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OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

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SPECIAL 301 REVIEW PUBLIC HEARING

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March 1, 2016
10:00 a.m.

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

COMMITTEE MEMBERS:

CHRISTINE PETERSON	Chair, Special 301 Committee Director, Innovation and Intellectual Property, USTR
PROBIR MEHTA	AUSTR, Innovation and Intellectual Property
OMAR KARAWA	U.S. Department of Agriculture
STEVAN MITCHELL	U.S. Department of Commerce
EMILY BLEIMUND	U.S. Department of Health and Human Services
MATTHEW A. LAMBERTI	U.S. Department of Justice
MAUREEN PETTIS	U.S. Department of Labor
JEAN BONILLA	U.S. Department of State
WON CHANG	U.S. Department of the Treasury
MARIA STRONG	U.S. Copyright Office
MICHAEL SMITH	U.S. Patent and Trademark Office
MARY CRITHARIS	U.S. Patent and Trademark Office

Free State Reporting, Inc.
1378 Cape St. Claire Road
Annapolis, MD 21409
(410) 974-0947

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P R O C E E D I N G S

(10:00 a.m.)

MR. MEHTA: Good morning, everyone. My name is Probir Mehta. I am the Assistant U.S. Trade Representative for Innovation and Intellectual Property. I would like to warmly welcome everyone to the 2016 Special 301 Hearing.

I would like to note for the record that this is being transcripted as well as recorded. Today is Tuesday, March 1, 2016. This hearing is taking place at the Office of the United States Trade Representative in Washington, D.C. Both a transcript and video of today's hearing will be made available to the public within 2 weeks of today's event on USTR's website, which is USTR.gov. Links to these will also be available on STOPfakes.gov.

Today's hearing is scheduled to go until approximately 2:10 p.m. I would like to ask for everyone's cooperation in the endeavor of keeping the hearing on track, as there are many commentators today and we'd like to ensure time for everyone.

At this point I'd like to invite

colleagues on the hearing panel, all of whom represent U.S. Government agencies that serve on the Special 301 Committee, to introduce themselves. I'll start with my left. Christine?

CHAIR PETERSON: My name is Christine Peterson. I am the Chair of the Special 301 Subcommittee, and I am Director for Innovation and Intellectual Property here at USTR.

MR. LAMBERTI: Good morning, everyone. My name is Matt Lamberti, and I am with the U.S. Department of Justice.

MS. PETTIS: Hi, good morning. I'm Maureen Pettis, and I'm with the Department of Labor, Bureau of International Labor Affairs.

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

MS. STRONG: Good morning. My name is Maria Strong with the United States Copyright Office.

MR. SMITH: Michael Smith, United States Patent and Trademark Office, Office of Policy and International Affairs.

MS. BONILLA: I'm Jean Bonilla, the Director of the International Intellectual Property Enforcement Office at the State Department.

MR. MITCHELL: Stevan Mitchell, International Trade Administration, Office of Intellectual Property Rights, Department of Commerce.

MS. BLEIMUND: Good morning. Emily Bleimund, Director of the Office of Trade and Health, at the Department of Health and Human Services.

MR. CHANG: Won Chang, Department of Treasury, Office of International Trade.

MR. MEHTA: Thanks, everyone. The Special 301 Subcommittee of the Trade Policy Staff Committee is comprised of the agencies you just heard from. It's chaired by USTR, and these agencies conduct the annual Special 301 Review. The review is driven by stakeholder contributions and by the contributions of Washington-based agencies and our embassy-based personnel around the world.

In that vein, today, we will hear from

interested parties, a range of them, including foreign government officials, private sector interests, and civil society, who responded to USTR's January 11, 2016, Special 301 *Federal Register* notice and voluntarily requested the opportunity to appear at this public hearing. This is the seventh time we have held a public hearing in connection with the Special 301 Review, and each year we look forward to this opportunity.

As a reminder, the purpose of today's hearing is to provide the Special 301 Committee with the additional information that we can use in deliberations that will lead to the publication of the 2016 Special 301 Report to Congress on or about April 30, 2016.

This year, we have received filings that address over 75 different countries on dozens of discrete market issue access, substantive IP, and enforcement issues. Those filings are available to the public at www.regulations.gov, and the docket number is USTR-2015-0022.

So I'd like to recall the statutory

authority for what we're doing here today. The 301 Report is the result of the congressionally mandated annual review of the state of intellectual property rights protection and enforcement in trading partners around the world, which the Office of the United States Trade Representative conducts 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. The provisions of Section 182 are commonly referred to as the Special 301 Provisions of the Trade Act, hence the Special 301 Report.

Specifically, Section 182 of the Trade Act requires the United States Trade Representative 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 to determine which, if any, countries should be identified as priority foreign countries. 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 out in Sections 301 to 308 of the Trade Act.

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

The format of today's hearing will be as follows. First of all, we have at the front of the room or at the back some updated, revised hearing agendas and with respect to each of the speakers. Each party has been allotted 10 minutes. Each person will start with 7 minutes of prepared statements, leaving 3 minutes for panel questions. However, we will remain flexible within the 10-minute period, making adjustments as needed.

We will be watching the clock and will interrupt with time cues. My colleague, Stevan Mitchell, has them right here. There will be a 2-minute warning before the end of your 7 minutes, and then 30 seconds at the end of your 7 minutes.

The panel will hold its questions until the presenter concludes his or her statement. In some cases, we have prepared questions based on written filings. In others, we will provide questions in response to your testimony today. In general, please keep in mind the purpose of this hearing, to provide information that the committee can use in discharging its duties under the statute, when conveying your testimony and responding to any questions that we may ask.

We will break twice, very importantly, once for 10 minutes after the government testimonies at around 11 o'clock, and once for 20 minutes about halfway through the non-government testimonies. So without further delay, I would like to invite the Government of Bulgaria to start us off.

Welcome, sir.

MR. KONSTANTINOV: Good morning.

MR. MEHTA: Please introduce yourself and begin your testimony.

MR. KONSTANTINOV: Thank you, State Commission. My name is Ivo Konstantinov, Trade

Attaché and Commercial Representative in the Embassy of Republic of Bulgaria, presenting the report of the IP Coordinating Body of Bulgarian government, Ministry of Economy, on behalf of the Embassy of Bulgaria in Washington, D.C., and depositing to you recent submission of Bulgarian government's activities in intellectual property rights protection in the past year, 2015, following the country's inclusion in the U.S. Government's Special 301 Watch List.

With regard to the annual Special 301 Review under the U.S. Trade Act, we would like to present to you the basic facts from the recent submission of the Bulgarian government, in brief, on its activities in the field of IPR protection last year.

The Bulgarian authority is quite seriously concerned about the inclusion of Bulgaria in the Watch List and they made further efforts in 2015 to improve the intellectual property protection in various areas. Let me highlight the following facts and figures that present the achievements in the

field of IPR protection.

In 2015, the competent institution in our country worked hard for, first of all, reducing internet piracy by increasing control over the numerous online services possibly infringing IPRs; improving coordination of activities between the institutions; strengthening the penalty measures for internet piracy, in particular; and reducing difficulties in collecting royalties by the companies for collective management of copyright and enforcing administrative and judicial protection of their rights; aligning the rights of authors with the rights of other stakeholders, such as internet service providers, especially; dealing effectively with complaints from rights holders against offenders of IPR; improving coordination between investigating and judicial authorities for effective enforcement in cases of IPR protection, reaching dissuasive convictions. Addressing the issue of internet piracy is part of the efforts for drawing up a new penal code to overcome the numerous difficulties in enforcement in this area.

Bulgaria undertook decisive measures to enforce the recommendations of the 2015 Special 301 Report of the USTR and particularly aiming at, Number 1, transforming the cybercrime department and moving it back under the hat of the Ministry of the Interior, which is the equivalent of the Department of Homeland Security in our country.

In 2015, the department was transformed into the so-called now Cybercrime Sector at the Transnational Organized Crime Department, at the General Directorate for Combating Organized Crime, and is a part of the Ministry of the Interior back again.

The Cybercrime Sector pursued its activities in the field of IPR enforcement in combating criminal infringements of IPRs. The main direction of the work of that agency is mainly combating crimes against intellectual property committed on the Internet. A great part of these crimes is committed through the creation of links, servers for storage of information in type of cloud services and storage; online transmission within

real time, and that is the streaming sort; and peer-to-peer technology, as well as sharing an enormous number of files, sites, hubs, torrent sites, forums, blogs, chat channels and so on, through which information is exchanged by the users of internet in Bulgaria in a different manner. The main characteristics of each type of sites infringing copyright is the fact that there is no profiling of their contents, and music, films, software, literary works, photographic materials and so on are distributed usually through one site.

So the small torrent sites reduced their popularity in our country as a result of the systematic pressure and the preventive measures of the officials from the General Directorate for Combating Organized Crime at the expense of the being ratified such, which try more and more to cooperate with the right holders, including removing torrent files which they receive alerts for from the right holders. That is an interesting sign that they try to gradually legalize their activities.

Number 2 involves the Bulgarian

government's allocating the resources needed for the improvement of the criminal prosecution under cases in the area of IPR, including establishment of specialized in the area of IPRs prosecutors' units and courts.

So far, there is no specialized court in the area of IPR in our country due to the fact that the number of cases is quite small. In practice, however, there is the following specialization:

The claims under the Patents and Utility Models Registration Act, the Marks and Geographical Indications Act, and the Industrial Design Act are under the jurisdiction of the Sofia City Court, the capital city. The claims under the Integral Schemes Topology Act and the New Plant Varieties and Animal Breeds Protection Act are under the jurisdiction of the Administrative Court of, again, the City of Sofia. The disputes under the Copyright and Related Rights Act are under the jurisdiction of the Regional Courts. And, again, the Sofia Capital City Court has exclusive competence with regard to the civil cases for infringement of rights over targets

of industrial property.

Number 3 is of particular importance to our presentation this year. Progress is improving of the efficiency of the justice system in Bulgaria in the consideration of cases in the area of IPRs and the imposition of sentences with a dissuasive effect. Particularly, the draft of a new penal code developed by the Ministry of Justice of our country is evidence for the consistently pursued policy of the Bulgarian government for the protection of intellectual property, and special place was set out for crimes against intellectual property as such. The anticipated legislation for crimes against intellectual property is differentiated in an independent section of the code.

Number 4 is ensuring compliance by the cable operators with the legal requirements regarding the deduction of royalties to the companies for collective management of copyright.

Number 5, undertaking actions for coping with the illegal collection of fees from smaller -- companies.

Our appeal, in conclusion, is that the Bulgarian competent authority has followed the recommendations of the U.S. Government and focused on the weaknesses highlighted in the 2015 Special 301 Report. The efforts were directed on copyright piracy over the Internet most of all, software piracy, and collection of royalties by companies for collective management of rights. Real and consistent results were achieved that continue enhancing the level of IPR protection in Bulgaria for the period under review report.

Thank you for your attention. I'm available for questions.

MR. MEHTA: Thanks very much. For our first question, I'd like to go to the U.S. Copyright Office.

MS. STRONG: Thank you for your presentation. I'd be curious to know if you could provide a status update on the work of the working group that was established in June of last year with respect to collective management and perhaps revising various laws.

MR. KONSTANTINOV: I appreciate the question and would like to convey to my authorities for the presentation after these talks within the presented time.

MR. MEHTA: Our next question, the Department of Justice.

MR. LAMBERTI: Thank you.

Dobar den. (Untranslated.)

MR. KONSTANTINOV: Oh, thank you for Bulgarian.

MR. LAMBERTI: We are very pleased you testified to -- I see last year that the police cybercrime unit has been moved from the State Agency for National Security, or DANS, back to the General Directorate for Combating Organized Crime, or GDBOP, at the Ministry of Interior. However, even though the cybercrime unit has returned to GDBOP, apparently the unit has been told that it can only investigate intellectual property offenses that constitute, quote/unquote, "organized crime," which is defined under the Bulgarian criminal code as an offense being committed by a group of three or more

people.

As you know, many significant intellectual property crimes can be committed by one or two individuals. Is this a change in the unit's responsibility? Is this a permanent change or is the government going to allow the unit, as it did before, before it was transferred to DANS, to investigate all types of substantial intellectual property crimes, even those that involve fewer than three people?

MR. KONSTANTINOV: Thank you for the question, Mr. Lamberti. It's quite pertinent, relevant, and I would also like to convey to my authorities for the submission of the response.

MR. MEHTA: Thanks very much. For our third question, we'll go the Department of State.

MS. BONILLA: Thank you so much. Unfortunately, I cannot greet you in Bulgarian, but I'm very happy to have your testimony today.

In your government submission, you mention that the Government of Bulgaria had strengthened punitive measures or penalties in combating internet

piracy. We are specifically interested in some examples of that and whether you feel that this really has served as a deterrent? We're hoping that those figures would demonstrate that. And we also want to know what types of fines have been imposed for those actions.

MR. KONSTANTINOV: To be particularly effective as a response -- thank you for the question. As quick response, part of it, particularly effective for clamping down smaller file exchange sites infringing on intellectual property, and it's pushing the bigger ones into initial attempts of legalization. As for the other, I will submit examples within the presented time frame. Thank you for your question, again, duly noted.

MR. MEHTA: Thanks. I think we have time for one more question, also for the Department of State.

MS. BONILLA: Yes, thank you. We'd like to know if there have -- if you could also give us some statistics on how many criminal prosecutions

there have been? And we note that there have been instances of suspended sentences, so it's particularly useful if we could have some of that data as well.

MR. KONSTANTINOV: Thank you for that question. Again, I shall submit the response in due course. Could you repeat the question, please, once more?

MS. BONILLA: No problem. It's just that we'd like to know how many criminal prosecutions there have been and if you could address the issue of suspended sentences, whether in fact in those instances of criminal prosecution you have seen the imposition of actual penalties or whether the sentences were put aside for other punishment mechanisms.

MR. KONSTANTINOV: Understood.

MS. BONILLA: Okay.

MR. MEHTA: Thanks very much, sir, for appearing today, and that concludes your testimony.

MR. KONSTANTINOV: Thank you for the opportunity.

MR. MEHTA: If we can now call the Government of the Czech Republic, please.

MR. ZAJICEK: Good morning.

MR. MEHTA: Good morning. Welcome, and please introduce yourself, and begin your testimony.

MR. ZAJICEK: Thank you very much. My name is Jaroslav Zajicek, and I am Deputy Chief of Mission of the -- oh, the microphone.

Good morning, again. My name is Jaroslav Zajicek. I am Deputy Chief of Mission of the Czech Republic here in Washington, D.C. And this is Tomas Hart, the Head of Economic Section at the Czech Embassy again.

First of all, thank you for giving us the opportunity to speak here today. We didn't have to appear here, but we wanted to. I wanted to make a case of the development that our country made, let's say, in the last decade and to demonstrate on that ways through mutual cooperation and determination on our side at hand.

When we were part of the Watch List in 2008 and 2009, actually the pressure led to efforts

on the Czech side and it took us 2 years to convince you that that determination is there, that the inspections are for real, that the penal code was really amended in a way and enforced as it should be.

When I appeared here in 2013, 3 years ago, I tried to defend the Czech case. Now in 2016, I think we can sum up that the peer pressure has helped us in many respects. The Czech Republic and the United States are strategic partners. You look at us very often through the lenses of the 301 Special Report and we have been enjoying U.S. investment very much. So, in a way, we would hate for strategic lines which there is between our two countries to be shadowed over by any negative aspects.

But, now, we are moving to a stage where we can jointly work on benchmarks, helping the situation get better in the countries. I think there is a tremendous potential and mutually inspiring lessons learned to be exchanged and we will demonstrate that throughout the course of

today.

My basic introduction which consists on four major areas, first of all, is the IPR infringement in the cyberspace. The trend is clear we are moving from the physical marketplaces into the cyberspace. This has been for quite some time. The cyberspace, internet, is central to the minds of the Czech authorities. Especially if it is high among the young generation, it deserves a lot of attention.

The number of infringements slightly rose last year. At the same time, the percentage of cases that were clarified rose quite dramatically, as well, from 59 to 68 percentages, quite a good achievement, in my view. But there are several challenges that lie ahead of us in fighting the illegal content and file sharing and copyright piracy, in general terms.

First of all, it's the best way perhaps to detect infringements on diplomatic forums that unfortunately do not gather localization of data users. The anonymous Wi-Fi routers that are used to

cover IP addresses, that's another source of our worries. And social media more and more becoming a platform for counterfeit goods and IPR breaches are the trends that we need to respond to.

When I was here 3 years ago, I presented the Digital Czech Republic 2.0 strategy. Now it has been alive and kicking, and this year we have introduced an action plan that actually the plan reflects the trends that I mentioned just a minute ago. These trends are being regularly also considered by the government office and checked twice a year, which is very important.

So confirming the trend, IPR trends in the cyberspace, we still need to spend some time also on the controlling activities and enforcements of IPR, which is the second, I would say, topic I would like to spend some time at least briefly on. This is basically about effective cooperation of the enforcement institutions. Here, I can demonstrate a record number of inspections. In 2015, around 2,400 inspections took place, which is about 400 more than last year.

But what is more important is the amount is counterfeit pieces was reduced from 60,000 to 36,000, which kind of demonstrates that a trend is there, the number of cases clarified that we went after is 92 percent. So I think the trends that are in general there, which is moving from shoes and CDs to batteries or alcohol, we are after it and we are tackling it quite successfully.

Third will be the prevention and education, which is an indispensable part and vital in our hands. Among the organizers of seminars and lectures are, of course, the intellectual property office, it's the police, it's the Czech customs administration. But it's important where you do these seminars. You need to start rather early.

We have introduced a series of seminars that go to secondary schools already, which is mainly concentrated on the social media. At the Czech Metropolitan University, we introduced both bachelor and master, and post-graduate, specializations on intellectual property. I think this is the way we should continue in the future.

Of course, we should organize and we are organizing seminars for those that are undertaking the controls as well, and judges included. What I would note, underestimated is also the public awareness campaigns. Last year, we had the NATO Days, which is probably the biggest NATO event in Europe, and the ideal hold for the visitors some information about the negative impact of IPR infringements. And as I said, around 220,000 people passed by there last year. So that is, in my view, something that needs to be stressed.

I spoke with the national level, on the international level. One thing that is worth mentioning is the creation of the Visegrad Patent Institute that will become operational the first of July, next year, which basically serves not only in increasing the awareness among the Visegrad four countries, and the Czech Republic is currently the residency of the Visegrad Group, but also about facilitating registration of technical solutions for protection abroad. So I think that is a good direction of regional cooperation.

Last but not least, the level of legislation that is before us, I would say, the group of issues that we needed to work on, last year we amended the Copyright Act, which basically enables for better transparency of collective management enterprise and multi-territorial licensing. It introduces also the possibility of cross-border licensing, and also the Customs Administration was helped by set of regulations that basically enhanced competence itself for the Czech Customs Administration on the IPR enforcement.

To conclude, before I would give the floor to my colleague, I strongly believe that the Czech Republic should remain out of 301 Special Report in 2016, but I see a lot of common ground for presenting some of the benchmarks that we have come to you and I had noticed there is some interest also on your side, to share those with you. I will now give the floor to my colleague.

MR. MEHTA: Unfortunately, I think your time has expired. We have time for one question from the Department of Justice.

MR. LAMBERTI: So thank you. In your submission, also your testimony today, you mentioned the Digital Czech Republic 2.0 strategy, and you also mentioned the action plan that was adopted to implement several measures in the strategy.

Could you provide us with some more information on exactly what proposals the Czech Republic adopted and implemented pursuant to the action plan, specifically with regard to the protection of intellectual property rights over the Internet?

MR. ZAJICEK: Thank you for the question. I'll give the floor to my colleague. The action plan was introduced in the summer, last year, so we are still to see the concrete benefits of that. But if we don't satisfy you today with our answers, we will definitely submit it in writing. Tomas?

MR. HART: If I may, as what we have seen what is happening online is that a lot of criminal activities is obviously getting smarter, in a way, and the pirated activities related people and criminals are moving more and more in the shadows.

