulation was eventually adopted.

On December 12, 2013, the Italian Communications Regulatory Authority, also known by its acronym AGCOM, approved the regulations on the protection of copyright on electronic communication networks. It will enter into force on March 31st

this year. With this crucial progress, Italy becomes one of the most active countries in the global fight against multimedia piracy, while ensuring adequate procedural guarantees at the same time.

The submission on IPR issues provided by the Italian government for the Special 301 Review includes a detailed description of the five chapters composing the new regulation. So, today I would just like to underscore that the aim of the regulation is twofold. On one hand, it promotes the legal supply of digital works, as well as encouraging and supporting users' education in this respect. On the other hand, it regulates the procedures applicable to cases of violations of copyright and related rights.

And, indeed, part of the regulation focuses on educational activities for the benefit of users, encourages the legal fruition of online contents, fosters the development of innovative and competitive commercial offers, and establishes a multi-stakeholder committee for the development and

the protection of the legal offer of digital works.

Its members represent consumers, authors, artists, producers, audiovisual media service providers, and Internet service providers, as well as Italian institutions in charge of copyright protection in its various declinations.

Before continuing on with my presentation on the procedural part of the regulation, I would like to underline an essential element; that is, notice and takedown self-regulation procedures already adopted by the main websites operating in Italy, such as YouTube, remain valid.

As mentioned earlier, the regulation also provides for enforcement procedures for online copyright violation and copyright violations concerning audiovisual and media or radio services.

The relevant proceedings are initiated by the right holders. Subsequently, all interested parties, such as ISPs, uploaders, page or site owners, are invited to participate and present relevant documentation.

Where an infringement of the copyright law

in the online environment is a certain, the Italian Communications Regulatory Authority is entitled to adopt different measures depending on the location of the server hosting the content. In other words, if the server is located in Italy, the Regulatory Authority may order the host provider to remove the digital work from the website; whereas if the server is located outside Italy, it may order access providers in Italy to disable the access to the website disseminating illegal content. It should be noted that the selective removal of the illegal content in the second case is not feasible because it would imply deep packet inspections which would be against EU law.

With specific regard to audiovisual media service providers, on demand, providers may be ordered to remove illegal content from their catalogues, and linear service providers may be ordered to refrain from retransmitting illegal works in their future schedules.

In cases of noncompliance with the orders, the Italian Regulatory Authority is entitled to

impose a fine from euro 10,000 up to euro 250,000, pursuant to Article 1 of Law 249 of 1997.

Procedures are in Internet time, a maximum of 35 days and a special 12 days fast track for serious cases of piracy. Obviously, the procedures introduced by the regulation will coexist with the judicial protection of copyright. However, should the applicant approach the judiciary during the course of a proceeding before the Regulatory Authority for the same case and should the case involve the same parties, the Regulatory Authority will dismiss the case and transmit the documents to the competent court. On the contrary, the administrative proceedings before the Regulatory Authority would continue regularly if the judiciary is approached by another subject.

Finally, it should be noted that peer-to-peer programs aimed at the direct file-sharing activity and end users remain outside the scope of the regulations but are covered by civil and criminal laws.

On enforcement, let me briefly refer to

activities carried out by Italy's Fiscal Police, Guardia di Finanza, last year. Our Fiscal Police increased its focus on online copyright enforcement in 2013 and succeeded in closing 84 platforms of online marketing, distributing, and broadcasting of copyright-protected contents. This data reveals that those pertaining to the previous year have doubled.

Concerning software problems -- programs, illegal copies for profit purposes, Italy's Supreme Court has repeatedly affirmed that companies copying a software program to use in their computers commit a crime. Therefore, a person who illegally copies or stores, for commercial or entrepreneurial purposes, programs for computers to make a profit commits a crime, as provided for in Article 171 of Law, April 22, 1941, Number 633.

As far as counterfeiting is concerned, the Supreme Court Criminal Chamber affirmed the principle that the concept of illegal copy includes not only the unauthorized creation of perfect copies of a software program, but also the creation of

software programs deriving from the development or changes in the original product when the copy concerns a part of the program which functionally affirms and constitutes the core of protected work.

Let me also inform you that the Italian Ministry of Foreign Affairs hosted a one-day workshop titled "Intellectual Property: a Strategic Factor for Economic Development in the Global Market" on January 27, 2014, a high profile event. And the topic of the IP issues addressed provided evidence of Italy's increasing commitment to intellectual property rights protection.

About 200 policymakers, representative of national and local institutions, members of the academic community, associations, businesses, and media, as well as foreign diplomats, participated, providing an opportunity to increase awareness on the economic aspects of intellectual property rights from an international perspective.

In particular, the key role of creativity and innovation for companies operating in a globalized market in the year of knowledge economy

was highlighted during the meeting.

CHAIR WILSON: We're at the eight-minute mark.

MR. GALANTI: Okay.

CHAIR WILSON: You're welcome to continue. We have one question for you, so please continue.

MR. GALANTI: All right, so I'll cut short on this event, which was indeed an important awareness-raising event. The Minister of Foreign Affairs participated, as well as the Minister for Economic Development, who offered his concluding remarks.

Finally, let me conclude by adding that Italy expects that its position be thoroughly assessed in light of the detailed submission from the Italian government provided within the 2014 Special 301 Annual Review process, as well as the additional pieces of information provided during this public hearing.

Based on all that, it is our assessment that Italy should be removed from the Watch List as an outcome of the current review. We look forward

to continuing this dialogue with the U.S. authorities and all stakeholders in the future. Thank you.

CHAIR WILSON: Thank you very much. Do we have a copy of your submission?

MR. GALANTI: Yes. There are copies outside. I have one more and I can --

CHAIR WILSON: Okay. I apologize that the format here doesn't allow for a full discussion of all of the issues.

MR. GALANTI: That's perfectly fine.

CHAIR WILSON: One, congratulations on the adoption of the long-waited AGCOM regulations and thank you for your detailed description --

MR. GALANTI: Thank you very much.

CHAIR WILSON: -- of those. We'll certainly read your testimony, as well as everything else that Italy has submitted and perhaps even follow up with a meeting during the course of the deliberations.

We had one question which I will just ask very briefly. We are interested in knowing the

regulations take effect March 31st.

MR. GALANTI: Correct.

CHAIR WILSON: How soon after do you anticipate receiving complaints and being able to act on complaints under the new regulatory procedures?

MR. GALANTI: I guess pretty soon, if not immediately, because there have been several public consultations about this regulation. So, the public and the stakeholders are aware of the content of the new regulation, and I guess they are prepared to make the best use of it.

CHAIR WILSON: Okay, that's excellent news. And one last question: So you have reached out to stakeholders? We've had situations elsewhere where new regulations are set up, but the right holders aren't familiar with the regulations and don't use them properly, and so a dialogue between those who want to use the regulations and those who are administering them is very important. Do you have plans for that?

MR. GALANTI: Well, the regulation itself

has been crafted in collaboration with stakeholders, in fact. And, like I said, the public consultation has taken place extensively, so the regulation has been discussed with stakeholders. Of course, it will be, at its entry into force, I assume that there will be even more publicity so that all the right holders, who are those who will activate the procedure, will be aware that they have this new tool to make sure that their right is protected.

CHAIR WILSON: Thank you very much. Thank you for joining us today.

MR. GALANTI: Thank you.

CHAIR WILSON: And we'll certainly follow up during the course of the review. Thank you.

MR. GALANTI: Looking forward to it. Thank you.

CHAIR WILSON: Next, I'd like to invite the Government of Paraguay. Welcome. Thank you for joining us today. Thank you for making the trip from your capital. Please introduce yourself and spell your name for the transcriber.

MR. FERREIRA: Good morning, Mrs. Wilson.

Good morning, members of the Committee. My name is Octavio Ferreira. I am Director of Multilateral Economic Organization of the Ministry of Foreign Affairs of Paraguay.

MS. HASHIMOTO: Good morning, everyone -- I'm sorry, good morning, everyone. My name is Kuni Hashimoto. I am from the Embassy of Paraguay.

COURT REPORTER: And the spelling of your name?

MS. HASHIMOTO: K-u-n-i. The last name is H-a-s-h-i-m-o-t-o.

CHAIR WILSON: Thank you.

MS. HASHIMOTO: You're welcome.

MR. FERREIRA: In the past 12 months, the Republic of Paraguay has followed a path of significant progress in the defense and promotion of intellectual property rights. Last year, Paraguay participated for the first time in these important public hearings by a representative from our embassy. Now, for the first time, we are present with an official coming from our capital. These, along with the action that I will summarize in a

moment, are clear demonstration that the Government of Paraguay is committed to step forward in the protection of intellectual property rights and extend its bilateral relation with the Government of the United States.

Despite this improvement, we recognize that much remains to be done. At the same time, we recognize that the resources we have for this important challenge are very limited. And in this regard, the cooperation in all sorts of forums of foreign government and international specialized agency will be essential to achieve the objective set.

In order to comply with the schedule, I will present a brief summary of the main actions taking place in my country. In 2013, the Law 4798 of 2012 that create the National Intellectual Property Directorate, DINAPI, were regulated by presidential decree Number 460. This regulation create the organizational structure, and give the DINAPI financial independence by assigning its own budget from January 2014.

In November 2013, DINAPI launched a project that will help develop the national strategic plan on intellectual property with the support of WIPO. This will improve the national policy in all the areas regarding the protection and promotion of intellectual property.

Also, in its first few months of existence, DINAPI has signed agreement with institutions that facilitate its role in the protection of intellectual property and now is working with other institutions to create a network of research and development in the field of intellectual property. DINAPI is also working on a project for the legalization of software in both public and private sectors.

This office has also improved administrative procedures and register for the first time in 10 years a pharmaceutical patent. They awarded in 2013 more than 70,000 titles of grant, of which nearly 7,000 were awarded only in the last quarter. That demonstrates that efficiency has been growing.

The General Directorate of Enforcement has conducted in the last quarter of 2013, 100 percent of the verification procedures of allegedly infringing goods. Between September and December, 24 verification procedures and seizure of counterfeited goods were made. The procedures were performed in public and private ports and airports in Ciudad del Este and Asunción, and in the ports of San Antonio, Lambaré, and Puerto Falcón.

Each time that allegedly counterfeited products were found, the complaint was addressed to the prosecutor, and the products were sent to fiscal warehouses. DINAPI, along with the National Directorate of Customs, has conducted verification of a cargo plane from China in the Guarani Airport close to Ciudad del Este, and that verification was the first joint presentation of the Attorney General, the National Directorate of Customs, and DINAPI.

The procedure was covered by Article 37 of the Criminal Procedure Code, which established the jurisdiction of the capital, Asunción, for offenses

produced abroad that take effect in the territory of Paraguay, declaring competent court specializing in intellectual property and referring the case to that court. And all goods seized are in the public ministry warehouse located in Asunción.

One hundred percent of last year's piracy procedures were performed in the last quarter of the year, and something similar happened with the National Directorate of Customs where 22 out of 28 procedures were performed in the last quarter, coinciding with the change of government and the appointment of new national directors.

The district attorney's office reported that his unit in Asunción performed, in 2013, 58 procedures of seizure of counterfeited goods and 12 procedures of destruction. It also reported that there are currently 46 investigations in course, 21 of which include a DA indictment and 4 sentences in case of IP violation. The district attorney's unit in Ciudad del Este reported that they have currently 140 cases under investigation, all of which received an indictment and one sentence.

Interlocutory injunctions issued by the Supreme Court in criminal cases are brought before the specialized intellectual property court, highlighting the 34 alternative and 33 destruction of goods made under judicial review.

Performing the summation of the product seized in Paraguay in 2013, its market value is estimated at approximately $180 million U.S. In August 2013 was enacted the Law 4989 that created the National Secretariat of Information Technology and Communication, SENATICs, under the executive branch. This act provides for the first time the general framework for the formulation of the public policy in this sector.

The creation of SENATICs allows achievable plans and promoting good practice in the management of IPR. One of the purposes of this department is to monitor the public procurement system and all that relates to the incorporation of technology in public institutions. It must also advise in procurement of equipment, systems, and softwares. SENATICs has signed an agreement with the National

Directorate of Public Procurement to standardize procurement of computer programs by public institution.

Finally, I wish to inform that on March 11th and 12th, we will resume the negotiation on the Memorandum of Understanding between Paraguay and the United States on IPR. On that occasion, the new National Director of Intellectual Property will be part of our delegation. Thank you very much.

CHAIR WILSON: Thank you. Obviously, we are very encouraged to hear about these positive developments, in particular the establishment of DINAPI, as well as President Cartes' recent public statements about Ciudad del Este and his administration's goal of transforming the city into a legitimate business hub. And, also, thank you for your interest in renewing the discussions on the renewal of the bilateral MOU. We very much look forward to that process beginning in March.

I believe we have two minutes? One minute? So I think we have time for one question. We have some additional questions, but we'll provide

those to you in writing after the hearing. So one question, I believe, PTO, you have --

MS. URBAN: In last year's Special 301 identification, we noted the issue of protection against unfair commercial use of test data for agricultural chemicals and pharmaceuticals. I was just wondering if you had any update on that issue that you could provide with us.

Oh, sorry. Last year, we identified the issue of unfair commercial use, protection from unfair commercial use for agricultural chemical data and pharmaceutical test data. And we were wondering if you had any update on that issue for us?

MR. FERREIRA: That is related to the year that products are protected or that use the --

MS. URBAN: Protection for the data, for a certain period of time.

MR. FERREIRA: Yes. We don't have much information about that, but with the new administration, with the new National Directorate of Intellectual Property, we are revising all the measures in this area. And some of the improvements

are in this report, and some other we can give you later. So this specific issue, I'll take note and I give you that.

MS. URBAN: Thank you.

MR. FERREIRA: Sorry. Thank you.

CHAIR WILSON: That's great. Okay, thank you so much for joining us today, and we'll follow up after the hearing. Thank you.

And now I'd like to invite the Government of the Philippines to the table, please.

UNIDENTIFIED SPEAKER: I apologize for interrupting, but --

CHAIR WILSON: [LOUDSPEAKER ADJUSTMENT] -- We're taking a pause for those of you watching on videotape to move the [loud]speaker forward.

(Off the record.)

(On the record.)

CHAIR WILSON: …Okay, without further ado, welcome to the Government of the Philippines. Sir, please introduce yourself, Mr. Ambassador, and I will provide the spelling of the Ambassador's name. Thank you.

(Pause.)

AMBASSADOR CUISIA: Ms. Susan Wilson, Chair of the Special 301 Committee, and distinguished members of this Committee, I am Jose Cuisia, Jr., Ambassador of the Philippines to the United States of America, and I am with our Commercial Counselor, Ms. Maria Alvero, or called Mimi for short.

On behalf of the Government of the Philippines, may I express my appreciation for the opportunity to appear before this Committee and to convey the Philippines' request to be removed from the Watch List of the 2014 Special 301 Report. The endeavor to earn a way out of the Watch List has been a long one, beginning from the time the Philippines succeeded in getting itself removed from the Priority Watch List in 2005.

It required responding to the concerns raised by stakeholders and the evolving challenges in IPR enforcement, and took the specific form of resolutely working for the passage of necessary legislations, establishment of institutional

infrastructures, and the intensification of enforcement operations to create an IP regime that, in fact, provides adequate and effective protection of intellectual property rights.

These efforts have not gone unrecognized by the world, but not yet by the United States, I regret to say. The Philippines is recognized by the Association of Southeast Asian Nations as a champion on IPR enforcement among the members of ASEAN. European IP enforcement experts have also recognized the progress and development of the IPR regime in the Philippines. No less than Director General of the World Intellectual Property Office has cited the IP office in the Philippines to be one of the model offices in the region for being extremely dynamic.

Finally, the 2013 Intellectual Property Rights Index, or IPRI, released by the Property Rights Alliance ranked the Philippines Number 2 out of 18 in patent protection in the Asia and Oceana region, and Number 25 out of 130 in the world.

The crux of the case for the removal of the Philippines from the Watch List may be simply

stated. The Philippines has substantially addressed all the U.S. concerns raised in the Special 301 Report of 2013.

These concerns expressed in the form of actions that they called for are the following: (1) adoption of implementing regulations that will further strengthen and clarify Republic Act 10372, which amends and updates the Philippines copyright law; (2) taking important steps to address piracy over the Internet, in particular with respect to notorious online markets; (3) strengthening criminal enforcement of IPR; improving predictability with respect to search and seizure orders; (5) amendments to the patent law that limit the patentability of certain chemical forms, unless the applicant demonstrates increased efficacy; and (6) protection against unfair commercial use and unauthorized disclosure of undisclosed test or other data generated to obtaining marketing approval for pharmaceutical and agricultural chemical products.

All of these actions have been taken. Our submission details the actions taken and identify

which measures addressed which concern.

