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OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

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SPECIAL 301 REVIEW PUBLIC HEARING

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1724 F Street, NW
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M E E T I N G

(10:05 a.m.)

CHAIRMAN McCOY: All right, I think we'll go ahead and begin. Thank you all for joining us today for the Special 301 Public Hearing for 2012.

My name is Stan McCoy. I'm the Assistant U.S. Trade Representative for Intellectual Property and Innovation, and I want to welcome you to the hearing on behalf of Ambassador Ron Kirk, the United States Trade Representative. This is the Public Hearing on 2012 Special 301 Review.

I'll just start by asking the members of the subcommittee to introduce themselves. Could we start with USDA?

MR. KARAWA: My name is Omar Karawa.

MS. PETTIS: Good morning. My name is Maureen Pettis. I'm from the Department of Labor.

MS. URBAN: Good morning. I'm JoEllen Urban with the U.S. Patent and Trademark Office.

MS. WILSON: Good morning. Susan Wilson, Director of the Intellectual Property Office in the International Trade Administration at Commerce.

MS. PINHA: I'm Paula Pinha, Director for Intellectual Property and Innovation at the U.S.

Trade Representative.

MS. BONILLA: I'm Jean Bonilla, head of the Intellectual Property Office of the State Department.

MS. STRONG: Good morning. My name is Maria Strong. I'm Senior Counsel for Policy and International Affairs at the U.S. Copyright Office.

MR. CANNER: Good morning. I'm Marty Canner of U.S. Customs and Border Protection.

MS. MILLA-KING: Hi, I'm Patricia Milla-King with the Department of Homeland Security, Immigration and Customs Enforcement; Policy Advisor.

CHAIRMAN McCOY: Thank you everyone.

And, of course, we have the entire Trade Policy Staff Committee that is an active participant in the Special 301 process. I'm grateful to those agencies that were able to be here today, and those that aren't, of course, for participating fully in our internal deliberations.

Our entire objective today is to listen and to gather information in advance of the annual Special 301 Report, so I'll keep opening remarks very brief.

I want to begin by thanking the members of the USTR staff who helped to set up for today's

hearing. I also want to thank all of the participants for being here and taking the time to share your views with us. I also want to thank the agencies represented here, again, today for their participation.

Activities like today's process are designed to ensure that Special 301 decisions are based on a robust understanding of complicated intellectual property issues, and to help facilitate sound, well-balanced assessments of IPR protection and enforcement in particular trading partners.

In preparation for this year's process, USTR requested written submissions from the public through a notice published in the *Federal Register* and received numerous comments from interested parties. The submissions that we received are available to the public to be viewed online at the website www.regulations.gov.

The Special 301 designations and actions that will be announced in this year's report will be the result of deliberation among all the relevant agencies within the U.S. Government, including those represented here today, informed by extensive consultations with affected stakeholders, foreign governments, the U.S. Congress, and other interested

parties. USTR, together with the Special 301 subcommittee of the Trade Policy Staff Committee, works to make a well-balanced assessment of U.S. trading partners' IPR protection and enforcement, as well as related market access issues, in accordance with the statutory criteria set out by the U.S. Congress.

That assessment is necessarily conducted on a case-by-case basis, taking into account diverse factors such as a trading partner's level of development, its international obligations and commitments, the concerns of right holders and other interested parties, and the trade and investment policies of the United States. It is informed by the various cross-cutting issues and trends that you see identified in Section I of the Special 301 Report. Each assessment is based on the specific facts and circumstances that shape IPR protection and enforcement regimes in a particular trading partner.

Input from the public is critical to ensuring that we make the most effective and appropriate use of the Special 301 process. As you deliver your statements today, I encourage you to all please bear in mind the statutory instructions

Congress has given to USTR: to identify countries that "deny adequate and effective protection of intellectual property rights" or deny fair and equitable market access to persons that rely on IP protection. Your comments will be most helpful to this review if you can use the short time available for your oral presentations today to direct our attention to the information you or others have provided that we should consider in carrying out the tasks set for us by the Congress.

With that I want to thank everybody again for their participation.

The schedule we have set out today begins with 10-minute presentations by three governments, and then we'll take a short break and we'll continue with 10-minute presentations by various submitters. So I think we've set it out as five-minute presentations and five minutes for questions, if there are any.

I'll just let people go ahead and use the time, and if you want to stop and invite questions, then we can certainly do that. But I think we found in past years that just letting you proceed and pause is appropriate and may be the best way. We've got 10-minute blocks to divide up between your

presentation and whatever questions might arise.

So with that I will go ahead and -- unless there's anything else. No? I will go ahead and introduce the first speakers. We're honored to have representatives of the government of the Czech Republic with us today.

Mr. Zajicek and Mr. Dvoracek, the floor is yours.

MR. ZAJICEK: Thank you, Mr. Chairman. Good morning, ladies and gentlemen. I'm privileged to be here.

First of all, I need to apologize to a certain extent. I lost my voice, but I really wanted to show my determination and define the Czech case, so I definitely was willing to come.

Deputy Minister Tlapa sent you a letter in which he enumerated all the improvements that were done in the Czech Republic in the course of the year 2011, sharing also best practices that we have and we are ready to share with other partners.

For many of you it's not news that we consider the issue of IPR to be a long-running issue. That's not a one-off event. We are not pressing with last-moment information to you. We try to be in contact with all the relevant people

throughout the year, to demonstrate that we really care. And the embassy shares that, too. So we have been rather active. But it's not about the embassy. We are, of course, in very close contact with Prague, with the headquarters, with the intergovernmental committee that is composed of several ministries, and to different authorities in the Czech Republic.

So I'm very glad that I can present here something that is kind of omnipresent throughout the Czech administration, both in Prague and in here, governmental and nongovernmental actors. And we have tried to prove that throughout the year, as you well know.

I would like to speak about three or four different topics in this respect. I have to start with the internet crime, of course. We also look to global trends. We notice what is happening.

UNIDENTIFIED SPEAKER: That's the most flattering way.

(Laughter.)

MR. ZAJICEK: This is getting more intimate.

(Laughter.)

MR. ZAJICEK: You brought the light again.

Thank you, ma'am.

So as you may know, in 2011, the Czech government adopted a state policy on electronic communication that is called Digital Czech Republic, and it includes many measures that are directed also in the IPR protection and enforcement. A new subcommittee for corporate was created, that is specifically with the copyright issues. And the Czech Customs Administration strengthened and mobilized the work of the Department of Internet and Internet Crime. So at the institutional level, many things have been done.

If we speak about the controlling activities now, we can experience two different trends. Although we have managed to raise the number of raids in the open marketplaces by 25 percent, amounting to about 2,150 raids and inspections just throughout the last year, the number of confiscated goods was actually lower. I think this is actually the trend that proves that the open markets are not, anymore, the number one distribution channel in this respect of counterfeit and pirated goods. So we have to follow this trend.

Having said that, I can assure you that the number of checks will not go down. There is no room

for complacency in our case. But we simply have to follow these trends.

On what I think is crucial in this respect is the prevention and education aspect to it. And the intellectual property office in Prague in the Czech Republic has stepped up efforts in terms of educating and lecturing about the importance of IPR at various fora, first at the universities. I think that it's important for the students to be aware, very early, what the implications are.

But not only that, we have been in very close contact with individual companies. I will get back to that. But also with public authorities and judges. I think this is actually the crucial thing to do, to concentrate on the prevention aspect and education among the Czech society at all different levels.

When I mentioned business contacts that we have had, you are well familiar with the fact that some of them put a complaint against the Czech Republic in the recent history. Well, I'm glad that if I get back to cases like Philip Morris, they themselves acknowledged an improvement in countries, including the Czech Republic. The PhRMA didn't complain this time. I'm actually happy that neither

of the two institutions, the International Intellectual Property Alliance and the International Anti-Counterfeiting Coalition, did not file a specific comment to the Czech Republic.

To sum up, IPR protection and enforcement is a moving target. I can confirm that it is the issue for the Czech authorities both in Prague and in here. We are also very active in the EU, following the EU patent discussions -- we had been at one of those -- that promote the discussions in reaching considerable outside results. But we are in a moving target. We need to align our policies back home to the new trends, which we are currently doing. The determination is fully there.

Thank you for your attention. I'm ready to take any questions.

CHAIRMAN McCOY: Thank you very much for your presentation. That's very helpful.

We appreciated your submission and the reports on the intensified enforcement efforts, particularly at the border and online environment.

We noted that your submission talked a bit about the online environment. We'd be interested in any additional information you'd like to provide about the Digital Czech Republic initiative or

efforts to address piracy in the online environment as well as the physical markets that you mentioned.

MR. ZAJICEK: I'm not sure whether you have got at your disposal the English version of the Digital Czech Republic, which we are more than ready to provide you with.

There are many things going on at the same time. This strategy was just approved by the government. So we would be around the time when we do one-year's stock-taking, what it has brought in concrete terms.

At the same time there is development at the EU level with ACTA and many other things. As you know, the Commission is to propose the revision of the e-commerce directive, which the Czech Republic is a very strong advocate of. We have been strong advocates of that already during the services directive proposal that was actually adopted.

But on this one we are looking very much forward for the Commission to fulfill what it promised, and it will come up with an e-commerce directive. So at the EU level, I think a lot of changes will be brought by just transposing the e-commerce directive, which we have got strong views about.

On the Digital Czech Republic, which -- whose main aim is, of course, to spread the broadband to the widest possible target audience, especially outside the big cities. But that goes hand in hand with the educational aspect to the people, for them to realize what IPR protection means.

I don't want to be long on this one, but I would like to provide you with an English translation of that, and that should be soon. It's an evaluation of the policy which has just been introduced, and to be able to report on that.

Thank you.

CHAIRMAN McCOY: Well, thank you very much again for coming today. We appreciate your participation and the information you've provided. It's very helpful. Thank you.

So if I could invite the representative of the government of Poland, Mr. Pietrasienski. Did I get that right? Thank you. The floor is yours, sir.

MR. PIETRASIENSKI: Thank you very much for this opportunity to be here today and to present a Polish position and Polish efforts on this matter.

And this is very important for Poland. We

are very determined. And I'd like to just give you a general overview, in short, what we are doing in Poland. But, of course, we also submitted the position of our Ministry of Culture and National Heritage of the Republic of Poland, of the official standpoint of our government regarding the Special 301 Report for 2012. It, of course, is practically 50 pages, but I'll try to make it as short as possible.

Just a few words regarding my position here. I am head of the trade and investment section of the Polish embassy in this matter. Also we are representing the minister of the economy of the Republic of Poland.

And regarding the 301 Report, this is very important, and it should be emphasized that Poland has been removed from the Special 301 Report in recognition of considerable curbing of operability of pirated carriers and counterfeited products, and more effective law enforcement, as well as for close cooperation between IPR holders and outreaches in Poland.

The Polish government acts in a consistent manner with record to its policy of combating counterfeiting and piracy. The actions are

supported by the figure exhibited in our submission document I just mentioned.

In 2011 there was a total of 8,018 cases initiated with regards to infringement of copyright material. On the enforcement side, the outreaches were very successful in stopping serious activities related to copyrights of films, computers, software, TV signal, book publishing, and counterfeit products, with a total value of secured items estimated in millions of dollars.