We have seen lately more on Facebook and social media, which are scrolled through by only people in certain manner, like audited or controls can be let in so only the people with intention, original intention to buy something today what they know is counterfeit product are let in.

To such an extent, the training which has been given to Czech police is becoming more and more online-related, rather than just going through the open public market. So this is the second year there has been an introduction, although I don't know exactly at what year, but recent, that I would say holders or administrators of a site are responsible for the content. So if they see some illegal activities which they detect on their own, they are supposed to delete it or take measures to stop it.

And as to what we have seen on the police, let's say, vis-à-vis physical ground activities that, obviously, the public market which was being kind of very popular back in 1990s, the counterfeit programs are disappearing from them. And some

certain activities are, again, kind of moved out to special buildings, where only certain number of people is allowed in. So I would say it is becoming not so much public, but more kind of background check manner of doing business so people who intentionally come to the market and they show the interest in acquiring some counterfeit or illegal programs are basically let in and physically enter the building where such things are displayed. So it makes certain pressure on the police to be smarter.

Perhaps the last thing which is related to Czech Republic now in global trade, as you know, geographically, in Central Europe, for most of the goods we are traffic country, meaning that a lot of illegal and counterfeit stuff is not destined for the Czech Republic, but is actually physically passing through. And until recently our customs office didn't have the authority to seize or stop products from passing to another country, should it be on the west or somewhere else, and now they can do that.

MR. MEHTA: Thank you very much. If I can

now invite the Government of Ukraine to please come up?

Welcome. Please introduce yourselves and begin your testimony.

MS. MYKOLSKA: My name is Nataliya Mykolska, and I am Deputy Minister of Economic Development and Trade and Ukraine's Trade Representative. I am here with Mr. Shymkiv, the Deputy Head of the Presidential Administration of Ukraine, and Olena Minitch, who is the Director of the Department of Innovation and Intellectual Property Protection at the Ministry of Economic Development and Trade.

I will make a welcoming and noting introduction and then my colleagues will provide some updates on the specific issues that people have the major concern for U.S. Government and U.S. industries.

Last year, Ukraine's upgrade was a gesture of trust in our country and a confirmation that the legislative amendment initiatives launched by Ukraine earlier constitute a step in the right

direction. This year, despite the military and economic aggression threatening the very existence of Ukraine's fate, the Government of Ukraine has worked deliberately and systematically to ensure notable improvement of Ukraine's status.

Our work on IPR infringement issues have taken place in the following six areas that I would like to mention here. First is legalization of software products installed at the executive government bodies. Second is tackling pending issues in the sphere of collective management of property rights. Third is addressing piracy in the sphere of copyrights and related rights. Fourth is the strengthening IP rights protection and the reform of the enforcement agencies being kicked off, including establishment of the cybersecurity unit with the National Police. The fifth is reform of the system of the state administration in the IPR area. And the sixth is audit of the U.A. IP service and firing the head of the service as a result of this audit, which has happened quite recently.

And with that, I will give the floor to

Mr. Shymkiv to provide you with the update on utilization of software.

MR. SHYMKIV: Thank you very much, ladies and gentlemen. It is an honor to be here. The question of IPR within the state board has been on top of the agenda for the prime minister, the president of Ukraine, and the cabinet.

During 2015, we went through the audit of the 23rd state audit, and being able to identify 40 percent of infringements of the software which is being actually published on the official website of the SIPS so that everybody can see what the liability is and how it is addressed.

During 2016, 38 government agencies will be going through a similar audit. The audit is done by professionals who are auditing actually all computers, all details, so all the versions of the software are fully complied for the software asset management practices.

When we are looking at the result of 2015, there are a couple of things I would like to mention. During just 2015, the state audits

acquired 20,000 copies of the software. And just to give you a perspective, the state's treasury services was $340,000. They are planning to spend in 2016, $350-; the Ministry of Internal Affairs, $250,000; State Migration Service, $350-; SIPSU and Ukrainian Patent, $130-.

The biggest portion of their infringement is also taking place within state-owned enterprises and 2015 was another step into addressing this issue. Just during 2015, the Government of Ukraine, through the state-owned enterprise, acquired 40,000 copies of illegal software products. Just to name ENERGOATOM, the one that works with Westinghouse, acquired for a total amount of 4 million U.S. dollars; the Ukraine Sea Ports, half a million; ANTONOV, half a million. So there is a strong bracket of commitment of the Ukrainian government to continue to address the issue.

As a part of the legalization process, the Ministry of Economic Development and Trade signed as part of the plan that was agreed with USTR, we signed a memorandum of understanding on execution of

legalization process through the necessary budgetary support on addressing the reduction of the number of the unlicensed software in the ministry from 67 percent to 30 percent. And the plan is actually only in execution phase.

What I would like also to mention finally, one of the comments which is not related to legalization. There is some concern on the validity of some facts expressed in the Motion Picture Association America submission related to open markets. The report is referencing open market Mayak, in Donetsk. During 2015, due to the security situation in Ukraine, the territory of Donetsk, particularly that market, is not controlled by Ukrainian forces and Ukrainian government. At the same time, the report is referencing Russian illegal movies on territory which is currently controlled by Russian military forces and terrorists.

I think that Ukraine is committed to address intellectual property rights protection on the territory which is controlled by Ukraine and we are looking forward, if we are able to reestablish

the presence of Ukraine on Donetsk in regards to territory. Thank you.

MS. MINITCH: Hello. And really good morning. I am pleased to be here and to deliver the information about two main topics: collective management organization, and piracy and internet piracy.

On collective management, during last year, we were delivering and developing the draft law together with European Union Twinning Project, but unfortunately this draft law did not comply fully to the EU Directive Number 26. Despite the fact that the same draft law was also registered in the Parliament, it was not supported by the Parliament members.

We realized that we will need completely to redesign the draft law and focus on the main issues which we did not address in this draft law. It's a transparency of collection of royalty, transparency of the royalty distribution, and really proper reporting of collective management organization, and how the collective management

organization will be selected and enforced in terms of their duties.

Despite that, we did following actions. We changed the law which allow us to limit the registration of new collective management organizations. It was fully approved by Ministry of Justice end of February this year. During last year, we also dismissed or cancelled the registration of two collective management organizations which we note -- the time is over. Can I have another 2 minutes to continue?

MR. MEHTA: I'm sorry, unfortunately, if you can go on for a little bit and finish your thought, but we'd like to have some time for questions as well.

MS. MINITCH: All right, thank you.

MR. MEHTA: First question from the U.S. Copyright Office?

MS. STRONG: Perhaps this will give you an opportunity to continue on the collective management organization question. As you know, there are numerous CMOs operating in Ukraine and no funds are

being paid to rights holders. How does this new draft legislation that you are going to be composing specifically address the question of unauthorized CMOs operating in Ukraine?

What happens to -- for the new regulations and charge and effect with authorized new entities, what happens to these unauthorized entities that are still apparently doing business? We'd appreciate any information you would have about the current problem and then going forward what the new law is going to attempt to cover.

MS. MINITCH: You're absolutely right. We have 19 organizations registered on the market. At the moment, what we are doing, during last year we did a lot of inspections trying to find what they are doing wrong in terms of the reporting. This is the only way how we can do it at the moment. So we issued 15 notifications for them.

As I mentioned just minutes ago, two organizations been already cancelled, the registration been cancelled. So we intend to go through this process during the year 2016.

The main change we would like to introduce in year 2016, we had a very good successful reform in the public procurement. The public procurement process is called ProZorro, coming from piloting the automated process of the procurement. So we'd like to look at this issue from this perspective introducing that automated process of royalty collection and distribution, which is how we can really take on the issue and make it transparent and eliminate the corruption.

Also during last year, we did a deep inspection on the government organization on collective management, that we are part of this country who still have a government CMO. Unfortunately, we found a lot of issues related to corruption over there. We saw that approximately 70 percent of the royalty they are distributing to three companies, and the shareholder or beneficiary of these three companies is the same person at the end.

So we need to do the reform on this area, really deep reform, modification changes really to

keep excellence in the form of collective management.

MR. SHYMKIV: Quick comment, 2014, we paid out zero through the collective society. In 2015, it's $100,000. Still a little, but versus zero, it's good progress.

MS. MINITCH: Approach.

MR. MEHTA: Thanks very much. And as a reminder, of course, there will be opportunity for rebuttal submissions to enhance what is being posed today. One final question from our colleague from DOJ?

MR. LAMBERTI: Thank you, Probir. Let me just say I'm very pleased to see such a high-level delegation from Ukraine here today and we very much appreciate the detailed submission from Ukraine and also the testimony today.

In Ukraine's submission, you indicated that last year the administrators of three pirate sites in Ukraine were convicted and sentenced to prison. I assume those were not suspended sentences and the terms, I believe, were 2 to 5 years of

incarceration.

In addition, I think in December of last year, the court in Ukraine fined the administrator of a torrent site 3,400 hryvnia, a relatively small fine, but still significant for Ukraine. Last year there were no convictions in this area at all in Ukraine. There have been few prosecutions, let alone convictions or sentences of recent years in Ukraine, both before and after the political situation, the political instability.

So what I'd like to ask you is what do you think has contributed to this improvement in Ukraine in the past year? What specifically have you done that has led to this improvement?

MS. MYKOLSKA: Thank you. The basic idea was mentioned by myself and my colleagues as a political will in the priority of IPR protection in terms of the president's agenda, prime minister's agenda, and definitely our personal agenda. A lot of people at the Government of Ukraine came from the private sector. We know what IPR means. We know what we need to pay for IPR. Therefore, I think

that's a vision of all of the bodies and the political will to move forward.

We believe that the special units with the National Police of Ukraine, the recently reformed militia, you know, old Soviet style, actually police units to the new police with a young generation people coming to this unit will definitely contribute much in terms of bringing the people to justice.

And then definitely the judicial reform which is underway in Ukraine would also contribute not only for the Ukrainian prosecutor's office to bring the cases, but also for the court, you are right, for the court to give the sentence to the people that infringe those rights. You've seen the numbers of the cases that has been initiated by the Ukrainian police, but then at the very end we have not so many sentences as it should be. But, in any case, that is a huge progress.

MS. MINITCH: I'd like to add to that that together with the Minister of Internal Affairs, we had a joint plan. We discuss it during July in USTR

here, and since July, we implemented this plan with the Minister of Internal Affairs of creating the special unit responsible for intellectual property.

MR. MEHTA: Thanks very much. And thank you very much for your testimony today.

I would propose at this point that we break for just a few minutes to assist us in recalibrating the speaker system. We'll begin at 10:50 with the Government of Egypt.

(Off the record at 10:50 a.m.)

(On the record at 10:53 a.m.)

MR. MEHTA: Thanks very much. And now we have the Government of Egypt. Thank you very much, sir. Please introduce yourself and begin your testimony.

MR. EL SAYED: Thank you very much. My name is Magued El Sayed. I am First Secretary at the Egyptian Embassy in charge of Economic and Commercial. Good morning. And I'm sorry I'm not keeping the traditional. The Arab language, I am not --

Before I give you a heads up of the

development that happened in the IPR field in Egypt, I would like first to share with you the methodology that was used in reaching these conclusions. Up till 2008, Egypt was on the Priority Watch List and Special 301. Starting 2008, it is on the Watch List. Up till 3 years ago, we started a new methodology which is looking at the root cause of being on the Watch List and trying to fix the problem from the source.

During the past 3 or 4 years, we have been working closely, because we noticed in the Special 301 that the main problem was in the IPR with the pharmaceutical company, specifically, not in other domains, because we have been going through also the public testimony that is published on your website. So that's how we worked. And we worked closely with the companies to address their problems, to address the main issues.

We also took into consideration all the recommendations that were presented in the previous Special 301, and we worked on ameliorating the IPR situation and standard in Egypt, which is well

illustrated in the reports that I have submitted to you.

Let me go through some of the developments that were done in the regulation and decrees involving the IPR and the pharmaceutical sector, in specific. The Ministry of Health issued decree reorganizing the registration procedures of human medicine. The decree emphasizes on the importance of companies' commitment to the intellectual property rights.

Article 9 of this decree states that companies are committed to provide a pledge acknowledging their commitment to the provision of IPR law of 2002, which is the same as stated in the article which regulates the procedures of registration of biopharmaceuticals, vaccines, and blood products.

Another decree that was issued regarding the IPR which is the pharmaceutical track and trade system that was issued in order to control the Egyptian pharmaceutical market and secure safe and appropriate pharmaceutical supply and product

against counterfeit medicines.

I am giving also notice on another regulation which was a major problem for the pharmaceutical companies that we addressed, which is all registration procedures, which is permission of product, are done in parallel, which leads to shorten the registration process and make medicines available at market as soon as 6 to 8 months, and up to maximum of 18 months. This is instead of previous 3 years maximum time.

The number of companies that are allowed to register their product is open. That gives the chance for more foreign companies to register their product in Egypt.

One of the very important points that was achieved and we got recognition from many companies regarding the fast track system for registration was developed and the system is applied by default on products which were registered through the fast track program in U.S. FDA, so in addition to other criteria set for that purpose.

There was also a breakthrough in the field

of medicine and seeking to register new pharmaceutical in Ministry of Health as soon as it was registered. Many products for Hepatitis C treatment were registered in a period of 8 months.

Other than the rules and decrees, the Ministry of Health participated in a roundtable that include most of the pharmaceutical companies, the U.S. pharmaceutical companies. This ongoing cooperation between the ministry and the private sector stakeholders mentioned above resulted in a set of processes intended to working to advance this sector and joint effort to raise the quality of health care in Egypt, and thus the quality of life for the Egyptians.

Back to the report submitted, we have testimony that was submitted from PhRMA in 2016 that says during the past several years, PhRMA and its member companies that have tried to work in good faith with the Egyptian officials to address health and industrial issues. While serious challenges remain, PhRMA notes that for the most part Egyptian officials have shown willingness to meet and discuss

issues concerned and have expressed interest in supporting the renovated biopharmaceutical industry and encouraging investment in the country. This is regarding PhRMA.

As for BIO report in 2016, I can quote from them, that "During 2015, BIO continued regular outreach to Egyptian officials, and notes the willingness of government representatives to engage on policy issues affecting patients and health care system, and the innovative life science and biopharmaceutical sector in Egypt. BIO notes that as part of Egypt's drive to strengthen its competitiveness in the sector, government officials have demonstrated a willingness to analyze challenges and engage in meaningful dialogue."

Part of the report I have submitted includes testimony that was submitted to the USTR from major U.S. companies and I quote them, "This decision by the Egyptian Health Ministry sends a reassuring signal to investors and companies operating in Egypt that government recognizes Egypt's commitment to modern intellectual property

standards and will take measures to uphold these rights." Another testimony said that the Egyptian government has embarked on a new partnership with innovative pharmaceutical industry.

So, in conclusion, based on all the previous positive developments, evidence-based facts, and testimonies with regard the Egyptian IPR environment, we strongly request the removal of Egypt from the Watch List in Special 301, because this removal will send a message from the USTR that these efforts are being appreciated, encouraged, enforced, and to be continued based on the effort we have made. Thank you very much.

MR. MEHTA: Thanks very much. If we can go to our first question from our colleague in Department of Justice.

MR. LAMBERTI: Thank you. Egypt's submission to the United States this year in the Special 301 process and also your testimony is focused on the pharmaceutical sector. However, Egypt is today probably the largest market -- for pirate and counterfeit goods, mostly imported from

China.

As you know, many shops in Cairo and other Egyptian cities sell infringing mobile phones, clothes, computer parts, and other hard goods, as well as pirated movies, software, games, books, and other copyrighted works. This unlawful activity has reduced tax revenues that should be paid to the Egyptian government and discourage direct foreign investment in the country.

For example, once recent study found that just a 10 percent reduction in software piracy alone in Egypt could generate hundreds of millions of dollars in increased gross domestic product.

Could you explain what Egypt has done in the past year to improve enforcement against trademark and copyright violations?

MR. EL SAYED: I would be pleased to send your request to the specific authorities and get back to you. However, in the 2015 submission for the International Intellectual Property Alliance last report requested in their testimony to the Special 301 that Egypt be omitted from the list, and

we were referring to this, that there is no problem regarding the counterfeit or the piracy of software in Egypt. However, I am pleased to address your question and send it today.

MR. LAMBERTI: I think the software piracy rate is probably over 60 percent. And having been to Cairo in the past few years, I can assure you that there's plenty of pirated and counterfeited goods readily available.

MR. EL SAYED: I'll make sure to --

MR. LAMBERTI: Thank you.

MR. MEHTA: Thanks very much. For our second question, Department of Commerce.

MR. MITCHELL: Thank you. 2012 Pricing Decree No. 499 would have treated foreign made products differently than Egyptian made products. That decree was discontinued. But my question is whether there are plans to replace it and, if so, will it be replaced with a decree that is more transparent and less discriminatory?

MR. EL SAYED: I'm willing to send your questions and get back the answer. However,

regarding that you have actually answered that first part, the decree was discontinued. Most of the companies I meet here in the U.S., they are requesting that regarding the pricing issues, there should be a moving around regarding the prices that they have requested.

And let me tell you this correctly, that most of the pharmaceutical companies are on board of a committee headed by the Minister of Health, and they submit their request regarding the decrees and recommendation and it has taken into consideration their request. They are a part of the team working on this. They have asked to release the prices gradually even on five products per year, so they can pick like five products and start releasing the price on these products. However, I could get you further detail on that.

MR. MEHTA: Thanks very much.

MR. EL SAYED: You're welcome.

MR. MEHTA: That concludes our panel of government commentaries. We now invite the American Apparel and Footwear Association.

And just as a reminder to everyone, we have my colleague, Stevan Mitchell, from the Department of Commerce providing some time cues. Again, should you wish to amplify your comments here with further information, of course, we do have post-hearing rebuttal submissions that are also available and those will be due March 4th. I'll give more information at the end.

With that, welcome. Please introduce yourself, sir, and begin your testimony.

MR. LAMAR: Great, thank you for providing an opportunity to testify this morning. My name is Steve Lamar. I'm Executive Vice President of the American Apparel and Footwear Association, the national trade association representing apparel, footwear, and other sewn products companies, and their suppliers which compete in the global market. We represent more than 1,000 world famous name brands. Our membership includes 340 companies drawn from throughout the supply chain. AAFA is the trusted public policy and political voice of the apparel and footwear industry, its management and

shareholders, its 4 million U.S. workers, and its contribution of $360 billion in annual U.S. retail sales.

We very much appreciate the opportunity, the attention the U.S. Government shows to the defense and protection of U.S. intellectual property rights worldwide. We consider the U.S. Government a strong partner in this area.

For its part, AAFA has been very active and vocal in the promotion and protection of U.S. IPR for the apparel and footwear industry. In addition to our active participation in the annual Special 301 and Notorious Markets Reports, we work with our Brand Protection Council to educate policymakers and other stakeholders on the importance of strong IPR for our industry.

Success in these issues support U.S. apparel and footwear jobs, particularly since our members' competitiveness is highly dependent upon the global protection of the intellectual property embedded in their designs, their brands, and their images. We estimate that intellectual property

theft cost our members upwards of $68 billion in 2013. This is a figure that as no doubt increased as this problem has worsened.

In our comments, we compiled a detail list of countries where systematic IPR enforcement problems exist and where IPR practices need to be improved. Our submission also highlights some successes in countries where AAFA members have traditionally faced resistance for the protection of their brands. In total, we identified 15 countries.

We relied heavily on our members in the development of this list. They provided recommendations based on their direct experiences working with foreign governments, including enforcement agencies, intellectual property policymakers, other IPR stakeholders, and foreign judiciaries.

A number of our members are active in dozens of countries, enabling them to make comparisons over time and between jurisdictions. Their enforcement activities also gave them firsthand experiences conducting raids, observing

any incidents of counterfeit products in notorious markets, and understanding if IP efficiencies can be remedied through additional resources, changes in laws or judicial practices, or an increase in political will.

In the comments, we also raise concerns related to foreign internet registries. Counterfeiters are increasingly using the Internet to expand their business while shielding activities from enforcement efforts. They are registering domains that advertise and sell counterfeit goods and infringe on a brand owner's trademarks, both in the domain name itself and in the content of the website.