Allow me to highlight the efforts taken by the Philippines to the Intellectual Property Office and the National Committee on Intellectual Property Rights in addressing the concerns of the U.S. government over the protection of IPR in general and in addressing the specific concerns as laid down in the 2013 Special 301 Report.

In February 2013, Republic Act 10372, which amended and updated the Philippines copyright law, was signed into law. Some of the groundbreaking provisions in the law are the grant of enforcement and visitorial powers for the Intellectual Property Office of the Philippines, or IPOPHL; the introduction of secondary liability in copyright infringement, legal remedies for the circumvention of technology protection measures, or TPMs, and rights management information, or RMI; accreditation of collective management organizations and the creation of the Bureau of Copyright.

In less than a year after its signing, the government implemented, completed all the rules and

regulations necessary for the implementation of this new law. IPOPHL now is now empowered to conduct physical piracy visits to establishments violating IPR, and to conduct investigations relating to online infringements, as well as issue warning or compliance notices to Internet service providers, or ISPs.

The provision and secondary liability reinforces copyright liability by also making liable those who facilitate, induce, or contribute to the commission of copyright infringement under certain conditions.

Recently, the IPOPHL was able to take down one of the notorious Internet sites, Kat.ph or KickassTorrents, by issuing a 72-hour temporary restraining order, TRO, and later on expanding it to 20 days, prompting the owners of the Kat.ph to switch to another domain.

Legal remedies against circumvention of technological protection measures and alteration or removal of rights management information has likewise been incorporated in the new law, in

compliance with the country's obligation under the WIPO Internet Treaties.

As this remains an issue of the USTR, the Philippines will also study and evaluate the need to come up with a legislative measure that will treat mere circumvention of TPM and RMI as a separate offense.

In addition to Republic Act 10372, three more IPR-related laws were signed in 2013. Combined, all these measures help in setting the stage ready for the Philippines to introduce a more holistic approach to IP protection and development.

These are RA 10151, by Cable Television and Cable Internet Act that penalizes the unauthorized access to cable TV and cable Internet.

The second one is RA 10557, or the Philippines Design Competitiveness Act of 2013. That seeks to promote and strengthen the protection for design.

And last but not least is RA 10365, or the amendment to the Anti-Money Laundering Act of 2001, that includes IP code violation as an unlawful

activity or predicate offense in the crime of anti-money laundering offenses.

To complement the legislative reforms, the Philippines established programs and other collaborative efforts with other agencies geared towards a cohesive and holistic approach to IPR protection and enforcement. These programs and collaborative efforts include the following:

Based on IPOPHL's institution arrangement with the Bureau of Internal Revenue, or BIR, the IP violators will now be subjected to tax investigation and filing of possible tax evasion cases. (2) The IPOPHL promulgated in 2012 its examination guidelines for pharmaceutical patent applications involving known substances to guide patent examiners in evaluating patent applications given the provisions of the Universally Accessible Cheaper and Quality Medicines Act. These guidelines clarify standing concerns on patentability.

The Supreme Court promulgated the rules of procedure for IP cases that govern civil and criminal actions for IP violations lodged before the

regional trial courts which are designated as special commercial courts.

IPOPHL regularly conducts training for justices, designated commercial court judges, court personnel, and prosecutors on IP cases. And a Department of Justice investigation of IPR cases has recorded a high disposable rate of 83.67 percent. From 2011 to 2013, IPOPHL already obtained six reported convictions of IP crimes, a good improvement compared to the past years' records, showing that the implemented reforms supplemented with the continuous capacity building seminars for judges and prosecutors, and complemented by the proactive stance of right holders to prosecute IP cases, are working.

IPOPHL established a mediation and arbitration office in 2011 with rules that are consistent with the WIPO arbitration rules and in partnership with the Philippines Dispute Resolution Center, or PDRC. This has made IPOPHL the first country in Asia to provide two mechanisms for alternative dispute resolution, ADR, in mediation

and arbitration. In ADR, IPOPHL has a record of 44 percent success rate for this year.

IPOPHL has made available a warehouse facility which can be used by right holders for free to store seized goods during the pendency of IPR violation cases. IPOPHL sealed an institutional arrangement with the Department of Justice to provide full-time prosecutors for the handling of IPR violation cases, with the optical media board for certain IP IPOPHL personnel to be deputized as OMB agents with the Bureau of Customs to allow the grant of mission orders for IPOPHL to conduct visitorial and inspection powers on imported items in violation of the IP code and the tariff and customs codes of the Philippines.

CHAIR WILSON: Mr. Ambassador, we're at 10 minutes.

AMBASSADOR CUISIA: I'm sorry?

CHAIR WILSON: We're at 10 minutes.

AMBASSADOR CUISIA: Okay, I'll be short then.

CHAIR WILSON: Absolutely.

AMBASSADOR CUISIA: And institute arrangement National Telecommunication Commission to address piracy on the Internet. I have some others which I will not read any more.

All these measures taken in response to concerns stated in the 2013 Special 301 Report, on top of the measures taken earlier in accordance with the suggested focus area, have succeeded in establishing an IP regime in the Philippines, and that may be said to provide adequate and effective protection of intellectual property rights.

We make no claim to perfection, as I am sure you make no demand for perfection. What we claim to have achieved is an IP regime that has demonstrated the capacity to improve and that may reasonably be expected to keep improving in the foreseeable future.

Intellectual property right holders may still have, I'm sure, more concerns that they want to be addressed. Let us together join to assure them that those concerns are more likely to be addressed when the great effort mounted in recent

years by the men and women in many Philippines agencies working together to improve the IP regime in the Philippines is given the recognition that they deserve. Thank you.

CHAIR WILSON: Mr. Ambassador, thank you very much for your comments today. And thank you to the Government of the Philippines for the outstanding efforts that you have undertaken over the past few years, and for all of the successes that you have had. We look forward to continued dialogue with you. Thank you for the invitation --

AMBASSADOR CUISIA: Thank you.

CHAIR WILSON: -- to work with stakeholders. Please know that we will give full and fair consideration to all of the information that you provided and to the status of the Philippines in this year's review.

My colleagues had several questions for you today. We will provide those in writing after the hearing and would very much appreciate answers to those questions. And, of course, we will continue our very collaborative and cooperative

dialogue. So, thank you very much for joining us.

AMBASSADOR CUISIA: Thank you very much, too, Madam Chair. And to all the members of the Committee, thank you.

CHAIR WILSON: Thank you.

And now I would like to invite the Government of Ukraine to take the table, please. Welcome. Thank you for joining us today. Please state and spell your names.

MR. KOVINYA: Thank you for the invitation. My name is Mykola Kovinya, M-y-k-o-l-a K-o-v-i-n-y-a. I am Chairman of the State Intellectual Property Service of Ukraine.

MR. BARAMETSKY: My name is Ihor Barametsky, I-h-o-r B-a-r-a-m-e-t-s-k-y, head of Economic Department of the Embassy of Ukraine.

MR. KOVINYA: As a Priority Foreign Country, I suppose you will have a lot of questions for me and is reason why I go so briefly. The authorized collective management society by the State Intellectual Property Service of Ukraine, it is our first question. According to report of

International Intellectual Property Alliance, it's true that procedure for remaining as an authorized collective management society, which will collect and distribute a royalty for the use of phonograms and videograms published with the commercial proposed was approved by the order of the Ministry of Education and Science, which according to the decision of the higher administrative court of Ukraine from October 17, 2012, it was declared that it is not compliant with illegal acts that take procedure over the order and invalid. In view of revocation of this order, a legal vacuum came up in the sphere of collective management that led to the conflict of interest in relations between authors, performers, producers, other copyrights and related rights subject, and collective management society.

The State Intellectual Property Service of Ukraine tried to resolve this conflict through preparing a new order with different rules. But, in October 16, 2013, the Circuit Administrative Court of City of Kiev made decision to cancel the order as well. A representative of European Union Commission

and Economic Department of the United States Embassy in Ukraine also has been a part of this court procedure.

Of course, the SIPSU filed an appeal against the court decision in January 25th of this year and we hope will cancel this decision. Anyway, with propose of reforming the system of collective management of priority rights, of copyrights, and related rights subjects, provision of illegal activities of collective management societies, as well as improvement of legislative base in sphere of collective management, the SIPSU has developed proposal to the draft law on collective management of property rights, of copyrights, and related rights.

Other acts of the SIPSU follow. We tried to improve our management system in Ukraine through the state organization, Ukraine Agency of Copyright and Related Rights, which is under sphere of the SIPSU's management, and we tried to use as a tool for, to get in order our collective management system.

Just briefly a few words, in 2013, according to statistics, all 15 collective management societies registered in Ukraine collected royalties, about 65 million hryvnia, and state organization collect half of this amount.

And, of course, such acts shows much more effective situation in Ukraine this year and such steps of the SIPSU also showing in the report of Alliance.

Our situation in the copyright and related rights enforcement in Internet, I should tell you that we have fourth edition of this draft law because we tried to find some compromise between rights of, how do you say, rights of copyright society and what we call service providers. Now we are starting fifth edition, which will be published, I hope, in one week.

And about our activities of the state inspectors of intellectual property, during the 2013, our inspectors issued/held 400 inspections and 265 joint inspections with the general prosecutor's office. As a result, we have about 300

administrative offense reports. We have drawn up more than 90, 100 exemplars of counterfeit products, total amount more than two million hryvnias.

According to information from Ministry of Internal Affairs, we have more than 500 criminal cases. Our Ministry of Internal Affairs provide special operation, which give us half of announced criminal cases in this operation. During last year, we closed 25; but in spite of the said activities, some sites are still available since they transferred the servers with illegal content to the hosting platform beyond the Ukraine territory, which is not so good for Ukraine.

And according to our State Judicial Administration of Ukraine, in 2012, 262 persons were convicted for crime, with real terms violation.

Our enforcement of intellectual property rights on the border, our Department of Custom Affairs reports about 2,000 cases during customs clearance, suspensions, and also decision on administrative sanction for goods about 100,000 Ukrainian hryvnias.

Actually, I would like to finalize my speech. I think Ukraine has some progress in IP protection, and I am ready for your questions. Thank you.

CHAIR WILSON: Thank you very much for your testimony. You mentioned both today and in your written testimony the allocation of budget resources for the legitimization of government uses software, and that you have done inspections and you've identified many instances in which there is unlicensed software on government computer systems. Can you please briefly describe for us what your plans are going forward now that you have made these identifications? What are the plans of the government to address this from both a budgetary standpoint and a practical standpoint, please?

MR. KOVINYA: Thank you for your question. The SIPSU has provided the Ministry of Finance of Ukraine with relevant proposal to the amount of 500 million UA hryvnia, which is necessary for legalization in 2014. But although Ukraine has a state budget of Ukraine for 2014, it does not

provide the funds for legalization. These amendments have been in development to the mentioned law in order that ensures the state financing of legalization procedure.

The SIPSU also developments the draft of special acts to optimize information, which is necessary for legalization procedure. I hope in new parliament, after Ukrainian revolution, we will revise our low -- our state budget, and we hope to continue with the legalization procedure with amount at least 250 Ukrainian hryvnias in 2014.

CHAIR WILSON: Thank you very much for your response. We find ourselves at the 10-minute mark. So we did have some additional questions, so we would like to pass those to you in writing after the hearing, and you will have two weeks to respond.

MR. BARAMETSKY: Excuse me?

CHAIR WILSON: Yes, please?

MR. BARAMETSKY: Maybe one small remark? So the IPR enforcement issues was sent, will remain the priority issue for the new government. It will be formed very soon, so probably this week. And,

moreover, it's not only priority for Ukraine as far as this year we are going to sign the association agreement with EU that will include deep and comprehensive trade agreement. It will be additional impetus to enforce and to protect IPR in Ukraine. So we do hope, moreover, assure that Ukraine will do even better progress in this sphere, this year. Thank you.

CHAIR WILSON: Thank you very much for that. We very much look forward to --

MR. KOVINYA: Also, we hope our parliament will be much more active than last year.

CHAIR WILSON: Thank you. And we will definitely be in touch after the hearing. Thank you again for coming today.

So we'll take a 10-minute recess and reconvene promptly at 11:24, well, what is -- yes, 11:24.

(Off the record.)

(On the record at 11:27 a.m.)

CHAIR WILSON: Okay, welcome back from the recess. Can everyone in the back hear me? I

understand there are still volume issues. So-so?

Okay, so I apologize that there aren't enough seats. We've done what we can to get all the seats that are available in the building down here. And I apologize for the sound. I think next year we'll probably take an informal anonymous poll of how many people are interested in coming so that we can have a more accommodating venue.

So, let's go ahead and get started since we're a little bit behind schedule. So, the foreign government testimony is finished, and now we move onto what I call private sector stakeholders, which are non-government stakeholders.

First up, we have the Alliance for Fair Trade in India. So, please introduce yourself and spell your name for the transcription service. Thank you very much and welcome.

MR. POMPER: Thank you. My name is Brian Pomper, B-r-i-a-n P-o-m-p-e-r, and I serve as the Executive Director, the Alliance for Fair Trade with India. So, good morning. And thank you for providing me with an opportunity to testify on

behalf of the Alliance for Fair Trade with India.

AFTI was launched in June 2013, in support of increased action to resolve discriminatory trade practices in India, including the erosion of intellectual property rights. Our diverse membership is made up of organizations representing a range of U.S. industries adversely impacted by India's industrial policies, including manufacturing, agriculture, pharmaceuticals, biotechnology, telecommunications, and beyond.

In light of this mandate, I am here today to call on USTR to designate India a Priority Foreign Country in its annual Special 301 Report. For 25 years, since the inception of the Special 301 process, India has been featured prominently in every one of USTR's annual reports, either as a Priority Watch List country or a Priority Foreign Country.

As I sit here today, after having reviewed the testimony of the other witnesses and more generally having surveyed the landscape of India's IP policies and practices, it is tempting to quote

the great Yogi Berra with regard to India and its discriminatory IP policies; it feels like "déjà vu all over again." But the truth is that, taken as a whole across multiple sectors, India's treatment of IP is now qualitatively worse than it has been in a generation.

India has made extremely limited progress over the last two decades in addressing a range of discriminatory IP policies and practices that deny adequate and effective protection to U.S. companies. In 1991, USTR identified India as a Priority Foreign Country because it provided an inadequate level of patent protection, including too short a term of protection and overly broad compulsory licensing provisions.

As outlined in our recent submission to USTR, India still struggles with these exact issues in a manner that has an adverse impact on U.S. industry. Furthermore, over the last year, the Indian government has engaged in a number of other discriminatory practices, including the revocation of numerous patents held by U.S. entities, the

denial of patent applications, and the marketing approval of generic medicines during a patent's term.

The simple reality is that over the last 12 months, India has reached an inflection point both in terms of the egregiousness of its treatment of IP rights and its work against IP rights in international fora. It is time to send a signal to India and to other countries who may seek to emulate India's IP practices that those practices aren't acceptable. It is time to once again designate India a Priority Foreign Country.

India's compulsory licensing and forced tech transfer policies are of particular concern to AFTI and its membership. In addition to being very likely WTO non-compliant, India's approach to compulsory licensing and the forced transfer of technology is clearly intended as a tool of industrial policy to be used against foreign companies for the benefit of domestic Indian enterprises.

The direct beneficiaries of these policies

are companies and industries in which India has become or aspires to be a global player, including in pharmaceuticals, green technology, telecommunications, and semiconductors.

Copyright infringement has long been problematic in India and remains a point of major concern for AFTI. India has become a haven for the illegal downloading and distribution of movies, music, and books.

Moreover, 14 years after its first mention in the Special 301 Report, India has still failed to implement WTO-compliant regulations to protect confidential test and other data. As an extension of the protection that is required for these data, we believe that USTR should demand the same protections for trade secrets from India that it has from China in past years. This request is in line with the Obama Administration's recently published "Strategy on Mitigating the Theft of U.S. Trade Secrets."

Finally, despite longstanding concerns expressed by the United States and other

governments, India has made very little progress within bilateral and multilateral fora in remedying IP-related issues. Equally as troubling, some of these discriminatory IP practices have begun to be emulated by other developing countries, as India has publicly advocated that they adopt its policies. This is a trend which will continue unless the U.S. government takes appropriate action.

Practices that have long adversely impacted U.S. companies by denying them adequate and effective IP protection have, over the last 12 months, reached unprecedented levels. Actions and statements by the Indian government in the last year with regard to its approach on patent protection, compulsory licensing, and forced tech transfer, in particular, have alarmed U.S. industry and helped give rise to the creation of AFTI.

The Indian government may claim it is acting in the public interest in justifying certain actions and measures. But from the perspective of AFTI members and many U.S. policymakers, the actions seem more clearly motivated to benefit domestic

Indian innovation and industry at the expense of U.S. innovation and U.S. industry.