Activities undertaken by the custom service over the period of the last three years resulted in 3,000 cases, which have doubled as compared to previous years. There is a strong growth in number of initiated investigations as well as seizures of counterfeit products at the border.

In the field of pharmaceutical products, the Office of Chief Pharmaceutical Inspectorate conducted over 6,000 inspections, which included 196 inspections of manufacturers and importers, 520 inspections of wholesalers, and more than 5,000 inspections of retail sales of medicinal products.

In addition, the inspectorate posted 15 notifications to enforcement outreaches about

suspicion of crime related to trading medicinal products as well as fake dietary supplements. In 2011, a new regulation related to counterfeit and illegal trading in medicinal products was enacted.

These are just some examples of our continuous efforts in strengthening the protection of IPR in Poland, to enhance cooperation between various stakeholders and the outreaches. Each year we strive to make improvements and enhancements to our programs. We improve our regulations and enforcement efforts.

Throughout the last three years, Poland has earned its right to be among countries who are very serious about IPR protection and fight against trade and counterfeit goods. Our government firmly executes the law related to violation of IPR, and this matter remains our key priority.

So just to sum it up, it should be strongly emphasized that problems connected with the crimes against intellectual property are constantly the focus of attention of Poland's government and remain one of our strongest priorities.

Thank you very much.

CHAIRMAN McCOY: Thank you very much for those comments. We appreciate your presence here

today and the information that you provided.

I guess what I would suggest by way of questions is I could ask the same thing that I asked of your colleague from the Czech Republic. On the internet side, is there anything you'd like to elaborate on with respect to Polish government efforts in that area?

And then I note that we received one submission from -- raising some pharmaceutical issues around market access for pharmaceuticals. I don't know if you've had a chance to look at that, but if you'd like to react to that, we certainly would welcome that.

MR. PIETRASIENSKI: Um-hum. Let me say, regarding the pharmaceutical aspect, it's that it's not directly connected with counterfeiting the products. But we're purchasing new drug technologies and reimbursements. So this is the new reimbursement policy introduced in Poland. And consequently, there's no connection whatsoever with the intellectual rights protection about this matter, since it's more on the commercial side of the problem and policy of reimbursement of the pharmaceutical aspect.

Regarding the second question, regarding

the internet issue, of course, the consultations in Poland are already taking place, but also we are waiting also for how -- the European Commission also has several inquiries regarding the question of internet and intellectual property rights in the internet. So we are still waiting for the, also, European Commission standpoint on this.

CHAIRMAN McCOY: Thank you very much for coming today, Mr. Pietrasienski.

MR. PIETRASIENSKI: Thank you very much.

MR. CANNER: Can I ask one question?

CHAIRMAN McCOY: Yeah, go ahead.

MR. CANNER: I'm just curious. You mentioned that the number of cases have been -- are up in terms of filed with customs. What would you say accounts for that? Like, you mentioned the number of inspections. I couldn't tell if they're -- I might've missed it -- if they were growing. Or is there any other driver behind the number of increased cases filed?

MR. PIETRASIENSKI: No, no, definitely we are increasing the number of inspections every year. This is one of the major efforts to stop -- also to trade and to count the inflow to Poland -- the counterfeit products, for example. So this is kind

of the efforts which is -- year by year we are trying to be better and better and increase the number of inspections.

MR. CANNER: Okay, thank you.

MR. PIETRASIENSKI: Um-hum.

CHAIRMAN McCOY: Thanks again.

MR. PIETRASIENSKI: Um-hum. Thank you very much.

CHAIRMAN McCOY: So I'd like to welcome the representative of the government of Mexico, Mr. Behar.

MR. BEHAR: Thank you.

CHAIRMAN McCOY: The floor is yours.

MR. BEHAR: Well, I'm not sure whether I use the large presentation or the short presentation. Well, I have a larger one, which you have the graphics and information. We don't have a PowerPoint. If I were to know that we can turn off the lights and put it on, I would be happy to do so.

(Laughter.)

MR. BEHAR: Well, thank you. Good morning, Mr. Chairman and members of this committee. We very much appreciate the opportunity to appear before you at this hearing and express our views for the 2012 review of the Special 301.

For the record, again, I'm Salvador Behar, legal counsel for international trade at the Embassy of Mexico.

Let me start by saying that IPR protection is an important issue for Mexico and the reason for which we have been participating in various international negotiations and working to advance our IP legal reform.

Due to the short time allocated to this hearing, to participants, this presentation should be taken just as a short brief of actions undertaken by the Mexican government and responsible efforts of policing and enforcement of intellectual property rights. Also it is important to highlight that those strategic measures implemented by the Mexican government in 2012, 2010, and 2011, as we showed in previous hearings, have been maintained.

I would like to briefly address the specific issues during my testimony related to IPR protection and enforcement efforts.

Since amendments of the Article 429 of the Federal Criminal Code and 223(b) of the IPR law on June 28, 2010, Mexico has made tremendous progress in the prosecution of crime, and PGR crime effort related to IP increased by almost 300 percent.

With regard to enforcement actions taken by the attorney general's office, we have carried out 2,941 search warrants in property, we have dismantled 159 labs, and we have taken and dismantled six factories.

It should be noted that thanks to the hard work of the Mexican government, 2011 was the year of the largest number of actions against crimes related to IP violations during the current administration, including 17 convictions.

2011 actions to detect counterfeit goods were enforced at customs through the implementation of a trademark recordation system by the General Customs Administration. SAT, our agency, has collaborated with other governmental agencies to detect counterfeit goods, particularly in the detection of apocryphal goods.

In 2011, 702 actions were carried out, resulting in the seizure of more than six million goods. At the same year, SAT had more than 35 million pieces of counterfeit goods seized both in actions of customs and posterior revisions.

Let me tell you that we have received 2,281 requests for initiative procedures. All were resolved in the same year, so we have no backlog.

And in 2011, a total of 3,963 inspection visits were carried out.

It is important to highlight that almost 3,000 of those were ex officio and only 938 were ex parte. The results of that is more than three million goods seized.

To combat for counterfeiting, SAT instituted a pilot program to exchange information through an animated database where customs authorities can access the registered trademarks.

Now, let me talk about INDAUTOR, which is our copyrights office.

The INDAUTOR has focused much of its efforts on educational awareness of IPR in Mexico. This includes the publication of an IPR chapter in the civics and ethics textbooks used by all elementary schools nationwide, and its relation of 75 courses and workshops for officials and the general public alike.

On the arbitration side, INDAUTOR's consultation procedures have proven to be effective. Seventy percent of these cases were ruled in favor of right-holders.

March 1st, 2011 also, it's -- IMPI launched a Patent Prosecution Highway, joining with USPTO to

expedite a pilot examination process by using substantial examination results of signatory offices. Mexico's examination process has decreased from 27 months to three because of the PPH.

I can happily announce that Mexico has committed to renew its PPH with the U.S. in the near future and sign the upgraded version to 2.0.

Last summer, DHS and Mexican officials coordinated a joint operation called Safe Summer, to target health and safety related items smuggled in both countries. These resulted in more than 800 seizures in the U.S., worth hundreds of millions of dollars, and 300 tons of counterfeit goods seized in Mexico.

Collaboration, training, and increased intelligence sharing among law enforcement agencies of both countries have also taken place to promote IPR protection.

Mexico worked with the World Customs Organization, the U.S. government, and the private sector to train 727 Mexican customs officials, also have an active participation of identifying counterfeit goods.

Mexican customs also had an active participation on international imperatives

instituted by WCO and APEC. INDAUTOR and WIPO established an educational seminar for judges of the Federal Tribunal of Fiscal and Administrative Justice, a program that will be implemented this year for all judges and magistrates.

It has also signed cooperation agreements with Ecuador and Guatemala, while in the process of doing so with Brazil, Peru, Paraguay, and many others.

The Mexican interagency group has been working to further ensure that the Mexican legal regime is in compliance with WIPO treaties, particularly in the internet WIPO treaties, including technological protection measures, rights information management violations, and neighboring rights. And results of these efforts will be shared in the near short time.

We'll work through the linkage decree. On September 19, 2003, amendments were made to the regulations on health supplies and in use of property law. These amendments require applicants to prove that they are the patent holder or have a corresponding license and establish a link between the sanitary and the IP authorities. COFEPRIS have stated that it complies with these laws and by not

issuing registries to generics when a patent is still in effect.

Neither of these amendments explicitly addresses formulation patents. Nevertheless, judicial review was requested, which led to a decision that ordered the protection of formulation patents. In response, COFEPRIS issued no registries for generics where a formulation patent was in force.

The above-mentioned confirms how COFEPRIS is committed to protect health and public -- health of the public in Mexico and, at the same time, pharmaceutical innovation.

However, both COFEPRIS and IMPI are in close communication, and efforts have been made during 2011 to reach out to all the interested parties in the private sector in order to identify possible ways to improve the legal framework on this matter and to relate the issue of data protection.

We were asked to ACTA. And this is my final point. We are fully fulfilling all the necessary internal requirements, considering all the comments and concerns expressed by the Mexican Congress, to be able to sign ACTA. These may take some time, but we are committed to signing no later

than April 2012.

For the above-mentioned summary of actions carried out by Mexico, we formally request that we are removed from the Special 301 Report.

Thank you very much.

CHAIRMAN McCOY: Thank you very much, Salvador. We appreciate your attendance here today.

Let me give you the same opportunity as I gave to the representatives of the other governments. If you'd like to elaborate on efforts in the digital environment, that would be of interest. That was mentioned in some of the submissions we received. Or on any other subject. I think you've got another minute or so left on your time.

MR. BEHAR: Yeah, I can certainly elaborate on that. The Mexican government is committed on the digital environment. We are in the process of reviewing our law and to make it clear that we comply with WIPO and that we implemented WIPO correctly, as well as we have -- WIPO is implemented in Mexico, and it's in force. We are reviewing the law. We're making an upgrade to it. We're making it consistent. We are contemplating a full reform that complies with -- also with the criminal code.

So we need to ensure that all the legal bases are consistent, and we are in the process. So this goes also with the implementation of ACTA. That will be reflected.

CHAIRMAN McCOY: Thank you very much. If you'd like to provide a copy of your remarks today, we'd be happy to make that part of the public record as well.

MR. BEHAR: Sure, I can.

CHAIRMAN McCOY: Thank you.

MR. BEHAR: Thank you.

CHAIRMAN McCOY: I think maybe we can get one more presentation in before the break. I don't know.

The next we have is ASCAP, American Society of Composers, Authors and Publishers. Would you like to go ahead, sir?

I don't have everyone's names on the schedule at this point. So if I can ask everybody to introduce themselves, that would be welcome.

MR. WEBB: Yes. My name is Jimmy Webb. I'm Vice Chairman of the American Society of Composers, Authors and Publishers, and I write songs for a living and have been lucky enough to support myself since I was a teenager. I'm here on behalf

of thousands of other writers who have not been so fortunate, and I thank you for allowing me to testify before you today.

I appear in my capacity as Vice Chairman of the Board of the American Society of Composers, Authors and Publishers. Thus, I am here representing ASCAP's 400,000-plus songwriter, composer, and music publisher members.

