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OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

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SPECIAL 301 REVIEW PUBLIC HEARING

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Office of the U.S. Trade Representative
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Washington, D.C. 20508

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P R O C E E D I N G S

(10:00 a.m.)

MR. McCOY: Good morning. So you are all familiar with this annual process, and I won't dwell at length on the process or details. I will, however, invite my colleagues here on the panel with me, the members of the Special 301 Subcommittee, to introduce themselves, starting with my colleague to my right, the Chairwoman of the Special 301 Subcommittee. So, Paula, if you'll lead off, and we'll move down the table.

MS. PINHA: Sure. Good morning, everyone. My name is Paula Pinha. I am the Chair of the Special 301 Subcommittee, and I am with USTR's Office of Intellectual Property and Innovation.

MR. DuBORD: Good morning. I am Damon DuBord in the Intellectual Property Enforcement Office of the State Department.

MS. URBAN: JoEllen Urban, the U.S. Patent and Trademark Office, Office of Policy and External Affairs.

MS. STRONG: I am Maria Strong with the

U.S. Copyright Office and the Library of Congress.

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

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

MS. CORNWALL: Good morning. Andrea Cornwall with the U.S. Department of Commerce, Office of Intellectual Property Rights.

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

MS. MILLA-KING: Hi, good morning. Patricia Milla-King with Department of Homeland Security, Immigration and Customs Enforcement, at the IPR Center.

MR. McCOY: And I understand that we may have some colleagues from other agencies joining us a little later on this morning, including HHS and perhaps others. So we'll welcome them onto the panel when they arrive here.

I would like to keep us on schedule, so I won't dwell long on introductory matters, just to say that this represents a continuation of an annual process that we've been engaged in for some 24 years now pursuant to congressional mandate.

Just to review with you briefly the results of the 2012 Special 301 Review, we decided in that process -- we reviewed in that process 77 trading partners. And following the extensive process, USTR listed 40 trading partners on the Priority Watch List, Watch List, or under Section 306 monitoring.

I won't repeat the whole list to you, but the Priority Watch List comprised Algeria, Argentina, Canada, Chile, China, India, Indonesia, Israel, Pakistan, Russia, Thailand, Ukraine, and Venezuela, and then an additional group of countries on the Watch List and under Section 306 monitoring.

So the purpose of this process is to revisit that set of listings from last year, to hear input from trading partners and the public at large about how our analysis should be revised for the

2013 report. And without further ado, I think we'll get on with that.

The way that we have conducted these hearings for the past couple of years is again the way we plan to do it this year, that is, everyone has 10 minutes allocated. We will routinely pause a few minutes into the presentation and check in and see if there are questions. If you'll pause for me, I will let you know whether we have questions or invite you to continue on with your presentation, or if appropriate I'll interrupt and let you know that we have some questions that we'd like to explore with you. But with that one constraint, we look forward to hearing from everyone.

MS. PINHA: I agree, and I think we can get started with today's agenda. Our first witness for the day is the representatives from the Government of the Czech Republic. And whenever you are ready, you can go ahead and get started.

MR. ZAJICEK: Good morning, ladies and gentlemen. My name is Jaroslav Zajicek, and I am the Deputy Chief of Mission of the Czech Republic

here at the Czech Embassy.

Now, the Czech Republic has not been on the list of the 301 Special Report for 3 years. I believe there is a good reason to that. The Ministry of Work, of Industry and Trade sent you a letter summarizing the enhancements that took place in the Czech Republic in the last year, so I will not go into detail on that one. I will just pick up on let's say four major I will say pillars, based on which the IPR protection in the Czech Republic --

Well, first of all, I need to stress that this is a teamwork both in Prague and here. The Czech Embassy tries to keep a close eye on that. We try to have regular contacts with you. I am glad I can see some faces that I know here. And it only proves that we take this seriously.