Many of these counterfeiters use a country code top-level domain in order to avoid detection by the United States brand owners and enforcement of United States court orders. Individual top-level domains have varying requirements and fees for registering domains; however, most top-level domains do require that the website registrant be a citizen or have a registered office in the country in

question and that the registrant provide true and complete contact information upon registration of a website. Most of these top-level domains also have policies against cybersquatting.

All that is good, but despite these registration requirements and polices, a number of foreign registries do not make registration information publicly available and don't provide information or assistance to brand owners whose intellectual property rights have been violated on a website using top-level domains.

We also note that many top-level domains are not subject to the ICANN consensus policies, such as the Uniform Domain Name Dispute Resolution Policy. This adds another hurdle to the enforcement of intellectual property rights against bad actors on the Internet.

Finally, our comments address three cross-cutting issues that I'd like to raise here. First, facilities that make knockoff shoes, clothes, and accessories do not typically meet the high standards or comply with the regulations upon which our

members insist to ensure product safety, worker safety, and workers' rights. In addition to stealing the identity of world famous brands, counterfeiters put millions of workers in danger through substandard conditions, while exposing consumers to unknown product safety risks.

Second, as we note in several of our country -- in our country comments, we are hopeful that the recently concluded Trans-Pacific Partnership will help improve recognition and enforcement of brands worldwide. While it is expected to have an immediate impact on the countries who have signed onto the TPP, we hope it will have a beneficial impact on countries that are currently outside the agreement. It is with this in mind that we urge the expeditious approval and implementation of the TPP, including the IP provisions in all 12 countries.

On a related point, we remain concerned that some of the existing pre-trade agreement partners continue to demonstrate insufficient production of IPR. Forty percent of the countries

who were nominated this year are FTA partners, including Mexico and Canada, which are also part of the TPP. It is simply not acceptable that FTA partners are unable to ensure high levels of protection and cooperation on this important right.

Finally, we applaud the process in the United States to coordinate interagency IPR enforcement and priority setting in an office in the White House through the IPEC, the Intellectual Property Enforcement Center. Knowing that the Administration is hoping to replicate this approach in other countries, we would recommend that you use the Special 301 Report to call out those countries that have successfully adopted this same mechanism.

I appreciate the opportunity to raise these concerns and look forward to working with USTR and other U.S. Government agencies to address intellectual property rights issues worldwide. I look forward to your questions. Thank you.

MR. MEHTA: Thanks very much. For our first question, Department of Justice.

MR. LAMBERTI: Thank you for your

testimony today. You mentioned in your testimony and also in your submission that counterfeiters deliberately register -- at least some counterfeiters deliberately register their domains with certain country code top-level domains, ccTLDs, to avoid detection and enforcement by brand owners.

In particular, you single out as especially problematic ccTLDs in Sweden, Spain, Germany, Denmark, the Netherlands, China, and Switzerland. As you know, some ccTLD managers voluntarily follow ICANN's UDRP, the Uniform Domain Name Dispute Resolution Policy, and some also agreed to let a panel of the World Intellectual Property Organization, WIPO, resolve their disputes.

So we appreciate you flagging the issue, but what specifically do you believe ICANN, WIPO, and/or the U.S. can and should do about this matter?

MR. LAMAR: One of the things we're trying to do is raise awareness of this, that there is inconsistencies, that there is greater migration of counterfeit problems onto the Internet. And that's manifesting itself in a number of different ways, as

counterfeit goods become directed into smaller and smaller shipments, for example. We are hoping that either through the ICANN process or maybe through WIPO that there will be an opportunity for best practices to be learned and applied across other countries so there is more consistency.

MR. LAMBERTI: And also as a follow-up to this matter, I think we had at least a couple of submissions suggesting that the committee should not address this issue in the Special 301 Report. How would you respond to that?

MR. LAMAR: Well, as I said, I think as the counterfeit problem begins to magnify or already is within the Internet, probably we should be putting more and more attention onto the way in which the Internet is used as a traffic for counterfeit goods and what governments and the other stakeholders in the Internet space can do to help prevent that, so I would disagree with that recommendation.

MR. MEHTA: Great. Thanks very much. The next question from the Department of Labor.

MS. PETTIS: Hi, good morning.

MR. LAMAR: Good morning.

MS. PETTIS: You mentioned in your testimony the lack of property protection and highlighted particular problems with specific countries in your written submission. You had said that $68 billion in losses. But can you break that out for me further, I mean specific countries or percentages in terms of legitimate versus illegitimate by country? Are you able to do that? That would be more interesting to find out as we look at the various countries.

And, as well, you also talked about that employers who -- the employees, themselves, who make these knockoff shoes and clothing work in facilities that don't typically meet high product standards or comply with regulations to ensure product safety, worker safety, or worker rights. Based on the amount of illegitimate product out there, do you have any idea of the scale in terms of number of workers that work in this illegitimate economy?

MR. LAMAR: So to answer your first

question, we didn't do a country breakout. What I would do is point to the customs numbers that they generate. It's a good proxy for sources of counterfeit goods. The European customs agencies, they publish comparable numbers. So that's kind of a good indication that maybe it is -- you know, we're seeing those numbers really across the world that same way from a country breakout perspective.

I don't have specific numbers on the scale of the problem and this is actually something that we are working on, trying to develop more data on this. There should be a lot of anecdotal evidence on that. When folks conduct raids, they'll just see casually that there's evidence of improper work conditions, improper work environments.

And certainly when counterfeit goods are intercepted, tests that are performed on them, we'll find that they don't meet, for example, the restricted substance list requirements or other product safety requirements that our companies have to meet, whether it's in the United States or in other countries. And so this is something we're

trying to develop more information on, too, but again, wanted to flag it because we do think it's an area that needs a lot more work.

MS. PETTIS: Thank you.

MR. MEHTA: A quick follow-up from Department of State.

MS. BONILLA: I just wanted to ask you quickly about whether one of the issues you're looking at in terms of infringement is fabric issues, because it doesn't appear to me that that was mentioned in your statement, just the high-tech fabrics, super wicking sportswear and Levis fabrics.

MR. LAMAR: We didn't call out that specific level. I mean there's a couple of ways in which fabric issues will come up. Either it's through patent issues such as the ones you mentioned; there is a whole area of concern relating to the copyrights that go on to -- copyrights such as designs that go onto the fabrics, too. That's probably more of a domestic legal problem that we're encountering, but again, one that extends back into the countries where product is produced because of

the lack of a clear and consistent library to find designs and to make sure that you're using the legitimate design, for example.

So that is an area that we work on, but we didn't call that out in our comments specifically. I suspect as fabrics become more prevalent in the marketplace, you'll be seeing that more in our comments in the future.

MR. MEHTA: Thanks very much and thank you for your testimony.

MR. LAMAR: Great, thank you.

MR. MEHTA: Next, if we can invite the Alliance for Fair Trade with India, please.

Thanks very much. Welcome, sir, and please introduce yourself and begin your testimony.

MR. POMPER: Good morning. I'm Brian Pomper. I serve as the Executive Director of the Alliance for Fair Trade with India. Good morning and thank you for providing me with the opportunity to testify on behalf of the Alliance for Fair Trade with India.

The Alliance for Fair Trade with India, or

AFTI, was launched in June 2013 in support of increased action to address the barriers to trade and investment U.S. companies are facing in India, including the erosion of intellectual property rights, and to serve as a mechanism for engaging with U.S. policymakers on these issues.

AFTI's diverse membership is comprised of organizations representing a range of U.S. industries adversely impacted by India's IPR policies and practices. In light of this mandate, I am here to call on USTR to again place India on its Priority Watch List and to conduct another out-of-cycle review of India's IPR regime.

AFTI and its members were encouraged by the Obama Administration's efforts at commercial engagement with India over the course of the last year. Our members watched with cautious optimism as the two countries held their first ever Strategic and Commercial Dialogue and meeting at the U.S.-India Trade Policy Forum in the fall of 2015. However, despite the convening of these dialogues, the Indian government has yet to take any

significant steps towards improving the business climate for innovative American companies.

In fact, numerous longstanding issues remain unresolved. These include weaknesses in the Indian copyright system that harm U.S. and Indian creators alike; the use and threatened use of compulsory licensing on biopharmaceutical, environmental technology, and other products as a tool of industrial policy; and measures in Indian law that add a legally questionable additional criterion for the patentability of medicines and agrochemical products.

Additionally, AFTI and its members have serious concerns with several of the policy pronouncements and proposals included in the version of the National IPR Policy leaked in April of 2015. As an extension of a campaign promise made by now Prime Minister Narendra Modi, the Department of Industrial Policy and Promotion constituted a think tank, the National IPR Think Tank, in October 2014, to draft a national IPR policy.

NITT has since drafted and circulated a

revised plan, which was leaked to the public in October of last year. Among the most disconcerting aspects of the document are plans for increasingly onerous local manufacturing requirements and a continued failure to ensure regulatory data protection.

These issues have been longstanding frustrations of AFTI and its members, along with many other innovative American companies. The continued failure by the Modi government to address these and other issues has left AFTI and its members concerned by the apparent disconnect between the diplomatic momentum, positive rhetoric, and commitments emerging from the recently convened dialogues, as there has been little concrete movement on key issues.

Particularly as we enter the final year of the Obama Administration, we are left wondering how can these bilateral forums be used to productively address the issues we have repeatedly highlighted in these and other fora.

We agree with the sentiment USTR expressed

in announcing its 2015 Special 301 Report that, "Attention to our IPR priorities and action to resolve concerns through bilateral fora can benefit both the United States and India." We note that USTR stated it expected India would make substantive and measurable improvements in India's IPR regime for the benefit of a broad range of innovative and creative industries. USTR added that it would, quote, "Monitor progress over the coming months and prepare to take further action if necessary."

As detailed above, we believe that India has not made substantive and measurable improvements in its IPR regime for the benefit of a broad range of innovative and creative industries, and that, therefore, further action in the form of an out-of-cycle review, at a minimum, is warranted.

For these reasons, we recommend maintaining India as a Priority Watch List country and would encourage the U.S. Government to maintain its focus on key IP issues by implementing a new out-of-cycle review. We believe that this increased pressure and oversight is necessary to make progress

and to avoid backsliding on issues of concern to AFTI and its members.

Thank you for your time and for what we know are your constant efforts to address these issues as meaningfully as possible in what has long been and I'm certain will continue to be a challenging environment. AFTI appreciates all the U.S. Government has done and we know will continue to do to try to improve the U.S.-India trade relationship.

MR. MEHTA: Thanks very much. With respect to the questions, can we start with USTR, please?

CHAIR PETERSON: Some of the submissions, including your own, note some actions that the Government of India has taken in the past 12 months, including reports of enforcement authorities taking action and deterring the unauthorized use of satellite reception boxes, the court's issuance of John Doe injunctions against cable operator piracy to curb the spread of pirated sports broadcasts, denial of compulsory licensing requests for patented

pharmaceuticals, and court rulings that uphold patent rights for pharmaceutical companies through the granting of injunctive relief.

I'm wondering how you would characterize those actions that have been taken over the past 12 months?

MR. POMPER: I think there have been some positive developments. I should say AFTI is much broader than just IP and so we've been looking at sort of a broad sweep of different actions. There have been some positive movements. I would say maybe two steps forward, one step back.

There are some major issues that are of longstanding concern both to AFTI members and I know to the U.S. Government that we really haven't seen much movement on at all. I'd say data exclusivity, 3(d), much of the other measures that I know you are all very well familiar with that I think would have the greatest impact.

So I guess my answer is we'll take the wins wherever we can get them, but there is a lot more to be done.

MR. MEHTA: Thanks. For our second question, Department of State.

MS. BONILLA: Thanks very much. One of the new initiatives that Prime Minister Modi has announced is this so-called Made in India outreach and I wanted to know if you had views on how it intersects with India's intellectual property regime. And relatedly, I also wanted to know how companies are responding to the IP problems that you see, whether you're seeing less investment, less trade, some of those types of issues?

MR. POMPER: Thank you, good questions. First, on Make in India, I think as a general policy matter there is nothing wrong with a country saying they want to try to increase their domestic manufacturing. We even have this in the United States.

MS. BONILLA: SelectUSA.

MR. POMPER: Sure. And Steny Hoyer has Make It In America, his program. The difference is a lot of these programs focus on incentives and training, and these sorts of matters, rather than

forcing countries to invest in -- or to invest in-country. There are parts of Make in India -- the one that I can think of immediately right here, there was a suggestion in the draft national IPR policy that entities that commit to manufacturing in India would get expedited review with the patent office. Those sorts of things I think we would not support. We think that's the negative aspect of Make in India.

In terms of how countries are reacting, it is often the case that those who are defending India's practices will say, well, look at the investment flows in India. And I would say there certainly is investment in India, but if you look at what kind of investment, there may be a plant being cited in India, but they won't do any of the high value, R&D innovative research there. And they affirmatively won't do that because of the poor IPR regime. And, of course, I think we all think that's where truly a high value of employment is heading.

MS. BONILLA: Thanks.

MR. MEHTA: We have time for one more

quick question from the U.S. PTO.

MR. SMITH: Thank you. Your remarks and submission raise a number of issues, patent, market access, copyright, and trade secret, that affect different industries. Can you give a sense of which of these are AFTI's priorities or which areas do you see as being the most likely candidates for progress in the short term?

MR. POMPER: It's a good question. I mean these are, of course, many very longstanding, very difficult issues, and I don't think we are Pollyannaish about the prospect of solving in the near term. But we think that the U.S. Government has done a great job pressing India on these issues and hopefully will continue to do so.

We think not only can you make progress that way affirmatively on the issues that we raise, but also to perhaps keep other bad policies from cropping up, and also importantly to keep other countries from maybe looking at India as a guidepost for a kind of development policies issue.

It's hard for me to pick and choose which

of these are more important than others. They are all things that -- different aspects of AFTI, which is a coalition of associations, so they each have their different issues that they care most about. It's hard for me to really pick among those.

MR. MEHTA: Thanks very much for your testimony.

If we can invite the Business Software Alliance? Welcome, please introduce yourself and begin your testimony.

MS. LEWIS: Good morning. My name is Leticia Lewis. I am the Director for Policy at the Business Software Alliance. Thank you, ladies and gentlemen, and members of the committee for the opportunity to testify on behalf of BSA, The Software Alliance.

BSA and our members share your goals of protecting intellectual property rights and we offer these comments to contribute to your efforts. BSA is the leading advocate for the global software industry in the United States and abroad. Our members are in the forefront of driving the global

digital economy and invest substantial resources into developing cutting edge technologies. These companies strongly rely on intellectual property protection in order to continue innovating.

BSA members receive half or more of their combined $600 billion in annual revenues from overseas. That revenue number, $600 billion, is many times greater than all other copyright intensive industries combined. Given the amount generated from overseas, removing barriers to trade is essential to BSA members' long-term success, but more importantly essential to the American economy. It is undeniable that adequate and effective intellectual property protection and enforcement remains critical for our members.

The fair and equitable market access, an often overlooked component of Special 301 consideration for many years, is even more important. We urge you to focus on this prong of the Special 301 and use this process to forcefully and clearly establish removing market access barriers as a dispositive criterion for your

determinations.

In terms of intellectual property protection and enforcement, the main issue faced by BSA members is the continued use of unlicensed software by government agencies, state-owned enterprises, and businesses. According to the latest information available, the commercial value of unlicensed software globally exceeds $60 billion. The software industry is the only industry that actually measures the economic harm done by illicit use of software. I know that should make a key point; losses are extremely large. Illicit use of software is 43 percent of total global software use and in too many countries it exceeds 60 percent.

BSA also remains highly concerned about inadequate enforcement of unlicensed use of software in many countries. Software today is more and more often downloaded online or used on remote servers such as through cloud computing services. It is therefore critical that appropriate regulatory environment prevent circumvention of technological protection measures in the digital environment.

The inability to properly protect trade secrets including source code and other proprietary information is also a concern for BSA members. Patent protection is also extremely important to our members. It is paramount that countries provide effective patent protection to eligible computer-implemented inventions in line with their international obligations.

Since our Special 301 submission, we've had a very troubling development in India. On February 19th, the Indian patent office issued revised guidelines on the patentability of computer-related inventions. The new guidelines may prevent many software-enabled innovations from receiving patent protection in India. They direct the patent examiner to look for a novel hardware element in addition to novel software for the invention to be patentable.

This is a very negative development, one which places India in a unique posture that is out of step with international practice and potentially in violation of its TRIPS obligations. We are

currently reevaluating our recommendation in our Special 301 submission and will send you a letter supplementing our views.

BSA is deeply concerned about steps several U.S. trading partner are considering or have taken to erect digital trade barriers, denying fair and equitable market access to U.S. companies. For example, policies that restrict cross-border data flows are detrimental to the economy as a whole. Data-related market access barrier requirements take many forms. Sometimes countries expressly require data to stay in-country or impose unreasonable conditions in order to send it abroad. In other cases, they require the use of domestic data centers or equipment.

Recognizing the trade disruptive impact of measures that impede cross-border data flows, the United States insisted and succeeded in including specific prohibitions against such practices in the recent concluded Trans-Pacific Partnership Agreement. BSA strongly supports this important outcome and urges the United States government to

seek similar results through all available trade mechanisms including Special 301.

In addition, we are concerned that governments around the world are using or proposing to use security concerns to justify the creation of trade barriers. China's recently enacted counter-terrorism law and draft cybersecurity law are key examples. We are also concerned that a number of countries are imposing significant restrictions on foreign suppliers' ability to serve public sector customers.

Finally, a number of countries have developed or are developing country-specific standards for software and related services. This creates a de facto trade barrier for BSA members, raising costs of cutting edge technologies for consumers, for customers and enterprises.

Addressing the challenges that I have summarized today, it will be critical for BSA members to continue to power the digital economy. In our submission, we recommended the markets, including China, Indonesia, and Russia, be listed on

the Priority Watch List, and Brazil, Mexico, and Korea, among others, be listed on the Watch List.

In many cases, we've identified market access issues in this market as equally important for your review and consideration as to whether the trading partners provide adequate and effective intellectual property protection and enforcement.

BSA and its members thank the USTR and all agencies of the Special 301 Subcommittee for your efforts to address inadequate and ineffective intellectual property protection in countries that are U.S. trading partners. We also urge you to use the Special 301 mechanism to focus even further on a variety of policies that deny fair and equitable market access for BSA members and other companies who rely on intellectual property rights. Thank you very much for your time.

MR. MEHTA: Thank you very much.

For our first question, we go to the Department of Commerce.

MR. MITCHELL: Thank you. I was wondering if you could speak a little bit more specifically to

the country-specific technology standards that you referenced and how they are hurting software companies particularly in China, India, Nigeria, and Vietnam. And as a second level question, is BSA recommending particular approaches or particular solutions that these countries should consider in setting those technology standards?

MS. LEWIS: Absolutely. Thank you very much for the question, a very important one. Just to be clear, BSA doesn't recommend the use of any specific standards. The one ask that we have for all governments is that they use standards that are global, and that they are voluntary, and that they are created through a mechanism that includes multi-stakeholder engagement.

This is so because the standard that will come out of this process will be much more effective and in this way countries can rely on the experts that get together to create the standards. So our recommendation to all governments in our exchanges has always been that it is we don't necessarily point to the use of any one specific standard, but

that they will use the standards as I mentioned.

In terms of the second part of the question, I think, is how those countries are doing that. They do that in a variety of ways. It is not necessarily just regulations that enforce the standards, but sometimes these requirements come through other pieces of legislation or different regulations. This is really detrimental. Sometimes, they will be regulating an area that is not necessarily standard related, but that will include some standard requirements that in most cases will ask industry to rely on domestic standards, which is very detrimental.

MR. MITCHELL: Thank you.

MR. MEHTA: Thank you. Your second question comes from the Department of State.

MS. BONILLA: Thank you very much. I think we are very eager to see what your supplementary submission on India will say about those new issues that you mentioned.