I'm a songwriter and not a lawyer, luckily for ASCAP, so I won't try to reprise the written filing that ASCAP, together with its sister performing rights organizations, PROs, has already made. Instead I want to explain why the future of professional songwriting and, by extension, a good chunk of American culture depends in great part on your response to that filing.

ASCAP exists to ensure songwriters, composers, and music publishers receive fair payment for the public performance of the musical works they create and own. To do this we grant public performance licenses to a wide range of users such as television and radio broadcasters, hotels, nightclubs, universities, municipalities, and internet services.

A unique feature of this PRO system is

ASCAP's reciprocal relationship with foreign PROs in over 90 countries. We collect and pass on to them the royalties for public performance of their members' music in our country, and in turn the foreign PROs collect royalties for performances of American music in their territories and send it to us for distribution.

We are talking about real money here because American music is popular worldwide. ASCAP receives over $300 million each year from overseas PROs. That accounts for about one-third of all the distributions we make to ASCAP members. In other words, it's one-third of my income, for instance. And that is a critical and increasing source of income for ASCAP members.

For many American songwriters and composers, a healthy stream of performance royalties now means the difference between being a professional music creator who constantly hones his craft or a musical hobbyist with a full-time job. This means that when the reciprocal system breaks down, the livelihoods of American creators are at risk.

Many cable TV operators, broadcasters, and other music users in foreign territories profit from

public performances of U.S. music but spurn their obligation to pay for the rights. When they refuse to pay the foreign PROs for these performances, it's also American songwriters and composers who don't get paid. That's why we need your help to make sure that overseas broadcasters, cable operators, and other users live up to their legal obligations and pay for the music they use.

Let me offer two examples, the Caribbean and China.

A string of jointly controlled cable TV companies in the Bahamas, Jamaica, Trinidad and Tobago are among the most egregious violators of the public performance rights of U.S. songwriters and composers. They transmit lots of American music, but they refuse even to negotiate with their own PROs for a public performance license.

Similarly, some leading Caribbean television and radio broadcasters refuse to pay for the public performance of music, notably in Barbados.

Courts in these countries have proven incapable of enforcing the public performance right. That hurts the local music creators, of course, but it also hurts us.

It's critical that the U.S. government step in, use the Special 301 Report to call out these Caribbean scofflaws and to vindicate the rights of U.S. songwriters and composers.

Governments in these countries could pressure their cable operators and broadcasters to comply. After all, these companies operate under license issued by their local governments. But these countries seem to need a little encouragement in the form of placement on the Special 301 watch list in order to bring these companies into compliance.

Shifting locales, but in the same vein, U.S. songwriters, composers, and music publishers are being grossly underpaid for public performances of our works in China. ASCAP's written submission provides a number of different statistics that show how low the performance royalties in China are.

I'd like to add one more, because I agree with our ASCAP chairman, Paul Williams, that this statistic says it all. ASCAP members receive more in performance royalties from Honduras than from China. Think about that for a second and you'll begin to grasp the magnitude of the unfairness.

The Music Copyright Society of China, MCSC,

is China's only authorized PRO. Despite this authority and a reciprocal agreement in place with American PROs, MCSC almost completely fails to compensate American songwriters, composers, and music publishers. MCSC collects only a tiny amount from Chinese TV and radio broadcasters for public performance, and literally nothing at all for the public performance of music in movie theaters or theatrical exhibitions or hotels.

As a result, American creators receive a pittance for the extensive exploitation of their works in the world's largest nation and second largest national economy.

While I know China has long been on the Special 301 radar screen as a major IPR violator, I ask that you add the performance rights issue to the list of grievances that you will try to correct.

And I thank you very much for your time and attention. I hope I haven't gone over.

CHAIRMAN McCOY: No. In fact, you've gone under, so we really welcome your participation and --

MR. WEBB: Oh, thank you very much.

CHAIRMAN McCOY: -- your perspective as a songwriter on this is valuable. Can I just ask you

-- I mean, I thank you for the substance of all your submissions in the particular countries. Can I just ask you to reflect a little bit on how the music business is changing on an international stage and why that makes the payments of royalties from overseas, as you're suggesting, particularly significant?

MR. WEBB: Well, I think that it's essential that we cement global agreements with all the PROs in existence, including this newly formed one in China, which is basically a symbolic gesture on their part; but that, I think, they were granted membership in the WTO is essentially conditional on the fact -- on a promise that they would live up to these obligations, and it's been something like eight or nine years now and there are no signs of them complying.

This money is very important to us. As I said, sometimes our foreign money is a significant part of our income. It can be as much as a third of our income. And we're only asking that they be put on the watch list and prompted to try to persuade them to comply.

CHAIRMAN McCOY: Well, thanks very much for your participation today. We really appreciate your

presence and elaborating on those issues for us.

MR. WEBB: Thank you very much.

CHAIRMAN McCOY: I think what we'll do at this point is take our 10-minute break. I have 10:50 now, so we'll start again at 11:00, and that'll be 10 minutes for -- hopefully we can find a couple more chairs and get everyone a seat. So we'll resume again in 10 minutes.

Thanks, everyone.

(Off the record.)

(On the record.)

CHAIRMAN McCOY: I think the next speaker on the agenda is Doctors Without Borders. Welcome. I'll just remind you to introduce yourself for the record, and the floor is yours.

MS. SANJUAN: Thank you, sir.

My name is Judit Rius Sanjuan, and I'm the U.S. Manager of the Access Campaign for Medecins Sans Frontieres/Doctors Without Borders.

This statement is too long. I have 10 minutes, so I'm not going to take it personally if you cut me --

CHAIRMAN McCOY: No, no, you can take 10 minutes.

MS. SANJUAN: It's basically based on a

grievance submission that was much more longer than we submitted, so everything is there.

I'm going to deliver this statement on behalf of Medecins Sans Frontieres/Doctors Without Borders.

We would like one more year to start by expressing our disappointment that U.S. government agencies that have a mandate to promote and protect global health are not present in this room, and that civil society from developing countries have not been provided an opportunity to participate. We acknowledge the presence of the State Department, but we miss here the Department of Health and Human Services, USAID, the Global Health Initiative, and specifically also a representative of PEPFAR.

Medecins Sans Frontieres/Doctors Without Borders is an independent international medical humanitarian organization that delivers medical care to patients in over 70 countries. Our projects focus on the needs of poor people living in developing countries where medical needs are often the most neglected.

We seek increased access to affordable lifesaving medicines, vaccines, and diagnostic tools in developing countries and to stimulate the

development of urgently needed better tools for our field teams and people in countries where we work.

Patients in developing countries are denied access to medicines, vaccines, and diagnostic tools either because they do not exist due to inadequate incentives for the development of appropriate and effective tools, like tools for neglected tropical diseases, or because they exist but they are not available in their countries due in part to intellectual property barriers and high costs.

MSF is concerned by the U.S. government's continued use of trade pressures to challenge efforts by developing countries to ensure access to medicines for their populations. Through the release of the Special 301 list every year, the U.S. government is trying to drive countries to implement intellectual property standards above those required by international law. We urge the U.S. government to abstain from threatening developing countries with trade sanctions simply for trying to respond to public health needs.

The Special 301 mechanism is only one tool that USTR has used to this end. The United States is aggressively advancing a TRIPS-plus agenda, seeking intellectual property protections more

extensive than those under international law and the WTO TRIPS Agreement through ACTA and TPP. Our recent press releases and statements on the Trans-Pacific Partnership Agreement and ACTA should therefore also inform this process.

The problem of access to medicines extends to any new drug, diagnostic test, or vaccine needed to treat, detect, or prevent a range of diseases affecting the people MSF treats in developing countries. The problems of access to medicines is not limited to HIV/AIDS and other communicable diseases. The global burden of non-communicable diseases, like cancer and inherited diseases, is increasing worldwide, with the heaviest burden falling on the low- and middle-income economies. However, the magnitude of the HIV/AIDS pandemic has highlighted the fact that millions in the developing world do not have access to medicines and the import of generic competition.

Today, more than six million people are on antiretroviral therapy in developing countries. This is only possible because generic competition caused annual first-line drug prices to reduce from over $10,000 around 10 years ago to $150 per patient per year today.

MSF could not provide ARV, an HIV/AIDS treatment, to more than 170,000 patients in more than 19 countries without generic competition. More than 80 percent of the products that we use come from India and are generics of high quality.

The U.S. government also acknowledges the significance of generic competition in its global AIDS contribution. U.S. government-funded schemes, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, and PEPFAR, are also heavily reliant on generic medicines. In data from last year from PEPFAR, PEPFAR reports that generic formulations account for almost 98 percent of the ARVs purchased with PEPFAR funds, up from 14.8 percent when PEPFAR started in 2005, and this has saved $380 million alone in 2010.

2011 was a historical year for the global HIV/AIDS response. In a June meeting of the U.N. High-Level Meeting on HIV/AIDS, the United States government, with other U.N. member states, committed to 15 by 2015, meaning to scale up the global AIDS response to put 15 million on treatment by 2015.

A few months later, NIH released new data that has proven that treatment of HIV/AIDS can reduce the transmission of the disease by 96

percent, so that treatment is also prevention, making the scale-up of treatment all the more urgent to save lives.

During the World AIDS Day, the Obama Administration responded to this new science and this new political commitment calling for an AIDS-free generation and announcing an increase in the U.S. government global commitments for the fight against HIV/AIDS. We welcome these announcements and this news.

Alongside the tremendous progress in its treatment, there however remains tremendous needs. Ten million people are in urgent need of treatment and are not having access to it.

The price difference is massive between the basic-line -- first-line treatment regimen and the newer lines that patients will need to have access when they develop resistance.

MSF data shows that intellectual property and patents are going to affect access to newer drugs. The WHO-recommended second-line treatment is three times more expensive than the more affordable first-line regimen, and possible third-line and treatment failure lines are around 20 times more expensive than the current first-line regimen.

And funding for global health and for HIV/AIDS in general has declined, leaving the Global Fund to Fight HIV/AIDS, TB and Malaria and the U.S. government PEPFAR-funded initiative short of resources.

A few days ago, last week, the Obama Administration presented its budget request for 2013, with a request for budget cuts on bilateral HIV/AIDS and PEPFAR. However, they justified in these budget cuts that the Obama Administration could still fulfill its targets on HIV/AIDS because of -- I am quoting the U.S. government on that -- the "relentless work to bring down costs and find efficiencies. The per-patient cost to the U.S. of providing antiretroviral treatment has fallen by over 50 percent since 2008 because PEPFAR has invested carefully, tailoring prevention to countries' urgent needs and using generic drugs."

However, USTR-pursued strategies in the Special 301 process and other forums are in complete contradiction and in fact directly threaten these U.S. government global health priorities and MSF work in the field.

In our 2011 submission last year, we highlighted the importance of a variety of TRIPS

flexibilities: the rights of developing countries to define patentability criteria; the issue of compulsory licenses; define patent protection provisions, and define enforcement regimes from a public health perspective. We provided concrete examples of different countries where we work.

In this year, in our 2012 submission, we have focused in one specific flexibility, that's the flexibility to define patentability criteria with a public health perspective.