I mean there is no room for complacency, not at all, in our case. This intergovernmental committee that was created has been extremely active. It comprises experts from all the relevant to line ministries, starting from the Ministry of Industry and Trade, Ministry of Culture, Ministry of

Health, but also the Czech Customs Administration, Czech Trade Inspection, the Business License Offices, and of course the police of the Czech Republic.

Now, on the four pillars that I wanted to speak to you about: One is, of course, the open markets. The situation there I think is stable. There is a significant decline in the sales of pirated goods. There are several reasons to that. Of course, we have maintained a very thorough surveillance over the marketplaces, some of them even on day-to-day basis. And there is good cooperation among the relevant bodies, with also tax offices of the Ministry of Finance, for instance. A series of rates called to market have been undertaken, which doesn't only concentrate on counterfeited goods, but also on accounts and taxes of the vendors. I think that's a very good direction where to go.

Some statistics, although the number of Czechs remain to be approximately the same, the number of confiscated goods went down by 12 percent.

Having said that, still the Czech Trade Inspection undertook over 1,700 inspections. The counterfeited goods amounted to like $6 million U.S. dollars. The Czech Customs Administration again counterfeited [sic] like $2.5 million in goods, but still in relative terms, the numbers are going down, which is good.

What is good is that also business licenses are being revoked and suspended when there is a good reason for that. So I'm glad to know that the clear-up rate is going up. That's very important. The number of convicted persons is going up again. But in relative terms, I think this demonstrates that the situation is not only stable, but it demonstrates that marketplaces, open marketplaces are not anymore the primary source or primary channel of counterfeit and pirated goods.

Which brings me to the second pillar, of course, and which is the internet. Now, there are, of course, new forms of infringements that take place. And the trends are simply going towards internet piracy. If 24 percent of any activity on

the internet is illegal, that should, you know give us really some alert.

Now, we have to react to that, of course. It is not always easy. What we have to do is, first of all, have the, of course, legal environment ready. I'll speak about that later. Have a clear strategy how to tackle this problem.

When I was here last year, I presented you something that was called the Digital Czech Republic. Now, we are finalizing -- the Ministry of Industry and Trade is finalizing the review of this process, taking into account all these new trends. And it will be done within a couple of weeks.

A special subcommittee for copyright was created. That comprises all the relevant stakeholders. But they also meet very often with the IPR holders, with the FBI, with the Czech Anti-Piracy Union. There are meetings that take place in the Senate and so on. So this is, I think, the crucial point that we all need to concentrate on, and we are very well aware of that.

Pillar Number 3, education and prevention,

of course. The activities clearly continued in the Czech Republic. Of course, the main focus was put on training and controlling, of controlling authorities and judges, especially with the area of internet piracy. Industrial Property Office organized a series of events for entrepreneurs, students, innovation centers. Eight events were organized, for instance, for the Czech Union of Inventors and Rationalizers. I think this is a very good trend.

But not only that, we start quite early with this, you know awareness raising. We try to bring that even at the secondary, but even the primary schools, which is important so that, you know even kids get acquainted with what IPR means. So I think it is never too late to start with that. Definitely, this is the way we want to pursue.

Of course, we managed to get police involved and also the Judicial Academy in these awareness growing processes, and it has turned out to be very efficient. Now, the Minister of Culture is preparing something that is called the Guide for

Teachers, to have guidance to be given out in a uniform manner. This is at the national level.

On the international level, we also try to cooperate. We have done a seminar together with WIPO that was concentrating on registration of industrial designs. So it is not only at the national level, but we also think it is very important to have lessons learned with other countries.

MR. McCOY: Let me just interrupt you briefly to say you have about three minutes left, and you have already anticipated I think both of the questions we had for you, which was about the open-air border markets and the internet and Digital Czech Republic Initiative. So I'll just invite you to continue. Thanks very much.