My question relates to Greece, where you specifically stated, I think, in your submission

that the government uses little criminal enforcement to combat piracy. I'd like to know if you can state whether that is an issue related to bandwidth or to a lack of political will.

MS. LEWIS: To the first part of your question, again, the India development is a very recent one, so we are looking to that hoping to be able to offer more information as soon as we are able to.

To the second part of your question, I think it's a mix. I think there is definitely needed more political will to address the issue in Greece, but there is also lack of resources. And I think that it goes hand in hand, because to the time that they establish that intellectual property protection is a priority, then they may start changing things around in terms of budgets and allocation of necessary resources to address the issue.

MR. MEHTA: Thank you very much. Thanks for your testimony.

MS. LEWIS: Thank you.

MR. MEHTA: Next, if I can invite the Computer and Communications Industry Association? Welcome. Can you please introduce yourself and begin your testimony.

MR. SCHRUERS: Hi, my name is Matt Schruers. I am a VP in Law & Policy at the Computer and Communications Industry Association, which is a trade association of internet and technology firms that has promoted openness, competition, and free trade for over 40 years.

Our written submission and my comments today urge USTR to take action on two issues. First, a problematic trend identified as ancillary copyright in which countries deny market access and adequate and effective protection of rights guaranteed under international IP law through the creation of sui generis pseudo IP right, in quotations. Secondly, I'll address the importance of insisting on complete implementation of important intermediary liability protections that we have included in international agreements to date.

So first let me focus on the question of

ancillary copyright. This term ancillary copyright is sometimes referred to as a quotation levy or a snippet tax. Under any label, these provisions are inconsistent with international IP norms. In 2010, actually, I appeared before this panel having warned that at some future date foreign countries might in fact abrogate these commitments to allow for free quotation and, should that happen, the Special 301 process should identify those as inconsistent with IP norms. Today, that day has arrived.

There are these snippet taxes appearing in multiple countries. Our testimony, our written submission, focuses on two, Germany's 2013 Leistungsschutzrecht, under which automated search indexing can lead to liability, providing only for an exception of the smallest text excerpts, which German authorities recently seem to have construed to mean seven words or less.

Similarly, in 2015, Spain legislated a reform of their Ley de Propriedad Intelectual, in which they created a similar quotation levy vesting un-waivable rights in publishers of online news

content such that electronic aggregation services are taxed even for using, quote, "nonsignificant" fragments of aggregated content. As a result of this law, several U.S. and, actually, Spanish news aggregators exited the market, including news.google.es.

As you surely know, Spain has recently been the subject of an out-of-cycle review for other aspects of IP compliance. Our view is that there is no principal reason why this issue should not also be the basis for inclusion in an evaluation of where Spain is out of compliance with IP law.

I will note it only recently came to my attention that, in fact, today, a provision which appears to be a sort of ancillary copyright for image indexing has advanced in the French legislature. My suspicion is that principles like this or proposals like this are likely emboldened by our acquiescence to these legislative initiatives in other European countries.

So, as is described more fully in my written statement, it's fairly clear that these

snippet taxes violate Article 10.1 of the Berne Convention, which requires free use of works. Article 10.1 pertains to news quotations -- I'm sorry -- quotations, news of the day, and that is incorporated by reference into TRIPS. It states that it shall be permissible to make quotations from a work which has already been lawfully made available to the public provided that's consistent with fair practice. Berne specifically says including quotations from news articles and periodicals. USTR has previously Watch Listed countries for TRIPS violations and, frankly, European countries should not get a pass.

Let me just finish by saying a few things about noncompliance with international norms on intermediary liability protections. In a variety of international instruments, most of our free trade agreements going back to 2003, in TPP, in the European e-commerce directive, we have seen the evolution of protections for online intermediaries. The United States created the gold standard for intermediary protection in the mid-'90s and that

norm has spread around the world.

In some countries, we frankly don't see as much effort in complying with obligations that have in fact enacted these. Our written testimony, written submission focuses on Australia, which entered into an FTA with the United States in 2004, and it agreed to create a series of protections for online intermediaries. But over a dozen years have passed since that obligation came about and the Australian law today only protects its domestic carriage service providers. It doesn't protect online intermediaries like U.S. companies that are exporting services to the Australian market.

Generally speaking, I think both of these items indicate that it is time that this process place a greater emphasis on ensuring that the balancing provisions in international IP law are a part of our international policy. That was identified in the 2010 Joint Strategic Plan and it should be an ongoing part of our Special 301 process. I'm happy to take any questions about that.

MR. MEHTA: Thanks very much, Matt. Your first question comes from USTR.

CHAIR PETERSON: Can you elaborate on your views of the statutory and legislative history of the Special 301 statute that provides for your recommendation, specifically the IP protection and the enforcement of market access barriers for U.S. persons that rely on IP?

MR. SCHRUERS: Yeah, absolutely. I think this has been described in greater depth in some of our Special 301 submissions over the past few years. But, generally speaking, 2242(a)(1)(b) provides, if I've got that right, provides U.S. persons that rely on intellectual property are to be granted the same entitlement to protection under Special 301 as what we might think of as protection for the traditional intellectual property goods, patented products, copyrighted works. And, no doubt, that language was designed to reflect that the export of goods, cultural goods or patented goods, was not going to be the only business model that U.S. persons would rely upon.

Indeed, the United States is largely a services economy and if we interpret 2242 to exclude the exports of services, in a few years it's likely to be a largely irrelevant provision. Much of the issues that I am describing and, indeed, that my colleague from BSA described, involve the export of services. For that reason, we need to think about 2242(a) as providing for services that depend on intellectual property.

Indeed, many of the online services that were explicitly targeted in the legislative history, if one drills down into what these countries are talking about when they enact these ancillary copyrights, they are U.S. internet services that are exporting into those countries and they represent the most prominent brands in the world. And they provide IP intensive services, even if they are not selling cultural goods directly as their primary business model. Although, I would add that many of these services do, in fact, provide platforms for the sale of cultural goods.

There is, in my view, no question -- there

is no principal reason why we can say if you're exporting CDs, you get services, but if you're exporting a different kind of service that depends on IP, that we're going to exclude that from 2242.

MR. MEHTA: Thanks. Your second question comes from the Department of State.

MS. BONILLA: Well, this is a really important question for all of us because you know at the State Department whenever you ask for a new position or a new piece of equipment, the first question the management people always ask you is, is this the first time you've asked for that?

You mentioned that the issue with Australia includes a commitment they made a dozen years ago. And so I think the really relevant thing for this panel's consideration is whether there is some new feature or some newly detrimental impact of this particular requirement?

MR. SCHRUERS: So, ironically, the United States might be, in part, the source of the newly detrimental impact in that a lot of countries we have urged countries to raise their IP norms, with

good cause, and only recently are we more aggressively insisting on the implementation of those commitments. And as we are finding, often when those commitments get implemented, they sometimes wind up producing liability risks for exporters of U.S. services into those countries because we haven't insisted on the same level of limitations and exceptions that we have here in the United States. So, frankly, I'm quite concerned that limitations and exceptions such as the safe harbors that are in TP are implemented in Pacific Rim countries --

MS. BONILLA: TPP?

MR. SCHRUERS: Yes, just by way of example, which of course includes Australia. If you look around the Pacific Rim, one probably need not worry as much about limitations and exceptions; although, I will say there still are some cases in part because IP norms have been somewhat under-enforced. As we raise that degree of enforcement, we need to ensure that the flexibilities that U.S. companies depend on in a very high enforcement

environment are also available in those countries. Or what we're going to find is that we raise IP norms and we create a hostile environment for U.S. exporters because limitations and exceptions like fair use aren't present in those marketplaces.

MR. MEHTA: Thanks very much and thanks for your time.

We next invite the Footwear Distributors and Retailers of America.

MR. PRIEST: Good morning.

MR. MEHTA: Good morning. Welcome. Please introduce yourself and begin your testimony.

MR. PRIEST: Great, thank you. My name is Matt Priest. I'm the President of the Footwear Distributors and Retailers of America, and I'm honored and privileged to have the opportunity to spend a few moments with you talking about IP protection.

Founded in 1944, FDRA represents the entire footwear industry from small family-owned footwear businesses to global footwear companies. In all, we support over 130 companies and 250 brands

for 80 percent of total U.S. footwear sales in the United States. Our member companies manage supply chains that span the globe, providing them with hands-on familiarity with the importance of intellectual property and innovation.

We are acutely aware of the need to aggressively challenge the failure of other nations to protect patents, trademarks, and copyright, in both law and practice. After all, FDRA members incorporate cutting edge designs and technology into their products and rely upon the integrity of their brands.

As an organization, we support USTR's efforts to fight counterfeiting and piracy across the globe. These efforts support thousands of American jobs, jobs that are put at risk by such counterfeiting and piracy. In fact, global trade in counterfeits increasingly targets American footwear brands. The two most recent annual World Customs Organization Illicit Trade Reports found that seizures of counterfeit footwear increased by 356 percent during the latest 3-year reporting

period, and that footwear went from being the 12th most seized product for IP violations in the world to the 6th, which we think is a stunning increase over a 3-year period.

FDRA members have noted four general concerns or trends globally, some of which have been noted by USTR in the past Special 301 reports. These include, number one, often penalties are inadequate to deter criminal enterprises from engaging in trademark counterfeiting operations. In many countries, the penalties imposed on these enterprises are so low that they only add to the cost of doing business.

Number two, infringers often use express mail and postal services to deliver counterfeit goods in small packages, making it more challenging for enforcement officials to intercept these goods. Illicit websites and e-commerce platforms, the vast majority of which are based in China, ship counterfeit goods from the United States primarily using international mail services. The sheer volume of small shipments makes it impossible for CBP to

adequately screen or x-ray all incoming mail to detect such shipments. The tremendous acceleration in growth of e-commerce globally will only exacerbate this already troubling trend, not just here in the United States but globally.

Number three, in numerous countries, legal and procedural obstacles exist to securing and enforcing trademark rights. For example, many countries need to establish or improve transparency and consistency in their administrative trademark registration procedures. Also, at times the judicial systems in developing nations lack transparency and independence, making it difficult for rights holders to pursue claims.

And last and our fourth point is that counterfeiters now commonly register domains that advertise and sell counterfeit goods, an issue that was raised by my colleague Steve Lamar, as well as others who have had these challenges. Many of these counterfeiters use a country code top-level domain to avoid detection and to avoid the reach of the U.S. judicial system. FDRA member companies face

significant trademark infringement and lose valuable internet traffic because of misleading and fraudulent domain names.

FDRA would ask USTR to work with U.S. trading partners to provide procedures that allow for the protection of trademarks using domain names and to ensure that dispute resolution procedures are available to prevent the misuse of trademarks.

In addition to the above-mentioned issues, FDRA notes that the theft of trade secrets has become an increasingly important issue for global brands such as our member companies. At times, foreign governments are complicit and indeed even participate in the theft of trade secrets.

We are pleased that the customs bill passed by Congress and signed by the President last week expands the Special 301 Report process to include trade secrets. The current U.S. law does not allow for companies to pursue a civil action against entities that have engaged in the theft of these trade secrets. We believe that legislation to permit a federal civil cause of action for the theft

of trade secrets would have a strong deterrent effect on overseas competitors who may otherwise engage in such theft. It would also better equip the United States government to advocate for strong trade secrets protection with foreign governments particularly through trade agreements.

Now I am going to briefly go through some of the challenges we have in specific countries, first and foremost, China. We remain hopeful that the Chinese government, both at a national and sub-national level, will over time become increasingly aware of the value to both Chinese consumers and the Chinese economy of vigorously protecting IP rights; nevertheless, counterfeiting is all too common in China and the country remains the leading source of counterfeit goods. USTR, in the 2015 Special 301 Report, noted the rampant infringement of footwear IP in China and USTR should continue to do so in its 2016 Report.

Basic IP enforcement in China is grossly inadequate. China continues to be the number one source of counterfeit and pirated goods imported

into the United States, accounting for more than 60 percent, 63 percent to be exact, of the value seized, while Hong Kong rates second, accounting for more than 20 percent.

Within China, knockoff footwear purportedly from American's best known sportswear brands is commonly found in brick and mortar stores and Chinese retailers, and in well-trafficked markets. Actually, my comments submitted have a much more kind of detailed list of the challenges we see in China.

In Russia, massive markets of counterfeit goods both physically and online continue to flourish there. Enforcement procedures are generally slow and inefficient, a particularly negative sign in a country where infringing goods are not only imported but also domestically manufactured.

In Canada, Canada's IP regime falls short of standards maintained in the rest of the developed world. Despite Canada's passage a little more than a year ago of legislation granting Canadian customs

authorities the power to seize imports of counterfeit goods, Canada still falls short in sharing information between enforcement authorities and rights holders.

In Turkey, it serves as a key transshipment point for counterfeit goods manufactured in Asia and the Turkish government has shown inadequate results to crack down on this illicit trade. Serious issues exist with regard to enforcement, not the least of which is Turkey's requirement that rights holders must pay for the storage of seized counterfeits.

Brazil has challenges as well. As my time comes to a close, obviously, with the Olympics and the 2014 FIFA World Cup, Brazil has been an important market for U.S. brands, athletic in particular, and we have challenges in Brazil.

But, ultimately, we appreciate the opportunity to submit comments on the challenges faced by our member companies around the world in protection of IP rights. As leading global innovators, our members are driving advancements in

product design never before seen. Our industry stands on the cusp of innovations that will alter the way global footwear manufacturers produce footwear and diverse footwear consumers purchase that footwear.

Now, more than ever, it is vitally important that the U.S. Government takes all actions necessary to protect these innovations, designs, brands, and images worldwide. We stand ready to work with USTR to bolster respect for and enforcement of IP by our trading partners because doing so protects American jobs and benefits our consumers. Thank you for the opportunity to participate today.

MR. MEHTA: Thanks very much. So for your first question, it will come from the U.S. Patent and Trademark Office.

MR. SMITH: Thank you. With regards to Brazil, you suggested that the Olympics in Brazil present counterfeit challenges and you also suggest creating a fast-track registration process for trademarks and designs related to the Olympics.

How successful was the fast-track registration process for FIFA-related marks for the World Cup, after which your suggestion is modeled, and can you explain how such a fast-track registration process would help ameliorate the counterfeit problem?

MR. PRIEST: Sure. I will make general comments about the fast track with FIFA World Cup and then submit post -- have a post-hearing submission. I think in general there are some positives that came out of the fast-tracking procedure.

The challenge for U.S. brands particularly in Brazil not only stem from the IP challenges but also from the increase in anti-dumping duties that really impede our ability to get product to Brazilian consumers in a cost-effective way. So we kind of have a twofold challenge in Brazil. While at the same time, just based on demographics, the Brazilian marketplace is one of great export growth and great growth of the importation of U.S. brands, which obviously supports jobs.

So, in general, I think that there has been some wins in Brazil, but when you have these two vitally important events, the World Cup and the Olympics back to back, 2 years apart, we're going to see kind of, I think, an increase in challenges on the IP side. What we will do -- what I will do is come back to you with a post-submission response after talking with our membership.

MR. MEHTA: One more question on trade secrets from the U.S. Trade Representative Office.

CHAIR PETERSON: Can you explain how your member companies rely on trade secret protection and give a couple of examples of countries in which you lack recourse?

MR. PRIEST: Yeah, I think as I kind of indicated in my comments about how we're on the cusp of innovations that some of us haven’t even thought of or dreamed of, it's really amazing how footwear is being produced these days and some of the technologies that are being supported, whether it's 3D printing or advanced manufacturing, a lot of stuff that's been out in kind of public domain.

But on the other side of that is development that occurs both here in the United States, the vast majority of which is here, but also at production hubs in Asia and around the world. And it is vitally important for the continuation of our ability to innovate to have trade secrets protection. I think it's one of those things when you think of footwear, you don't really think of trade secrets. But I can't tell you how many times I've signed an NDA or had my phone taken away from me so I can go and see some of these new advance technologies.

So in regards to specific countries and our challenges, I will follow up with a post-submission response and provide more specific details of some of our challenges in those areas.

MR. MEHTA: Thanks very much for your testimony.

MR. PRIEST: Great, thank you.

MR. MEHTA: If we can next invite the Intellectual Property Owners Association. Welcome, sir. Please introduce yourself and begin your

testimony.

MR. LAUROESCH: Good morning. I'm Mark Lauroesch, and I'm the Executive Director of the Intellectual Property Owners Association, or IPO.

IPO is an international trade association that represents corporate and individual members in all industries who own IP or are interested in IP. On behalf of IPO, I'd like to thank you for allowing us to have the opportunity to testify today and for your continued work ensuring U.S. trade partners have effective IP systems.

IPO members make vital contributions to the U.S. economy through its successes in developing advances that drive exports and create jobs. Innovators assume considerable risk and we rely on our IP assets through IP protections.

The written comments IPO submitted outline a host of existing and emerging threats to IP rights of our members. Today, I will highlight a few alarming trends that if left unchecked could erode U.S. competitiveness, constrain export growth, and reduce high-paying U.S. jobs.

First, globally, trade secret protection is often inadequate in foreign countries. Although momentum is building to help our defenses in this area, the protections around the world have not kept pace with the technology that has allowed misappropriators to steal our innovators' most valuable information. Additionally, we cannot create or collaborate at the breakneck pace that our marketplace demands today without meaningful improvements in our trade secret protections.

Significant gaps exist in the protections such as Austria's failure to protect nontechnical confidential information, India's requirement that contractual relationships exist between the patent owner and the would-be misappropriator in order for an action to be brought for misappropriation, and China's overwhelming burdensome requirements to bring trade secret misappropriation actions.

We are poised at a point when tremendous potential exists to improve this environment. We will hopefully soon see U.S. legislation that can create a gold standard by which countries can model

their own trade secret laws, as well as the possibility of establishing better trade secret norms through the TPP. But our competitiveness hinges on whether we take advantage of this momentum and foreign trade secret protection upgrades are actually realized.

IPO members also continue to witness concerted efforts to weaken IP rights in the name of development, access to health, and environmental concerns. IP rights have been unfairly portrayed as a barrier to tech transfer based on arguments that they limit availability of technologies and make them more expensive.

It is the threat of intellectual property erosion, however, that increases the cost of technology and slows the adaptation and deployment across countries. Sadly, attempts to place limitations on IP rights by developing countries are adversely impacting the transfer of needed technology and slowing those countries' innovation growth.

More specifically, initiatives aimed at

impairing incentives to innovation continue to grow in a number of international fora, as well as at the national level. To provide one example, an instruction manual for introducing exceptions and limitations to IP rights are regularly on the agenda of the World Intellectual Property Organization, WIPO.

Similarly, certain expressed preferences for forced technology transfer over arm's-length commercial arrangements make it more difficult for IP owners to engage locally without fear that they will never erase the years of R&D expenditures. The real cost of these policies is fewer investments in innovation and a chilling of technology diffusion.

Last, competitive pressure is driving our members to innovate faster than ever before and, in many cases, product lifecycle times are becoming extremely short. In some countries, debilitating application backlogs at both the patent and trademark offices is not aligned with the technology innovation pace. Inability to timely secure IP rights discourages entry into foreign markets and

encourages free-riders of others' innovation.

The difficulty in securing IP rights on a timely basis is attributable to more than the growing number of applications. Multiple agency application reviews, shifting patentability criteria, and requirements to inform patent offices of related prosecution already known to examiners exhaust our members' resources.

We are confident that streamlining IP procurement processes at the patent and trademark offices, and embracing work-sharing programs could help relieve the strain on U.S. innovators. Our members are encouraged by the U.S Patent and Trademark Office's work in these regards, particularly with the recent patent prosecution highway agreement with Brazil's intellectual property office. And we look forward to working with you to help tackle these impediments for protecting U.S. innovation.

In conclusion, innovation brings growth and prosperity to the U.S., as well as all around the world. IP is the engine for that innovation.

As a consequence, we need you to help refine and build, in some cases, better trade secret protection around the world. We need you to encourage timely and efficient IP procurement processes abroad. And, finally, we need your help to combat concerted efforts to diminish IP rights. Thank you.

MR. MEHTA: Thanks very much.