According to the WTO TRIPS Agreement, countries have an obligation to grant patents on pharmaceutical products and processes, but the question of what criteria to use to define what is patentable is left to countries to determine. Yet India, among other countries, were named in the 2011 Special Report because of the use of these flexibilities.

India became fully compliant with the TRIPS Agreement and introduced a product patent regime in 2005. It coupled its law with a critical safeguard of refusing patents on routine improvements on discoveries of new forms, combinations, or new uses of known substances. The Indian patent law does not consider routine improvements to be patentable,

unless an enhancement in efficacy is proven.

That's incorporating Section 3(d) of Indian patent law. That provides for a strict patentability criteria in an effort to prevent companies from continually extending their 20-year drug patents by patenting minor changes to existing drugs.

The aim of Section 3(d) and similar laws in other developing countries is to prevent the so-called evergreening by prohibiting the patenting of new forms of existing pharmaceutical substances that do not demonstrate significantly enhanced efficacy. India's strict patentability criteria --

CHAIRMAN McCOY: You have about two minutes left.

MS. SANJUAN: Understood -- promotes access to medicines and allows to continue having access to lifesaving generics.

In my 2012 submission, I provide you with different examples of drugs that are currently in the market and the price discounts that we have -- we and the U.S. government and many other governments have benefited because of this law and how, basically, thanks to similar provisions, we could be expanding access to medicines if the U.S.

government allows.

We are therefore very concerned with USTR reference of these flexibilities and specifically the pressure that USTR is imposing in developing countries to change their laws.

I'm finishing by saying that the Special 301 Report must no longer be used to encourage TRIPS-plus measures not required by international law. The Special 301 Report must no longer threaten developing countries for acting within their rights to ensure access to medicines for their populations.

Rather than using the Special 301 Report to unilaterally impose a heightened IP regime in developing countries, the U.S. government should use its law, policies, and financial resources to ensure that research and development is needs-driven and encourages innovation and to ensure sustainable access to medicines for all.

Thank you.

CHAIRMAN McCOY: Thank you, Judit. We appreciate your participation here today and the good work that MSF does in the field around the world.

MS. SANJUAN: If we don't have any questions and if I still have a couple of minutes --

CHAIRMAN McCOY: You still have about 30 seconds, so go ahead.

MS. SANJUAN: Thirty seconds, fantastic. Thank you.

So I wanted to highlight one case and maybe that could be part of the record for USTR. It's my understanding -- of course I'm not a U.S. lawyer, as you know, but it's my understanding there's a new jurisprudence in the United States with the KSR and Teleflex case. The Pfizer.

There are several new jurisprudences in the U.S. court system through the last two, three years that are really renovating the concept of the obviousness within U.S. patent law, and I was just wondering if I could ask you how you have reflected on this new jurisprudence that U.S. is currently embracing new demands to developing countries. And I understand that you're not prepared for that response, so maybe that could be justifying the Special 301 Report.

CHAIRMAN McCOY: Yeah, we'll be happy to take that into consideration in the process of looking at the report.

MS. SANJUAN: Thank you. And also if you could justify how USTR demands on patentability

criteria as it relates to two specific norms the U.S. government has agreed to. One is the Doha Declaration, how basically -- coherence with Paragraph 4 specifically as a Doha Declaration, and the Global Strategy and the Plan of Action, that was agreed in 2008, the World Health Organization, on global health, intellectual property, and innovation. That would be very interesting, too.

CHAIRMAN McCOY: Thanks for those points. We'll take them into consideration as we work on the report.

MS. SANJUAN: Thank you.

CHAIRMAN McCOY: The next person on the schedule is -- the next group on the schedule is Essential Inventions, Incorporated. And if I could just remind you to introduce yourself as you sit down.

MS. COX: Morning. My name is Krista Cox, and I work as an attorney. I'm here today testifying on behalf of Essential Inventions, Incorporated.

To begin with, I'd just like to echo what Judit said a moment ago, that we are very disappointed not to see any representatives from other U.S. government agencies such as DHHS and

USAID and PEPFAR.

Essential Inventions, Incorporated is a U.S.-based corporation created to distribute generic medicines. In order for this small company to operate, it must overcome patent and other barriers to enter markets.

Essential Inventions has previously been involved in several compulsory licensing cases. Although it has not yet distributed generic medicines it has, nonetheless, offered benefits to the public. For example, Essential Inventions files a march-in rate case under the Bayh-Dole Act after Abbott Laboratories raised the price of ritonavir 400 percent.

In the case of ritonavir, an important HIV/AIDS drug, Abbott Laboratories ultimately made very large concessions in the pricing of ritonavir to the federal program after Essential Inventions brought its march-in case. It has therefore saved American taxpayers millions of dollars through lower prices for ritonavir.

As a corporation involved in compulsory licensing requests, with a goal to distribute lifesaving medicines, Essential Inventions opposes actions in the USTR Special 301 process that create

patent and non-patent barriers that go beyond what is required by international law.

I must question what the Special 301 Report is intended to achieve and what value it provides. As I will detail, the Special 301 process has not been merely a way to check a country's compliance with TRIPS, but instead encourages a number of TRIPS-plus measures that hinder access to affordable generic medicines and creates roadblocks for the business of Essential Inventions.

The Special 301 process overemphasizes intellectual property rights for the right holder, at the expense of consumers, patients, and the public interest. There's a lack of balance in the report, which focuses on rights and enforcements without promoting positive proposals for the public. If the design of the system is to increases rights or enforcement levels beyond global norms without regard to human rights and the public interest, I do have serious objections.

The World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights, known as the TRIPS Agreement, has set global norms for intellectual property. Other international instruments exist that are relevant to

intellectual property rights and their relation to the public health, including the Doha Declaration on TRIPS and Public Health, and the World Health Organization Global Strategy and Plan of Action.

Taken together, these instruments set forth global commitments and standards. It is not the role of the United States to change these standards through a unilateral process.

It appears that the U.S., through its Special 301 process, pressures countries to provide for higher levels of intellectual property rights than are required by TRIPS. Prior reports clearly indicate that the U.S. has encouraged countries to give up their TRIPS flexibilities, and a number of countries have appeared on Special 301 lists over the years, at least in part because of their decisions to exercise TRIPS flexibilities rather than adopting a U.S. model. By pressuring countries to adopt U.S. norms in order to avoid placement on Special 301 watch lists, without regard to a country's development concerns or culture context, appears to be a form of cultural imperialism. There are a number of ways to implement TRIPS obligations; the U.S. model is not the only way.

It is highly inappropriate to push for

these higher norms that clearly exceed the requirements of TRIPS outside of the existing multilateral systems such as the WTO and WIPO. The Special 301 list, as well as secretly negotiated free trade agreements such as the currently negotiated Trans-Pacific Partnership Agreement, are inappropriate means for changing norms on intellectual property.

Because Essential Inventions is in the business of promoting public health, it has serious reservations to U.S. practices of pressuring countries to enact TRIPS-plus measures. We oppose, for example, USTR pressure to lower patentability criteria or define the meaning of Article 27 of TRIPS. Although Article 27 lays out the standards for patentable subject matter, countries retain the key flexibility to determine what inventions meet the standards of new, inventive step, and capable of industrial application.

India and Philippines were both placed on last year's Special 301 Priority Watch List and Watch List, respectively, with an objection noted as to these countries' exercise of the TRIPS flexibility.

In the case of exclusive -- also, as stated

in our written submission, we object to patent term extensions and patent linkage.

In the case of exclusive rights over regulatory test data, I note that we not only object to pressuring countries to adopt U.S. models of protection, but that the U.S. system may be both inappropriate and unethical.

Article 39.3 of TRIPS lays out the requirements for protection. Member states must protect undisclosed test or other data that involves considerable effort from unfair use. However, these obligations do not apply when necessary to protect the public or unless steps are taken to ensure that data are protected against unfair commercial use. There's no requirement in TRIPS to provide protection in the form of exclusive rights over regulatory test data, which is the U.S. model.

Numerous countries on the 2011 Special 301 Watch List and Priority Watch List were encouraged to provide protection against unfair commercial use, as well as unauthorized disclosure of undisclosed test or other data generated to obtain marketing approvals for pharmaceutical products. If USTR means to pressure countries to adopt the U.S. model, we have serious objections both on public health

grounds and ethical grounds.

Exclusive rights over test data results in delays of generic entry into the market, keeping prices out of reach for many patients by extending monopoly rights over lifesaving medicines.

Alternatively, a generic competitor would be forced to replicate test data, a wasteful practice in violation of certain medical ethics.

It is important to note that exclusive rights and test data is not the only way to implement Article 39.3 of TRIPS. It does not even represent the most efficient method and conflicts with established medical ethics.

Paragraph 20 of the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects notes:

"Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results."

The WHO Global Strategy and Plan of Action

on Public Health, Innovation, and Intellectual Property explicitly cites the Declaration of Helsinki and notes the importance of promoting ethical principles.

As I've noted, the agreement on TRIPS does not require the granting of exclusive rights. Where test data should be protected, there are alternative mechanisms to the granting of exclusive rights, such as through cautioning mechanisms that would avoid unnecessary and unethical duplication of clinical trials. Such systems, which have been -- for which proposals have been made in middle and high-income countries, would fairly compensate the originator of test data, comply with medical ethics, and minimize the barriers to entry for generic medicines.

That the U.S. would make demands for other countries to enact unethical standards is unacceptable, and we strenuously object to any pressure on foreign governments to enact systems of exclusive rights over regulatory test data.

I would like to voice one additional objection to the Special 301 watch list, with respect to the addition of countries who have exercised their sovereign rights to grant TRIPS-compliant compulsory licenses.

Although the U.S. has said that it respects this sovereign right, it has placed countries such as Ecuador and Thailand, citing concerns over compulsory licensing. Although the U.S. has issued its own compulsory licenses, such as the numerous judicially imposed compulsory licenses after the Supreme Court case eBay v. MercExchange, it seeks to eliminate this flexibility in other countries.

The Doha Declaration, I would remind you, explicitly stated that countries have the right to grant compulsory licenses and have the freedom to determine the grounds upon which such licenses are granted.

Pressuring countries not to use compulsory licenses impacts the public health and impedes the ability of Essential Inventions to conduct its business. Countries should not be forced to give up their internationally recognized TRIPS flexibilities, such as the ones I've just discussed, particularly at the expense of dying patients.

Thank you for your time.

CHAIRMAN McCOY: Thanks, Ms. Cox. We appreciate your contribution today. You have about a minute and a half left in your 10 minutes. I would personally be interested to hear more about

Essential Inventions and what it is that you do.

MS. COX: Certainly. Essential Inventions was incorporated with the goal of distributing essential inventions not only, you know, for developing countries, for patients who cannot afford the brand name product. It does so by encouraging the use of generic medicines. Essential Inventions has been involved in a number of compulsory licensing cases. I did include a reference to those cases in my submission, my written submission.

For example, I did, today, talk about the ritonavir case that Essential Inventions was involved in. In addition, Essential Inventions was involved in a case of generic versions of a drug used to treat rare forms of cancer from Canada to Chile. It was also involved in a compulsory licensing case to import AIDS medicines from India to Cameroon.