The annual Special 301 Report provides USTR with a key tool for identifying those countries whose IP practices are the most damaging to U.S. industries. India's IP practices grow more damaging each day they go unaddressed, as the Indian government feels more emboldened to expand them to other industries and to advocate them to other countries. A Priority Foreign Country designation is needed to stem this troubling tide. Thank you.

CHAIR WILSON: Thank you very much for your testimony. As you can imagine, we have a few questions for you. I'll lead off by saying, and you did address some of this in your testimony, but as you point out, India has been a feature of the 301 process since the beginning, in the past, Priority Watch List designations in the recent past.

What is different now? What is different this year? What specific actions or events of the Indian government make a PFC designation appropriate now versus last year or the year before?

MR. POMPER: Sure. I think, and we go through this in the written testimony, but there are a variety of compulsory licensing revocations on 3(d) that really ripened over the last year, in 2013 specifically. I would say in addition the -- if you take this in context, as well, with the publication of the national manufacturing policy that India has published, which also seems to indicate a desire for industrial policy on certain key sectors, it specifically mentions compulsory licensing in that policy with respect to green technologies.

I would say, also, with the publication of the Administration's -- the Obama Administration's "Strategy on Mitigating Trade Secrets," where it specifically references the use of Special 301 to call out countries who lack trade secrets protection, that was published in 2013, I think it shows a renewed focus on the Administration on using this tool to encourage countries to update their IP practices.

Certainly, India has been for a long time, I think if you talk to folks who work or who are

members of AFTI, they will say that in the last year or so, they have noticed an up-tick in India's actions related to their practices in India.

This is what caused them to look around and think, hey, individually, we are all working on these difficult problems in India; why don't we get together and form this group that, together, we can all row and row together in the same boat and try to raise the profile of the problems we are facing in India. So, just a few answers to your question.

CHAIR WILSON: So the companies think now is the time because there have been -- there have been some changes, there is a shift in momentum, that it seems --

MR. POMPER: That's a good way, shifting moment, I think, is a good way to put it.

CHAIR WILSON: Okay. So given that and given India's, the longstanding issues and they have been the same issues for decades, how is India's behavior affecting, has it affected, will it affect the investment decisions of the companies that you represent?

MR. POMPER: Well, to be clear, AFTI is a coalition of associations, so I don't represent any company specifically on this stuff. So you'd have to really talk to the companies. I can't tell you about their investment decisions.

I can say there is a real concern about what's called the contagion effect, that if this manufacturing policy, this industrial policy that we, in our view, we believe India is pursuing with respect to these range of industries, if it goes unchecked, if the U.S. government, as it has for many years since, just put India on the Priority Watch List and doesn't make a special effort to designate India a Priority Foreign Country, it will send a signal to everybody else, well, it's just business as usual. Other countries may feel secure in following India's practices. That is, I think, a real concern from the standpoint of the companies who form -- the coalition of companies who form AFTI.

CHAIR WILSON: Thank you. I believe other colleagues have questions for you as well.

MS. BLEIMUND: Hello. Thanks for your testimony. This might be better addressed in a post-hearing submission --

MR. POMPER: Sure.

MS. BLEIMUND: -- based on your comment, but the Department of Health and Human Services would be interested in if there are impacts on investment decisions of --

MR. POMPER: Yeah.

MS. BLEIMUND: -- the companies involved, what, if any, impact on public health do these investment decisions have both in India and around the world? Thanks very much.

MR. POMPER: Okay.

CHAIR WILSON: Just to clarify for those of you who were not here this morning, there will be a post-hearing comment period open for two weeks of the docket at regulations.gov. We'll be reopened and we'll be accepting comments from the hearing participants and organizations who wish to respond to any of the testimony that has been offered today.

In some cases, we'll have time to ask the

questions that we have; in other cases, we won't. We will, when we don't have the time or if an answer cannot be given today, I will ask that we'll provide the question in writing to the hearing participant and request a written response. So that's what my colleague from HHS is referring to.

MR. POMPER: Thank you.

CHAIR WILSON: Any other questions?

MS. CORNWELL: Thanks for your testimony. Recognizing what you just said about not representing specific companies, if you could comment on how easy or difficult it is for businesses to engage with the Indian government on the concerns you have cited in your submission and how you would describe the ability to access policymakers and to maneuver through the administrative and judicial processes with regard to IP issues?

MR. POMPER: That's a good question. I would say I think companies have had varying degrees of success dealing with the Indian government. I think there has been a decision within the context

of the Indian government not to cooperate with the ITC's 332 investigation. People may be aware of this. I understand the Indian government is denying visas to the ITC staff who would like to go out there.

I think that is -- personally, I think that's not helpful. I do think dialogue is always the best way to solve these problems. From the standpoint of the companies I work with, or I should say, to be more precise, the associations that I work with, there has been some interaction with the Indian government. There is a new ambassador. I think we hope to engage with the new ambassador.

We have had a lot of success I think working with the U.S. government who has, I think, taken these concerns very seriously and been very responsive in their interactions with the Indian government. So it is that way, perhaps, indirectly have a bank shot through our U.S. government representatives, there has been quite a bit of engagement with the Indians.

Their counterparts, from obviously

Secretary Kerry, Ambassador Froman, Secretary Pritzker, and Treasury Secretary Lew, the Vice President Biden, and President Obama, himself, I believe have raised these issues that AFTI has talked about for a while with their respective counterparts. So, maybe not as much direct interaction with the Indian government, but indirectly so.

CHAIR WILSON: Thank you. I believe we are at 10 minutes, so thank you very much for joining us today. Thank you for your testimony.

MR. POMPER: Thank you.

CHAIR WILSON: And we will definitely follow up with any additional questions that we have. Thank you.

I'd like to call the next witness, American University Washington College of Law, Program on Information Justice and Intellectual Property. Please introduce yourself and spell your name for the transcriber.

PROF. FLYNN: My name is Sean Flynn, S-e-a-n F-l-y-n-n, which is probably a lot easier

to spell than a lot of the names you heard this morning. So, welcome, Ms. Wilson. It is great to see that you moved two chairs over to your left and occupy the center of the table now. We will, of course, miss Stan in our annual opportunity to have this kind of public forum, but we look forward to working with you on Special 301 as it goes forward.

And we are also very excited because you are a WCL alum and you hire many WCL alums, and so Dean Grossman has instructed me that whatever disagreements we have today, that everybody should defer to you going forward.

So, now for the disagreements. Actually, I want to start off with some kind of positive comments before the disagreements, and that is that I have always believed that this public hearing is extremely important. Too little of U.S. trade policy is done in the public, where we can actually see the industry submissions that are traded back and forth and respond to them.

I know that's an issue that USTR Froman is attempting to address. Of course, this isn't the

place to talk about his proposal for a new PITAC [Public Interest Trade Advisory Committee], but we would welcome an opportunity to have that public discussion on that proposal. And we would also welcome an opportunity to have a public discussion about Special 301 more generally, and what it should look like, its process, its legality, etc.

I know many parts of my submissions here and in the past have focused on process and legality. Those concerns, I'll just reference them and resubmit them here, that, you know, we still do not feel that this is an adequate public process. There are many things you could do to improve it. And we still do not feel that this program is lawful, lawful under U.S. law and lawful under WTO law.

But I want to address specifically the PF listing request for India and the past PFC listing of Ukraine in reference to those legality problems. So the Special 301 operates in a legal catch-22. It was passed, of course, before the WTO courts went into effect, but now the WTO courts are here. So

Special 301 was not -- it was altered to, you know, say fairly specifically that TRIPS-plus issues could be incorporated, but it did not alter the way the program operates in reference to the WTO.

So, on one level, you have the WTO's ban on unilateral adjudication. The U.S. cannot find violations and act on violations of TRIPS without going through the WTO dispute resolution. That is also Administration's statement and a statement of Administration policy that was used to settle or respond to Special 301 -- or the Section 301 case in the WTO.

But, on the other hand, you have the GSP enabling clause issue, which is you also cannot unilaterally reduce GSP benefits for a foreign country unless the criteria are crafted not because of interest of the United States, but actually because of the needs of those developing countries. And that was adjudicated in the EC tariffs case which said that in order to have those kind of criteria, they need to be reflected in broad, multilateral agreement of the kind that TRIPS

represents.

So, in order to withdraw GSP benefits, as was done in the past for Ukraine before it was a WTO member or in the past by other countries before they were a WTO member, in order to withdraw or reduce GSP benefits legally under the WTO, the criteria have to be TRIPS related. So that's the catch-22. You can't reduce GSP benefits for TRIPS-plus issues, and at the same time, you have to be focusing on the developing needs of other countries and not be basing those decisions on the kind of criteria that are expressly stated in Special 301, which for PFC determinations, which countries have the greatest impact on the United States.

So I'm interested to see what's going to happen in the Ukraine issue that we have listed them as a PFC last year, you listed them for a series of issues that are not part of TRIPS, so collecting societies are not managed by TRIPS and DMCA takedown issues are not managed by TRIPS. So it's a series of TRIPS-plus issues.

So I think that brings you headlong into

the GSP clause, enabling clause issues. How do you justify a clear threat to reduce Ukraine's GSPs for issues that have not been adjudicated to violate TRIPS? And now you move into India, where the threats are clearly TRIPS-covered issues, so the issues that have been raised by Mr. Pomper and others.

In response to your question what has changed, well, two things have changed, right? India 3(d), India Section 3(d), which people are saying violates Article 27 of TRIPS because it adds a fourth criterion. I don't believe that that is true. And there is a submission by myself and Srividhya Ragavan and other professors which describe our reasoning there. And a second issue is a compulsory license for a cancer drug, Nexavar, by India. And that is also being challenged as not TRIPS compliant because of a dispute over the definition of its local working requirement.

I do want to speak a little bit more, and I'm happy to respond to it in questions. I think that interpretation of the TRIPS issue is frivolous.

I think if you read the actual IPAB opinion, it is clear that local working defined as import substitution is not what happened in the case. So the opinion, itself, actually disagrees with the comptroller below it that you can't meet the local working requirements through an imported good, and it expressly lays that out, but then finds a lack of working based on the traditional definition of lack of working dating all the way back to the Paris Convention, which is a failure to meet the reasonable demands on reasonable commercial terms and conditions within the country.

And a canonical example of that is excessive pricing. And excessive pricing is exactly what the Doha Declaration is about. The Special 301 discussions on the Doha Declaration, in another, you know, quick moment of praise, have gotten better. And you have actually stated that, you know, restated the commitment to respecting the Doha Declaration and its commitment to promoting access to medicine for all.

And that's a very important statement in

Special 301, because the pharmaceutical industry comes up and tells you, well, the real intent of Doha is just about AIDS drugs, and that's not what you said. You said access for all medicines, for all people, which is what the access-to-medicines community thinks the Doha Declaration is about. So that includes cancer drugs, includes other kinds of drugs and other kinds of drugs that are excessively priced outside of the hands of people they were meant to serve.

So there is an article that I have, that I am happy to resubmit, which discusses the basic problem here, which is that patent rights and other kinds of intellectual property rights on essential goods in countries with extremely high income inequality promotes a profit maximizing incentive to price to the super rich in those countries.

And the way we respond to that is through the so-called TRIPS flexibilities. We narrow the grounds in which patents are granted. That is India's Section 3(d). And we use compulsory licenses to force the licensing of patents without

revoking or forfeiting, forcing the forfeiture of those patents in order to bring down those prices as well.

In the Nexavar case, and this is the same chart I showed at the ITC last week, but the Nexavar case is a canonical example of why you need compulsory licenses to get over pricing problems. So the red line at the top is the price that Bayer was demanding, $5,000 a month in a country with an average income of just over $1,000 a year. So if you look at that, very few people are going to be able to afford that drug.

I just did some anecdotal surveys with people last night and through the last week about how many people are covered with insurance in a country like India. And the answer was about 5 to 20 percent of the country have any health insurance whatsoever. And a very small percentage of those people have any medical coverage, medicine coverage whatsoever. And of those people with medicine coverage, which is now a percentage of a percentage, most of them have caps at about $1,000 a year.

So even the top tier of the country, so this is the top fifth of income-earners, who the price of Nexavar would be five times higher than the average income for the top fifth of the country, even those people are not going to have insurance that would cover this drug.

And this line down here is Bayer's access price. So their quote/unquote "access price," the price for the poor, is about 200 percent higher than the top quintile of income. So it would take 200 percent of their entire income to pay for that drug. So the problem is, is that that's profit maximizing behavior for Bayer. Bayer has to serve its shareholders by getting the highest price it possibly can within the public policy that we force upon them.

India has taken huge efforts to transform its patent law and recognize patents in ways that create exactly this pricing problem, and it needs to be able to use the policy tools to overwhelm them. So I would encourage you to not mention, remove the mention from the 2013 Special 301 Report of anything

negative related to this compulsory license and instead recognize that this is exactly the kind of situation which the Administration's own policy mentioned in the first part of the Report is applicable to. Thank you.

CHAIR WILSON: Thank you, Professor. Very interesting, as always. This format doesn't really allow us to pick up a lot of the things that you mentioned in this, but know that we are reading your submissions with great interest and we may follow up with additional questions.

I would like to point out for everyone that the Committee has actually agreed to convene at the end of this year's 301 Review cycle to do exactly what you have asked, which is take a top-to-bottom look at the Special 301 process. And we plan to publish a *Federal Register* notice, solicit public input, so any interested stakeholders are welcome to do that. Watch for that sometime in the late spring, early summer.

I know several people have asked on both sides of the aisle, so to speak, for us to take a

look at the process, and we are going to do that this year.

PROF. FLYNN: I think that would be great. And a lot more time for questions would be super so we could have these kinds of discussions on the record.

CHAIR WILSON: Great. Thank you very much.

I'd like to call the next witness, Biotechnology Industry Organization. Welcome, thank you for joining us today. Please introduce yourselves and spell your names. Thank you.

MS. FEISEE: I'll start first. My name is Lila Feisee, and I am the Vice President for International Affairs at BIO. And my name is spelled L-i-l-a F-e-i-s-e-e.

MR. ZWAHLEN: Roy Zwahlen, also with BIO, R-o-y, last name is Z-w-a-h-l-e-n.

MS. FEISEE: Thank you very much. As I said, my name is Lila Feisee, Vice President for International Affairs at the Biotechnology Industry Organization. Today, I am testifying on behalf of

BIO and its 1,100 members who innovate in the healthcare, agriculture, and industrial and environmental sectors.

The vast majority of our members are small- and medium-sized enterprises with no products on the market currently. And with no source of a product revenue and long development times before market launch, biotechnology companies must leverage the strength of their global patent portfolio to raise the large amounts of capital that's required to get their innovations to the market.

In this global economy where investment decisions often include the growth of potential and emerging markets, IP setbacks like as in places like in China, India, and Brazil can have a significant impact on the delivery of scientific progress, the availability of the next generation of biotech innovation, and on its ability to create jobs here in the United States. These IP setbacks are outlined in our written submission in much more detail, but my testimony today will focus on the areas of most concern.

In contrast to 20 years ago, the global intellectual property environment is viewed to be deteriorating in many countries around the world to standards that harm innovation everywhere. Some of the deterioration has been more subtle, such as requiring unnecessary information in patent applications for certain technologies in places like China and in Canada. Some deterioration has been more dramatic as countries like India institute a pattern of seeming unconcern for broad areas of intellectual property no matter what the impact on local or global innovators.

While BIO's members express concerns about many countries in our Special 301 submission, we thought it best to spend our limited time on our recommendation to name India as a Priority Foreign Country.

In the healthcare space, only a few dozen innovative and patent-protected medicines are on the market in India. Yet, in the last two years, more than a dozen patents have been revoked, compulsory licensed, or threatened to be compulsory licensed or

otherwise rendered unenforceable.

In addition, several biotechnology inventions in the health and agricultural fields have been denied patent protection. These same products have been granted patents in many other jurisdictions around the world. There are perhaps other anti-IP actions that we just don't know about yet.

The fact that these same patents are valid around the world in both major and emerging markets reveals a clear lack of concern for protecting innovators in India, presumably for the benefit of India's industry. The Indian government claims that it is taking these steps to keep prices of medicines and improve access to medicines, especially in the pharmaceutical sector. However, we contend that these actions are in reality a form of industrial policy designed to improve local commercial interest at the expense of U.S. biotechnology companies.

These steps by the Indian government benefit in a very tangible manner its domestic pharmaceutical industry. The medicines being

targeted, such as Bayer's Nexavar, Pfizer's Sutent, BMS' Sprycel, Roche's Tarceva, and Novartis' Gleevec, are highly specialized anti-cancer medicines that benefit a small fraction of India's patient population and only those who can already afford the highly specialized medical talent and facilities to properly diagnose and treat the relevant forms of cancer. Yet, to our knowledge, only one of these medicines, Gleevec, appears on India's national list of essential medicines list.