For your first question, it will come from the U.S. Patent and Trademark Office.

MR. SMITH: Thank you. How does the introduction of utility model protection, such as proposed for India, increase litigation as claimed in your submission, I think on page 14?

MR. LAUROESCH: With utility models, there is not examination and so probably more questionable IP rights are formulated and then maybe asserted and that increases the amount of litigation.

MR. MEHTA: A second question also I think is going to come from the Patent and Trademark Office.

MR. SMITH: Thank you. You pointed out something we haven't heard from other panelists

today, that extended patent pendency makes it harder and more expensive for inventors and companies other than the patent applicant who was waiting on their patent, quote, "Extended patency makes it harder to identify the IPR of others, leads to costly and inefficient redesign of product offerings after they have been introduced, or to reduced margins from payment of license fees for a patent that could have been designed around."

Can you describe this in more detail and provide a real-world example?

MR. LAUROESCH: I can't give you an exact example, but I can kind of describe the scenario. In some of these countries, we see patent applications not even being examined for 7 to 10 years. During that time period, if a competitor wants to put a product into the market, he does not know whether that application is going to be granted or not and, therefore, he may design his product within the claims that ultimately issue. But he might have been able to avoid doing that if the patent had more timely issued and he knew exactly

what the scope of the claims were.

MR. MEHTA: Great. And I think the final question coming from USTR?

CHAIR PETERSON: You noted that there is building momentum for upgrading our defenses to trade secret theft. And you also -- you mentioned the Trans-Pacific Partnership. What other avenues would you suggest for improving the protection and enforcement of trade secrets for other countries?

MR. LAUROESCH: Well, I gave one example. We've had a dialogue start with the State Department in trying to get like-minded countries that are interested in improving their trade secret protections to have a standing dialogue, and I think that is a nice starting point to establish norms that other countries would adopt that might not be as like-minded in the future.

MR. MEHTA: Great. Thanks so much for your testimony.

If we can now invite the International Intellectual Property Alliance? Welcome, sir, if you can introduce yourself and begin your testimony.

MR. METALITZ: Thank you. I'm Steve Metalitz. I'm counsel to the International Intellectual Property Alliance. We welcome the change to engage again in the crucial annual dialogue that this process represents and thank the U.S. Government for making the Special 301 Review a catalyst for positive change to address the challenges faced by the U.S. creative industries around the world.

IIPA is a coalition formed in 1984 of trade associations representing U.S. copyright-based industries. In the interest of time and since I'm standing between you and the break, I won't list them here. But these companies and these associations comprise over 3200 companies producing and distributing materials protected by copyright laws around the world.

How do they reach those markets? They rely on four main elements that are relevant today: first, consistent modern standards of copyright protection; second, efficient copyright enforcement; third, sound legal structures for licensing

copyright materials; and, fourth, the elimination of market access barriers. Progress in these areas advances U.S. trade goals and it enables our trading partners to develop and expand their own cultural and creative output.

What is the ultimate objective? It is markets where the creative industries can bring more products and services in an increasing variety of ways, greater diversity of sources before an ever-growing global audience. If we can advance that objective, we know that we can grow U.S. exports, create good American jobs, and enhance U.S. global competitiveness that's been the track record. IIPA has had this broad vision in mind as it has participated in every Special 301 Review since the 1988 Trade Act created this process.

At the opening of the hearing, Mr. Mehta read out the statutory authorization here, and it's important to focus on that, and to maintain the focus on intellectual property protection and on market access for those who rely on intellectual property protection, in our case, copyright

protection.

There are those who are asking you to dilute this focus and to accommodate the perceived interest of business sectors that, in their own words, think that raising IP norms creates a hostile environment in overseas markets. The advocates for those interests need to know that this is not what Congress intended when it created the Special 301 process. It is not the approach that has made Special 301 so successful. And Special 301 is not the place to advocate that our trading partners weaken their company right regimes.

In this year's submission, IIPA recommends 17 countries be identified in the 2016 Special 301 Report. Our hearing statement, which is available here, includes capsule summaries on Ukraine, which we recommend for Priority Foreign Country status, and our six nominees for the Priority Watch List: Chile, China, India, Russia, Thailand, and Vietnam. I would also like to mention Hong Kong, Switzerland, Taiwan, and UAE. None of them currently appears on a Special 301 list, but we believe they all require

focused attention from the U.S. Government that a Watch List ranking would signify.

Our submission lists 10 overarching challenges that we urge the USG prioritize in its bilateral engagement with our trading partners. Of course, I won't go through all of those now, but the issue of internet and mobile network piracy really impacts all businesses that depend on copyright.

The growth of new channels for reaching consumers around the world with creative content is very exciting and very positive, but the entrenchment of infringing online services, including those that profit from enabling others to infringe copyright, is the leading barrier impeding the full access of U.S. creators into markets worldwide. This infringement threatens the viability of license platforms and it makes it much harder for creators to earn a living from their craft.

We commend the U.S. Government for establishing the annual review of notorious markets. That has already made a significant contribution in

combating systematic online copyright theft. And we urge you to redouble efforts to encourage our trading partners to adopt legal frameworks that create incentives for legitimate network service providers to work with right holders to advance the common goal of a safer, cleaner online marketplace. Achieving that goal requires the active cooperation of all participants in the e-commerce ecosystem. Our trading partners should be doing much more to foster and encourage such cooperation and the development of best practices.

Finally, where notorious online marketplaces are hosted in one country but target consumers in another or worldwide, the failure of the host country to take effective action against them dilutes markets around the world. Increasingly responsible governments are pushing back against this effort to offshore enforcement responsibility. As long as less responsible states fail to institute effective means to crack down on pirate operations based within their borders but readily accessible worldwide, this trend will continue.

I would like to also highlight the need for vigorous enforcement of the matrix of international agreements including, but not limited to, a score of free trade agreements that have been negotiated over the past decades by Democratic and Republican administrations alike. These agreements have helped U.S. copyright industries to compete fairly in foreign markets.

The recently signed TPP Agreement marks another important step forward in this market-opening strategy. But as we debate the new agreement, it is more critical than ever to ensure that our trading partners fully comply with the copyright and market access obligations that they have already taken on in their agreements with the U.S.

For too many of our trading partners, and we provide a number of examples in our submission, both partners within the TPP and outside the TPP, there are significant gaps and shortfalls in compliance. These countries are already enjoying the benefits of these agreements because they have

enhanced access to the lucrative U.S. market, but the U.S. has not fully realized the corresponding benefits because the creative sector that is so crucial to our economy has yet to achieve the full access to these markets that was bargained for.

Finally, all efforts to address copyright infringement will be for naught if legitimate products and services can't be brought into a market to meet consumer demand, so we encourage U.S. officials to continue to strive to eliminate or phase out market access barriers that affect copyright-dependent industries.

The health and competitiveness of the U.S. economy depends on a thriving copyright sector, but promoting and respecting copyright, and opening markets to products and services that depend on copyright also helps our trading partners. Special 301 remains a cornerstone of the U.S. effort to advance modern levels of protection for effective enforcement tools and freer, more open markets.

We look forward to continuing to work with the agencies represented here to advance these

goals. I'm glad to try to answer any questions.

MR. MEHTA: Thanks very much. Your first question will come from the U.S. Copyright Office.

MS. STRONG: Thank you. In IIPA's filing this year, there seems to be a heightened attention to collective management issues and singled out include countries such as Ukraine, Russia, Canada, Taiwan, and Brazil. And so we have two questions. One, what approaches are IIPA and its members taking on the ground in these countries on issues to address either problematic legislation or operational issues? And, secondly, IIPA, in its Thailand submission, called unwieldy and unclear collective management system in Thailand, and we're trying to figure out what aspects of that system are specifically unwieldy. Thank you.

MR. METALITZ: Thank you for the question. In terms of the general trend, yes, this is an issue in many territories. In some cases, it's simply the failure to adopt legislation that embodies modern standards for transparency and accountability of collecting societies or failure to implement

authority that may already exist. That's the case in the UAE, for example, where the collecting society simply hasn't been recognized.

You already heard from the Ukraine representatives here about some of the problems there. It's a failure to meet international standards. In Canada, for example, there is ongoing litigation reflecting the apparent inability of the Canadian system to deliver reasonable levels for royalties to be administered by these collective management organizations.

So those are some of the problems that we see. On Thailand, I'll be happy to get back to you with more detail on what our concerns are there.

MR. MEHTA: Thanks. Your second question comes from the Department of Commerce.

MR. MITCHELL: Thank you. This question concerns IIPA's recommendation regarding Taiwan, Switzerland, and United Arab Emirates, where IIPA has recommended Watch List treatment, elevation to Watch List for those countries, as IIPA had also recommended last year. And so our question is what

has happened in the intervening year or what has not happened in order to support your recommendation? We would appreciate elaboration.

MR. METALITZ: Okay. I think in two of those cases, the situation is relatively unchanged from last year, UAE and Switzerland. Switzerland, of course, is the glacial pace of progress toward updating their copyright laws so that copyright effective online enforcement can begin or can recommence in that country, which has become quite a haven for notorious online marketplaces. The problem is quite serious and there seems to be no urgency to address it.

UAE, as I mentioned, it's a failure to recognize the collective management organization and enable revenues again to start flowing to the recording industry for use of their product.

Taiwan, I think there have been some developments. First of all, they're moving ahead on a revision of their copyright law and it's a missed opportunity for Taiwan to actually bring its law more up to date with international standards and,

for example, to more closely approximate the TPP standards which they say they wished very much to join. That statement is somewhat belied by what's in that legislation. Also, obviously, there is now a new government in Taiwan and hopefully that will be the catalyst for change there.

But I think that those are some of the changes that have occurred since last year.

MR. MEHTA: Great, thanks very much.

MR. METALITZ: Thank you.

MR. MEHTA: So we have reached the end of our first set of non-governmental panelists. At this point, we'll take a break and we will recommence at 12:35, so a 10-minute break.

(Off the record at 12:25 p.m.)

(On the record at 12:36 p.m.)

MR. MEHTA: Great, we're right about on schedule to begin. Thanks again for everyone who is appearing. Just two brief housekeeping issues. Of course, as you know, there is an opportunity for rebuttal submissions to be filed by March 4th. We'll provide information at the end of today's

testimony. And, second, I would like to again recognize the efforts of my colleague, Steve Mitchell, who is helping us keep time, and appreciate all of your efforts in keeping us moving on that front so we can have a full opportunity for everyone to provide testimony.

I would also like to recognize my colleague, Mary Critharis, Deputy Director over at the PTO's Office of Policy and International Affairs. She is joining us for the afternoon.

So with that, let me invite the Internet Association to come up to the front, a warm welcome, and if you could introduce yourself and begin your testimony. Thanks.

MS. SCHRANTZ: Good afternoon. My name is Ellen Schrantz, and I currently serve as the Director of Government Affairs and Counsel at the Internet Association. The Internet Association is the unified voice of the Internet economy representing the interests of leading internet companies and their global community of users.

Paramount to internet companies' continued

ability to operate and compete in global markets is balanced copyright law, including protection of the robust limitations and exceptions that have allowed U.S. internet companies to flourish. In our submitted comments and in today's testimony, the Internet Association specifically requests, first, that USTR's Annual Report include substantive discussion of and attention to the limitations and exceptions central to the adequate and effective protection of IPR.

Second, that USTR immediately issue warnings to states that have enacted or are considering enacting ancillary copyright laws.

Third, that USTR ensure that distant intermediaries, such as internet domain name registrars, are not reassigned IP enforcement responsibilities, which would have detrimental consequences for management of the Internet ecosystem.

Limitations and exceptions are at the heart of the balance in copyright law to fulfill the constitutional purpose of promoting the useful arts.

These robust provisions have a rich history in U.S. law and have been vital in ushering in the digital age. Cloud services, search engines, social media sites, blogs, video, and music sharing platforms, and many more innovative online services rely on limitations and exceptions such as fair use and intermediary liability protections to allow the public access to legal content and create new forums that follow along creative works.

Internet platforms, in turn, are a global driver of the innovation economy with internet industries representing an estimated 6 percent of U.S. GDP in 2014, totaling nearly $967 billion.

The United States has repeatedly emphasized the critical nature of exceptions and limitations, including in trade agreements dating back to 2004 and most recently in the IP chapter of the Trans-Pacific Partnership.

Broadly, USTR's report should reflect this longstanding and successful policy of balance by including in its report efforts around the world to support fair use and other limitations and

exceptions. Specifically, USTR's Annual Report frequently discusses recent legislative initiatives in countries that would impact U.S. stakeholders' access to markets through intellectual property laws.

In its assessments, we urge USTR to commend countries that are making strides to balance intermediary liability and copyright laws, and to carefully advise nations examining new enforcement regimes of the critical role that limitations and exceptions play in fostering innovating environments that would open markets to U.S. companies. The Internet Association has provided country-specific suggestions in our written comments.

One instance where U.S. companies are under threat in terms of market access is in states that have enacted so-called ancillary copyright laws. These laws act as a tax on quotations or snippets and directly contravene established international obligations under the TRIPS Agreement, which clearly states that quotations from works lawfully available to the public shall remain free

of such a levy.

Unfortunately, Germany and Spain have already enacted ancillary copyright laws, which have proven detrimental for U.S. companies seeking legal clarity and certainty for operations in those states. These levies on snippets deny equal protection under IP law to U.S. companies whose business models include aggregation of quotations protected by international copyright standards.

Despite the consequences of the German and Spanish laws, the European Commission is continuing to consider more widespread attempts at enacting ancillary copyright throughout the European Union based upon recent copyright communications.

The Internet Association requests that USTR immediately include countries with anti-competitive ancillary copyright laws on its list and that special attention be given to this issue to deter our trade partners from similarly harmful action.

Effective protection of intellectual property rights should be the responsibility of the

appropriate authorities only and forum shopping should be discouraged. In particular, the Internet Association is concerned about any efforts or suggestions that domain name registrars should be liable for online content, which reflects an inaccurate understanding of the role of registrar accreditation agreements and sets a dangerous precedent of reassigning enforcement roles to intermediaries unequipped to monitor content online.

For over 20 years, U.S. federal policy has carefully monitored the role of intermediaries in management of content, ensuring that the Internet is not policed by those who lack the expertise and enforcement tools needed to identify and combat infringement. In the case of DNRs, the contractual agreement under ICANN does not require monitoring or take down of domains, and compliance with the requirement to take appropriate action is best left to the global multi-stakeholder model. Therefore, we respectfully urge USTR to refrain from the listing of domains or further suggesting that distant intermediaries be assigned a policing role

not imposed by U.S. or international law.

As internet companies continue to drive the global economy, we urge you to ensure that our trade partners worldwide are well informed on the balance necessary in copyright law to cultivate markets that allow U.S. companies to compete and thrive. Thank you for the opportunity to testify, today.

MR. MEHTA: Thanks very much. Your first question will come from the U.S. Copyright Office.

MS. STRONG: Thank you. Your testimony, like that of the CCIA, mentioned concerns with the ancillary copyright issue in both Germany and Spain. Your testimony recommends that they be placed on a list, but it does not specify which list. Do you have a specific recommendation for those two countries for us today?

MS. SCHRANTZ: I believe in our filings that we recommended the Watch List. I'd be more than happy to double-check our filing.

MR. MEHTA: Great. Do you also want to handle the second question, as well?

MS. STRONG: Sure. To follow on, on the discussion about domain name registers, Internet Association asks, quote, "that USTR refrain from listing of domains or further suggesting distant intermediaries be assigned a policing role not imposed by U.S. or international law." And we note that there are other stakeholders that have different views.

Can you explain your position in more detail and then follow up, what do you believe ICANN, WIPO, or the U.S. can and should do about these related issues?

MS. SCHRANTZ: Sure. Thank you for that question. To clarify our position, our position is simply that the Special 301 process should not be leveraged in an inappropriate way to address an issue that we believe is outside the scope. So the registrar accreditation agreement is a private contractual agreement with ICANN. The United States historically has supported a robust multi-stakeholder model.

And going to the second part of your

question, we do support efforts to cooperate and inform the best ways to combat infringement. In my written submission, we do outline, I believe, the healthy domain initiative as one such way that that multi-stakeholder model is looking at new ways to cooperate and work together. And so our position is that, that is -- the 301 process is not the appropriate place to leverage or suggest that distant intermediaries have new responsibilities. The registrar accreditation agreement is, I think, misunderstood oftentimes. And so our written submission details what is actually required by that and requests that we look to the global multi-stakeholder model for those solutions, examples of which are in our written submission.

MR. MEHTA: Thanks very much. I think the final question for the USTR.

CHAIR PETERSON: As a follow-up to the Copyright Office's question and based on your response, do you think that Special 301 could be an appropriate mechanism for encouraging the type of cooperation that you support in ICANN and WIPO?

MS. SCHRANTZ: I think we would like to know exactly what cooperation would be pushed. We, in our written submission, I think clearly state that the global multi-stakeholder model, when it comes to the registrar accreditation agreement, is the appropriate place to look at those solutions.

And so in terms of combating infringement, I will say broadly that our companies have played a great role in combating infringement and looking at initiatives, private sector initiatives, and we support that process as it moves forward.

CHAIR PETERSON: And since I also asked this question earlier to CCIA, I'll ask it to you now, what part of the Special 301 statute mandates or empowers us to consider the exceptions and limitations as part of the adequacy and effectiveness of IP protection?

MS. SCHRANTZ: Sure. Thank you for that question. It is an important one and one that I'm glad we'll get to talk about twice here, today, so far. The statute provides two instances where USTR should look at countries, the first where the

interests of IPR rights are at stake, and I will say that our industries, internet industries, rely on copyright law as much as traditional industries.

The line between industries is blurring now more than ever. Our companies produce original content and have new and innovative platforms unlike what we have seen ever before. And so when we talk about stakeholders in foreign markets examining copyright law for legal clarity, for the legal certainty necessary to operate there, our companies, internet companies rely as much as, I think, traditional stakeholders on that.

Secondly, the statute addresses market access issues. Ancillary copyright is a great example of where we have seen barriers to market access based on not having a complete perspective of those laws. In fact, one company, I think as my colleague at CCIA mentioned, withdrew from one of those countries. And although I can't give specifics here today, I can tell you that our companies do look every day at foreign markets and have failed to launch in certain foreign markets

based on a lack of clarity and a lack of certainty in copyright regimes.

And so I believe under both of those instances, as laid out in the Trade Act, our companies have a valued stake at hand that belongs in the Special 301 process.

MR. MEHTA: Thanks very much for your testimony.

MS. SCHRANTZ: Thank you.

MR. MEHTA: If I can now invite Knowledge Ecology International?

MR. LOVE: Thank you very much.

MR. MEHTA: A warm welcome, sir. Please introduce yourself and begin your testimony.

MR. LOVE: My name is James Love. I'm the Director at Knowledge Ecology International. My first comment is that we have reviewed the submissions of PhRMA, BIO, BSA, IIPA, and the U.S. Chamber of Commerce's Global IP Center just to look at what is a country on their list of targets. And I would say certainly Northern Africa, South America, and Asia, being big makes you a target.

We're happy to provide a detailed statistical analysis of this in a follow-up submission. And I say that because just the size of your economy relative to other countries in a region basically puts you on the list, just to be clear about that.

The BSA submission, I'd like to say that we agree with and appreciate the concerns of BSA regarding government involvement in the use of unlicensed software, so we're supportive of their complaints about that.

We also understand and appreciate the BSA's concerns over government policies that discriminate against foreign suppliers of software. Here we note that the activities of the United States in spying on everyone, including anyone working for a foreign government, creates an environment where people around the world have legitimate concerns about backdoors and surveillance.

BSA has also raised concern about rules that ban government use of cloud-based email programs and require data to remain within

countries. We also understand those concerns. However, again, the Snowden revelations of U.S spying and the lack of effective regulation of consumer privacy contributes to these problems. So as long as the United States is seen as an aggressive actor in surveillance and as having weak protections on privacy, these problems will probably get worse. I think Tim Cook at Apple is trying to explain this to the FBI right now.