In addition, Essential Inventions has been involved in other march-in right cases in the United States. For example, Essential Inventions filed a request to the NIH to exercise its march-in rights on the patents on Xalatan, which is a government-funded invention that Pfizer sold for higher prices in the United States than were charged for other

high-income countries, which was also the case in ritonavir.

For ritonavir, for example, Abbott, when it raised its prices 400 percent for the standalone product, ritonavir, patients in the United States were being asked to pay between five and ten times more than the price in other high-income countries, such as in Canada or the European Union.

CHAIRMAN McCOY: Thanks again for your participation. We appreciate the information and views that you've provided, and we'll take them into consideration as we work on the report.

MS. COX: Thank you.

CHAIRMAN McCOY: Thank you.

So next on the schedule, I have Public Knowledge.

And I'd just remind you to introduce yourself as you take your seat. Thank you.

MS. RANGNATH: Thank you.

My name is Rashmi Rangnath. I work for Public Knowledge. We're based in D.C., and we advocate for the public's right and access to information and participation in the culture on fair terms.

I thank the committee for giving me an

opportunity to testify today. In response to concerns expressed at last year's hearing that comments should be focused on specific countries, my comments today will focus on Canada and explain why Canada should not be placed on the Priority Watch List or Watch List of this year's Special 301 report.

We believe that Canada is a clear example of a country whose laws and practices are similar to those of the U.S. and therefore does not qualify for increased attention under the Special 301 process. Furthermore, I hope that my comments would also inform evaluation of other countries similarly situated as Canada. These comments have been prepared with the assistance of Dr. Michael Geist, professor at the University of Canada and Canada Research Chair in Internet and E-commerce Law.

Section 182 of the Trade Act requires the Office of the USTR to identify countries that fail to provide adequate and effective protection to the intellectual property rights of U.S. persons. However, the Act does not define the scope and strength of IP rights that need to be protected. In making that decision, the committee must be guided by principles that underlie U.S. copyright laws that

define the scope and strength, as well as limitations of various IP rights, while recognizing that other countries will implement those principles in ways tailored to their particular domestic environments.

Furthermore, the Trade Act defines adequate protection as the ability to "secure, exercise, and enforce" IP rights. To the extent that Canada's laws are based on similar principles as U.S. laws and provide U.S. rights holders with a means to sell their creative products, receive appropriate compensation, and enforce their rights, it satisfies the requirements of the Trade Act and cannot be placed on the Watch Lists.

Canada is a member of the Berne Union and the World Trade Organization. In accordance with the requirements of these agreements, Canadian laws provide exclusive rights to copyright owners, much like U.S. law does.

In some respects, Canadian copyright protections are stronger than in the U.S. For example, Canada has a more developed collective management system than the U.S. and this system ensures that copyright owners have a greater ability to license their works.

Limitations and exceptions to exclusive rights in Canada are designed to permit users' access to copyrighted works on fair terms, and use them for purposes such as scholarship and commentary.

Many of the Canadian limitations and exceptions are much narrower than their U.S. counterparts. For example, unlike the U.S. law, Canadian law has no exception for parity. Similarly, unlike in the United States, Canada does not have a clear time-shifting exception. Expansion of these provisions would be justified by the goal of improving the Canadian public's access to works while at the same time not jeopardizing rights of copyright owners.

Second, Canadian law provides effective enforcement mechanisms, including effective civil remedies and criminal penalties. Civil remedies for copyright infringement includes statutory damages, which can result in very high damages awards. Criminal penalties includes fines that can be as high as a million dollars and jail time of up to five years. Canadian courts have imposed these penalties in many cases.

Furthermore, Canadian law enforcement and

border officials actively enforce IP rights. For example, in 2010, the Royal Canadian Mounted Police reported a significant increase in the enforcement of IP crime with 818 occurrences of IP crime investigated, a 37 percent increase from previous years.

Despite the diligent law enforcement efforts of Canadian authorities, some have characterized Canada as a "piracy haven." Contrary to this claim, evidence from independent sources, as well as industries that benefit from this process, indicate that infringement rates have been declining in Canada. At the same time, markets for content have been expanding.

For instance, the operating revenue for motion picture theaters has grown steadily since 2005, with industry enjoying operating profit margins of 11.3 percent in 2010. Canada is the sixth largest market for recorded music in the world. The entertainment software industry has enjoyed similar growth, as well.

In view of these positive trends, the presence of some copyright infringement should not constitute grounds for placement of Canada on the watch lists. If that were the measure of success,

the U.S., itself, would not meet the standards that the Special 301 process seems to apply to other countries.

The most diligent and effective enforcement efforts, whether in Canada or in any other country, would fail to bring infringement levels down to zero. In fact, efforts to bring infringement levels down to zero would require an enforcement overreach that would claim due process, privacy, and free speech rights as collateral damage. If the USTR pressures countries to take overbroad enforcement measures, the credibility of the Special 301 process will suffer.

I will end my comment with an observation that law reform efforts in Canada would not undermine the effectiveness of protection available to IP rights owners. Provisions in the proposed bill include measures designed to strengthen Canada's limitations and exceptions. If these measures were to pass, Canadian limitations and exceptions would still be narrower than U.S. limitations and exceptions.

I would also like to mention that more than 1500 U.S. citizens support our request to the USTR to not consider limitations and exceptions as a

derogation from the protection of intellectual property rights. These citizens have signed a petition that Public Knowledge drafted, and I ask that you permit me to submit this petition into the record.

Thank you.

CHAIRMAN McCOY: Thanks very much.

We welcome the additional information for the record and appreciate the country-specific information you've provided.

I just want to see if any of our copyright experts want to -- go ahead, Maria.

MS. STRING: Thank you for your comments. I'd be curious to know, and I did not see this in your submission, what Public Knowledge's view is on the current bill pending in Canada on C-11. I know that separately, Professor Geist has opined previously, before his work with you, on the adequacy of that bill.

So I'd be curious to know, as the hearings begin in March, what is Public Knowledge's view on the adequacy of the bill as presently developed, and would you be able to provide any input or comments on to the extent you might be asking for further modifications of the bill in Canada?

MS. RANGNATH: So we don't have a developed position on the bill, and we are not asking for modifications. We think that is Canadian domestic processes.

Our view, with respect to the Special 301 process or mission is that the bill does not -- and its versions don't undermine the protections that are available to U.S. rights holders in that there are changes to suit the needs of Canadian citizens and expanse of limitations and exceptions would still not make Canada a candidate for placement on the watch lists. And our view is limited to that.

CHAIRMAN McCOY: Thanks very much.

Are there any other questions?

(No response.)

CHAIRMAN McCOY: If not, we appreciate your input and the information you provided, and we'll take into consideration as we work on the report.

MS. RANGNATH: Thank you.

CHAIRMAN McCOY: Thank you.

So next I have Global Intellectual Property Center.

If you could just remember to introduce yourselves as you take your seats. Welcome.

MR. ELLIOT: My name is Mark Elliot. I'm

the Executive Vice President of the Global IP Center at the U.S. Chamber of Commerce. And this is my colleague, Gina Vetere, who is also a member of the GIPC.

I want to thank you all for the opportunity to testify before the Special 301 Committee.

The GIPC was established back in 2007 as an affiliate of the U.S. Chamber of Commerce, as the world's largest business federation representing the interests of three million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations across the country.

The GIPC is working to champion intellectual property rights that we believe are vital to creating jobs, saving lives, advancing global economic growth, and generating breakthrough solutions to global challenges.

This is the first time that the GIPC has submitted comments to the Special 301 process. We did so because we believe that the Special 301 report is a critical tool to spotlight on countries that are threatening American jobs and economic growth by undermining intellectual property rights of our innovative and creative industries.

Intellectual property-based industries account for more than $7.7 trillion worth of United States gross domestic product and drive about 60 percent of all our exports, and they employ over 19 million Americans.

Sound IP policies and the enforcement of IP rights in the United States and abroad are therefore essential to advancing U.S. economic recovery, driving America's competitiveness, economic growth, and creating high-quality, high-paying American jobs.

The Special 301 report is an essential measure of business climate for our members who wish to export to, invest in, and conduct business with foreign countries.

We have divided our submission into a thematic overview and a country assessment. The first half of the report highlights what we are seeing as growing challenges for overall intellectual property protection and enforcement environment in areas needed to build a stronger IP climate globally.

The second half of the report provides an assessment of eight countries that present significant concerns across all our industries and

we believe require some effective IP protection and enforcement. These countries are Brazil, Canada, China, India, Mexico, Russia, and the Ukraine.

We chose to divide the submission in this way because the GIPC is a broad-based industry association representing a wide range of IP issues across multiple sectors. As such, rather than categorizing countries as Priority Watch or just simply Watch, we believe we are in a better place to provide a broad assessment of IP issues in those countries that present the greatest opportunities and challenges for our members across all sectors.

We also believe that many of our member companies, through their own industry associations, submit their own Special 301 comments that analyze their issues at greater depths and are better qualified to make their determinations what should be Watch and what should be Special Watch -- Priority Watch, I'm sorry.

In many countries that we highlighted, we did see some progress. In China, for example, the government took significant steps toward a better IP environment by making permanent their 2010 Special IPR Campaign.

We also commended the Russian government's

successful conclusion of the WTO accession process through which the government demonstrated a willingness and ability to improve its IP protection and enforcement regime, even if much more still needs to be done in this area.

We also highlighted significant concerns with the failure to provide adequate and effective IP protection and enforcement in a number of key markets.

For example, in a number of countries, we raised concerns regarding inadequate and ambiguous IP laws and regulations. These concerns span a range of issues, from the failure to implement the WIPO Internet Treaties to the lack of ex officio authority to combat counterfeiting and piracy at borders to the protection of pharmaceutical tests.

These are a few examples from our submission that highlight the need for USTR to continue to work in these key areas and to create action plans that provide a roadmap to secure much-needed IP reforms.

Adequate and effective protection and enforcement of intellectual property abroad is vital to America's economy, and the GIPC looks forward to working with the U.S. government to ensure that all

necessary steps are taken to achieve this goal.

Thank you for the opportunity to testify here today.

CHAIRMAN McCOY: Thanks. Thanks very much, and we always welcome new participants to the process, so your participation is welcome. And thank you, also, for elaborating on some of the specific country issues. As the previous speaker reflected, that's something that we've encouraged in the past, so both thematic and country-specific information is welcome.

You have about four minutes left, if you want to elaborate. I'm sure the members of the panel would be interested in any additional information on particular countries or themes that you'd like to highlight from your submission. I'll leave that up to you.

MS. VETERE: I think that we don't necessarily need to go into the specific countries, since we already detailed the concerns, but what we did, just to reiterate, try to do is look at the countries that we really see as priority areas for opportunities and challenges, and that these represent probably the broadest level of cross-industry input that you receive versus some the

industry-specific associations.

So, certainly, if there are areas that you have found from our brief where you would like to see us elaborate, we'd be happy to provide greater specifics in a post-hearing brief or try to answer the questions now, if you have them.

CHAIRMAN McCOY: I think we have your information, and we'll continue to study it, and we appreciate your participation today. Thank you.

MR. ELLIOT: Thank you very much.

CHAIRMAN McCOY: The University of Wyoming College of Law, Center for International Human Rights Law and Advocacy.

Please do introduce yourselves. Thank you.