No amount of patent revocations, compulsory licenses, enhanced efficacy requirements, or other methods to render patent rights unenforceable will address any of the systematic healthcare problems that are plaguing India today. The real tragedy underlying the anti-IP rhetoric is not simply that it diverts attention away from the real problems of access to healthcare that many millions of Indians face, but that it undermines India's goal of becoming a healthcare and science innovator.

There are companies around the world

interested in collaborating in research, science, and development of medicines in India. These measures make it difficult and often impossible for such deals to happen. In our view, this is a problem for innovators in India, as the deals will simply go to other countries with more respect for IP rights. Nonetheless, a number of our member companies continue to strive to be successful and to help the Indian poor through patient assistant programs which provide the medicines for free or even below generic price to the poor. There are creative licensing strategies to allow Indian generic companies to manufacture medicines to reduce cost, technology improvements to enhance storage life of medicines to survive the lack of infrastructure in India, and many more initiatives that contribute to addressing the healthcare burden in India.

Yet, American companies cannot fix this problem alone, and the current set of IP policies impedes them from doing more. The Government of India spends around one percent of the country's GDP

on healthcare. That is lower than all other emerging economies and even lower than several heavily indebted nations. India's vast economic growth over the last decade has clearly not been matched by an equivalent increase in public spending by the government.

While it may not be our place to set priorities for the Indian government, we wish to point out that both the significant cost of this current approach in undermining its potential as a global biotech innovator, and we also wish to observe that the benefits to healthcare in India, to the extent that they exist at all, would not appear to offset these costs.

Perhaps of greater concern to us is that if India is left unchecked and is successful in its efforts to weaken its IP laws to benefit its local industry, it will not be an outlier in its policies, but other countries, emerging and middle income countries, will follow suit, creating a significant burden on the U.S. economy. This is not sustainable, especially in view of the current

economic environment of the U.S.

Upholding the system of intellectual property rights is essential to guaranteeing future innovation and future jobs, not just for U.S. biotechnology companies, but also for other countries and other industries around the world. Thank you for this opportunity.

CHAIR WILSON: Thank you very much for your testimony. We do have several questions. I would like to lead off by repeating some of the questions that we asked a little bit earlier of AFTI, three in particular.

You did touch on some of the investment decisions that are being made by your member companies in response to some policies that are coming to the forefront in India. Can you elaborate on those either today or in a post-hearing submission, generally speaking, but also with respect to its impact on the U.S., U.S. jobs and the U.S. economy, and also impact on public health?

And then I'd like to also pick up the question that Commerce asked AFTI, which is how

difficult is it for your businesses to engage with the Indian government? Are they having any success? Are you able to have the conversations that need to be had? Are the procedures open and transparent? How are your companies finding the engagement with the Indian government, please?

MS. FEISEE: Thank you very much for the questions. So in terms of investment decisions, I can't say. Because we are an association, we hear various companies and their concerns. But in terms of investment decisions, what we have experienced is that our organization has been a convener of meetings and conferences to enable Western companies or multi-national companies, and even small and medium size companies in the U.S. and in Europe, to go to India at our BIO-India conference. That was held annually for three years in a row to actually do, you know, partnering. We have partnering softwares that allow our companies to meet with innovators in other countries and do partnering deals and research and development and contract out research.

And we did that for three years in a row. But last year, we were not able to get any companies from either the U.S. or anywhere in Europe to want to go to India, to actually do these deals. So in terms of investment, I can't say for sure, but it seems to me that there is conscious decision being made to, you know, look to other areas potentially to do deals.

Now, with respect to what it does for healthcare or investment in India, obviously, you know, if the deals are going to other places or to other countries, that's potentially a problem. But, also, India has amazing research institutions, amazing universities that are doing a lot of cutting edge research. The problem is that if there is unpredictability in their IP systems, and if it is difficult to protect those, you know, those innovations, then it is very difficult to actually develop or translate those discoveries into tangible products.

So if the research in India is being done in the area of healthcare, which I know that there

are several of the institutions that are working in that area, then there, you know, if there is a dearth of investment or partners willing to take up some of these research projects and work with them, then their own, you know, the products that they could create for their own population, that's at stake as well. So I think a little bit of the responsibility also lies on what India can do for its own population.

Now, what was the second part?

CHAIR WILSON: The last question was on the ability of your member companies to interact with the Indian government to try to find other avenues for addressing some of these concerns.

MS. FEISEE: Yeah, I mean I think, I think our companies really do want to, especially the small and medium size companies that are looking for partners and investors, they do want to work and reach out to the Indian government or other governments that are willing to work with them.

But I think that, and I think they have gotten mixed signals and mixed reviews, I think the

government has. They have reached out to the government. I think in certain instances they have been able to have conversations. Whether anything comes out of some of these conversations is unclear.

But we have had an opportunity to meet with the Indian government as an association. We are trying to reach out to the new Indian ambassador. So I think we are still open to seeing what India is willing to do. But I think, at this point, we haven't seen anything that's shown that, you know, allows our companies to believe that there are going to be opportunities in India the way that they were several years ago.

CHAIR WILSON: We're at our 10 minutes, so unfortunately we are going to stop there. Thank you so much. There were some additional questions that the panel had, so we will submit those to you in writing and request that you respond to them within the next two weeks. Thank you very much for joining us today.

I'd like to call the next witness, the United States Chamber of Commerce.

MR. MacSLARROW: Good afternoon.

CHAIR WILSON: Welcome. Thank you for joining us. We're just making sure you have the right nameplate, although there is nobody photographing you from -- well, yes, there is, actually. Just a reminder, this is being videotaped and a transcription is being prepared, and all of that will be available within two weeks of the date of the hearing at USTR.gov.

So thank you for joining us today. Please introduce yourself and spell your name.

MR. MacSLARROW: My name is Jasper MacSlarrow, that's spelled J-a-s-p-e-r, last name MacSlarrow, M-a-c, capital S-l-a-r-r-o-w. I am a fill-in for Mark Elliott, who was scheduled to testify from the U.S. Chamber today, but he grew ill over the weekend, and so he asked me to fill in, so I hope that's acceptable.

As I said, my name is Jasper MacSlarrow. I am the Executive Director for Intellectual Property at the U.S. Chamber of Commerce's Global Intellectual Property Center. I want to thank you

for the opportunity to testify and for your continued efforts to promote the importance of intellectual property worldwide.

The GIPC, in cooperation with the U.S. Chamber's International Division, welcomed the opportunity to submit joint comments on this year's Special 301 Review. Our submission highlights key improvements, as well as challenges, with regards to IP systems in nine markets.

It is important to note the critical role IP plays in creating jobs and spurring innovation. According to the U.S. Department of Commerce, U.S. IP industries account for 5 trillion of our nation's GDP, 60 percent of exports, and 40 million jobs. In short, IP drives knowledge economies.

Robust IP rules and effective enforcement systems are an essential measure of the climate for companies that wish to conduct business with foreign countries. To that end, the Chamber recently released the 2014 edition of the International IP Index, which maps the IP environment of 25 countries around the world using 30 indicators. And we

attached it to our testimony as well, and we have got some copies today, if you are interested.

The Index covers patents, trademarks, copyrights, trade secrets enforcement, and ratification of international treaties. The indicators used were developed in consultation with an academic researcher and industry sectors. The Index measures specific provisions that industry sees as crucial to creating and maintaining an innovative business environment. It also includes global best practices defined by a number of international treaties.

As I mentioned, we have submitted a copy of the Index with our Special 301 submission for the record and refer to it where appropriate throughout the submission.

Now, I would like to discuss a few global trends on the protection and, in many cases, the erosion of IP rights. Firstly, we are seeing an increase in laws and regulations that undermine IP rights, which is detrimental to innovation and economic growth.

Examples include India's issuance of its first compulsory license to allow for the generic manufacturing of a patented anti-cancer drug, and Australia's legislation that strip trademark owners of their ability to use their brand on tobacco products. Such actions establish a dangerous precedent for the protection of IP for all industries.

Second is the importance of bilateral and regional trade agreements. The Chamber supports the negotiation, conclusion, and enforcement of all trade agreements that advance global IP standards, in particular, the ongoing Trans-Pacific Partnership negotiations, the TPP.

Thirdly, while the Internet has developed into the greatest marketplace of goods and ideas, online IP theft is massive and growing. It is critical that law enforcement has the tools, the resources, and the will to fight theft in both the online and the physical environments.

Fourth is the need to improve enforcement efforts and resources in the United States and

overseas. In addition, it is important that the United States continues to work with foreign governments to promote bilateral enforcement efforts.

And, lastly, the Chamber is also particularly concerned about the transshipment of illicit goods, including counterfeit products and the process by which these goods are destroyed and seized.

In addition to these global trends, the GIPC submission also highlights specific country assessments. Over the last year, a number of countries have taken steps toward improving their IP systems by securing effective and transparent IP rules. For example, Canada recently concluded negotiations with the European Union on the Comprehensive Economic and Trade Agreement, CETA. Should the provisions of CETA successfully be implemented, Canada's IP environment would improve significantly.

In China, we continue to see progress made to protect IP rights through certain amendments to

their copyright, trademark, and patent laws, and in the recently concluded judicial interpretation on Internet liability. Russia's new notice and takedown provisions with regard to the responsibilities of information intermediaries indicates progress in protecting copyrights. Malaysia introduced significant changes to its copyright laws, as well.

While a number of countries have taken positive steps toward improving their IP environments, some countries have taken steps backward that will stifle innovation and arrest the ability of creators and inventors to have their intellectual property protected.

Some examples of this are India. Both the inaugural GIPC index, which was produced in 2012, and the 2014 edition found that India ranked last overall behind countries such as Brazil, Russia, and well below China. In the past two years, the Indian government has demonstrated a pattern of behavior that caused a rapid deterioration of the IP environment, making India an outlier in the

international community.

And as the GICP index suggests, the IP issues in India are affecting a wide variety of industries. Within the biopharmaceutical industry, there have been a number of policy, regulatory, and legal decisions to revoke and deny patents. Notably, these patents are recognized elsewhere in the world, positioning India as the international outlier.

India has an extensive copyright industry; however, the government's copyright legislation passed last year fails to adequately protect Indian and international creators and innovators. While the copyright legislation was much needed, this legislation contains many deficiencies that fall well short of the intended purpose of the legislation, which was to implement the WIPO Copyright Treaty.

India is also a bad actor in multilateral negotiations. India is not participating in the ongoing negotiations to update the WTO Information Technology Agreement. At WIPO, India stalls

discussions, openly accuses right holders of abuses, focuses exclusively on exceptions and limitations, and has not signed onto treaties on copyrights. It has called for compulsory licenses for clean technologies before the United Nations and pushes other middle income countries to support an anti-IP agenda at these institutions.

It is important to note that the Chamber's submissions on Special 301 have not previously recommended specific rankings of countries, but only highlighted concerns. However, given the rapidly deteriorating climate in India, we urge USTR to designate India as a Priority Foreign Country in the 2014 Special 301 Report.

In Brazil, we are concerned that the Brazilian National Health Surveillance Agency is acting beyond its congressional mandate when reviewing patent requirements and applications filed with the Brazilian National Industrial Property Institute. We also note that there are several bills related to the Internet and copyright protections that are being considered in Brazil. It

is imperative that these initiatives not erode or limit the ability of right holders to protect their IP.

Canada's inadequate level of IP protection and enforcement continues to be worrisome. Our submission highlights recent decisions by the Canadian federal courts that have imposed an onerous test for utility which is inconsistent with its legal precedent and international obligations. While we commend Canada for its passage of Bill C-11, we urge Canada to do more to combat IP theft, particularly online.

We continue to have serious concerns about the size and scope of IP infringement in China, despite reported efforts by government agencies to clamp down on these problems. We also strongly urge the Chinese government to advance the development of new medicines, including through the establishment of effective regulatory data protection.

We are concerned that the current proposed policies of the European Medicines Agency provide unrestricted access to and publish the clinical

trial data and other confidential business information contained in regulatory submissions for marketing approval. These practices harm patient privacy, undermine the integrity of the regulatory system, and undermine incentives for innovation by allowing competitors to gain unfair commercial advantage over innovators. Such practices are also not consistent with EU's obligation under the TRIPS Agreement.

A couple more. Our submission notes that Mexico's ability to combat the transshipment of pirated and counterfeit goods through its borders would be significantly enhanced by providing ex officio authority to its customs officials. We also urge Mexico to provide clarity that the June 2012 data protection guidelines also cover biologic medicines and to fully implement the WIPO Internet Treaties.

While Russia has made positive steps in 2010 by providing six years of regulatory data protection, there has been no implementation observed to date. Copyright piracy also continues

to be a significant problem in Russia. Russia needs to amend its laws to provide effective copyright enforcement on the Internet, including modifying the civil code to create clear liability for acts that induce or promote infringement.

Although there are laws and regulations in place that protect IP in Ukraine, implementation of these laws has been inconsistent. Piracy rates in Ukraine are among the highest in Europe. In order to curb this growing problem, we encourage USTR to work with Ukraine to increase informant -- increase enforcement in the markets identified in USTR's Notorious Markets report.

And while the Chamber welcomes some aspects of South Africa's draft National Policy on Intellectual Property, there are also elements that cause serious concern for industry. For example, the currently considered proposal states that developing countries can adopt IP policies that limit the extent of patenting and facilitate the introduction of generic competition.

Further, the pharmaceutical patentability

requirements included in the draft policy closely resemble that of Section 3(d) of India's Patent Act. Due to the rapid deterioration in India's IP environment, the Chamber finds this troublesome. We urge the U.S. government to work with the South African government to reconsider the existing clauses in the draft policy which would restrict, if not eliminate, forms of incremental innovation.

Adequate and effective protection and enforcement of IP is vital to America's economy. We look forward to working with you and our trading partners to secure meaningful IP policy improvements that produce economic benefits in the U.S. and throughout the world. Thank you very much for your time today. I really appreciate it.

CHAIR WILSON: Thank you very much for your testimony. We do find ourselves at the 10-minute mark, so we won't have any time for questions.

MR. MacSLARROW: Okay, happy to do the follow-up, though.

CHAIR WILSON: Yes, we'll pass the

questions to you in writing. And the questions will be posted at regulations.gov for everyone's benefit.

MR. MacSLARROW: Okay.

CHAIR WILSON: Thank you very much.

MR. MacSLARROW: No, thank you; appreciate the time.

CHAIR WILSON: I'd like to call the next witness, Intellectual Property Owners Association. Welcome, sir. Thank you for joining us today. Please introduce yourself and spell your name.

MR. WAMSLEY: My name is Herbert Wamsley, H-e-r-b-e-r-t, Wamsley is W-a-m-s-l-e-y. I'm Executive Director of Intellectual Property Owners Association, or IPO. I want to thank you for the opportunity to testify today.

IPO is a specialized trade association in Washington, D.C., representing more than 200 companies in all industries and fields of technology that own or are interested in IP rights.

I want to highlight some key points from the 16-page letter that we submitted on February 7 and to emphasize patent and trade secret rights. I

will try to avoid too much duplication with the previous witnesses.

IPO members create and commercialize new products and services that drive exports and create jobs. Innovation is not without risk. And we rely on our IP rights at home and abroad to protect our investments in new technology.

We have observed a growing trend in international intergovernmental bodies to focus on exceptions and limitations to IP rights or to otherwise weaken IP rights. While such exceptions and limitations are said to be designed to increase access to technology, we believe they produce exactly the opposite effect by creating uncertainty that deters investors.

We have observed attempts to weaken IP in a range of UN bodies, including the UN Framework on Climate Change Convention and WIPO, an organization whose very mission should be to foster innovation. Similar proposals are being made in the World Health Organization and the WTO. Sometimes, the proposals call explicitly for IP weakening. At other times,

the proposals employ a more subtle approach of calling for the removal of barriers to technology transfer.

I would like to mention some specific countries briefly, India, China, Brazil, South Africa, and Canada. India, of course, is an important market for U.S. innovators with an economy that draws heavily on global investment and trade. Several members of our association have a significance presence in India. However, India's government pursues an agenda of forced technology transfer and intellectual property weakening that is disadvantageous to American business.

For example, India's national manufacturing policy calls for involuntary licensing of clean healthcare-related technologies. India has also infringed, overridden, or revoked nearly a dozen pharmaceutical patents held by foreign firms, in part because the patented products were manufactured outside the country.

The stated rationale for such actions is high medicine prices. We believe, however, that

expropriation of IP assets is inappropriate and deprives the U.S. innovators of market opportunities.

India has developed a national competition policy that provides a helpful framework for fair competition, but IP rights owners must grant third party access to essential facilities under the competition policy.