We disagree with the BSA opposition to government mandates to make source code of software open. But, again, we note that open source code allows third parties to find surveillance backdoors and to address the need also for greater inoperability between programs that ensure competition, particularly in the many markets where monopoly power exists.

On the CCIA comments, we agree that ancillary copyright is a threat to both the U.S. internet companies and more generally a threat to the public, and it undermines access to knowledge. Governments have legitimate concerns over tax

avoidance by companies, but taxing quotations and hypertext links is not the solution. We think this is a violation of the TRIPS and a barrier to trade and we recommend placing the countries that do this on the Priority Watch List and consider an out-of-cycle review.

As regard to the PhRMA, BIO, and U.S. Chamber submissions, we note that PhRMA targeted 20 countries in the Special 301 this year. This included complaints about reimbursement policies in 18 countries, making pricing rather than IPR the most common complaint raised by PhRMA.

In the United States, in 2015, a Kaiser Family Foundation survey found that 72 percent of the public believes that direct costs are unreasonable. In another survey, nearly 7/8ths of the country's top health care leaders favored government taking a bigger role in curbing the rising cost of prescription drugs, and 86 percent of CEOs responding to the survey supported giving the federal government the authority to negotiate direct prices on behalf of Medicare and Medicaid

beneficiaries.

We note that both the Democratic candidates and Donald Trump for the GOP are campaigning they would introduce tough curbs on higher prices. I mention this because the perception in this proceeding in this room is it's a bad thing if people do things to bring prices down. But you walk outside of this room and everybody is disgusted with the high prices of drugs.

You have surveys, you have speeches, you have editorials, you have donors giving millions of dollars to people to work on this problem. You have the CFO for Home Depot complaining about the cost of drugs for Home Depot. You have companies involved in manufacturing processes complaining about this issue. And you have payers, private payers, insurance companies, and others that have to pay for drugs. So I think it's important to keep in mind that if you think your job is to keep drug prices high, you might have a conversation with the rest of America about that.

We note a lot of complaints by companies

were focused on India. India is important not only in its own right, because there's more than a billion people live in India, most of them poor, but I think India is a go-to source for people that want to get generic drugs in other countries.

There was testimony in a couple of the submissions that claim that there is an agreement that India has made not to issue compulsory licenses. If that agreement is with the United States government, given the fact that 80 percent of the world's population is essentially priced out of new prices for new cancer drugs and drugs for other severe illnesses, I think that that agreement should be made public. We'd certainly like to see it.

We are right now working on a compulsory license request in the United States on the prostate cancer drug, Xtandi. It's a drug developed at UCLA and on Army and NIH grants. It's priced at $129,000 here in the United States and I think roughly a third of that in Japan where the company that acquired the rights from UCLA is from. There is no country that is remotely close to the U.S. price on

that. As part of our application, I think we anticipate that we may have to, at least in the short term, source drugs, generic versions, from India if we prevail on that effort.

I know that we're right now involved in a separate effort in Scotland where a cancer drug for HER2-positive breast cancer patients is not reimbursed in that country, not really a third-world country, but it's just too expensive there. And, again, it will be -- if the U.S. is leaning all over India as a supplier, that will make that effort more difficult.

We pointed out that the United Nations has just concluded as of Sunday, day before yesterday, a request for submissions from people that deal with the issue of access to medicine problems and how to reconcile the policy coherence between human rights and access to medicine and innovation. I would recommend that you look at it. I think there's like an unbelievably large number of submissions. Several people testifying after me have been participating in this as well.

One of the things that has come up is some countries have looked at the issue of R&D mandates, including some U.S. groups in the past, of advising some of the political leaders in this country that they think about focusing on the mandate to fund R&D as a different issue than looking at driving the prices up. I would just encourage that. I'd like to do some follow-up submissions on describing what some of the U.S. submissions do in the area of delinking R&D costs from direct prices, and reconciling and increasing policy coherence between human rights and innovation. Thank you very much.

MR. MEHTA: Thanks very much, Mr. Love. Your first question will come from the Department of Commerce.

MR. MITCHELL: Thank you. One of the concerns that was expressed earlier today by the Alliance for Fair Trade with India is that trade secrets are not adequately protected in India. And as the Subcommittee analyzes the adequacy and effectiveness of India's trade secret laws, are there any principles or considerations you would

suggest we keep in mind in doing that analysis?

MR. LOVE: Yes. I would hope that you didn't have an overly broad view of what constitutes a trade secret and that you didn't discourage governments from mandating transparency, including in some cases, in terms of know-how, when it's necessary.

The United States faces very big problems and challenges in getting affordable copies of biologic drugs to the market. One of the barriers to that are the regulatory barriers relating to the know-how, and a number of people are going to push for more mandates of manufacturing know-how in biologic drugs so that after the initial 15-year monopoly that they typically enjoy in the United States, you don't have like a 4-year monopoly on a biologic drug. We would like to sort of see the prices drop for biologic drugs in the same way they do for small molecules.

I think that the other thing is that there are concerns that some of the overly broad claims on trade secrets is used to withhold information about

requiring disclosures on things like R&D costs and results in clinical trials.

MR. MITCHELL: Thank you.

MR. MEHTA: Thanks. The next question comes from HHS.

MS. BLEIMUND: Hi. I had a question specific to the issue of compulsory licensing, which is something that you have commented on in the past. PhRMA has submitted a written comment this year that cites a study and a specific example of how compulsory licensing may not always be effective at achieving its intended purposes of lowering prices and enhancing access, which was Brazil's issue into the compulsory license for an antiretroviral treatment in 2007 where it took the manufacturer, the local manufacturer 2 years to launch production of a generic version.

The question is just if you've had a chance to review that and do you have any response?

MR. LOVE: I can tell you right now I'm involved in several compulsory license applications and I don't think it's unusual to take a couple of

years after you get the legal authority to do something to have a product on the market. You have to figure out how to make a product. You have to figure out how to make bioequivalent. There's a lot of regulatory tests.

If you look at the hep C market, you had voluntary licenses from Gilead, including know-how. I think Gilead did a great job with that in the countries that were involved in the licenses. But we are only now beginning to see the products enter the market. It didn't happen like within a few days. It took a while. So I think that the 2-year thing is -- I'm a little bit perplexed on that, because you talk to anybody in the generics industry, things don't happen overnight.

They may have had also, in the case of Brazil, they may have been moving up a learning curve in terms of some of their manufacturing capacity. But if PhRMA didn't think that the compulsory license reduced the price of drugs, I don’t think they'd be complaining about it so much.

MR. MEHTA: Thanks very much, Mr. Love.

I'd like to invite the next group, the Pharmaceutical Research and Manufacturers of America. Welcome, sir. Can you please introduce yourself and begin your testimony?

MR. MOORE: Thank you very much. I am Chris Moore. I am the Deputy Vice President for International with PhRMA, the Pharmaceutical Research and Manufacturers of America. On behalf of biopharmaceutical innovators in the United States and the more than 810,000 women and men they employ across the country, PhRMA appreciates the opportunity to testify before the Special 301 Committee.

Intellectual property, including patents and regulatory data protection, thrives and sustains biopharmaceutical innovation. It enables access to today's medicines and promotes investment in tomorrow's treatments and cures. Where markets are open and intellectual property is protected and enforced, biopharmaceutical innovators have the predictability and certainty necessary to research, develop, and deliver new medicines for patients who

need them.

Innovation saves lives and helps reduce overall health care costs. New medicines have cut heart disease deaths by 30 percent and AIDS deaths by 85 percent. They account for more than 80 percent of increased life expectancy for cancer patients.

There is much more to come. PhRMA members are developing close to 400 new medicines for infectious diseases including viral, bacterial, and fungal infections, smallpox and drug-resistant malaria. Advances in genomics are propelling the discovery of new medicines. Derived from living proteins, biologics are revolutionizing the treatment of cancer, autoimmune disorders, and other chronic conditions.

PhRMA members are working to overcome systemic challenges that can prevent the poorest from accessing medicines. They are leading more than 340 initiatives with more than 600 partners for sustainable solutions that improve health for all. But around the world some of America's leading

trading partners maintain or are considering laws, policies, and practices that deny or would deny adequate and effective intellectual property protection and fair and equitable market access.

PhRMA's submission highlights six top barriers and threats that are preventing biopharmaceutical innovators from securing patents, maintaining and effectively enforcing patents, and protecting regulatory test data. All require urgent action.

For example, in Brazil, Thailand, and elsewhere, patent backlogs that can stretch as long as 10 years or more are delaying introduction of new medicines to patients and undermining incentives to invest in future treatments and cures. Backlog challenges are made worse by dual examination policies in countries like Brazil and Colombia.

Restrictive patentability criteria in Argentina, India, and other countries are preventing innovators and generics alike from introducing new dosage forms and combinations that can promote adherence and lower overall health care costs.

Among the most concerning examples of restrictive patentability criteria is Canada's Promise Doctrine, which imposes a heightened and unworkable patentability standard. It confounds the time-tested process by which innovators transform promising molecules into valuable new medicines. Based on the jurisprudence developed by Canadian courts, 24 patents on 20 innovative medicines have already been invalidated. Patents on many other products are at risk.

PhRMA members are seeing progress in Taiwan toward a mechanism that would provide for the early resolution of patent disputes, but weak patent enforcement remains a serious problem in China, India, Russia, and many other countries. Many U.S. trading partners, including Algeria, Turkey, and countries in Latin America, do not adequately protect regulatory test data. Regulatory data protection is particularly critical for biologic medicines, which may not be adequately protected by patents alone.

High tariffs and approval delays deny fair

and equitable market access for medicines invented, developed, and manufactured in the United States. A growing share of global trade in medicines now occurs outside the WTO zero-for-zero initiative. After additional duties and assessments are factored in, effective tariffs on medicines in India can be as high as 20 percent. Federal and state taxes in Brazil can add 38 percent to the price of medicines, the highest tax burden on medicines in the world.

Because of lengthy regulatory delays, getting approval to make a new medicine available in China takes much longer than international practice. Patients are forced to wait for the treatments they need. These challenges are compounded by a growing array of localization barriers, from mandatory technology transfer requirements in Indonesia to discriminatory import barriers and procurement practices in Algeria and Russia.

PhRMA urges USTR to prioritize these countries and concerns in the 2016 Special 301 Report and to use all available tools to address and resolve them. Meaningful out-of-cycle reviews are

needed to assess processing results in Canada, Ecuador, and India.

We particularly encourage USTR and other federal agencies to address longstanding intellectual property and market access barriers in countries that are U.S. Trade and Investment Agreement partners. These agreements require strong intellectual property frameworks and protect regulatory test data, and enable inventors to resolve patent disputes prior to the marketing of potentially infringing products. However, many U.S. Trade Agreement partners fail to adequately comply with some or all of these obligations. Federal agencies should systematically review compliance and take steps necessary to ensure agreed rules are followed.

Thank you for the opportunity to testify, today. We look forward to answering any questions and to working with you to address the serious concerns described in our submission for the 2016 Special 301 Report. Thank you.

MR. MEHTA: Thanks very much. Our first

question will come from the Department of Health and Human Services.

MS. BLEIMUND: Hi, thank you. I have a question with regard to your written comments on the need for transparency and due process in pricing reimbursement policies. Keeping in mind that it's not possible or may not be possible for every country to adopt U.S.-style practices and noticing comment procedures, what do you think is the minimum level of transparency and due process that countries should be expected to provide? And does your expectation depend on the country's level of development?

MR. MOORE: Thank you very much for that question. This is one of three challenges that we specifically highlighted with respect to market access, the others being the tariff and other import barriers, as well as the regulatory approval delays.

When we look at the process for engaging in pricing reimbursement conversations with governments, there are some very basic provisions that are included in many U.S. trade agreements now

that we think are very valuable as a basic level. It's important for participants in regulatory processes to know what the rules are, to have some expectation that the rules will be stable over time, and that they will have a meaningful opportunity to engage with the government as decisions are made and with the government as decisions are made about any changes to the rules.

So we think the types of procedures that are set out in our trade agreements provide that very basic level of concern about those issues and focus on some of the most primary issues that need to be addressed.

MR. MEHTA: For the second question, Department of Labor.

MS. PETTIS: Hi. Your submission identifies restrictive patentability criteria in Canada and India as trade barriers. How much economic impact do these criteria such as the patent utility standard in Canada or Section 3(d) in India have on the U.S. pharmaceutical industry? And are pharmaceutical companies laying off employees in

these markets or within the United States as a direct or indirect result of these patentability criteria practices?

MR. MOORE: Thanks very much. You have highlighted, I think, one of the principal concerns that we have outlined in our submission. If we are not able to secure patents as an industry, that's a really threshold challenge that really is a huge barrier to being able to innovate, but also to deliver medicines into new markets.

The challenges with respect to Canada and the impact on the U.S. economy, I believe there was another submission that looked in particular at that issue. With respect to the employment aspects, we certainly don't have a -- you know, it's always difficult to identify particular jobs that are related to particular challenges like this, but certainly it is having an impact on the United States, our ability to -- the incentives that are there to enable us to continue to innovate and the jobs that the industry supports, which we've mentioned in our submission.

MR. MEHTA: Thanks very much. Thanks for your testimony, today.

If I could then invite the Program on Information Justice and Intellectual Property?

Welcome, sir. Please introduce yourself and begin your testimony.

MR. FLYNN: Good afternoon. My name is Sean Flynn. I'm the Associate Director of the Program on Information Justice and Intellectual Property, a research and academic program at American University.

Let me start off by congratulating Christine Peterson for being the chair of the Special 301 Committee. This is the second chair and third year that this committee has been chaired by a WCL grad, and we expect that to continue indefinitely. I'd be happy to help you with that.

So this has been a fabulously interesting hearing. I've been participating in this for a number of years and I feel like when this process started there were a series of academics and public interest organizations kind of advocating for more

balance within the process. But this year and perhaps last year, as well, you see more U.S. industries, particularly the technology industry, advocating for that same purpose. And I think that reflects a couple of different realities that I want to speak to.

So my testimony, and I'll just refer to it broadly, but then I really want to get into some of the questions that I think the committee is dealing with, speaks about first the legal interpretation issues that I think have come up here a couple times. And I'll speak to that.

But then, second, the policy issues, so that on the legal interpretation, I actually think that it's, and it's the way I framed the issue in our report, USTR itself has been changing the interpretation of what it is to be adequate and effective intellectual property. We see that as a result of the Trans-Pacific Partnership Agreement, a specific balance clause, but even going back before that, and I'm sure it's referenced, the long history of free trade agreements that have included ISP

liability safeguards and other mandatory limitations and exceptions components within those agreements.

Trade promotion authority language that requires the attention to intellectual property issues within free trade agreements has pretty much exactly the same language that governs 301. And although USTR and U.S. trade policy started only on the so-called protection side, it has evolved to represent a broader segment of American interest, and that is completely legally defensible.

So this is an administrative agency that is the implementing agency for those statutes. It has a large degree of discretion in interpreting those statutes. And I think the overall thrust of those statutes, the intent, as was alluded to by IIPA, is to protect U.S. interests, exporting interests abroad. But the language in the statute itself is definitely broad enough to include limitations and exceptions issues.

So if you look at 2242(d)(2), defining adequate and effective intellectual property standard, it refers to the mandate to protect

companies and their rights relating to patents, rights relating to copyrights, etc. And so I would submit that, in my opinion, similar to some of the technology companies, the fair use rights, the limitation exceptions rights, the rights to quote, rights to quote news of the day, etc., these mandatory limitations and exceptions found within copyright law, just like scope of patentability and other limitations within patent law -- did I say patent law first -- copyright law, fair use in copyright law, scope with patent law, are rights relating to intellectual property that affect the market access of those companies.

So I think it flows from the language of the statute itself. And more importantly, it flows from the way that U.S. policy has evolved lately to include limitations and exceptions issues within the scope of that interpretation.

The rest of my submission is really coming out of some of our research agenda. We've been focusing over the last year or so on developing an economic research program looking at the impact of

specifically copyright limitations and exceptions, not just on U.S. businesses but actually on the interest of other countries; so the question of is fair use good for other countries?

We are developing a very large survey to do a lot of econometric research kind of playing that out, but I have included as an appendix a very preliminary run of the data which shows that all classic fair use industries, the type of CCIA member type people, but also traditional copyright dependent industries benefit under a fair use system. So a number of countries outside of the U.S. have passed fair use, have emulated the U.S. model, and in those countries, we find that both the copyright-intensive and the technology industries seem to fare better.

Those are not complete econometric studies of the kind that we hope to be able to present to this committee in the future, but the correlations show that fair use is not bad for the independent industry. It's not bad for the local production industry. In fact, as the scholarly literature will

show, that all of those industries are as dependent on fair use systems as others.

Now the key with fair use and why it's so important, and why flexible limitations and exceptions, which the IIPA submission somewhat strangely castigates, are so important for U.S. businesses is because copyright laws change very infrequently. Many countries, it's been decades and decades since they changed their copyright law, and they don't map well onto current modern technology.

Until a few years ago, the Australia copyright law allowed reproduction only by a Xerox machine. It didn't allow digital reproductions. It was a 1960s era copyright law and it was only inclined to 1960s era technology.

If you don't have an additional flexible limitation exception, that is, what we would call open and flexible, open meaning it can apply to purposes not specifically enumerated as fair use does, and flexible in that it turns on a balancing test that can be applied to those new situations, without that then Google is literally illegal in

most the world. Reproductions through digital technology would be literally illegal in most of the world. Specific goods which rely on intellectual property protection like TiVos, like iPods, they would be illegal. So it's in the U.S. interest, but it's also in the interest of those other countries to have flexible copyright exceptions not just for today's technology but for future technology, and I think increasingly we hope to present to this committee the empirical proof that really proves that point.

But I mean I think we're getting to that point now, and I think U.S. trade policy already reflects it, as I've mentioned, in the way that trade is evolving. And that same policy should be reflected in Special 301 most importantly because it's guided by exactly the same language that's found in trade policy generally. So I'll end there, thank you.

MR. MEHTA: Thanks very much, Mr. Flynn. Your first question comes from USTR.

CHAIR PETERSON: The Special 301 process

is about identifying trading partners that fall short of the statutory criteria, and you have made your case for the statutory interpretation there. Your submission identifies deficiencies in limitations and exceptions in the copyright laws of more than 20 countries. Just so that we are clear, is it your position, is it PIJIP's position that you're not making an affirmative recommendation to place any of those 20 countries on a Priority Watch List or a Watch List?

MR. FLYNN: No. I don't think PIJIP, as an academic institution, first of all, falls under the statutory criteria of an entity that can really make a complaint and request for the listing. We point out that information to take account into your deliberations as you go forward. And we do try to identify them specifically country by country.

One point that I didn't mention but we mention in the written material, there is the Watch Listing function, but there are other parts of the report that are incredibly discretionary. And so the best practices areas of the report, and I think

there's one that's kind of the latest developments -- the positive developments, both of those areas of the report traditionally deal with issues that are not technically within the four corners of the statute. I would encourage that those areas of the report refer to positive developments on limitations and exceptions as well.

We know specifically, for instance, Marrakesh Treaty implementation, it's an area that is in accord with U.S. policy that we hope will be featured as a positive development as we move steadily towards the number of countries that will be needed to actually implement that.

And, in addition, the consideration of more flexible limitations and exceptions regimes in countries that have already passed such regimes, like our trade partner Korea, or countries that are considering such regimes. I would point out countries like South Africa, countries like Nigeria, countries like Hong Kong, other countries undergoing copyright reform. This is a key moment, a key process in which USTR can help reflect U.S. policy,

that copyright function include the kind of balancing language that was included in the TPP, for instance.

MR. MEHTA: Great, thanks. One more question, I think, from our colleagues in Department of Justice.

MR. LAMBERTI: Thank you very much. Let me just say I think that PIJIP is doing some excellent work. These are very, very important issues, so I really appreciate our contribution --

MR. FLYNN: This is on tape, right?

MR. LAMBERTI: -- to the process. Just don't use it as a vote for your book.

So, but I did want to kind of press you a little bit on essentially open systems of limitations versus closed systems. You mentioned fair use as being an example of an open system.