MR. TUETING: My name is Brooks Tueting.

MR. NOVOGRODSKY: My name is Professor Noah Novogrodsky.

CHAIRMAN McCOY: The floor is yours, gentlemen.

MR. TUETING: Thank you.

Hello. I'd like to begin by saying that I am currently a third-year law student at the University of Wyoming College of Law, and I would like to thank you for the opportunity to testify today and for your consideration of the proposals

that I will make concerning Thailand's placement on the Special I Priority Watch List.

I'll begin by acknowledging that I'm not a stereotypical human rights advocate. I'm a registered patent agent with the United States Patent and Trademark Office, and I will soon be a registered patent attorney. I'm well versed in patent law and an ardent supporter of strong intellectual property protections, especially patent rights.

However, during my studies, I was invited to participate in the Center for International Human Rights Law and Advocacy at the University of Wyoming College of Law. I was offered the opportunity to work on an issue concerning access to essential medicines in Thailand. This issue inherently concerns the patenting of pharmaceuticals.

In May 2011, I traveled to Bangkok to study the issues and gain an understanding of the concerns of Thai access to medicines activists.

In consultation with faculty advisors at the University of Wyoming law school, I've developed three modest suggestions to share with the USTR. These are my own views and they are shared by the Center for International Human Rights Law and

Advocacy, but since I don't purport to speak for the University of Wyoming as a whole, please consider this submission the result of an individual research project.

First, I invite the USTR to recognize the differences between pharmaceutical patents and other types of intellectual property by implementing a bifurcated review process for placement on the Special 301 list. Pharmaceutical products should be afforded separate recognition and review when considering trade treatment and sanctions, especially placement on the Special 301 list.

Now, there are two parts to this idea. If a state is accused of violating intellectual property rights solely for its treatment of pharmaceutical products, it should be subject to a separate process that considers the TRIPS framework and weighs the public health benefits of the government's actions against the patent holders' interests.

And if a state is placed on the Special 301 list for violations of other types of intellectual property, it is critical to engage in an inquiry into the effects that placement will have on public health and access to medicines.

I believe that countries violating other types of intellectual property should be held accountable by the USTR to increase the value of intellectual property and to protect American innovation.

The call for procedural bifurcation takes into consideration the human elements and life-saving reality of pharmaceutical patents while recognizing the innovation rationale, i.e., financial reward for substantial investment in their research and development for intellectual property more generally.

In both cases, I believe the USTR should review pharmaceutical patents separately from other types of intellectual property rights in relation to the Special 301 list. This procedural bifurcation would be especially relevant to Thailand, where pirating of DVDs and other copyright violations are rampant.

The 2011 Special 301 Priority Watch List made no mention of compulsory licenses on pharmaceuticals in Thailand. Implementing a bifurcated Special 301 review process could effectively increase access to essential medicines while maintaining effective protection for all other

types of intellectual property.

Second, I suggest that the USTR begin to consider states' reliance on the existence and adoption of the Medicines Patent Pool as an increasingly important variable in evaluating respect for intellectual property rights. I take no position on how wealthy countries or individuals pay for pharmaceuticals. These statements relate solely to the public health sector.

The pharmaceutical industry should profit from individuals and countries that can afford to pay market prices to enhance further pharmaceutical research and development. If designed and implemented properly, the Medicines Patent Pool will provide pharmaceutical companies and countries needing essential medicines a forum for bilateral agreement to facilitate access to lifesaving medicines. The long-term goal of the patent pool is to facilitate affordable, one-stop shopping for essential medicines while protecting the rights of patent holders.

To encourage states to make use of the patent pool, the USTR should develop a presumption against sanctions for states that source a percentage of their essential medicines for use in

the public sector from the pool. As the patent pool expands over time, this percentage could grow.

Should the USTR allow a state experiencing a serious health crisis to access patents from the Medicine Patent Pool without the possibility of penalties or repercussions levied by the USTR for those actions, we submit that the Thai people could gain access to essential medicines, lives would be saved, and the pharmaceutical industry would maintain patent protection on valuable inventions.

Finally, I respectfully request that the USTR seek to harmonize treatment of Thailand with other Pacific Rim states. In view of the ongoing Trans-Pacific Partnership negotiations, the USTR's treatment of Thailand, including proposed procedural bifurcation and increased reference to the Medicines Patent Pool, should facilitate the country's future entry into the compact while adopting the lessons of the Thai experience.

Balancing intellectual property protection and access to essential medicines is a delicate task. The USTR should advocate for principled intellectual property protections in an increasingly global marketplace. By implementing the aforementioned compromises, especially procedural

bifurcation, I believe the USTR can effectively protect pharmaceutical innovation and their respective patents while increasing access to essential medicines.

In conclusion, I would like to recognize the USTR's openness in the Special 301 Review process and for the opportunity to speak today. Thank you again for your time and consideration in these matters.

CHAIRMAN McCOY: Thank you. Thank you very much, Mr. Tueting, first of all, for your participation in the process -- as I said to the previous speakers, we always welcome new participants in the process -- and also for your thoughtful suggestions.

Could I just -- you have three or four minutes left. Could I ask you to elaborate a little bit on the idea of procedural bifurcation, as your thought, that we would have -- that we would do, sort of, a separate listing for each country for status on pharmaceutical patent issues and all other issues?

MR. TUETING: Yes. The procedural bifurcation takes into account the fact that pharmaceutical patents are very different in the

fact that these medicines oftentimes save lives, and it would be a separate review process, so a country that is not violating pharmaceutical patents but violating other types of intellectual property, such as trademarks, copyright, whatever that may be, there would be essentially two reviews.

And so if you have a country that is violating other types of intellectual property, they should be listed and recognized that they are violating those other types of intellectual property, but recognize that maybe they aren't violating pharmaceutical patents and that would hopefully increase access to essential medicines.

MS. BONILLA: Sorry. Jean Bonilla from the State Department.

I just want to clarify, so that then what your underlying assumption is, is that the pharmaceutical issues present a unique lifesaving opportunity or consequence in the market and that even patents on other types of things, or certifications like Underwriters Laboratories-type certifications for electrical appliances, would not have the same sort of impact on public health and safety?

MR. TUETING: Yes, I believe that is an

accurate statement.

CHAIRMAN McCOY: Well, thank you very much for your participation, and we look forward to considering the suggestions you made in the course of our review this year.

MR. TUETING: Thank you very much.

CHAIRMAN McCOY: Next on the schedule is American University Washington College of Law Program on Information Justice and Intellectual Property.

If I could remind you to introduce yourself, Mr. Flynn.

MR. FLYNN: I will repeat exactly what you said, which is I am Sean Flynn. I'm from the Program on Information Justice and Intellectual Property at American University Washington College of Law.

And so unlike this last speaker, I'm not new to this process. This is the third time, I believe, that I've been here, which I think is the three years that we've had hearings, is that right?

So I'd like to start by something that I wasn't preparing at all, which is to also express a lot of concern that the health groups are not here today. I just looked through the schedule, and of

the six public interest groups that are here today, three are exclusively dedicated to the medicines issues; two, myself and Jamie, work on both medicines and copyright and other issues; and there is only one that is exclusively dedicated to copyright issues.

In the future, I would call on you to please exert more pressure on the Department of Health and Human Services and USAID and PEPFAR to join this hearing. I think the hearing makes itself appear to public interest groups to be less effective, determinative, and important without their representation at this hearing.

I think it's not a coincidence that there are fewer public interest groups this year taking part in this process, and my comments today, I think, are going to focus on some of those issues.

So I think this hearing is very important. I think that the types of deliberations that go on in public are different than the types of deliberations that go on in private. I know a lot of industries meet with you all in private, and I think it's important that some of this discussion, at least, take place in public.

But my comments are geared towards changes

that you can make to make this process more open, more fair, and more legal. And the implication that I'll just state very bluntly is, I do not think that this process is open, is fair, or is legal.

And let me repeat, essentially, some of the submissions that we have been making over the years and call, very specifically, for you to do something in response, which is that you, within the report this year, should answer, in writing, the major complaints and challenges to this process the public interest organizations have been making over the last three years. This is a matter of good governance policy, but I also think it's a matter of your legal obligations within this process.

As I have indicated before in my testimony, this process is an informal agency adjudication under the Administrative Procedures Act. That flows -- it's a fairly easy read from the statute, but a process that is applying a statutory norm to past activities but is not required to go through formal adjudication is an informal adjudication under the APA, which means it is bound by the standard to avoid arbitrary and capricious conduct. You practice arbitrary and capricious conduct when you write a report that only reflects one part of

the record before you.

So when Public Knowledge and CCIA come up, as they have, many years in the past and say you should not only be advocating for the interests of rights holders, content industries, and pharmaceutical companies, you should also advocate on behalf of those industries within the United States and consumer groups within the United States that rely on limitations and exceptions to copyright.

It's a pretty plain reading of the 301 statute that adequate and effective intellectual property would include both sides of the intellectual property balance: both limitations and exceptions, and rights themselves.

Now, you can disagree with that statement of law, but I don't think it's lawful for you to disagree with that statement of law and then say nothing about it in the report. I think you need to explain, within the report, that that assertion has been made and why you reject it, if you do.

Second, it has been stated repeatedly, including, in my statement and written proposal, that this process and the way it is being undertaken violates the World Trade Organization Dispute

Settlement Understanding.

So the Dispute Settlement Understanding states very clearly, and it's quoted in my footnotes, that members shall not make a determination to the effect that a violation has occurred except through recourse to dispute settlement understanding. And there is a specific case on this, the panel report on United States Section 301 saying that what we're talking about is not just sanctions, it's also threat of sanctions.

Now, the Special 301 process, when you are describing the Special 301 process, you need to describe, I believe, how the threats that you make, by elevating countries to higher and higher lists up through the Priority Watch List and Priority Foreign Country list, is not a threat of sanctions and does not include determinations of what TRIPS requires.

Now, I've looked briefly over the IPA and PhRMA submissions, and they make dozens of TRIPS interpretations, which are contested and are not backed on any decisions by an actual dispute resolution panel. When you take those positions as the basis for listing, you are making a determination on TRIPS unilaterally, which I believe is illegal under the WTO rules, and I think you owe

it to the countries on the list, and the general public, to at least explain why that's not true.

Third, it has been also stated repeatedly before you that your interpretation of the ability to go into nondiscriminatory pharmaceutical reimbursement practices is in violation of the underlying 301 statute.

So for Special 301, there is a definition of market access. The definition of market access within the agreement states that you have to have a factual basis for the denial of fair and equitable market access as the result of a violation of international law or agreement, or the existence of barriers referred to in Section (d)(3). And if you go to that, you find, again, violation of international law or discriminatory non-tariff barriers.

Note that that definition is different than the definition in Section 301. Section 301 and Special 301 are different. You are implementing Special 301, and you need to follow the Special 301 statute. Every instance where you are listing countries or the introductory remarks where you are naming countries, identifying them under the Act, for nondiscriminatory reimbursement policies, even

if they lower the prices of patented medicines, is not authorized within the statute. And if you disagree with that, please explain why that interpretation of the statute is wrong.

Fourth, best practices. So last year, you announced that you were going to include best practices within the report, and a large number of public interest organizations actually issued additional filings naming what they think are various best practices. I've included some more of them in my written testimony. None of them were included.