India also requires patent owners to actively work their inventions on a commercial basis within India, as we understand it. Failure to do so can subject the patent to compulsory licensing. Apparently, to encourage more requests for compulsory licenses, the Ministry of Commerce has recently published the working status of Indian patents online.

Despite recognizing the link between trade secret protection and investor confidence through its national IPR strategy, no meaningful trade secret protection regime exists in India. And there has been no public move to establish one.

At the WTO, India has insisted that IP

rights are unrelated to innovation. At WIPO, India collaborates with Brazil to provide meaningful discussion of IP best practices.

Now, moving onto China, while much has been done to improve IP rights in China in recent years, achievement of an open and fair commercial landscape will require additional work. Technology developers may find themselves at a significant disadvantage through China's national standards, which are advanced through an invitation-only process, often to the exclusion of foreigners.

IPO members must also cope with laws that impose greater risks and liabilities on foreign technology licensers, compared to domestic innovators. Moreover, a recent trademark law change may expose American brand owners to risks caused by bad faith registrants.

IPO members face hurdles in expanding R&D operations in China. U.S. innovators must share their know-how with others to build new solutions, risking exposure of essential trade secrets. While trade secret laws in China exist, recovery of

damages is extremely difficult. Companies must also reveal their trade secrets to comply with regulations, with no assurance that their know-how will remain confidential.

China is complex. Employers must face the owner's requirements of service invention regulations governing employee inventor rights and navigate the uncertainties created by the unexamined utility model rights.

Briefly, on Brazil, Brazil's position on IP rights has improved domestically and globally over the past few years. Nonetheless, there are areas of real concern. For example, both INPI, Brazil's Patent Office, and ANVISA, the National Health Surveillance Agency, examine the same pharmaceutical patent applications with different standards. This dual system compounds the patent backlog in Brazil where patent examination takes eight to nine years. The patent office regularly interferes with technology transfer agreements, which can result in a loss of U.S. trade secrets.

Like Brazil, South Africa is also

considering its approach to updating intellectual property laws. Last year, South Africa published the draft to National Policy on Intellectual Property. IPO welcomes many of the perspectives the policy sets forth, but we are troubled by the suggestion that IPR protections must be limited in order for the country to develop and thrive.

In Canada, innovators in the pharmaceutical industry face unique and heightened standards of patentability. Patent applications must demonstrate or predict the commercial promise of an invention on the filing of the application. Canadian courts have rejected patents for the lack of utility when Health Canada has found the same inventions to be safe and effective.

In conclusion, we believe key elements of intellectual property systems can be strengthened through the TPP and the TTIP, in particular. We appreciate the efforts the United States has made to include trade secrets on those agendas.

We thank the Subcommittee for its efforts to preserve the tools that will sustain and grow

America's economy. I'd be pleased to try to answer any questions now or to make a submission for the record. Thank you.

CHAIR WILSON: Thank you very much for your testimony. We are at about the nine-minute mark, so we have time for one quick question. I think, Commerce, you had a --

MS. CORNWELL: Thank you for your testimony. According to a 2013 U.S.-China Business Council survey, 40 percent of respondents stated that trade secret misappropriation was their top area of IP concern. Is that also true for your members? And is trade secret theft your members' most significant IP challenge in China?

MR. WAMSLEY: It's certainly one of the most significant challenges in China. We also have concerns about the growing backlog of patent applications, the uncertainty over the utility models, but trade secrets would rank near the top.

As I indicated in my statement, we see trade secrets as an area for concentration in improving trade-related IP in a number of countries.

And even in the United States, which has perhaps the world's best trade secret protection, our association this year will be supporting in Congress the creation of a federal civil cause of action for trade secret misappropriation.

CHAIR WILSON: Thank you very much, and we will follow up with some additional questions post-hearing. So thank you for joining us today.

I'd like to call the next witness, the International Intellectual Property Alliance.

MR. SCHLESINGER: Michael Schlesinger, S-c-h-l-e-s-i-n-g-e-r. Good afternoon. I am pleased to appear before you on behalf of the IIPA, a coalition of seven copyright-based associations representing over 3,200 companies in the software, motion picture, recorded music, video game, and book and journal publishing industries.

In our 26th Special 301 submission, we document online and hard goods copyright infringement and market access barriers in over 46 markets. The Special 301 Program remains a cornerstone of U.S. IP and trade policy to establish

objectives for the year and to protect our nation's creative industries, boost U.S. exports, create good, high wage jobs here at home, and contribute to the overall health and competitiveness of the U.S. economy.

Our latest report confirms that the core copyright industries contribute 6½ percent of U.S. GDP and roughly 5.4 million high wage jobs. Yet, massive costs are imposed by overseas infringement and market access barriers to U.S. copyright products and services. Legitimate businesses face unfair competition from those who infringe as a high-profit, low-risk enterprise and who are unencumbered by costs associated with producing or obtaining rights in copyright materials.

Piracy and counterfeiting cause significant harm, as recognized by recent United Nations and Interpol initiatives, as well as damage existing legitimate distribution channels and impede the evolution of new ones.

Thus, it is essential to the continued growth and future competitiveness of the U.S. that

our trading partners provide high levels of copyright protection, more effective policies and tools to enforce copyright, and freer, more open markets.

We urge the Administration to use Special 301 to encourage the countries identified in our submission to take the necessary actions to bring real commercial gains to the U.S. through strengthened copyright and enforcement worldwide.

I'd like to say a word about some cross-cutting initiatives and challenges to the copyright industries. First, Internet and mobile infringement unfortunately compromise opportunities to build legitimate businesses in the online and mobile world.

Governments must address both supply and demand, including education, as well as enforcement and incentives for service providers to help curb both hosted and non-hosted infringements. The role of advertisers, payment processors, and search engines should also be more carefully scrutinized so that infringers are not given an upper hand and so

that these services are not knowingly benefiting from or contributing to infringement.

Second, severe damage is caused by enterprises and even governments that engage in end user infringement of software, published materials, and other copyrights. Adequate laws are needed, including statutory damages and, in appropriate cases, criminal penalties.

Third, retail infringement continues to cause mounting losses, including hard disk loading of software onto computer at the point-of-sale, mobile device infringements involving the loading of infringing material or illegal apps onto smartphones, tablets, or other devices, the trafficking in media boxes facilitating massive infringement, and high quality counterfeits manufactured mainly in China and exported to the world.

Fourth, while technological protection measures have enabled more access to copyright and more affordable prices than ever before, those who build their business models around circumvention of

TPMs have exacerbated infringement and undermined the development and deployment of legal services.

Other industry-specific problems include illegal camcording of movies from theater screens, infringement of books and journals, and pay TV piracy and signal theft. For example, there were 819 total detections of illegal camcordings of major U.S. motion pictures in 2013. These can trigger mass distribution of millions of Internet downloads. So a multi-faceted approach is needed, including education, cooperation with cinema owners, and adoption of adequate legal measures and enforcement.

Large-scale unauthorized photocopying of books, principally on and around university campuses, and sophisticated counterfeit printing cause publishers significant harm and must be addressed. The unauthorized broadcast, cablecast, satellite delivery, or retransmission of broadcasts require a regulatory and enforcement response focused on the trafficking and signal theft devices or technologies, and unauthorized decryption and redistribution activities.

Two additional challenges noted in our submission include the need for proper implementation of IPR provisions in trade agreements and the need to address market access barriers. Multilateral, regional, and bilateral trade agreements have proven to be of great value to the U.S. economy, featuring enforceable obligations to modernize copyright laws, improve enforcement procedures and open markets, and providing the win-win impetus for the development of our trading partners' domestic copyright industries.

The negotiations towards the Trans-Pacific Partnership FTA presents an opportunity to expand the benefits of existing FTAs to a broader range of markets around the Pacific Rim, promising contributions to U.S. job growth and increased exports in line with the Administration's goals.

Market access barriers, investment barriers, and discriminatory treatment, on the other hand, continue to make it impossible for U.S. businesses to compete fairly in many foreign markets or to crack down on copyright infringement which

fills the void.

In sum, we urge the U.S. government to use all its tools to uphold U.S trade laws to meet the challenges presented in the IIPA submission. We thank all those in the U.S. government who work steadfastly throughout the year to ensure that our trading partners respect U.S. intellectual property and open their markets to our products and services.

And with that, I'd like to -- I'd be pleased to answer any questions that you have. And I just want to recognize the significance of the participation of many governments in this process. We are reviewing their submissions, as I'm sure you are, and their testimony today, and we look forward to progress in the year to come through continued bilateral engagement. Thank you.

CHAIR WILSON: Thank you for that broad-ranging testimony. And thank you for leaving 3 minutes and 25 seconds for questions. And you gave me the perfect segue there, and this might be a little bit unfair, but I'm going to put you on the spot.

IIPA, I think, has "nominated," in quotes, more of the governments that appear here today than any other organization. So, specifically, in your 2014 submission, you provided information on Ukraine, Bulgaria, Italy, and the Philippines. And I'd like to give you a chance to just do a tour of the horizon for us on those governments, if you would.

MR. SCHLESINGER: Sure. You said Ukraine, Bulgaria, Italy, and the Philippines?

CHAIR WILSON: And the Philippines.

MR. SCHLESINGER: Sure. Well, on Ukraine, we absolutely appreciate the appearance and the testimony of the Government of Ukraine this morning. Our position is that the government has not yet corrected any of the three identified PFC investigation issues to date. On February 28th, that PFC investigation officially ends.

So, recognizing the political changes that are afoot in Ukraine and as mentioned in their testimony this morning, we believe it is appropriate that as the changes sort themselves out, the U.S.

government should once again turn its attention to those three PFC issues. I'm happy to say further word on those.

With respect to Bulgaria, you know, what I would say is in our submission you'll see that the cyber crime unit has been a bright spot in an otherwise difficult situation. And I think that it is very important to continue to monitor enforcement efforts in Bulgaria, which unfortunately stalled in 2013. So that would be the elevator pitch or the talking point on Bulgaria.

In Italy, I think that we recognize as an alliance that the AGCOM is a major development. We also recognize the positive developments in terms of the Fiscal Police activity in 2013. We believe that it is very important to follow up with monitoring the implementation to ensure fluency in continued enforcement, including obviously, very importantly, in the Internet environment where we highlight Italy's rise, unfortunately, in terms of illegal activities in that space.

Finally, on the Philippines, which I

didn't have to write here because I've been working on Philippines for many, many years, as you know. For a couple of years now, we have recommended that the Philippines come off the Watch List officially. We do still continue to believe that it is important to monitor, that, you know, out-of-cycle review is an appropriate way to measure the progress in the Philippines.

This is taking note of all of the accomplishments that they have taken to date, including the passage of an optical disc bill, the implementation or the beginning of implementation of supreme court rules on IPR, which should hopefully resolve some of the irritants that we have experienced in the courts in the past, such as the search warrant quashal issue.

And just in recognition of really the IPOPHL, as they said this morning, that their targeted enforcement and their continued willingness to work with us on every new challenge that's facing itself, and I think they mentioned the Internet this morning, and we were heartened by that and also

TPMs.

So we think that the situation in the Philippines is ready for them to graduate to really a more mature place on the Special 301 List through a continuing review process.

CHAIR WILSON: Okay, thank you. We find ourselves at the 10-minute mark, so I'm going to apologize to my colleagues for preempting your questions with my own, but we will go ahead and forward those to you after the hearing and would appreciate a response within the next two weeks, please.

MR. SCHLESINGER: Thank you very much.

CHAIR WILSON: Thank you.

I'd like to invite the next guest, Public Citizen. Welcome.

MR. MAYBARDUK: Thanks, everyone. Good afternoon. I have a few handouts.

CHAIR WILSON: Excellent. I'll take care of that for you. Thank you. Go ahead and introduce yourself, and please spell your name.

MR. MAYBARDUK: My name is

Peter Maybarduk, that's M-a-y-b, as in biologics, a-r-d, as in India 3(d), u-k, and I represent Public Citizen.

CHAIR WILSON: UK hasn't done anything?

MR. MAYBARDUK: I can -- we can pick the anagram, if you like. I represent Public Citizen, which is a consumer advocacy organization based here in Washington, D.C. We have 300,000 members and supporters, a number of different practice areas, 40 years of representing consumer interests before Congress, executive agencies, and the courts.

My program, in particular, is a global access to medicines program. We provide technical assistance to public agencies around the world that are interested in making use of their rights to promote access to medicines in public health under the TRIPS Agreement.

And I'd like to start off by indicating that I think this morning I've heard a pretty significant misunderstanding or mischaracterization of the nature of patents, copyright, and trademarks articulated over and over. I think it is very

important to note that these are not -- the rights that are embedded in each particular legal framework, patents, trademarks, copyrights, are not uniform and they're not absolute.

There are different policy balances struck in each area for particular reasons, and public interests and sovereign rights, state rights, federal rights, essentially public rights embedded in the same. And it is not the case that maximizing exclusivities forever and as broadly as possible is going to be necessarily in the public interest, and we have struck the balances we can in the TRIPS Agreement to govern some of these areas.

It is, actually in the seven years I've been doing this, I can say that it's actually quite difficult to enact a new pro-public health policy in a developing country in light of the sort of opposition that countries face. And I think we have a pretty serious question we have to address about which side are we on and how much is enough in the area of defending a pharmaceutical monopoly power around the world when so many lives are at stake.

In order to implement a pro-health policy under patent rules, you have to line up a number of different agencies and ever face -- in issues that are complex, and ever face the shadow power of industry and threats of sanction from our government and from the European Union, and it is quite difficult.

We had Ukraine up here earlier. This year, my understanding, the oral reports we were getting is that the U.S. Ambassador to Ukraine was taking meetings over at the Ministry of Health there to discourage the country from using its health rights under TRIPS, to discourage the country from developing a compulsory licensing regulation to promote access to medicines in public health, in spite of the guarantees that we have signed onto that we respect trading rights -- trading partners' rights in these regards.

And I only have oral reports, but they were to the effect that, you know, some of what was communicated was blatantly incorrect about what the scope of those rights are. And in my experience

working in developing countries, I have faced this type of problem over and over again, and I can provide you some of the WikiLeaks cables that came out in the case of Ecuador and others where our government was organizing with industry and opposition ministers within the government to prevent a policy like this from taking place.

So when we raise concerns such as transparency and due process in this area, I think we have to ask ourselves some rather difficult questions. I have here a set of principles in our submission that I think could perhaps guide the 301 process going forward.

And I understand, of course, that you are under -- that we're working in the real world, there are policy constraints, there are industry pressures here as well, and I follow this process year to year hoping to make some modest progress in the areas of pro-public health, TRIPS-compliant policies.

One of the principles I have here that I really hope we can agree to is that a compulsory licensing rule that is TRIPS-compliant is notably

different, is categorically different from a problem such as the prevalence of trade secret theft or willful trademark counterfeiting, things that are actually articulated as criminal conduct under the TRIPS Agreement. Perhaps that is a line that we can begin to draw.

It blows my mind that this morning we are hearing proposals that India be listed as a Priority Foreign Country for doing precisely what the Doha Declaration indicates it ought to do to promote public health. Perhaps we could differentiate between criminal activity and public policy is one quite modest reform.

So with regard to transparency and due process, I think it is also important to note -- first off, of course, we clearly believe that a TRIPS-compliant policy shouldn't be listed, whether expressly or obliquely, not an implied reference, not a vague reference, no reference of that sort. I know that we're not going to get there. I know that's not the direction that this panel is necessarily going to be able to go in the near

future. But I am hoping with time that might change.

But if we look further into the critiques of transparency and due process that are sometimes articulated, I think it's very important to note that the TRIPS Agreement provides for those standards as well. The transparency and due process standards as regard patents, for example, are embedded in the TRIPS Agreement. And you can look at the area of compulsory licensing, for example, and see the prior negotiation requirements and right of appeal requirements in particular areas. Those are the standards that should guide the process.

There have been references in past 301 Reports to pharmaceutical pricing policies that are not actually intellectual property policies. They are not patent policies or any other type of policy. They are most analogous to our Medicare and Medicaid programs here. Policies that are ancillary, that are not IP policies, are beyond the scope of the Special 301 Review and should not be in the 301 Report.

So, further, if we can get to the TRIPS standard, I would hope that in areas where countries have FTAs, that we might sort of work from that standard instead. If a country has an FTA with the United States and they have particular standards that they have committed to uphold, but it only goes that far, right, so countries shouldn't be listed for things that they haven't actually agreed to in an FTA.

And I think if you look, for example, at our country comments with regard to Chile, you'll see how we parse the patent linkage requirements to show that Chile is meeting its obligations in that regard.