As you know, a lot of the attempts to define the scope of limitations and exceptions in the U.S. are through our adversarial system, through litigation. Other countries, evolving countries don't really have the infrastructure and the

institutions in place to define those rights outside the process, the formal statutory process.

So do you think that the U.S. model can really be replicated that well in developing countries?

MR. FLYNN: Yes, I do. Actually, it's a piece of our ongoing research. I think what you have articulated is frequently a myth and the myth is that other countries outside of the U.S., except for a few that have actually adopted fair use, don't have open and flexible copyright limitations and exceptions. And that's actually untrue.

So if you break out fair use into its component parts, and I've talked about openness being the application to a larger number, an open list of purposes, and second turning on a balancing clause, actually, that's a fairly frequent attribute of copyright systems around the world, whether or not it's called fair use.

So, to take an example, South Africa's quotation right, South Africa's quotation right states that you can quote for any purpose as long as

it is consistent with fair practice. Well, that is an extremely open and also flexible limitation and exception that exists in a developing country. There is actually very little litigation about it.

But what's important about it is it provides that openness, a space for new entrants to come in and look at that copyright law, and say you know what, this quotation right isn't just for criticism, in our view. We can actually do Google news in this country because the quotation right is so broad. We can actually do Facebook postings in this country because the quotation right is so broad.

It's countries where you don't have that openness and flexibility that I think, and I hope to report back soon, that we're going to find real problems. Because companies do go and they look at copyright law and if you have fair use, that's a clear kind of green flag that you can do innovation.

But you can find those green flags in other portions of laws and we do find them. So I think that the actual prevalence of the systems

around the world kind of disproves the idea that only the U.S. can do fair use. Actually, countries are doing similar things all around the world right now.

MR. MEHTA: Great, thanks very much.

If I can invite Public Citizen to come up.

Welcome. Can I ask you to introduce yourself and to provide your testimony, please?

MS. KILIC: Hi, my name is Burcu Kilic. I am the legal and property -- Public Citizen's Global Access to Medicines Program. Thank you for providing me the opportunity to testify here today on behalf of Public Citizen and its 400,000 members and supporters.

Public Citizen is a national nonprofit consumer advocacy organization with a 40-plus year history presenting consumer interest in Congress, the Executive Branch, and the courts. We submitted our written comments for distribute earlier this month. My testimony will draw upon those comments and our experiences working in and around government agencies, with societal organizations, academics,

and patient groups.

I will follow the same methodology as our written comments. I will highlight some countries' laws and practices, and our own observations working in and with those countries. But before that, I would like to address specific practices that can and should be improved. We suggest the following principles to support this modest reform.

The Special 301 Report should omit any reference, whether expressed or implied, to any country's TRIPS-compliant or FTA-compliant policies that advance the public interest. The Special 301 Report should only address intellectual property, not ancillary public policies such as pharmaceutical reimbursement, pricing, or procurement.

The Special 301 Report shouldn't list countries for not adopting U.S. policy preferences if those countries have no bilateral or international obligation to adopt the same. We distinguish between TRIPS and FTA standards and we want you to do the same.

We observe that some countries are

criticized for not adopting measures such as data exclusivity or patent linkage even that country doesn't have an agreement with the United States expressly and specifically requiring the same.

Criticism in the Special 301 Report should be accompanied by express and clearly articulated criteria. Applying these principles to our analysis, I would like to share observations and comments about several countries. I am going to start with Turkey, the first country I called home.

I believe our -- to clarify some of the confusion about Turkey that are exclusivity system. As mentioned previously, Special 301 Report should not list countries who are not adopting FTA measures such as data exclusivity unless they have an agreement with the United States expressly and specifically requiring the same. Turkey provides 6 years of data exclusivity for pharmaceutical products including biologics.

However, Turkey is not part of any regional or bilateral treaty requiring data exclusivity or clinical trial data. Thus, Turkey's

obligation for the quotation of data are related to baseline compliance with the imprecise but minimum standards set forth in the TRIPS Agreement and EU-Turkey Customs Union Agreement. The Special 301 report shouldn't cite Turkey for its TRIPS-compliant, indeed TRIPS class interpretation of protection of undisclosed test data.

In recent reports, Canada has been fiercely criticized for the heightened utility requirements for patents. The North American Free Trade Agreement, NAFTA, in parallel with TRIPS, requires that patents be granted once patentability, novelty, inventive steps, and industrial applicability are satisfied. NAFTA doesn't specify how this criteria should be defined and applied. NAFTA and TRIPS parties have sovereign rights not only to adopt varying patentability standards, but to change and reinterpret them.

Canada requires utility to be demonstrated or soundly predicted at the time of application. The patent system is not designed to grant monopolies on the basis of hunches, guesses, or

hopes. It is also not designed to allow actual verification of the alleged invention after the fact. The data obtained and submitted to patent office after filing cannot cure the application's defect. Special 301 Report shouldn't cite Canada for its TRIPS and NAFTA-compliant interpretation of utility standards.

Indonesia. On September 2012, the Indonesian president signed a decree authorizing government use of patents for seven HIV/AIDS and hepatitis B medicines. Indonesia has considerably more involved process than any procedure required by TRIPS. The procedure on government licenses includes the president of the country, the minister of health, the minister of justice, the director general of intellectual property rights. When Indonesia issued compulsory licenses, the internal consultations between those ministries and the president took more than a year. Indonesia has government-use licenses, wholly comply with TRIPS and national rules. The Special 301 Report shouldn't cite Indonesia for its TRIPS-compliant,

government-use practices.

India. We observe that there is some confusion about the patent eligible subject matter which defines what qualifies as an invention and patentability requirements. If the subject of patent monopoly is not something that is patent-eligible subject matter, there is no possibility of a patent being granted, even if the subject matter claimed is new, involves an inventive step, and is industry related applicable.

Article 27.1 of TRIPS establishes minimum criteria for patentability but leaves countries flexibility to define the threshold level for patent-eligible inventions. Section 3(d) is structured as a subject matter eligibility threshold, not as a patentability test.

A thorough examination of Section 3(d) should consider all the principles clarified in the Supreme Court of India's ruling in this case. The decision of the court extended over more than 90 pages and 195 paragraphs. The paragraph quoted by USTR in recent Special 301 Reports must be

considered in its full context if it is to provide any informative value for analysis of Section 3(d).

India's Section 3(d) complies with the TRIPS Agreement. The Special 301 Report shouldn't cite India for its TRIPS-compliant interpretation of patent-eligible subject matter.

Plus, Special 301 Reports have criticized India's issuing of a compulsory license for a cancer medicine. This compulsory license fully complies with India's patent law which is narrower than what is allowed under TRIPS. The Special 301 should not cite India for its TRIPS-compliant compulsory licensing practices.

In the interest of time, I complete my comments here, but I encourage you to read our written submission which also includes -- which also addresses Chile, Peru, and Vietnam. Thank you very much.

MR. MEHTA: Thank you. If we can have the Health and Human Services first. Ms. Bleimund?

MS. BLEIMUND: Thank you. You mentioned in both your testimony and your written submission

that Public Citizen believes that the Special 301 Report should only focus on intellectual property issues and not on, quote, "ancillary public policies."

As you know, we are statutorily obligated to identify countries that, quote, "deny fair and equitable market access to United States persons that rely upon intellectual property protection." So the question is do you believe that these ancillary public policies, for example, pharmaceutical pricing and reimbursement policies, do not fit within that component of the statute? And, if not, what types of policies do you think that component should cover?

MS. KILIC: I think those ancillary policies, public policies, pharmaceutical pricing, or reimbursement policies, they are not -- they shouldn't be considered as intellectual property issues, unless we don't consider as intellectual property.

MS. BLEIMUND: Can I just clarify real quick? We're distinguishing between intellectual

property issues and the market access for persons that rely upon intellectual property protection. That's the distinction I'm asking about.

MS. KILIC: Okay. There is no discrimination against industries like the pharmaceutical industry in those countries for when the countries have pharmaceutical pricing or reimbursement regimes. And as James -- explained during his testimony, I think we have a problem with the cost of the medicines. And every country has a different way to deal with this problem. I know that the USTR has started to include certain provisions in its recent free trade agreements on this issue, but still even the TPP Agreement does not provide clear framework for the pharmaceutical reimbursement or pricing policies.

MR. MEHTA: Thanks. Our next question will come from the U.S. Patent and Trademark Office.

MS. CRITHARIS: Thank you. Another theme in your testimony, as well as your written submission, on page 12, regarding India, is how countries should be given the flexibility to

determine patentability standards.

Are there any situations that you believe in which a new form, a new formulation, or perhaps even a new structure can be given patent protection? Or, alternatively, do you believe that it be the policy that all such innovations should be barred in all situations? Thank you.

MS. KILIC: India and Section 3(d) is formulated as the certain inventions -- the inventions, or not inventions, the subject matter because it's before we start, whether the invention is patentable, we have to determine whether the subject matter is a new invention. And India Section 3(d) is formulated as a test to determine whether the subject matter is an invention or not.

And the subject matter, if it is a new use, if it satisfies the requirements that is set in Section 3(d), it qualifies as an invention, and then it passes the test, and then it is subject to patentability requirements and the patent office checks whether it is patentable or not. And in most of the cases, this is the problem we've been having

with most of the so-called inventions. Those patents are the second-rate patents. There is already one patent existing on those patents.

And that's the same problem with Canada's utility test, because the pharmaceutical companies, they run to the patent office and they want to get another patent on the new use or the new formulation, but most of the time those patent applications either fail the test of invention or the utility requirement as in the case of Canada.

MR. MEHTA: Thanks very much for your testimony and for appearing today.

If I could invite the Trademark Working Group to please approach.

Welcome, sir, please introduce yourself for the record and begin your testimony.

MR. KILMER: Thank you very much. Paul Kilmer. I'm the founder of the Trademark Working Group and alumni of American University's Washington College of Law, which seems to be some sort of criteria for being up here this morning. There we are, so off to a good start.

The Trademark Working Group again appreciates the opportunity to present hearing testimony in relation to practices that do not provide adequate and effective protection of trademark rights. We have provided you with a copy of our Global Trademark Report Card, which has been updated for this year. It highlights laws and practices of foreign nations that we think are important for you to assess and use as you go into discussions with representatives of foreign nations. I will therefore highlight a few matters for the record.

Again this year, China has formed the bulk of our comments in relation to issues encountered by U.S. trademark owners. These include especially the elimination of direct appeals from the China Trademark Office to the Trademark Review and Adjudication Board by unsuccessful opposers, most of which are foreign companies. That situation is now exacerbated by CTMO opposition examiners, who have become increasingly unpredictable and narrowly focused on whether the respective goods and services

of the parties are in the same subclasses and whether the marks are virtually identical. They therefore tend to overlook broader issues in assessing the likelihood of confusion between marks.

The Chinese trademark system also suffers from unnecessary notarization and legalization formalities required to file applications to bring oppositions and to support TRAB actions. It also suffers from inflexibility in relation to descriptions of goods and services that does not take into account new technologies in many cases.

The Chinese system also tends to disregard affidavits and witness declarations in inter partes proceedings, even regarding uncontested facts. And it continues to have unreasonably high standards for establishing well-known mark status.

This is all in addition to a continued glaring lack of transparency in all phases of trademark prosecution, opposition, cancellation, and invalidation practice.

The slows. In our 2015 submission, we called attention to nations such as India and

Brazil, which have failed to adjudicate opposition and cancellation proceedings within a reasonable period of time. Unfortunately, the formulation of various action plans and similar efforts have failed to alleviate the backlog of long-pending oppositions in these nations, some of which date back 9 years or more. In fact, I was working on one just this morning from India that is 11 years old.

Multi-class applications. This year's Global Trademark Report Card notes more than 30 nations that still require single-class trademark applications. This requirement leads to additional cost, both in terms of initial filings and in relation to docketing and maintenance of multiple registrations. Single-class applications are still required in nations such as Argentina, Brazil, Indonesia, Malaysia, Pakistan, Thailand, and the United Arab Emirates.

Certification marks. Despite USTR highlighting this issue in its 2014 and 2015 Special 301 Reports, many nations, ranging from Afghanistan to Yemen, still do not protect certification marks.

Standards for approving certification marks in other nations vary to such a degree and often impose unique requirements on the certification process such that owners of many certification marks cannot maintain consistent standards and regimes around the globe, thereby undercutting the entire certification process.

Formalities and recordations. Like China, there are a number of nations that continue to require a host of formalities that are overly burdensome on trademark owners. For example, Argentina, Egypt, Kuwait, Panama, the Philippines, Saudi Arabia, and United Arab Emirates all maintain legalization requirements. Similarly, a number of nations continue to require recordation of license agreements in order to ensure the validity of those contracts within the nation. Such requirements are unduly burdensome and set a trap for the unwary.

Oppositions. The absence of effective opposition proceedings allow trademark pirates to obtain presumptive rights and marks in nations such as Russia and Belarus. Similarly, the Ukraine,

which has opposition proceedings in name only, generally requires trademark owners of misappropriated marks to seek their remedy in court.

Stealth Paris Convention applications. We have noted this issue in previous years and there remain a number of nations in which newly filed applications cannot be effectively located during the 6-month priority period. These include China, Egypt, Indonesia, and the United Arab Emirates, among many others.

Other practices highlighted in our report that I would just briefly mention, a number of nations continue to give little or no weight to consents to registration. This includes Brazil, China, Japan, and Thailand. Others have not joined the Madrid Protocol. These include Argentina, Brazil, Indonesia, Malaysia, South Africa, and the UAE. Others such as the Bahamas and Zambia do not have service mark registrations. All of these practices and others noted in our Global Trademark Report Card continue to pose obstacles to adequate and effective protection of trademark rights abroad.

Thank you.

MR. MEHTA: Thanks very much for your statement. If we can go to the Department of Commerce for the first question?

MR. MITCHELL: Thank you. You had mentioned a couple of countries that are slow to implement opposition procedures and others where they are simply not present. I'm hoping you can drill down a little bit on the policy behind that. How do opposition procedures benefit the administration of a trademark system and how specifically do they help U.S. companies and the like?

MR. KILMER: In some cases the delays may at least initially assist U.S. companies if they happen to be the one bringing the opposition proceeding. In those countries that have very slow opposition processes, obviously, if the applicant has to wait 11 or 13 years to get a registration and the opposer is a foreign company, that may benefit you in the short haul. Unfortunately, more and more American companies are the applicants and they are

waiting 11, 12, 13, 14 years for an opposition decision, and in most cases, getting a registration and the statutory and presumptive rights that flow from those registrations.

In countries such as Russia and Belarus that do not have opposition proceedings at all, they allow pirates to register marks really without effective ex parte examination procedures, in which case those registrations by the trademark pirates are allowed all of the statutory presumptions until such time as they can be cancelled, mostly through court action, which tends to be far more expensive than the administrative procedures available through trademark offices.

I think those, in brief, would be the points.

MR. MEHTA: Great. And if I can turn to the U.S. Patent and Trademark Office for the second question?

MS. CRITHARIS: Thank you. The survey you provided in your Global Trademark Report Card is quite thorough. Are there any regional trends in

trademarks that emerged as you put together your submission? And, separately, do you know of any research or do you have any quantitative data on how these have raised the cost or prolonged delays of trademark registrations?

MR. KILMER: We actually do not collect data. We are not in that business, unfortunately. The Trademark Working Group is a volunteer group that gets input from its participants in some foreign council and really doesn't do quantitative research. We leave that to others, at American University and elsewhere.

But in terms of regional trends, one thing that we have started to look at, and this is not highlighted in this year's report, is relative grounds examination. More and more of our members and others that we speak with are concerned about countries and regional groups that have abandoned the relative examination processes such as the United Kingdom and the Community Trademark Office. This seems to be allowing a lot of deadwood to get on the register and we are very concerned about that

trend.

MR. MEHTA: Thanks very much, Mr. Kilmer.

If I can next invite U.S. Chamber of Commerce's Global Intellectual Property Center.

Welcome, and if you could introduce yourself for the record and begin your testimony.

MR. KILBRIDE: Thank you very much. Good afternoon, everyone. I'm Patrick Kilbride. I'm the Executive Director for International IP at the U.S. Chamber of Commerce's Global Intellectual Property Center. I have no affiliation with American University; however, the single best I ever made was a graduate of the program, so I am grateful to the institution.

I am willing to comment on two things as a subset of our broader testimony. Number one, to share with you some of the global findings of the U.S. Chamber's International IP Index, which I think will provide important context for the process here. And, second, to comment on a few country-specific developments that I think highlight the importance of this effort, and those countries are India,

China, and Canada.

First, in terms of context, one of the earlier witnesses said the global IP norms are low and under-enforced. I think U.S. Chamber's International IP Index shows that that, in fact, is the case. We looked at 38 countries in 2012, across a broad range of geographies, market size, levels of development, and it showed that every single country had a different IP profile. Some are stronger in patents and weaker in copyrights. Many have relatively decent trademark laws, but the enforcement is lagging. Application and ratification of international treaties, especially the most cutting-edge treaties that is going to set the norms in the multilateral space are uneven.

So what we find is that intellectual property is not a yes or no policy choice. Countries are really at every point on the spectrum. The point that we tried to make in our 301 submission, that we make when we talking to foreign governments is that it's not necessary for us to criticize your policy choices, but it is our right

and responsibility on behalf of the business community to point out what we believe those choices represent and what the outcomes and the views of the business community are.

For instance, we look at issues that have been raised today, such as broadening exceptions to laws that in many countries aren't even yet in place, and we would look at that suggestion with concern.

I think one of the things that has made the U.S. system especially strong, and we apply this characterization to some of the other most innovative countries in the world, is the way that our system instills legal certainty in the marketplace, because at its best intellectual property works to provide inventors and creators with an asset that can hold value that they can use to leverage financing to be able to bring an innovative product or service to market. And where that system breaks down, where there is less legal certainty, we have seen that the innovative output has faltered.

And I'll draw a distinction here. I don't want to pick on India, but because it has been so central to the conversation, I'll say in our conversations with the Indian government, we have been consistent in saying that the single biggest thing they can do is to find ways to instill legal certainty in the marketplace.

Compulsory licensing is frequently discussed as one of the challenges in the Indian marketplace, and the rejoinder is naturally, "well, there has only been one," and that's true. But certainly under the previous administration, the Indian government actively fostered an environment where every company in that space felt that they could be next. In that sort of environment, investors aren't inclined to put their capital in place, fixed capital. They're not going to invest in research and development. They are not going to hire the personnel who present the human knowledge capital.

So with some of India's principal goals of "Make in India" and "Digital India" and "Start-Up

India," we believe they are being held back by an IP system that doesn't provide that mechanism that lets inventors take their ideas and turn them into commercial products.

Contrast that with the United States, which by no means we believe it to be a perfect system, but the fact is in the United States if you are an inventor, you hold the patent, you have a reasonable presumption that your rights are enforceable. You may lose a particular court case. An administrative ruling may not go your way. But by and large, you have confidence in the system that IP rights are enforceable under the law. And anything that sort of creates, makes exception to the rule rather than intellectual property rights, the rule is going to create a circumstance that weakens that legal certainty in our own market.

With India, we are very hopeful that with the new administration we will see steps in the right direction. Several have been mentioned here today. The establishment of specialized IP courts was an important development.

There was a more recent development. On February 19th, the government issued a revised set of guidelines on the patentability of computer-related inventions. To do that, it reopened a consultation process that had been closed in the fall. Final guidelines had been issued and the new guidelines reappeared on February 19th, 180 degrees in the wrong direction. That raises for us not only a challenge with the policy outcome, which we believe is not in India's best interest, but a question of due process. It's this type of challenge that sort of seems to have cropped up continually in that relationship.

With respect to China, we see similar challenges in many respects, but at the same time, an incremental sense of improvement, including China's score on the GIPC index. The difference is, I think, that the Government of China seems to have made a policy decision that it needs a stronger IP system to facilitate its own innovative industries and to nurture those industries. We agree 100 percent.