The only best practices that were included were those submitted by content industries and pharmaceutical companies. You need to explain why. That's an arbitrary selection of one part of the record to reflect within your overall report, and I think it violates the APA to do that.

Finally, so I think it's interesting how few of the normal stakeholders that are involved in this process are here at this hearing. I think it's a reflection that there is an idea among many that this is not where the real action happens, that the real action happens behind closed doors in meetings with the committee that are not on the record and

that are not public.

I've actually been part of one of these meetings before, and a large number of the Special 301, the committee is present at those meetings. This triggers obligations under the Freedom of Information Act to have those meetings in public or to make a public decision on why you are closing those meetings to the public and still, within the *Federal Register*, publish the fact that the meeting has happened, so we know.

I think the meeting of private stakeholders, as a body, violates the federal open meetings laws if you do not publish that and make an on-the-record determination on why you are not having that meeting in public. I think following these kinds of rules might actually make this hearing more important and determinative and might drive you towards elongating this section of the process rather than the private, closed-door section of the process.

And I will cabin all of this with saying what you see going on around the world today, the protests in Europe around ACTA, the protests in this country around SOPA, are all about secrecy: secret lawmaking and norm setting that affects us all. And

people hate it.

People also tend to hate this process the more they figure out about it. And the way to get back at that is to change the process, have it in a more transparent, open, and fair fashion; reflect a broader range of views within it, and start taking positions that are not reflective of only one side of a narrow range of U.S. stakeholders.

And I'll end on that. Thank you.

CHAIRMAN McCOY: Thank you for your views.

Just a quick question on your second point about how we describe the process and its interaction with the process of bringing a WTO case.

And we had a description in the report, I think it was Annex A of the last report, that talks about, sort of, the statutory process and how it plugs in to the Section 301 process, which is distinct from Special 301.

And I wonder if you've taken a look at that section and if you feel, you know -- whether and how you feel it can be improved along the lines of your remarks.

MR. FLYNN: Yeah. So I have taken a look at that section, and I feel it's inadequate. I think that this process needs to more clearly state

the result of the 301 panel decision.

I think you should actually cite the statement of administration policy, whatever it is -- I don't have it on hand. But the way that that decision was settled in the WTO was by the United States, I'm sure you know, making assertions that they will not use the sanctioning aspects of Section 301 without going through dispute settlement first.

And the panel decision includes this passage that I've quoted to you about threats of sanctions are equivalent to sanctions, so you can also not threaten countries without going through dispute settlement understandings.

Now this, under U.S. law as I have cited to you, is an informal adjudication. You are deciding what the application of the statute means, and you are often deciding what TRIPS means. I think you should make a more clear statement that no country will be listed as a Priority Foreign Country under anything that is alleged to happen under TRIPS. I think you should state that extremely clearly, that that's the expression of your statement understanding.

I think you should describe what does it

mean to be elevated on the Watch List for something that's covered by TRIPS if it's not a threat of sanctions in the future. When you read the statute, itself, it's pretty clear that it's a threat of sanctions, it's a way to elevate the listing of countries up until the top level. And if you actually get to the top level, there is a statutory process that mandates a determination of sanctions.

Now, I am very cognizant that no WTO member, to my knowledge, has been placed on the Priority Foreign Country list after TRIPS, but that's not explained within the report. So you could be a lot clearer on stating which parts of the statute you are implementing and which kind of -- you know, whether this is a threat or not.

It is perceived as a threat outside of this room, and I've read all the reports between now and then, and nothing has changed in the description of the process since that panel report. You've never included a section that describes how we're changing the understanding of this process from how it was administered in 1989, for instance, or 1993, for instance. The process continues to essentially go as if nothing has happened when the WTO was passed.

CHAIRMAN McCOY: Okay. Thank you for your

comments. We appreciate them, and we'll take them into consideration as we prepare the report.

MR. FLYNN: And just to be clear, I'd like to ask you to do more than consider. I'd like to ask you to respond in writing to the various submissions that have been made.

CHAIRMAN McCOY: Noted, thanks.

Our next participant today is Knowledge Ecology International.

Jamie, although I know you need no introduction, I'll still ask you to introduce yourself.

MR. LOVE: Thank you. Jamie Love. I work with Knowledge Ecology International and -- just to get my timer going here. Let's see here. Wait a second here, reset.

I was going to take the extra four minutes the Chamber of Commerce didn't need, so --

(Laughter.)

MR. LOVE: I'm just kidding.

I'm Jamie Love. I work for Knowledge Ecology International, and I'm also the U.S. Co-Chair of the Trans-Atlantic Consumer Dialogue's Intellectual Property Committee. That's the group that has 80 member organizations in both Europe and

the United States. It represents consumer interests, including some of the groups are members, such as Public Knowledge is here. But I'm here to testify on behalf of Knowledge Ecology, International.

First, I wanted to start with the first thing I mentioned in my submission. I don't know if you had a chance to see it, but one of the recommendations we have is you considered moving away from an annual review of the 301 Committee. I mean, you know, it comes out on April 1st, there's a lot of work involved in the thing, and then already by -- before Christmas, you start asking -- you know, six months later, people are practically asked to start making comments on what the next list goes. You know, you got these, like, 345-page submissions from IPA. I mean, you know, there's a lot of work that goes into these things.

I don't know that people pay that much attention to lists from year to year because they -- you know, there's like a new one coming out all the time. Having to establish everything, I mean, we can just, sort of, concede China will always be on the list, no matter what happens, right? And I think people might take it a bit more seriously. I

also think it kind of degrades just -- I don't blame anyone in particular, everyone works hard. It's just that you all have a lot of things to do, it's a lot of work to do, the policies just are huge.

I mean, can you really do a good job year after year? It's got to be a little boring to do it year after year. If you do it every three years, you could maybe be a little more thoughtful about what you do. That's just one thing I'd like you to consider.

And since the president wants to abolish USTR, when you think about that whole process, you might, you know, think about that, right?

And then the other thing we mentioned is there's this thing we cite a lot about the idea of the evidence, which is kind of related to that. And I think the Hargreaves report -- and I put these objections from the Hargreaves report -- I think it was making a good point, is that there's always a lot of pressure from lobby groups and things like that to press their interests and things like that, and they have legitimate interests, and other people make complaints.

In some cases, you should think about the kind of evidence you need to make decisions and

whether or not you have it in the particular cases here and what kind of process would generate that.

I'll give you just an example. A lot the recommendations about jobs and employment will focus on the interest of the relatively small number of people in the United States that make their living, for example, as a musical performer or an author, or an author of music, and I think their livelihoods are important.

It's also the case that there's now a fairly large amount of wealth that's being generated in the United States around people that share, on a non-commercial or social level, things like Facebook or a million different social networks and websites. There's that one about cats, there's the one that Ann Romney uses that she's all wound about. I mean, there's like all these different, you know, things. And a lot of the billionaires and millionaires in the United States have been associated with those industries.

And so, you know, you tell me, like, where the high-paying jobs are between the two sectors and which is the dominant thing and which one actually increases the wealth of the United States. I don't think you know. I don't think I know, either. I

don't even know if there is a process where anybody would really think it was important to know.

But I think I would say that we should know the answer to that question, you know, what side is our bread really buttered on in terms of some of these policy things and norms that are promoted in the 301 process.

Next, on the pharmaceutical side, I think that there's a legitimate issue about who pays for R&D between, say, Honduras, China, and the United States, Germany, Canada, et cetera, like that. But, really, is sort of oppressing things that increase the price of drugs around the world the only way to think about resolving this thing in a useful way?

I mean, the PhRMA submission is against ad hoc price controls, mandatory rebates, international reference pricing, and therapeutic reference pricing. They just like high pricing. I mean, let's be clear about it. That's what, you know, data exclusive, e-patent extensions, patents all over the place, evergreen patents. It's all about keeping the price of medicine high.

How sustainable is a policy of pricing drugs out of the market for cancer drugs for the

majority of the world's population in the long run? Do you really think you're going to succeed at that politically? If you were a legislator from a foreign country and there was an issue about access to Herceptin, a cancer drug, an effective cancer drug, that's protected by data exclusivity, the biosimilars regulatory pathway, patent protection, process patents, this is sort of a test case on how you do the thing.

It saves a life. I know from intimate experience, it's a lifesaving drug. It's priced at a thousand dollars a week in India for a year's supply. Now, do you really think that's really the kind of thing you went into government service for, to promote that kind of inequality of access? It's a women's health issue. We had a meeting with the ambassador -- Stan was here -- and we asked a direct question, Do you think the Doha Declaration applies to breast cancer drugs? And we couldn't get a yes or no answer from the USTR staff. They'd ask us what our interpretation was of the Doha Declaration.

Part of your job in the 301 list is to incorporate the Doha Agreement, which the United States has agreed to, and it's referenced in a fair amount of documents, and figure out what it actually

means and figure out whether the norms you present really are consistent with that. And this is something that Judit mentioned earlier.

I would now go to my final page here and just talk about some elements of some of the other submissions.

The IIPA, in their submission on copyright, I mean, they mentioned Canada right off the top as a country to be under, like, bad list. PK made a very, I think, very good submission on this. If there's, like, real evidence standards about violations, there's no way Canada would make the list. You cannot argue that they're at the top of the list of IP violation. The United States is way ahead of them as an IP violator, if you look at the statistics that people are submitting.

It just doesn't make any sense to put Canada on the list based on evidence. It just makes sense to put Canada on the list if you think it's part of some lobbying campaign by the RRA or somebody, MPA or whatever, you know, to try and get them to change their legislation. But is that really what you want the 301 list to be known for?

It's just kind of like, you know, the U.S. government's partnership with lobby groups, but are

people supposed to have some intellectual, you know, content? I mean, I'm not saying that the intellectual content is the right way to think about the 301 list. I'm just saying if you do stuff like put Canada on it, don't expect people to think it has any intellectual content. It's pretty obvious what it is, if you do something like that.

Now, an issue that we've raised recently and we've had some extensive thing -- and Stan has been willing to be an unpaid peer reviewer on a potential unpublished article on, at least, about countries, which we're trying to accommodate to reflect his pithy comments, and that is, at least, about countries.

We've been concerned that -- you know, in the old days you used to put all the countries that had not complied with TRIPS together, and nobody complied with TRIPS initially. Even the United States had to change its law. And then, over time, some countries had transitions and the U.S. would say we look forward to everybody completing their transition and early, if possible or whatever.

LDCs had these special exceptions that were granted, and as the U.S. language was kind of consistent on the idea of complying with the TRIPS

agreement, eventually all the other categories kind of disappeared and what was left was increasingly isolated, are the LDC countries. And it looks like you're trying to force LDC countries, least developed countries, to have pharmaceutical patents.

Now, LDC countries -- after 2015 or 16. So LDC countries, in the western hemisphere, only Haiti qualifies; Bolivia is too rich. In Africa, Kenya is too rich. India is not an LDC, China is not an LDC, Malaysia is not an LDC. Even Vietnam is too rich to be an LDC. You have to be like, you know, Cambodia, Nepal, Sierra Leone, Haiti. Those are the countries that are LDCs. They barely have governments, a lot of these countries.