But at a bare minimum, I would hope that even if Special 301 subjects wealthy countries to criticism for TRIPS-compliant, public interest policies, then developing countries should be given greater leeway. This quite too-modest criterion does reflect the change of policy, as I understand it, we are seeing here at USTR right now in the context of the Trans-Pacific Partnership

negotiations where there is some degree of differential treatment between developing and developed countries, and perhaps an accommodation of that sort can be made in your final report.

And I'm probably rather short on time. What do we have?

CHAIR WILSON: You have 3 minutes and 30 seconds.

MR. MAYBARDUK: Okay. So just to hit on a couple of the country issues that have come up, we can review and have a more technical discussion, and we'll submit further comments. Some are in the comments here.

Canada and its utility doctrine, under Article 27, Canada has the freedom to define utility. And let's see if I can find the particular language. There is a policy purpose for the rule which is you prevent a race to the patent office. You cut off -- you cut off lines of research once the patent is granted. And if information, sufficient information is not put forward in the disclosure at the outset to indicate that something

is going to be useful for what it promises to accomplish, then you may actually cut off productive lines of research from competing firms.

For example, India, I think a couple of things that are important to note. One, there is a general -- I think there is a general misunderstanding of patentability criteria and patentable -- patent-eligible subject matter that should inform the discussion of both India and the Philippines, at a minimum. The United States Supreme Court recently ruled that isolated DNA is not patent-eligible subject matter in the *Myriad* decision, right? That is comparable to what India's 3(d) actually says. It is not structured as a patentability criteria. It's not part of novelty inventive step industrial application. It's under Chapter 2, Inventions, Article 3, what are not inventions. It's under the India's Article 27, TRIPS right to define what is and what is not an invention in the first place and excludes certain subject matter from patent eligibility in the first place.

And what India has done is exclude derivatives of known substances from the definition of invention. And they have actually been -- the rule is more narrow than India is obligated implement because they've given patent holders a chance to remedy that exclusion to get back into patent-eligible subject matter, as it were, if they demonstrate that their substance results in enhanced efficacy.

So India is sort of doing more than it is obligated under TRIPS. It's doing something that we are doing here in the United States and shouldn't be put on a Watch List for that, let alone a Priority Watch List.

Now, I probably have too little time to really get into the compulsory licensing grounds. I mean I think it is worth noting. In the case of India, there are three grounds under the rule. The Nexavar license is valid under any of the grounds under TRIPS. If you've got a real problem with working failure, the license is still issued under two other clearly TRIPS-compliant grounds. There is

not a problem with the license.

But if you want to talk about sort of actual working failure requirements and how they are placed in TRIPS, I think Sean Flynn's comments were good. I'd also say that there is, for one, the discrimination principle. One, there is no limit on compulsory licensing grounds in TRIPS, one. There could have been a specific prohibition indicated, if they had meant there to be. There is one in the area of semiconductors, for example.

But also working failure, well, a compulsory license, in order to have a discrimination claim under Article 27, you have to be able to -- you have to show a diminishment of the patent right. And this is an over-arching point that I think I really want to make is that having a patent turned down because it doesn't meet patentability criteria or isn't patent-eligible subject matter, one, or, two, having a government author use its sovereign rights to promote the public interest by authorizing others to use a patented technology is not a denial of a patent

right. Nothing is being taken away.

These public side rights are embedded there as part and parcel of the package, part and parcel of the patent, part and parcel of the legal framework that is established for these areas as much as the enumerated protections of the right holders and patent applicants. That is the balance that needs to be reflected in 301.

And I think with that I will thank you for your time. If we have a moment, I can take any questions.

CHAIR WILSON: Thank you so much for your testimony. Yours is always interesting as well. Thank you for joining us year after year. We are at the 10-minute mark, and I think we do have some follow-up questions, so we'll go ahead and provide those to you in writing.

I'm not sure if you were here earlier when I mentioned that the Committee will be convening the process --

MR. MAYBARDUK: Right.

CHAIR WILSON: -- post-review this year to

look at issues such as the ones that you have raised in your submission, so definitely invite you to participate in that. And can I ask you once the docket reopens today, to please submit this through regulations.gov so it becomes part of the public record?

MR. MAYBARDUK: Certainly, thank you.

CHAIR WILSON: Thank you.

MR. MAYBARDUK: We will participate in the post-hearing process.

CHAIR WILSON: Fantastic. Thank you very much for joining us today.

I'd like to call the next witness, please, the National Association of Manufacturers. Welcome, sir. Please state your name and spell it for us.

MR. MOORE: Thank you very much. My name is Chris Moore, M-o-o-r-e. I'm the Senior Director for International Business Policy at the National Association of Manufacturers.

The NAM is the largest manufacturing association in the United States, representing businesses small and large in every industrial

sector and in all 50 states. Manufacturing employs nearly 12 million women and men across the country, accounting for two-thirds of private sector research and development and contributing more than $1.8 trillion to the U.S. economy annually.

Innovation drives and supports U.S. jobs and global leadership in manufacturing. According to the Commerce Department, innovating industries directly support more than 27 million jobs across the country, and in 2010 accounted for more than 60 percent of U.S. merchandise exports.

But today, intellectual property rights are under threat around the world, and manufacturers are particularly concerned about the growing use of intellectual property as an industrial policy tool, and that includes acts, policies, and practices that deny adequate and effective protection of intellectual property rights to force local production and local innovation.

In India, for example, rules and regulations frequently condition market access on technology transfer and the disclosure of

confidential information.

To be eligible for certain government benefits, a right holder often must develop intellectual property in China or transfer their rights to a Chinese entity. China's technology licensing rules handicap overseas firms. Technology licensors based abroad assume greater risks and liabilities than domestic licensors. They are liable for their licensees' use of the licensed technology and cannot improve technology -- cannot own improved technology made by licensees.

China promotes patented Chinese technologies through its standard-setting process. Overseas manufacturers cannot participate in that process except by invitation. Often, they do not have access to the technical committees where standards are decided and, therefore, cannot join patent pools.

Under the terms of a national manufacturing and telecommunications policy released in 2011, India is seeking to force the local production of a wide range of manufactured goods.

It is implementing those policies through multiple means, including denying adequate and effective intellectual property protection.

For example, India's National Manufacturing Policy encourages compulsory licensing of green technology that is not manufactured domestically. Its National Telecom Policy establishes financial incentives for the local development of telecommunications products with an emphasis on products created with Indian intellectual property.

To benefit local drug companies, the Indian government has denied or revoked patents for more than a dozen innovative medications over the last two years, including a number that were distributed in India free of charge or at substantially reduced cost.

In Russia, recently proposed changes to a legislative framework governing the Customs Union between Russia, Belarus, and Kazakhstan appears to give trademark owners and users the right to block parallel imports of branded products, but only if

they have set up or will set up manufacturing of like branded products in Russia.

Manufacturers are very concerned that other countries will take similar actions. A recent study for Brazil's lower house of congress proposes expanding the use of compulsory licensing to promote local production, raising serious concerns about the future direction of that country's innovation policy.

The growing practice of denying adequate and effective protection of intellectual property rights to force local production and local innovation comes against a backdrop of high rates of counterfeiting and piracy and weak intellectual property protection and enforcement.

In fiscal year 2012, the U.S. Customs and Border Protection seized more than 22,000 shipments of counterfeit and pirated goods. China accounted for well over half those shipments and for more than 70 percent of all seizures by value.

The continuing threat of counterfeit and pirated goods to consumer health and safety and to

jobs in manufacturing in the United States underscores the need for global action to combat illicit trade and for additional measures to detect, detain, inspect, seize, and destroy counterfeit and pirated goods shipped by mail.

Copyright piracy is widespread across India. Nearly two-thirds of all software is pirated. A recent study conducted by the NAM and the Harvard Business School found that global software piracy cost the United States more than 42,000 manufacturing jobs over the last decade.

Russia remains a center of online piracy. It is home to two of the world's most prolific criminal release groups for motion pictures, as well as multiple sites that offer access to pirated music. Basic enforcement of online piracy has lagged far beyond -- sorry, far behind the rapid growth of Internet and wireless access in Russia.

For these reasons and others outlined in our written submission, the NAM urges the Special 301 Committee to retain China on the Priority Watch List with Section 306 monitoring, to designate India

as a Priority Foreign Country, and to retain Russia on the Priority Watch List.

The acts, policies, and practices of all three countries are onerous and egregious. They are having or could have a great impact on manufacturing in the United States, particularly given the size of these markets. According to the World Bank, China is the world's second largest economy on a purchasing power parity basis. India is third. Russia is sixth.

What distinguishes them is the direction of progress, and the presence and credibility of ongoing engagement. In China and Russia, we see engagement and progress, however limited. The 24th U.S.-China Joint Commission on Commerce and Trade saw movement on trade secrets, data protection, counterfeiting, and trademark regulations.

Russia recently joined the World Trade Organization and established a bilateral action plan on intellectual property rights protection with the United States. It is making progress in reducing software piracy rates. To be clear, these steps are

far from what is needed, but they are steps in the right direction.

By contrast, India appears to be shifting into reverse. Despite high level interventions by President Obama, Vice President Biden, Secretary of State Kerry, USTR Froman, and others, India's intellectual property environment is deteriorating. It is not engaging in negotiations or making progress in bilateral or multilateral negotiations.

The U.S.-India Trade Policy Forum established in 2005 has a mandate to address intellectual property protection and enforcement, but it has not met since 2010. No other potentially relevant dialogue has met since 2011. In multilateral forums, India is leading efforts to weaken intellectual property protections.

India is an important market for manufacturers. We can certainly see the promise in a range of sectors, including in defense and aerospace, but a successful partnership depends on regular engagement and a two-way street, and the willful absence of dialogue makes clear the Indian

government lacks any serious commitment to engage.

India is the only country in the world that has been on the Priority Watch List or higher since the first Special 301 Report was issued in 1989. Placing India on the Priority Watch List for another year is unlikely to result in meaningful progress. And we urge this Committee to consider elevation to Priority Watch List. Thank you very much. I look forward to addressing any questions you have.

CHAIR WILSON: Thank you very much for your testimony. I'll ask you a question I asked one of the earlier speakers. I mean clearly one of the things that you identified with respect to India as a differentiating factor is the lack of engagement. Obviously, governments engage when they perceive some leverage in other governments, and so we are doing what we can. As you mentioned, we have engaged the Indians at a variety of high levels.

The obvious investment question, how is India's behavior affecting investment by NAM member companies in that country, because it seems to me

that that is a critical leverage point?

MR. MOORE: Yeah, I think our member companies have been very concerned by what they see as a troubling pattern of behavior by the Indian government. Its industrial policies, forced localization policies, concerns about the protection of intellectual property rights, and a lot of these things have arisen over the last couple of years and become a serious concern. They have always had challenges working in the Indian market, but I think very concerned about the direction in which the environment for business is headed.

Certainly, there have been declines overall in foreign direct investment in the Indian market. The India's Department of Industrial Policy and Promotion shows that foreign direct investment in India fell by more than 36 percent between financial year 2011-2012 to financial year 2012-2013. In the telecommunications sector, there has certainly been a steep drop-off in investment between 2011 and 2012, from $2 billion to just $300 million.

We have certainly heard anecdotal stories from members who are either reconsidering investments that they were considering in the Indian market or holding off on things that they were doing. Always hard to link these types of figures to exact policies, and I'm not attempting to do that now, but I think we see some worrying signs in terms of the investment climate there, and I think you're starting to see some movement in the direction of the market.

CHAIR WILSON: Thank you for that. I think it would be -- numbers would be very helpful to us. In a lot of these discussions, we talk in terms of anecdotes, and we talk in terms of perceived cause and effect. And I realize that associations tend to be in a difficult situation because you are not the actual company that's making the investment. But to the extent that you can help us actually identify some of these figures, that would be hugely helpful.

MR. MOORE: We're happy to provide the information we have.

CHAIR WILSON: That would be great. And I would ask that you do that through the regulations.gov site.

I think we're at 10 minutes. So, again, I apologize to my colleagues for preempting your questions. But we would like to follow up with some of these questions in writing. We do have several on China, I think, that we would like NAM's insights on. So thank you very much for joining us today.

MR. MOORE: Thank you.

CHAIR WILSON: And I'd like to call the next witness, please, the Pharmaceutical Research and Manufacturers of America. Welcome.

MR. TAYLOR: Hi. Thank you. Thanks very much. Good afternoon. Thank you for the opportunity to speak today on behalf of the Pharmaceutical Research and Manufacturers of America. PhRMA is a nonprofit association --

CHAIR WILSON: Please introduce yourself and spell your name. Sorry about that.

MR. TAYLOR: Oh, sorry. Sorry, yeah, I jumped the gun. I got too excited. My name is

Jay Taylor. I am with PhRMA. It's a pleasure to be here today. I look forward to the discussion.

PhRMA is a nonprofit association that represents America's leading global pharmaceutical research and biotechnology companies devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.

PhRMA and our member companies strongly support the important work of the Special 301 Subcommittee of the Trade Policy Staff Committee and its chair, the Office of the U.S. Trade Representative, as they identify countries that deny adequate and effective protection for intellectual property rights and fair and equitable market access to U.S. companies and individuals who rely on IP protection.

Encouraging and fostering innovation and protecting IP of the U.S.-based innovative industries are critical to the future of the U.S. economy. IP is central to the productivity, growth, and the competitiveness of U.S. companies in the global marketplace. IP-intensive industries

contribute to greater and more sustainable long-term economic growth, accounting for nearly 35 percent of U.S. GDP in 2010 or over $5.1 trillion in economic output.

Robust IP protections have helped spark innovation and growth in countries, both developed and developing, throughout the world. As much as 40 percent of U.S. growth in the 20th century was a result of innovations, according to Nobel Laureate Robert Solow.

PhRMA member companies act as key economic drivers by generating high quality, high paying, and high productivity jobs in the United States. In 2011, the industry supported 3.4 million jobs, including over 810,000 Americans who were directly employed by the industry. And the industry exported over $50 billion in pharmaceuticals in 2012, making it the third largest U.S. exporter among R&D-intensive industries.

Protecting the industry's intellectual capital is important for the continued medical breakthroughs that are saving the lives of patients

all around the world. Patents and other IP protections are critical in securing the investment required to develop innovative medicines, which in turn will be the next generation of generic medicines.

It seems obvious to say that we have not -- we would not have copies of medicines without those original discoveries. And we would not have those original discoveries but for the IP incentives necessary for a high-risk and resource-intensive investment into research and development.

Our industry provides substantial contributions to patient health. With nearly $50 billion invested in research and development in 2012 and having produced more than half the world's new molecules in the last decade, our members are world leaders at medical research with more medicines in development in the United States than in the rest of the world combined.

The United States accounts for approximately 3,400 products in development in 2013, in large part due to IP protections and other strong

incentives that foster the environment needed to support continued research and development.

Medical research leads to advances in life-saving treatments for major diseases affecting patients all around the world. The improved use of prescription medicines can result in better health outcomes and result in lower costs for other healthcare services such as the 833,000 annual hospitalizations avoided through the use of recommended anti-hypertensive medication, as well as increased worker productivity due to few medical complications, hospitalizations, and emergency room visits.

More acutely, HIV/AIDS is perhaps the best example of the incredible progress that has been made in combating infectious disease in recent decades. The discovery and development of new treatments have turned HIV infection from a death sentence into a chronic disease. In the U.S. alone, death rates have fallen more than 80 percent since 1995 as a result of the development and introduction of multiple drugs used in innovative combinations.

As of December 2013, there are 394 medicines in development for infectious diseases that plague many developing countries for which new treatments are needed, including a medicine for the most common and difficult to treat form of hepatitis C, an anti-malarial drug that has shown activity against a form of malaria that is resistant to current treatments, and a novel treatment that works by blocking the ability of the smallpox virus to spread to other cells, thus preventing it from causing the disease.

Our companies are also hard at work at developing innovative treatments for chronic diseases such as 73 medicines in the pipeline for Alzheimer's. In addition, since 1980, life expectancy for cancer patients has increased by about three years, and 83 percent of those gains are attributable to new treatments.

These figures highlight the pressing need to defend the sector's IP rights against infringement and appropriation. The path from basic research to new medicines is extremely complex,

requires high-cost risk-taking, and is fraught with setbacks.

Unfortunately, many of our trading partners do not respect the value of innovative medicines, as demonstrated through limitations on the availability of pharmaceutical patents in places like India with Section 3(d) of its Patent Act, or even Canada with its patent utility doctrine. Other barriers include unfair or impermissible compulsory licensing rules, lack of adequate regulatory data protection, lack of effective patent enforcement mechanisms, and patent or marketing approval delays that erode the effective patent term for pharmaceutical products.

In addition to the IP system, other foreign government policies and practices such as price controls and cost containment measures impede market access for cutting edge drugs. Foreign cost containment measures create market access barriers that pose a significant threat to the U.S. economy because of our preeminence in the life sciences sector.