In Canada, probably the lowest-ranking developed country on our index, the problem as has been mentioned previously is patent utility. Again, by weakening the certainty in the marketplace, this creates all sorts of questions about whether a patent can really be an asset and hold value. And so we believe it undermines both Canada's interest and our own. Thank you.

MR. MEHTA: Thanks very much, Mr. Kilbride. For our first question, let's go to the U.S. Copyright Office, please.

MS. STRONG: Thank you. I'd like to ask you a question about one of the themes that was in your submission. The Center has listed camcording as a concern of many countries, including Brazil, Chile, China, Mexico, Peru, Russia, Thailand, and Venezuela. What have you and your members found to be the most effective tactic for dealing with camcording? Is it, for example, a case where a new law has to be passed and, if so, what key elements might we find in that law?

MR. KILBRIDE: Thank you. Like most

matters of law, I think a deterrent fact is -- the simplest and most straightforward thing that countries can do, criminal or civil liabilities need to be strong enough to provide a deterrent. And then it's important that prosecutors have the flexibility to respond to realities.

In the TPP negotiations, I believe, some countries raised objections based on the idea that teenagers could be prosecuted for getting their cell phones out. Nobody wants to see that happen. But if you have a strong law or regulation in place, and with the appropriate flexibility, governments can do their thing.

MR. MEHTA: Thanks. U.S. Department of Agriculture for our second question.

MR. KARAWA: Thank you, Mr. Kilbride, for appearing here today. In the GIPC International IP Index, there are challenges to trademark holders caused by overly expensive protection for geographical indications, lack of transparency, and due process for trademark holders. Is that a part of trademark indicator?

MR. KILBRIDE: Certainly, I think transparency and due process are critical to intellectual property systems across the board. So whether it's patent space, copyright space, or trademark, having access to rules that set the process in advance are absolutely indispensable and so that's why they are reflected in our index.

In terms of geographical indications, the index doesn't speak quite as directly to that issue, but we have watched with some concern developments in the World Intellectual Property Organization with the Madrid Protocol, and have worked with our counterparts overseas to help ensure that U.S. interests aren't unduly prejudiced by those developments.

MR. MEHTA: Thank you. One final follow-up from the U.S. Copyright Office.

MS. STRONG: In your written testimony and comments you had mentioned or the Center had mentioned that industry groups had previously been opposed to the safe harbors proposed in the Australian exposure draft of the Copyright

Amendment. This is the one on the Disability Access and Other Measures Bill. Would you be more specific and identify what are your priority concerns about these safe harbors and also what actions should be taken in the bill that would address your concerns?

MR. KILBRIDE: If I may, I'd like to get back to you with more detail on that. But the basic premise is that we don't want to see the types of broad exceptions or limitations to IP rules that make the exception the rule, rather than to right the rule. So, for instance, if we get to a circumstance where IP rights are considered discretionary or provisional, then that really defeats the purpose of having a system that provides legal certainty, allows that value-based, enforceable asset mechanism to work.

MR. MEHTA: Thanks very much, Mr. Kilbride.

If I could now invite the U.S.-India Business Council?

Welcome, sir, if you can introduce yourself and please begin your testimony.

DR. AGHI: My name is Mukesh Aghi. I am the President of U.S.-India Business Council. Thank you for giving me the opportunity to testify today.

USIBC is a premier business advocacy organization representing more than 350 of the largest global companies investing in India. The Council's mission is to serve as a primary interlocutor between business and government leaders, resulting in increased trade and investment, to strengthen the ties between the two nations.

The U.S.-India Business Council believes there have been important development related to India's IP regime in the last 12 months that have paved the way for substantive improvement in the country's IP environment. These developments are, number one, frequent G-to-G interactions. This past year was marked by several positive and sustained government-to-government dialogue on a broad range of IPR issues between India and the U.S. The level and frequency of engagement between the U.S and Indian government is very encouraging and we hope to

see continued momentum.

As an example of G-to-G coordination, the Government of India has already proposed relevant changes in the Cinematograph Act to prevent illegal camcording. Both governments will be conducting joint exercise on copyrights in April 2016 and trade secrets in June/July of 2016.

Number two, improved transparency and frequent dialogue with the industry. USIBC members believe the Government of India has been open and collaborative with industry over the past year, often meeting with industry to discuss IPR issues and approaching discussions with a willingness to solve problems quickly. USIBC also recently held a joint training program with the Indian Patent Office and Government of India, and has expressed interest in doing more training and capacity building with industry.

Judicial alignment. Judicial precedent on IPR this past year has been greatly improved. Courts in India have upheld decisions that have improved IPR, including in the pharmaceutical

sector, and in trademarks for our member, John Deere. Also, the passage of the Commercial Courts, Commercial Division, and Commercial Appellate Division of High Courts Bill in December 2015, which will allow for the creation of specialized commercial benches within the high courts to more efficiently adjudicate commercial disputes, including IPR, was another positive development.

USIBC member Boeing also enforced this concept by stating in their 301 written submission that India has a legal framework that is adequate to protect IP with no known cases of IP violation involving Boeing's activities in the defense and aerospace sector.

Denial of compulsory licenses. The Government of India has denied compulsory license applications providing companies with certainty and predictability that the patent will be upheld in India. No compulsory license has been issued by the government since 2013. The Ministry of Commerce within the Government of India has assured industry that it will be final decision-making authority on

the issue of compulsory licenses in the country. The Government of India has indicated to USIBC that the new IPR policy will not advocate a forced automatic policy transfer in green technology.

Capacity building. The Indian Patent Office continues to modernize and commit additional resources for patent examination, including quadrupling the number of patent examiners and integration of patent databases with global repositories. We see this as a good development.

Messaging at the top. Prime Minister Modi has been very vocal on the need for building a strong and robust intellectual property regime in the country. New initiatives for the prime minister such as the Start-up India initiative recognizes that the intellectual property are emerging as a strategic business tool for any business organization to enhance industrial competitiveness. Initiatives and statements like this demonstrate a change in tone and recognition of value of IPR to India.

As outlined above, significant positive

improvements in IPR have been made in the past year. I want to highlight a few recommendations which the USIBC is currently in dialogue with the Government of India.

Number one, we recommend that the Government of India consult with industry on the guidelines for the examination of patent application for computer-related inventions. They have given us a firm assurance that steps will be undertaken to resolve industry issues at the earliest.

Two, we recommend that responsibility for the enforcement of the Copyright Act of 1947 and related international convention be consolidated and shifted to one department, like the Department of Industrial Policy and Promotion.

Three, we recommend issuing regulations of guidelines that will specifically interpret Section 3(d), therefore, providing clarity to companies on when and they are patently protected.

Four, as a near-term step towards resolving the challenge of lack of patent linkage system in India, USIBC has suggested that a

mechanism be put in place that will ensure that all information related to the application for manufacturing and marketing approvals be made available in the public domain for a predefined period of time before any action should be taken on the application.

USIBC applauds the Government of India for taking positive steps in the last 12 months to protect intellectual properties of U.S. companies in India. The Modi government has been very proactive in building a strong IP regime in the country. It is evident from several policy interventions, a strong commitment by the government to work closely with industry to identify and resolve issues.

USIBC believes that positive reinforcement by this committee will further enable the Government of India to build on concrete steps. In closing, the U.S. India partnership is of great importance and promise; therefore, it is vitally important that we engage with India as equals, in a manner which enables them to implement an IP regime that is on par with global standards. Thank you.

MR. MEHTA: Thanks very much, Dr. Aghi.

For our first question, if we can go to the Department of Treasury, please.

MR. CHANG: Thanks very much for your submission. My question is the same that we posed to AFTI earlier: How will Prime Minister Modi's Make in India policy intersect with India's intellectual property regime? Without stronger IP protections, companies, both domestic and international, are wary of investing in India. Will Made in India policy lead to intellectual property policy reforms?

DR. AGHI: I believe that the Make in India is very critical for this government to be successful in creating jobs. And for them to be successful, I think a world class IP policy has to be issued and implemented by the Government of India to be successful.

MR. MEHTA: Thanks. For our second question, I look to the Department of Commerce.

MR. MITCHELL: Thank you. You are the second India-focused trade organization that we have

heard from today, the first one earlier being the Alliance for Fair Trade with India. I'm wondering if you have had a chance to review their recommendations and could describe how your views differ from that organization's views, and to what you attribute those differences?

DR. AGHI: I have not reviewed their submission. But I can talk on behalf of member companies on the commitment towards investment in India. If you look at last year, U.S. member companies invested almost $15 billion into India. We did a survey of a partial membership of 52 companies. They plan to invest another $27 billion in India because they see India as a lucrative market. As I testified in the case of Boeing and John Deere, they feel quite assured by the IP commitment the Indian government has made.

MR. MEHTA: Thanks. I think we have time for one more question. U.S. Patent and Trademark Office?

MS. CRITHARIS: In your submission, you reserve the right to amend your recommendation to

suggest an upgrade or downgrade depending on the final national IPR strategy. What would the plan include that would lead you to suggest a downgrade or upgrade to Watch List?

DR. AGHI: I think we are encouraging working on the new IP policy document which is about to be released. And what we have suggested to Indian government is have a liberal consultative process to make sure that meets the global standards. And, for whatever reason, if it does not meet the global standards, then we will definitely recommend a downgrade. But all the signs are that things seem to be moving in the right direction for U.S. business enterprises in India itself.

MR. MEHTA: Great. Well, thanks very much for appearing today, Dr. Aghi.

And that brings us to our next and final presenter, the Union for Affordable Cancer Treatment.

MS. RESS: Thank you. The good thing about being the last one is that I am the last one.

MR. MEHTA: A warm welcome to you. If you

could introduce yourself for the record and please begin your testimony. Thanks.

MS. RESS: My name is Manon Ress, and I am here to represent the Union for Affordable Cancer Treatment, UACT, which is a volunteer organization, a union of people affected by cancer, their families, their friends, people that take care of them, health care professionals, cancer researchers, all committed to increasing access to effective cancer treatment and care. We are, of course, concerned about the rapidly escalating cost cancer medication in the U.S. and all over the world.

As a cancer patient, myself, and I take treatment since 2010, and with all UACT members who are concerned, we agree with PhRMA, actually, PhRMA's comments that advances in biotechnology and genomics are propelling the discovery of new medicine -- I'm quoting them -- to treat a range of chronic and infectious diseases.

We note, as PhRMA did in its comments, that the American Cancer Society, in an article dated January 7, 2016, quite recently, reported that

cancer death rate has been reduced nearly 23 percent since 1991. This is all great news.

For many patients, cancer has become a chronic disease that when well-treated, including with new targeted therapy, like the one I receive, can be controlled and allows patient to live long, very long and useful life. However, PhRMA is also asking for trade policies that make these drugs more expensive and which will, of course, restrict access.

So, first, I would like to address some of the comments on India. PhRMA wants India to be placed on the Priority Watch List because India used only once compulsory licensing of patents on essential life-saving cancer drugs and that could happen again, even though India has already faced much pressure to not issue such licensing.

I would like to quote the PhRMA submission. "The Indian government appears to have taken a more measured and cautious approach in responding to recent CL cases, including the denial of two CLs this year. We are encouraged by this

trend. However, the grounds for issuing a CL under the provisions are broad, vague, and appear to include criteria that are not clearly related to legitimate health emergencies. The Ministry of Health continues to make recommendations to impose CLs on certain anti-cancer medicines under the special provisions of Section 92 of India's Patent Act, which would make it even more difficult for patent owners to defend their patents."

In support of this comment, PhRMA makes reference to a compulsory license for the cancer drug dasatinib, which treats leukemia -- once leukemia is resistant to Gleevec, you have to take dasatinib or you are dead -- which was proposed like other several case involving expensive cancer drug. It was never issued after pressure from industry and USTR.

Again, we strongly object to the pharmaceutical industry misrepresentation of the WTO rules, especially on the issue of national emergency. And if you will permit me, I will quote again the WTO FAQ following the compulsory licensing

statement. From the website, WTO website, "Does there have to be an emergency?" And their response, "Not necessarily. This is a common misunderstanding. The TRIPS Agreement does not specifically list the reason that might be used to justify compulsory licensing. However, the Doha Declaration on TRIPS and Public Health confirms that countries are free to determine the grounds for granting compulsory licenses."

And later, "For national emergencies, other circumstances of extreme urgency, or public non-commercial use, or government use, or anti-competitive practices, there is no need to try first for a voluntary license. It's the only instance when the TRIPS Agreement specifically links emergencies to compulsory licensing."

UACT members welcome the Indian Supreme Court rejection of the Bayer appeal of the Nexavar compulsory license that PhRMA complained about in its comments. At the heart of that case was the fact that Bayer was charging $65,000 per year in India for a cancer drug and only a small number of

patient that needed the drug could even be able to afford it. What is unfortunate is that India has been pressured to not issue more of this compulsory licensing.

PhRMA wants the USTR to ensure free reign to their greed while patients do not have any hope to have access. For us, cancer patients and people who care about cancer patients, India is particularly important because it has the potential to supply affordable generic drugs also to other countries, including the U.S. I, myself, benefited from a drug that was out of stock in the U.S. that was imported from India.

High prices for cancer drugs leads to a rationing of access around the world. For the cancer patients who are unable to have access to a drug that the need means a painful death.

Secondly, regarding Korea, UACT would like to comment on the PhRMA request to place Korea on the Watch List for its independent review mechanism, IRM. Under Article 5.3(5)(e) of the U.S.-Korea Free Trade Agreement and the side letter, Korea agreed to

make available an independent review process that may be invoked at the request of an applicant directly affected by a pricing reimbursement recommendation or determination. PhRMA complains that the Korean government has taken the position that reimbursed prices negotiated with pharmaceutical industry should not be subject to the IRM because the National Health Insurance Service does not make determination and merely negotiate the final price at which a company will be reimbursed.

PhRMA notes that local data indicates that from 2007 through 2012, the NHIS determined not to reimburse 59, or 20.3 percent, of the 291 new medicines for which it was tasked to negotiate the reimbursed price. And, again, according to PhRMA, for anti-cancer drug, the rejection rate was even higher, 37.9 percent. The Korean National Service decided to reimburse only 18 of the 29 anti-cancer drugs that Korea's Review and Service Agency had determined should be reimbursed.

We, thus, agree with PhRMA that the prices of drugs are too high. In Korea, patients do not

have reimbursement for a large number of cancer drug. But why? The high prices for the drugs are restricting access. If high prices are blocking access in Korea, the Government of Korea should be free to take measures, legal measures to break drug monopolies so prices fall.

PhRMA is highlighting the negative consequences of high prices. Korea should put the monopoly at risk and not the patients. But the U.S.-Korea Free Trade Agreement makes that more and more difficult.

Finally, regarding test data, PhRMA is using the 301 process to pressure countries to provide exclusive rights to clinical trial data to further block generic or a biosimilar version of drugs. PhRMA critiqued 15 countries for their failure to provide exclusive right on test data, including countries like Vietnam, Egypt, and Thailand, where most people are very poor.

PhRMA says that exclusivity is carefully balanced mechanism that improve access to medicine of all kind, citing the Hatch-Waxman Act, which was

passed over 30 years ago under very specific circumstances in the United States and which does not provide exception to the test data monopoly.

When the prices for life-saving cancer drugs are too high for any government, the best option is better price regulation or compulsory licensing of the patents. The worst option is, of course, to prevent access to life-saving drugs.

But what is the impact of policy on access? We call upon the USTR to initiate a period impact assessment to report upon the specific implication of the IPR policies that it has endorsed and continues to endorse through the Special 301 process and international trade agreements on patients and their families.

Specifically, we ask for detailed data that would illuminate precisely how many cancer patients suffer and die, or die too soon, because of the lack of an affordable generic or biosimilar medicine that they could have accessed via compulsory license were it not for the pressure by USTR and other agencies.

We can thank PhRMA for providing some data on the restricted access to cancer drug in Korea, but this is not just a problem in Korea. The filing of such a report would be an important addition to the factors taken into consideration by policy-makers. The data for this impact assessment should include a review of historical reports of cancer incidents, mortality and years of life lost. USTR should also encourage and facilitate the future collection of this data by cancer type. This impact assessment should also record the historical and future access to and cost of cancer treatment by medicines.

Documentation of this data would illustrate the number of patient eligible for newer, costlier cancer treatment who are forced to forego treatment due to financial burden caused by this medicine. The focus should be on R&D, rather than on IPR. And instead of preventing access and innovation of anti-cancer drug, USTR should include in its assessment of our trading partner their role in supporting investment in R&D, including public

sector R&D through programs similar to what the NIH does. The focus on high price kills patients, and there are better options and better targets for trade policies. Focus on R&D, not just IPR.

The USTR could also begin to collect data on government programs to fund medical R&D through grants, research contracts, and other methods which contribute to innovation and which do not depend upon high prices of drugs. Thank you.

MR. MEHTA: Ms. Ress, your time has expired, but I'd like to find some time, an advantage of being last, I guess, for at least one question from the panel.

MS. RESS: Sure.

MS. BLEIMUND: Thank you. Thanks for your testimony. I have a question about the market access version of -- I'm sorry -- the market access section of the 301 Report. As you know, we also report on market access concerns such as high tariffs on medicines, long regulatory delays, and long delays in listing new pharmaceuticals on national formularies.

I just was wondering, in your view, if you think that these types of issues are also important in the access to medicines conversation?

MS. RESS: Well, of course, they are very important and they are not all equal, actually, because they are not all linked to IPR. On the formulary question, because it's one thing where I have been involved, the drug I am taking is not on the formulary in the UK, for example, and therefore the UK is preventing the drug I am taking from being imported there since it is not made in England.

So there are all sort of issues and it's always linked to the high prices of the drugs, and I think that you should all focus on that. I think the American people won't care about the prices of drugs.

But on the specifics of market access of some drugs, I will have to get back to you from the UACT members.

MR. MEHTA: One final question, if we can. USTR?

CHAIR PETERSON: Some of the other

commenters have noted in their submissions that the prevalence of generics has risen dramatically in the United States over the past 20 years and they attribute that at least in part to the Hatch-Waxman system. Do you disagree with that or do you have any response to those?

MS. RESS: Well, we of course welcome the introduction of generics. It just takes too long usually, and it's a pity that it takes so long. A lot of the issues that cancer patients have to face is that sometimes when a drug is not under patent, it is not being manufactured. That happened to me. And the drug had to be imported from India because nobody wanted to manufacture it here.

I think that, in general, generics are too long to provide on the market; that when they arrive on the market, they should actually be sold and not for high prices of drugs like the brand names. But that's not your problem, it's regulation.

MR. MEHTA: Thanks very much for your testimony. We really appreciate it, Ms. Ress.

MS. RESS: Thank you.

MR. MEHTA: And that concludes today's hearing. Just a final few closing remarks.

On behalf of the Special 301 Committee, I'd like to thank all of you for taking time out of your day. I know many of you, even who didn't testify, came in to hear the different perspectives, the many different perspectives that we heard today. And we really appreciated the ability for these perspectives to inform us, to provide more insight, more information into the 2016 Special 301 Review.

We appreciate the research, the thought, the problem-solving efforts that were part of your written submissions, your oral statements, and the answers to our questions today.

As I noted throughout today, the Special 301 docket will reopen this afternoon and remain open until midnight on March 4th, I believe -- correct, that's this Friday. So post-hearing briefs by interested parties are, of course, optional, but we sincerely encourage the opportunity by all participants to make your views known, especially as a reaction response or amplification of some of the

perspectives you heard today.

So please follow the instructions on the agenda or in the original *Federal Register* notice. Again, the *Federal Register* notice is available online and our docket on regulations.gov is #USTR-2015-0022.

As I mentioned at the top of today's hearing, a transcript and a video of today's hearing will be available free of charge at USTR.gov within 2 weeks.

Thank you, everyone, including my colleagues on the panel and to those who testified today for your contributions and your time and attention. A special thanks goes to the personnel at USTR, including Anita Kyler, our folks in the press office, and of course Christine Peterson, who took care of today's logistics and set-up.

So, ladies and gentlemen, the 2016 Special 301 hearing is now adjourned.

(Whereupon, at 2:27 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

March 1, 2016

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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Edward Schweitzer

Official Reporter