It's just an embarrassment to have the U.S. 301 list say anything about enforcing pharmaceutical patents, suggest that you're in favor of that in LDCs, and there are nine million people with AIDS in LDCs and a lot of the PEPFAR budget is in those countries.

And every time you buy an expensive patented AIDS drug, that's like five patients that don't get AIDS drugs, and those people are dead people after a while because, you know, with AIDS, once you get infected, within 10 years, you're

either dead or you're on ARVs, and that's pretty much the only choices that you have right now.

The other thing I want to mention is the U.S. had cut its PEPFAR budget, the European countries have cut their PEPFAR budget, everybody's cutting back their donor funds on the AIDS programs and things.

So with the global fund -- and these countries are doing, is they're cutting off the middle-income countries, like Latin American countries and stuff. And they're focusing it on LDCs and really, really poor countries that have the least. Well, if you expect AIDS patients in middle-income countries to continue to get treatment, you can't be sticking it to them on the patent issue. That's why I think --

CHAIRMAN McCOY: You're eating into that extra four minutes from the Chamber of Commerce now.

MR. LOVE: Well, thank you very much.

CHAIRMAN McCOY: Can you wrap up, please?

MR. LOVE: I will wrap up.

CHAIRMAN McCOY: Thanks.

MR. LOVE: And that is to say that in March, the World Health Organization Consultative Expert Working Group is going to recommend that

there be a biomedical R&D treaty on research and development. I imagine it will be a fairly modest proposal.

But the basic idea of what it could be is that you could begin to sort of focus the drug thing more on international obligations to fund R&D like we do to through the NIH or we do through the Orphan Drug Tax Credit or the million other things we do other than high drug prices, not just on high prices, so that you're not asking countries to deny the access of the women that live in their countries to the latest breast cancer drug or people on AIDS drugs or things like that.

But you are making it appropriate to ask relative to their income and capacity on the medical side. It gets back to what the previous speaker from Wyoming said. For medicine, maybe you ought to sort of step back a bit and sort of treat it a little bit differently.

So I would encourage -- you know, we have asked both the State Department, TACD has, and the Department of Health and Human Services for consultation on the biomedical treaty. I think you need to think about this as a trade-related issue in R&D.

Thank you very much.

CHAIRMAN McCOY: Thank you, Mr. Love. We appreciate your participation and your input today. And we'll take it into consideration as we work on the report.

Next on the list, we have International Intellectual Property Alliance.

Please do remember to introduce yourself as you sit down.

MR. SCHLESINGER: Will do.

Good afternoon. My name is Michael Schlesinger, and I appear before you today on behalf of the IIPA, a coalition of seven copyright-based trade associations representing over 3,200 companies in the business software, motion picture, music and sound recording, entertainment software, and book and journal publishing industries.

I just want to say at the outset that it's an honor to be sitting in this seat where a legend like Jimmy Webb sat, and it's the hope that, in some small way, that this process is helping artists and creators like him.

We appreciate the opportunity to weigh in on the 2012 Special 301 process. In IIPA's 2012 Special 301 report, we report a snapshot on 41

countries or territories and recommend that 33 of them be ranked on the Special 301 Priority Watch List or Watch List, or monitored under Section 306 of the Trade Act, for denial of adequate and effective protection of intellectual property rights and/or failure to afford U.S. creators with fair and equitable market access.

Since its inception in 1988, the Special 301 process has been responsible for helping to generate significant revenues and jobs in the U.S. economy by elevating the levels of copyright protection and enforcement and dismantling market access barriers around the world.

In the mid-1980s, many countries in Asia and elsewhere had no or had seriously inadequate copyright laws and little or no IP enforcement. Piracy rates were 90 percent or greater throughout the developing world.

Today, despite the many piracy challenges our industries continue to face, only a small handful of countries have no copyright protection at all. The vast majority of countries have updated and improved their copyright laws, and most countries have enhanced their enforcement capabilities.

By driving U.S. engagement with our trading partners to address fundamental problems in the protection of IPR, the Special 301 program has produced positive results for the U.S. copyright sectors which, in turn, have generated millions of high-wage jobs and hundreds of billions of dollars in exports for the U.S. economy. The creativity and innovation of the American people have resulted in this country having very significant and valuable intellectual property assets, which have become drivers of economic and job growth and of exports.

Our latest report indicates that in 2010 the core copyright industries were responsible for adding almost a trillion dollars to GDP, a little bit more than 6 percent of the total U.S. economy; employed nearly 5.1 million people or 4.75 percent of total private employment in the United States. Average annual compensation for workers employed in these industries exceeded overall average compensation by 27 percent.

An estimated 2010 foreign sales and exports of key sectors of the core copyright industries amounted to $134 billion, exceeding foreign sales of other major U.S. industries such as aircraft, automobiles, agricultural products, food, and

pharmaceuticals. At the same time, these statistics do not reveal the massive costs imposed by overseas piracy and other market access barriers to U.S. copyright products and services.

Content industries continue to contend with those who, in the absence of good protection and enforcement, engage in piracy as a high-profit, low-risk enterprise. Independent studies have shown that the value of digitally pirated music, movies, and software is upwards of hundreds of billions of dollars. And in China alone, the U.S. ITC last year estimated the cost to the U.S. economy from piracy to be over $100 billion, which also results in up to 2.1 million fewer jobs in America.

While each of the copyright industries is affected by copyright piracy, and that piracy takes different forms, IIPA's filing seeks to help the U.S. government define and implement concrete solutions to these problems. We do this through identifying key copyright industries' initiatives and challenges for 2012.

These are the need for adequate laws and deterrent enforcement responses to copyright piracy, and this is obviously the overwhelming objective for the creative industries; to secure in countries

around the world effective legal frameworks capable of providing deterrent enforcement against copyright piracy; and working to ensure that enforcement authorities robustly use these legal frameworks to combat copyright infringement in all its forms.

Internet piracy: Governments around the world must recognize the need for proportionate and effective steps to curb online piracy, including protections compatible with the WIPO Internet Treaties, provisions recognizing online piracy as a form of cybercrime, and provisions that foster cooperation among the stakeholders, including ISPs involved in the online supply chain to combat online infringements.

Third is enterprise, including government and user piracy of software and other copyright materials. End user software piracy is the principal and most damaging form of infringement to the business software industry today with the commercial value of unlicensed software worldwide exceeding $50 billion in 2010.

Laws should prohibit the unauthorized use of software in a business setting and allow for deterrent level civil and criminal actions, inspections, audits, and ensuring legal software

licensing practices and implementation of software asset management best practices. Governments should also lead by example by legalizing their own software usage.

The fourth is unauthorized loading onto PCs, also known as hard disk loading, and also mobile device piracy, which is an increasing problem in many countries we have reported on.

The fifth is circumvention of technological protection measures or TPMs. Copyright owners use technological protection measures, TPMs, to ensure that works are not easily stolen. There are those, unfortunately, who build their entire business models around providing devices, tools, or technologies like modchips, game copiers, and soft modding to gain unlawful access to the content or copy it. Implementation of TPMs, protections in many countries is critically undermined by those countries, including some developed OECD countries that have yet to pass such provisions.

The sixth is illegal camcording of theatrical motion pictures. I'll just note here that approximately 90 percent of newly released movies that are pirated can be traced to pirates who use a digital recording device in a movie theater to

steal the copyrighted audiovisual work right off the theater's screen, and that all it takes is one camcorder copy to trigger the mass reproduction and distribution of millions of illegal internet downloads and bootlegs in global street markets just hours after a film's theatrical release.

We highlight the multifaceted approach that's needed in our filing. I'd only note that in 2011, MPAA identified 964 illegal recordings of just MPAA member company titles from cinemas around the world. And that does not include the numerous independent films illegally camcorded.

I'm almost done.

CHAIRMAN McCOY: If I could just interject.

MR. SCHLESINGER: Yeah, sure.

CHAIRMAN McCOY: You've got a couple of minutes left, and I think the panel is interested in a couple of specific countries that you mentioned in your report --

MR. SCHLESINGER: Sure, sure.

CHAIRMAN McCOY: -- where you identified some changing circumstances. Maybe you could just spend one minute on each of them. They're Spain and Saudi Arabia.

MR. SCHLESINGER: Well, first of all, on

Saudi Arabia, to say that the government had promised, two or three years ago, to implement measures in order to bring a deterrent level of enforcement in the country. It's a potentially very large market for creative industries, and it remains the one country in the Gulf that really hasn't taken the proper steps to address the piracy challenge.

In particular, we have several cases of, essentially, recidivists who have been caught time and time again, and been arrested time and time again, and go straight back into the business of selling piracy, and obviously that's because there's a lack of a deterrent remedy on the ground.

We think that the laws in place are okay, they're not perfect, but that what we need is a strong judicial response to these recidivists and that the piracy situation would improve as a result of that. Unfortunately, we've seen none of that.

The other endemic problem in Saudi Arabia is essentially the lack of transparency and thereby the lack of allowing the public to know that to essentially pirate copyrighted materials is not permissible, and therefore, there's a lack of deterrents and we don't see decline in the piracy level.

So that's the reason that we've asked for Saudi Arabia to be placed back on the Watch List.

With respect to Spain, I think all of the industries universally recognize the very strong and courageous step that the Spanish government has taken in passing legislation to deal with, albeit in a rudimentary way, to deal with the threat of online piracy.

What we can say in the market, itself, is that whereas Spain, a developed country, had a very developed creative market, a very strong music market, a very strong movie market, just several years ago, those markets have been virtually decimated by online piracy. So there needs to be a response.

Our filing is more in recognition of the factual situation on the ground as it exists today, which still remains serious, while recognizing the courageous step of the Spanish government.

That's with respect to the two governments that you asked about. We are reviewing, obviously, the government submissions, and where appropriate, we will be responding to, you know, any points that require a response on our part.

CHAIRMAN McCOY: Okay. Thank you very much

for your input today. We really appreciate it. I know there was more of your hearing statement that you submitted for the record --

MR. SCHLESINGER: Sure.

CHAIRMAN McCOY: -- that we've run out of time to go through, but we take note of that, it's part of our record, and the materials that you've provided, we're grateful for your participation in the process, including today. Thank you very much.

MR. SCHLESINGER: Absolutely. Thank you very much.

CHAIRMAN McCOY: Okay. And we'll consider your views as we work on the preparation of the report.

MR. SCHLESINGER: Thank you.

CHAIRMAN McCOY: So I think that brings us to the end of the agenda for today, except for Paula to make any closing observations.

Paula.

MS. PINHA: I just want to thank everybody for participating again, and I just want to remind everybody that the docket at www.regulations.gov will be open for post-hearing statements or comments until March 1st, so it's a week from today.

So if you want to make an additional

submission or you want to respond to anything that was said today, feel free to use the docket again. Just follow the same procedures as was described in the FR notice, in the *Federal Register* notice. So same docket number, same procedures.

Thank you.

CHAIRMAN McCOY: All right, thanks everyone. We're adjourned.

(Whereupon, at 12:35 p.m., the meeting was concluded.)

C E R T I F I C A T E

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

SPECIAL 301 REVIEW PUBLIC HEARING

February 23, 2012

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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CATHY BELKA

Official Reporter