Global impacts on the U.S. industry's ability to sustain and create exports, maintain and develop jobs, and stimulate future innovation can be felt here at home. Some governments have proposed or implemented cost containment measures such as ad hoc government price cuts, international and therapeutic reference pricing, and mandatory rebates, without predictable transparent and consultative processes. These policies typically put short-term government objectives ahead of long-term approaches that would ensure continued research and development into medicines that patients need most.

Other countries promote preferential trade policies, including local manufacturing requirements, forced technology transfer, and de facto bans on imports, which are intended to grow domestic industries by undermining opportunities for foreign or local innovation. In the midst of a robust trade agenda, it has never been more important for the United States to signal this message to current and future trading partners.

Our industry also continues to speak out against the scourge of counterfeit medicines which affect the health and safety of patients worldwide. According to the World Health Organization and Institute of Medicine, counterfeiting is greatest in areas where regulatory and enforcement systems are less developed.

For example, estimates indicate that between 10 to 30 percent of medicines sold in developing markets are believed to be counterfeit. Testing in 2012 found that one-third of anti-malarial medicines in Sub-Saharan Africa and Southeast Asia lacked any active ingredient. This is why U.S. government engagement on strengthening regulatory and enforcement systems, in addition to enhanced customs controls and information sharing around the globe, is so critical.

It is important that the incentives of the IP system promoting research investment be maintained because there can be no access to medicines unless medicines are discovered in the first instance. PhRMA member companies have been

and continue to be partners with key stakeholders, including governments in solving global health problems. Our companies are some of the largest contributors of funding for development of innovative cures for diseases affecting developing regions in Latin America, Asia, and Africa.

In the last decade, biopharmaceutical companies provided over $9.2 billion in direct assistance to healthcare for the developing world, including donations of medicines, vaccines, diagnostics, and equipment. Without these efforts, which are threatened when IP protections are eroded and the incentives for innovating new medicines are undermined, access to effective, sustainable healthcare for the developing world's patients would be impossible.

As stated by Bill Gates at the 2010 World Economic Forum, the key reason that we are making progress against these diseases is that there has been an incentive for drug companies to invent, and they have invented great drugs. These efforts are threatened when IP protections are eroded.

We stand ready to support USTR, this Subcommittee, and the entire U.S. government in seeking adequate and effective protection of IP rights overall to ensure that patients around the world have access to the state-of-the-art medicines our member companies develop and manufacture. Thank you very much. I am happy to answer any questions that you may have.

CHAIR WILSON: Thank you for your testimony. We have about a minute left. So I am going to not monopolize the conversation this time. I'm going to turn directly to my colleagues and see how many of these questions we can get through.

MS. PETTIS: Oh, sorry. Thank you for your testimony. Is it possible for you to estimate the overall cost to the U.S. pharmaceutical industry due to India's policies and also their impact on U.S. jobs?

MR. TAYLOR: We found it very difficult to date to come up with an exact figure. And part of the reason, I'm sure, has been touched on earlier today, but I'll reiterate it nonetheless. India

represents a threat both in terms of the policies taking place in the Indian market standalone, but also in terms of the spillover effect into other markets where our industry does business around the globe. In other words, whether there is any sort of contagion effect of India's anti-IP mercantilist policies into other markets where both my industry and other innovative U.S. industries are engaged.

It's very difficult in the IP space to attribute exact figures and losses to these sorts of policies. We can certainly provide you with whatever information we have in writing, and I'm happy to do so.

CHAIR WILSON: Thank you. Any additional questions?

MS. BLEIMUND: Thank you. From reading your submission and also from listening to you now, you seem to argue that price controls, as well as government purchasing and reimbursement policies, may constitute discriminatory non-tariff barriers that would fall within the scope of this Special 301 process. So is your argument that all types, all

these types of policies fall under the scope of this process and are considered to be discriminatory non-tariff barriers, in your opinion?

MR. TAYLOR: In my opinion, the way the Special 301 statute is written, as it relates to IP-intensive industries like the pharmaceutical industry, and not just the pharmaceutical industry but other industries in the United States that rely on IP protections, I believe it requires USTR to identify countries that, quote, "deny fair and equitable market access to United States persons that rely on intellectual property protection."

So if you take that for what it is, market access, these are market access issues. These are our companies which are highly regulated, and the pricing reimbursement systems that are in place in a lot of the markets where we do business are the key to market access into those markets. Our companies really cannot enter a number of these global markets where we try to engage, unless you can get through these pricing reimbursement systems.

They tend to be one of our sole purchasers

in the markets, the government, basically. So if there aren't transparent rules, if there isn't due process in those systems, we run into a major market access barrier which we think is captioned in the Special 301 statute, because really at the end of the day, it also orchestrates the IP rights inherent in the products, as well.

CHAIR WILSON: Thank you for that. We are at the 10-minute mark, so I think that concludes this segment. We will follow up with some additional questions and would appreciate anything that you can submit in response to the questions that were asked. Thank you very much for coming today.

MR. TAYLOR: Thank you for your time.

CHAIR WILSON: Next, I'd like to call the Trademark Working Group. Welcome. Please introduce yourself and spell your name.

MR. KILMER: Thank you. I am Paul Kilmer, K-i-l-m-e-r. I'm representing the Trademark Working Group. I want to thank you, first of all, for the opportunity to appear today. Unfortunately, you

were facing the wrong direction when the giant Pepsi truck drove by about half an hour ago, and that's what I'm here to talk about. So you can relax, it's trademark time.

Our group was formed in 2013 as an ad hoc collaborative of U.S. companies and organizations that have experienced challenges in protecting their trademark rights abroad. The 21 participants of the group include Fortune 500 companies and their subsidiaries, in addition to other well-known brand owners.

The group intends its Special 301 submission to be used for the improvement of trademark law and practice through education, technical support and assistance, and diplomacy. We, therefore, have not requested the designation of any nations as Priority Foreign Countries or Watch List nations. However, this does not mean that all nations mentioned in our submission present equal challenges to trademark owners.

Trademarks enhance consumer choice and provide consumers with handy and reliable ways to

identify, request, and purchase products and services. When adequately and effectively protected, trademarks help to prevent consumer confusion and deception in the marketplace. Trademarks provide a positive reward for risk opportunity to their owners. Their use in differentiating the goods and services of various producers encourages companies to constantly enhance the quality of their offerings and, thereby, the goodwill of their brands.

The experiences of companies like Lenovo in China and before it Samsung in South Korea and Toyota in Japan demonstrate that trademarks can be effective tools to create demand for products produced in developing nations without misappropriating brands created in the United States or elsewhere. Protection of trademarks through adequate and effective legal means is, therefore, important to the United States and its trading partners, including those whose markets or legal systems are not fully developed.

Our group has provided USTR with a lengthy

written report regarding certain nations and their laws and practices that deny U.S. trademark owners adequate and effective protection. However, certain nations because of their commercial significance or the number or nature of trademark issues raised about them appear to merit special attention. These include China, India, Brazil, and Russia.

I will highlight only a few of the issues to illustrate some of the problems confronted abroad by U.S. trademark owners. In China, achieving well-known mark status remains extremely difficult, especially for foreign companies. Since well-known marks have the potential to stop infringement across product and service categories, the ability to achieve well-known status is extremely important to brand owners in China. I would note the same issue also arises in Thailand and Venezuela.

China does not allow for a complete and effective searching of recently filed trademark applications. Because of the six-month priority period allowed under the Paris Convention and GATT/TRIPS, applications for these stealth marks

enjoy seniority over later filed applications even though the stealth application could not be found in a good faith search. This same problem also exists in Brazil, Egypt, Indonesia, and several other nations highlighted in our report. One member of our group lost several millions of dollars when it was forced to rebrand a new product after a stealth application suddenly was extended to the United States and elsewhere.

In China, it will soon not be possible for plaintiffs to file appeals from adverse trademark opposition decisions. This allows infringing marks to register and remain registered while the trademark owner begins a new proceeding to cancel the offending registration. That may take two years or more to complete.

China poses many other challenges to trademark owners including a lack of openness and transparency in trademark matters, rigid application of its trademark classification system, which may allow for registration of infringing marks, burdensome legalization requirements for documents

used in certain types of proceedings, extremely short response times to reply to office actions and submit evidence in opposition proceedings. China also gives very little credence to coexistence and consent agreements, I'd note.

In India, there are extreme delays in the handling of oppositions, cancellations, and most court actions, all of which may permit infringements to continue without redress for lengthy periods of time. Some delays in contentious trademark matters have reached more than seven years.

India also imposes burdensome requirements for certification mark registration that may lead to use of different certification standards in India than elsewhere. This undermines the uniformity and integrity of the certification process.

As in India, Brazil has extreme delays in trademark registration and handling of opposition and cancellation actions. Also, like China, Brazil's very slow indexing of newly filed applications allows for stealth filings that may be extended to other nations.

Russian law does not provide for trademark opposition proceedings. This means that infringing marks may be registered, and the only remedy is to bring a later cancellation action while the infringing mark remains registered and oftentimes in use. Russia is not alone in this regard, as Mexico, Ukraine, and several other nations highlighted in our report also have no trademark opposition proceedings.

Russia has burdensome trademark licensing and license recordation requirements, as well as ineffective protection against bad faith registrations. Russia offers no registration protection for certification marks. Unfortunately, many other jurisdictions share this deficiency, including the European Union, Korea, and Mexico.

Many other issues and nations are mentioned in our written submission. However, the Trademark Working Group has not been able to address all issues of concern to trademark owners. Therefore, our submission should be considered as only part of the fabric of concerns regarding

adequate and effective protection of the rights of U.S. trademark owners.

The Trademark Working Group hopes that its submission to USTR will be useful to it and other U.S. government agencies in pursuing the goal of improving global trademark law and practice. Thank you.

CHAIR WILSON: Thank you. Thank you very much for appearing today. And really thank you to the Group for what you have been able to put together here. This is a blueprint for trademark till the end of time. It really -- it's a fascinating compendium of problems around the world, and we can certainly spend the rest of the day asking you about each individual market and what the causes are. And we know what the effects are, because we know how important trademarks are not only to U.S. businesses, but to businesses that are trying to grow in these markets.

So I have three questions, and then I'll open it up, if we have any time left. We have about two minutes, at this point.

One, do you plan to continue this work on an ongoing basis as a group to supplement the information that's in here and to somehow keep this current?

And, two, do you have any plans as a group to sort of, for lack of a better way of putting this, take the show on the road, start to deal, you know, maybe approach the U.S. government in a more systematic way, maybe approach some of these governments, so that's kind of functionally.

And just having looked across the landscape, did you see any trends? Why does this happen? Is it a lack of political will, is it a resource issue, is it a technical assistance issue? What do you think is at the core of some of the things that are going on in the report that you have submitted? Just your general impressions would be really interesting and helpful. Thank you.

MR. KILMER: Okay. Great, thanks. Thank you for the kind words, first of all. We do plan to continue on, unless another group or organization decides to pick up the mantle. We have no dues. We

have no formal membership. We have no meetings and no secret handshakes. Really, it was because other organizations in the trademark field have not stepped forward and made 301 submissions that we have done so.

So, I would simply say that if one of those other organizations should come forward with a significant trademark submission in the 301 process, I would be happy to hand them our work product and walk away. It's an enormous time commitment, not just for me and my associates, but also for the companies involved.

In terms of follow-up, I am hoping that some of our individual companies will come forward and meet with agency representatives in the near future, and we are trying to plan some of those meetings now. And I think those one-on-one meetings will be very beneficial to you, because I think they will give you very specific problems and issues that have arisen in some of these countries. And I think that will be useful.

There is really no other plan to take the

show on the road other than to hopefully meet with some of you folks in the near future and on an individual company basis. So I think that's an extremely important thing.

In terms of -- could you rephrase your last question again? I'm sorry.

CHAIR WILSON: Basically, having gone through all of this, just your general impressions about why -- I mean, obviously, the situation is different in every country and the reasons, but did you identify any trend sort of across countries of why this submission is this long on all these --

MR. KILMER: On trademarks. Yeah, some of it is resource issues. And this is why I have not highlighted some of the countries. In sub-Saharan Africa, for example, I think it would be fair to say that resource issues may prevail in some of those countries in terms of joining some of the treaties and enforcing them. We note, for example, Sierra Leone has not implemented the Paris Convention, even though they have signed it. I would venture a guess that is probably a resource issue.

I think it is a political will issue in some other countries. I think China could be highlighted in that regard. I think that the amendments, for example, they have made to the China Trademark Act, some of them are very good. They tried to increase some of the penalties in civil actions and that sort of thing. But some of the changes are highly questionable, like eliminating appeals in opposition proceedings, which allow for registration of infringing marks. There just seems to be too much deference to Chinese domestic concerns in that particular instance.

And I think for the more developed countries, that is perhaps more true. For example, Russia, I fail to be able to explain to you why they don't have trademark opposition proceedings, same thing with Ukraine. Why not? I mean most countries of the world do. It prevents the registration of infringing marks.

And these countries, and that includes Mexico oddly enough, do allow for registration of infringing marks and then you, as the trademark

owner, have to start a separate new proceeding while that mark remains on the register sometimes for years and potentially in use. And, in fact, in China, if an infringing mark has been used for some period of time, the courts may even give deference to that usage.

So, as I say, I think some of these things are simply to protect domestic industry. Some of them, I can't imagine why a country like Russia would not have an opposition system other than to allow the registration of infringing marks. But I see very little incentive in the Russian case for that. So it may simply be oversight or lack of funding to the intellectual property protection agencies.

CHAIR WILSON: I think we're done. I think we're at the 10-minute mark. Thank you so much for coming today.

MR. KILMER: Thank you.

CHAIR WILSON: And we'll definitely look for opportunities to follow up on that.

I'd like to call the next witness, please,

University of Oklahoma College of Law. That was very kind of you to do that; thank you. Welcome.

PROF. RAGAVAN: Thank you. And thank you very much for working with me to make this possible, and I appreciate it very much. Thank you for the opportunity. I begin with the two big questions --

CHAIR WILSON: That doesn't let you off the hook for introducing yourself, though.

PROF. RAGAVAN: Oh, I'm sorry. Okay, so I'm going to restart the time. My name is Srividhya Ragavan. I am a Professor of Law at the University of Oklahoma College of Law. Thank you, once again.

So we have two questions here. The first of this is the jurisdiction of this forum, and I think Professor Sean Flynn covered it this morning very well. So the only thing I want to highlight with reference to that is as part of your process, that's something that you have to consider, the jurisdiction of this forum to conduct this exercise.

And the second of these questions, of the questions presented here, and I want to concentrate

on India, right, is whether India has violated any of its international obligations that affects the U.S. industry. So, it's not whether India has done anything that affects U.S. industries; it has to be qualified by has that, has it violated any TRIPS obligations? And India has not, is my submission. And because India has not, it should be removed from the Priority Watch List. In fact, its actions should be condoned.

So we begin with what India has done since 2005, when it instituted its product patent regime. It instituted a sophisticated product patent regime, made use of the flexibilities that is allowed in TRIPS, established patent offices, modernized them, right, established the product patent regime, created the Intellectual Property Appellate Board, created a due process for dealing with all intellectual property disputes. And all of this is indeed working very well, right?

So now we go to the criteria for patentability in India. In India, as is in the United States and as required by the TRIPS

Agreement, the three important criteria for patent protection is utility, novelty, and non-obviousness, right?

Now we go to the question of Section 3. Section 3 is what in the United States we would call as a threshold question. We call that as the patent eligibility requirement. And I substantiate it because one of the criteria to deny patent eligibility in the United States is abstract ideas. And Section 3 also talks about abstract ideas.

Now 3(d), the controversial section, presents a refined patentability criteria for a particular type of question. And we'll talk about the question. Now, having refined patentability guidelines is not alien to the TRIPS mechanism, nor to the United States. The best example -- or to other developed countries. The best example I can give is the 2001 utility patent guidelines that the United States had for biotech inventions. And 3(d) is comparable, right, to refined patentability guidelines for esters or for new forms of known substances like esters, polymers, and so on and so

forth, right?

Germany has that. In fact, Germany's patentability guidelines is that patents on genes are limited to the disclosed functions. So it's not a fourth requirement because it is not a requirement for all subject matters, nor for all inventions. It talks about one small scenario, which is a new form of a known substance.

So let's get to the Novartis case which talked about patentability of imatinib mesylate. It's important to know that imatinib, itself, was already patented by Novartis, right? The only question was with reference to the mesylate form of Novartis of imatinib, right, and that's the Gleevec drug that we have been talking about, right?

So I want to keep this aside and get to the United States and see what the Federal Circuit does in such situations. I get to *Pfizer v. Apotex*, a 2007 Federal Circuit opinion, where the Federal Circuit considered the patentability of amlodipine besylate, when amlodipine, itself, was subject to a patent. And the Federal Circuit said that in order

for a besylate form to be patented, we want to see unexpected results. That's the test that the Federal Circuit uses, a showing of surprising or unexpected results.

This is codified in the United States in Section 716.2 of the Manual for Patent Examination and Practice, 2144.8, which talks about prima facie requirements by showing superior or unexpected results in the United States. And the Federal Circuit held that the besylate form, the patent on the besylate form is invalid considering that there is a patent on amlodipine.

Now, in India, the test is called enhanced efficacy, and it is very similar, very comparable to the test of unexpected result. And I want to take a moment to highlight one other drug that BIO, the person representing BIO, the gentleman representing BIO talked about, which is Combigan. In fact, it is written in the submission, as well. The name of the drug is Combigan. It's a combination of brimoprost [sic] and timolol. And I can give the correct spelling and so on and so forth. I'm pretty sure

I'm a little tense and I am not pronouncing it correctly, right?

Now, this same drug was considered in *Allegra v. Sandoz* by the Federal Circuit. And, interestingly, the claim in question was invalidated by the Federal Circuit. I am pretty sure, and I've seen it 100 times, the BIO submission does not highlight that. The same claim that the IPAB invalidated in India was also invalidated. It's a combination for a glaucoma drug, right? It's a combination for eye drops, right? And the Federal Circuit invalidated it saying that there is a separate -- the combination patent is invalid in the United States, right?

So I do want to highlight that from this perspective, the 3(d) requirement is pretty much within the requirement of TRIPS and along the lines of what we have in the United States, right?

And now we get to the next question of Bayer's compulsory licensing. Now, so far, India, since its independence, has compulsory licensed one drug. It is not like there is a tendency to become

the drug compulsory licensist of the world, right? And that one compulsory license was well within its rights under the TRIPS Agreement, right?

And I do hope that other countries will actually follow suit to prevent the kind of ridiculous pricing that Bayer had made, which would be ridiculous not by Indian standards but by American standards, right? The cost of Bayer's medication was $5,000 a month in a country where insurance, if at all, covers only hospitalization, never covers medication. And as for the 2005 World Bank Report, 25 percent of the population lives at $1 a day, right? And 41.6 percent earn $1.25 a day, right? And Bayer's drug was priced at $5,000 a month, right?

And I do want to highlight some of the conditions under which it was compulsory licensed. Bayer was unable to prove that it supplied the market with the required number of bottles. That was a question that was repeatedly asked by the controller general. And it was repeatedly asked by the Intellectual Property Appellate Board.

Over a period of three years, Bayer showed a supply of 200 bottles in a country where there were at least 40,000 cancer patients, right? And that's exactly -- this is the one situation that the Doha Declaration wants to ensure, right? Access to medication, innovation for medication is ultimately to the people, right?

If we have to provide for medication, the ultimate goal is to reach people who need it. If there is no people, there is no need for innovation, and that cannot be lost on a forum like this.

So now I do want to highlight one other thing with reference to the compulsory license issue here. Despite this high price, right, India did not compulsory license Pegasys, another drug that was very highly priced in India; Sutent, another drug which cost, and I have the price, about $1,500 for a strip of 7 tablets, right? So that's, you know, that's the overall cost of Sutent. And $6,000 for six months for Pegasys, and that drug is taken in combination with Ribavirin, which costs approximately another $1,000. And roughly 1,400

patients were treated.

India is a country of 1 billion people, right, and only 1,400 patients. And I can give you an estimate of the number of patients who were not treated, if that's, you know, if that's something that you are looking for, right? So I do want to highlight the importance of this and why India exercised its right to compulsory license the drug.

All right, now I am very mindful of the time, because I want to ensure that I take some questions. So the first thing I want to highlight is we have talked a lot about the global innovation, the GIPC's report. There are other reports that is non-industry based and more, I want to say, less biased, I want to say. The Global Innovation Index by the Cornell University, INSEAD, and WIPO is a great example of this, right?

We have talked about a lot of industries that are unhappy with India. I want to urge this forum to look at the submission of Boeing, right, to India. And Boeing made a submission saying how they are fantastically happy. This is a submission made

to the ITC. ITC held a hearing last week, and Boeing made a submission saying how happy they were with its IP laws and so on and so forth, right?

And earlier we talked about this forum's self-reflecting exercise, and I want to urge the forum to stop and think about what is the limits, what rights do countries have under TRIPS, right? And then look at all countries violating those rights, because now, you know, there is a fluidity as to what rights or what flexibilities countries have, and that has to be established because those are flexibilities that sovereign nations have as a matter of right to take care of their social, economic, and welfare situations. And so that's something that has to be taken into account.

And my very last point is really, you know, we are talking about possibly the only country in that region that's friendly to the United States, right? And if you take that region, Middle East and India and, you know, China and so on and so forth, India is the only country where American -- where the public opinion of America is still running high,

right?

And the overall trade between the two countries is $63.7 billion, right? And there is trade, and patents are being issued not only in pharmaceuticals, but also in other areas which I didn't see was being represented as much as in some other areas, I want to say.

Given all of this, right, I want to urge this forum to be a little more self-reflective, right? And to show some restraint and to see how strategically, you know, the impact of the decision to continue India on the Priority Watch List would strategically affect the relationship between the United States and India.

So with that, thank you very much for your time. I appreciate it very much.

CHAIR WILSON: Thank you very much for your testimony. We find ourselves at the 10-minute mark, so there won't be time for questions. But I would like to invite you to please identify any additional data. You mentioned that you had some. We would be more than happy to receive that. I can

even provide you with a question and you can respond to it.

PROF. RAGAVAN: Sure.

CHAIR WILSON: And then I am going to take advantage of the fact that you are a professor and ask you to give me a reading list.

PROF. RAGAVAN: Oh, absolutely.

CHAIR WILSON: I think it would be very interesting for you to identify some additional studies --

PROF. RAGAVAN: Absolutely.

CHAIR WILSON: -- and things like that that the Committee should look at.

PROF. RAGAVAN: Absolutely.

CHAIR WILSON: So thank you for joining us today.

PROF. RAGAVAN: Thank you very much.

CHAIR WILSON: We are going to pause for a moment here. We have to switch out the memory card in the camera to make sure we capture our last speaker. So let's pause for a moment, please. Thank you. And then the next witness will be our

last witness, Knowledge Ecology International.

(Off the record.)

(On the record.)

CHAIR WILSON: Thank you for your patience during that technological interlude. Welcome to Knowledge Ecology International who is our last party this afternoon. So please introduce yourselves, and spell your last name. Welcome.

MR. LOVE: Thank you. My name is James Love. My last name is spelled L-o-v-e. And I am accompanied today by Dr. Manon Ress. The first name is spelled like the opera and then last name R-e-s-s. Thank you.

CHAIR WILSON: Please begin.

MR. LOVE: Knowledge Ecology International is a nonprofit organization. We have an office in Geneva, Switzerland, and in Washington, D.C. We submitted a statement. I'd like permission also to supplement the record. I understand that will be available later today.

One of the things I'd like to supplement the record with is the testimony that we -- written

testimony we prepared for, there is another proceeding. The International Trade Commission is having a proceeding about India, and I think it would be useful to have a lot of the information reflected in the record of this proceeding because many of the people have focused on India. and there was nine hours of testimony on that.

In terms of I think that the first thing I want to talk about is a lot of the impetus of putting India into the Special 301 has been about two actions they took explicitly on patents on cancer drugs. One was Gleevec. and one was Nexavar, but then also they talked about doing compulsory licenses where there has been issues about patents being granted on other cancer drugs.

I want to just spend a little time briefly going over this exhibit I passed out about the high price of cancer drugs. These are an extraordinary group. There was 19 -- there was 29 cancer drugs approved by the U.S. FDA between 2011 and 2013 that were new chemical entities, new molecular entities. That's really, historically, a very unusual group of

registrations. So we wanted to look at this, and I have done this really for some other work I'm doing as well.

Now, the average price for the 29, the un-weighted average price is over $100,000, and the median price is $9,200. Those are really expensive drugs.

I have also mentioned that if you look at 20 of the 29 were eligible for orphan drug exclusivity and also a 50 percent tax credit on the clinical trials that was provided by the United States as a subsidy. And if you look at the last two columns, these are the number of patients in trials, in the press release, when the product was approved by the FDA. Only three of the products on this list listed more than 1,000 patients in the clinical trials for efficacy. Joe DeMasi's famous study of the cost of drug development used about 5,300 patients as an average. These things, the average was less than -- or it's in order of magnitude, smaller, it was less than 500. It was 446, and the median was only 331. So I think one

thing I'd like you to know is the prices are really high, and the company's investment was deeply subsidized by the U.S. government, and the number of patients in trials was tiny.

The other thing I wanted to mention is that 16 of the 29 products are being marketed by companies that are not American. Thirteen are by American. In fact, in the last two years, the share of non-American products has gone up.

If you look at the two big cases in India that they're talking about, Gleevec and Bayer, those are cases where the drugs were developed with public support in the United States, Gleevec, and received various subsidies, including the orphan drug subsidy in the case of Nexavar, by U.S. firms or nonprofit institutions, but then now they are owned by in one case a German and one case a Swiss firm. So you can't really just sort of assume that everything about pharmaceuticals is necessarily about the U.S.

In my testimony that I submitted on regulations.gov, I spent a fair amount of time going over a related issue, which is the global share of

patents that are being issued worldwide and how the U.S. share has changed over time. I just want to like comment if you look at the PCT patents, the patents filed in the Patent Cooperation Treaty of WIPO, which are the most important ones, they tend to be the ones that are filed everywhere. In 1982, the United States was responsible for 45 percent of all the patents filed in the PCT of WIPO. By 2001, that was below 40 percent. By 2009, it was below 30 percent. And in 2012, it was 26.4 percent.

From 1997 to 2012, the U.S. share declined every single year. So I would like people to look basically at the fact that not all the drugs are affordable, even in the United States, and not all the products are owned by Americans. Not all the patents in the world are American patents, you see.

I want to talk briefly then in terms of people mentioned the Nexavar case, so I'll just add to what other people -- I was a witness in the Nexavar case on the issue of whether it met the standard, and I was out there during the appeal.

It was priced at 42 times the average

income in India. If you did that for Nexavar in the United States, the price would be $183,000 per month. Now, if that was the price in the United States, you could understand why, or $2.2 million a year, you can understand why that wouldn't be acceptable. That's really what they were looking at in terms of India.

The CEO of Bayer, during this controversy, when asked by the FT about it, didn't even mention the local working condition, like all these trade associations referred to. We talked about the pricing issue. We referred to the compulsory license as theft. But then he said we didn't develop this drug for the Indian market anyhow; it was for Western patients who can afford it. So what you're trying to decide is whether people that don't live in the markets they think are really the right markets for them, whether they should live or die. And if you take steps to deny access to cancer drugs around the world, you're going to kill people because it's a real problem.

There was a woman at the hearing in ITC

named Nina. She lives in Florida. She came up to attend the hearing. She talked to a number of journalists. Her father earns $300 per month in Egypt. Nexavar is priced at $900 a week in Egypt. He has gone through his entire life savings. Now he's contemplating -- he's been out of the drug since last Friday, and now he's contemplating whether he should -- or he's been out of the drug for a week now. He's contemplating whether he should sell his family-owned business in order to pay for nine months more of the drug, at which they'll have nothing actually.

I've been involved with possibly infringement activity, if anyone here from customs or the copyright or the patent police, they might arrest me afterwards, but I've been trying to basically find a way to get the $27 a week version of Nexavar, a cancer drug, from India where the compulsory license only applies to sale within the territory of India and does not permit the export to Egypt, where the product is under a patent.

That requires either infringing the patent

both in India and in Egypt on a $4,500 drug in terms of the Egyptian price, or getting compulsory licenses in both countries, which is quite a challenge, or smuggling it like somebody recommended to her that she hollow out books and smuggle the drug across the border using someone kind of like a mule or something like that.

That's the situation that PhRMA and BIO and NAM and all these people want you to enforce. They want you to basically just make it so those people can't get access to the drugs.

Now, I'm going to finish very briefly with two points. One is the U.S. has a lot of compulsory licenses that have been issued. The standards-compliant patents decision by the U.S. PTO and the Justice Department effectively are the biggest compulsory license in the world right now. It affects about 50,000 standards.

Under the *eBay*, there have been compulsory licenses granted right and left for things like contact eye lenses, heart disease valves, automatic transmissions, Windows software, DirecTV's set top

box, all kinds of things.

28 U.S.C. 1498 is a fairly broad authority. And I'll provide, if you'll permit me, a series of case under that. That has been used recently.

There is one case that is, I think, quite new and it is relevant to the discussion about local working. It's 42 U.S.C 17231, subparagraph 7. It's part of the U.S. Energy Storage Competitiveness Act. It's a local working requirement for patents that enter into this program of subsidies that the U.S. government runs to develop battery technology, to make the U.S. competitive in battery. And basically if you start rattling the cage on local working conditions, you have the Bayh-Dole Act provisions, which are local working provisions to work, but you also have the U.S. Energy Storage Competitive Act, and you should take a look at that.

Finally, the Affordable Care Act, of course, has a compulsory license provision on undisclosed patents and biologic drugs, and it's a mandatory, non-discretionary compulsory license.

The final thing I'll mention is a hep C drug sold by Gilead. It's priced at $1,000 a pill. It's a very good drug. It's a cure for hepatitis C. It's $84,000 for a course of treatment in the United States of America. There are 3.2 million persons in the United States that are hep C positive.

The way you do the math on this is you multiply 3.2 million people times $84,000, and you get a number of $269 billion. That is the price that Gilead has offered to treat everyone that needs, you know, that could be cured of this disease. It's an infectious disease. If you don't treat them, they are going to infect more people, and it won't be 3.2 million next year, it'll be a bigger number.

It's not like the government is going to pay $269 billion for this hepatitis drug. You're just basically not going to treat very many of the people that have hepatitis C. You're only going to treat the acute patients that are, you know, in acute conditions, which is a much smaller number. So you have an opportunity to pretty much wipe out

hep C, but you're not going to take advantage of it because of the crazy way the pricing system works. And there are 150 million hep C patients outside of the United States.

I think you have to sort of rethink the whole drug thing and pursue a different trade agenda that focuses on R&D and different models of pricing things, and pursue this as de-linkage strategy so that countries like Germany and Canada and India and Brazil, and everybody pays their share, but the medicines are available almost for free on the margin. But countries contribute both private sector incentives like innovation inducement prizes and grants and things like that, so that there is a robust financing involving billions of dollars to stimulate new R&D, but you don't have like $100,000 or $85,000 in the margin prices and a lot of people not being treated in the United States, elsewhere, Greece, etc., around the world, because of this crazy system that we are currently engaged in. Thank you very much.

CHAIR WILSON: Thank you for your

testimony. Time is up, so we won't ask any questions today, but we did have a few questions, and so we'll go through those and forward them to you so that you can respond to them during the next two weeks. You did refer to a couple of different outside sources. If you would like to submit those for consideration, we'd be happy to have those as well. So thank you for joining us again this year. I really appreciate your input.

So, at this point, I think I will wrap up with some post-hearing comments mostly in the logistical vein. As I have mentioned several times today, the Special 301 docket at regulations.gov, that's USTR-2013-0040, will be reopened this afternoon and will remain open through 5:00 on March 7th, Friday, March 7th.

Anyone who testified today who is going to submit additional information, responses to the questions that we'll be providing, etc., you're welcome to use that, to please put all of their materials in the public record. I would like to strongly encourage anyone who will be doing that to

do that as soon as possible, not to wait until March 7th, so that we can have an opportunity to review the additional materials and follow up with questions. Submissions should contain the phrase 2014 Special 301 Review in the type comment field. And, please, label your comments Post-Hearing Comments.

As I mentioned, also there will be a transcript and videotape of today's proceedings available within two weeks. That will be available free of charge through USTR.gov. And, again, mentioned several times today, upon the conclusion of this year's review, the Committee will reconvene to conduct a review of the review. We anticipate a public notice and comment period around that exercise and welcome anyone who participated today or joined us today, and as well as any interested stakeholders, to provide us with their views during that process.

I would like to thank everyone today, all of the parties that testified, all of you for joining us here in the audience, my co-panelists

from the Committee, and as well as USTR personnel and others who made today possible.

And with that, I would like to adjourn the 2014 Special 301 hearing. Thank you.

(Whereupon, at 1:35 p.m., the meeting was adjourned.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

SPECIAL 301 REVIEW PUBLIC HEARING

February 24, 2014

Washington, D.C.

were held as herein appears, and that this is the original transcription thereof for the files of the Office of the United States Trade Representative.

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TOM BOWMAN

Official Reporter

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