MR. ZAJICEK: Thank you very much. I'll be quick. On the fourth pillar, which is legislation, Ministry of Culture is preparing for the amendment to the Copyright Act. Now, this has got to do with both, of course, the EU legislation that is being transposed, for instance, this

extension of protection of artists from 50 to 70 years. These are very concrete provisions stipulated in the EU legislation, and we are transposing that, including the regulation of compensation of damage. But we want to bring into that, of course, some not gold-plating but some national aspects that would enhance the EU legislation, you know that in this respect there is room for a number, for individual member states. If these are directives, then we can add something that we think is useful in attaining the goal that the directive sets.

So we are definitely thinking of bringing higher fines as one of the very concrete issues of IPR infringements, both to legal and to natural persons. We very much hope that the Parliament is to approve this bill this year, which would bring, again, our code a bit more modern and up to date.

Last and concluding point, it was encouraging having spoken to some of you during the year, that instead of concentrating what we really need to do better in the Czech Republic, we can

start concentrating on what we can do together, the Czechs and the U.S., in third countries. That is a very useful, I think, tool that we have in our hands. One concrete example, the Industrial Patent Office just signed something that's called the Patent Prosecution Highway with the U.S. Patent and Trademark Office, which kind of brings a fast track procedure in this area. But, again, we are giving it a lot of thought where we can work together.

Now, there is no direct submission of the Czech Republic this year. That leads me to a conclusion that we are very confident that we will not appear on the reports this year again. But, of course, we'll be more than happy to come to talk to you again. And, of course, I am ready to take any of your questions. Thank you.

MR. McCOY: Well, thank you very much to you personally and the Government of the Czech Republic for taking the time to talk with us today. We appreciate your participation in the process. As I said, I think you have successfully anticipated most of the questions, so I will just conclude by

expressing our openness at the Office of the U.S. Trade Representative, and I'm sure I speak for the U.S. Government generally in working with the Government of the Czech Republic to advance our shared interest in this area. So thank you very much.

MS. PINHA: Next on our agenda, we have the representatives from the Government of Ukraine.

MR. McCOY: And, gentlemen, as you make your way up, let me just say that we do have a number of questions arising from the submissions about Ukraine this year having to do with issues on internet piracy, collecting societies operating in the Ukraine, and the issue of government legalization in the field of software utilization. So perhaps you can cover those in your remarks. I'd invite you to begin. Welcome.

MR. NALYVAIKO: Good morning. My name is Serhii Nalyvaiko. I am head of Department of Corporate Control at the State Service for Intellectual Property of Ukraine.

MR. YEZHOV: And my name is

Stanislav Yezhov. I am counselor of the Embassy of Ukraine here in D.C. I will interpret this submission.

MR. NALYVAIKO: The Ukrainian Government pays great attention to the implementation of the Joint Plan. And all ministers and central executive agencies take all necessary measures for the effective implementation of the plan. So in my speech, I would like to point out certain specific areas which are listed in the report of the Alliance, as the voice for Ukraine.

The first point is the criminal enforcement issues. The Ukraine Government issued an instruction to create coordinating councils at the regional administrations. And at the moment the process of creation of such councils, coordinating councils takes place in the Ukraine regions, and the local authorities report about this to the central government. The coordinating councils will consist of representatives from law enforcement agencies, local authorities, and representatives of public organizations interested in protection of copyright.

Due to the adoption of a new judicial procedure code, criminal procedure code, the Ministry of Interior is undertaking reorganization. And in order to enforce copyright protection efficiently, we will increase the number of police officers. A special cybercrimes department has been created inside the Ministry of Interior. And we provided you with the specific date on the number of police activities related to this. You could have seen them before.

As regards the blocking of websites that use pirated contents, I have the following to state. According to the Ukrainian laws, criminal prosecution may take place only after the copyright holder makes relevant statement, relevant application. The problem is that we usually have almost no such applicant, we'd almost receive no such applications. And even if we receive them, they come in small numbers, mostly from movie makers.

Ukraine is asked to focus on organized criminal activities of distributors of pirated

products and creators of peeling systems, pirate sites, and camcording. As regards camcording, we cannot agree with your position because in the last two years there has been not a single case of camcording detected in Ukraine. And this is the result of our ongoing work in this area.

And as far as crimes related to internet concerns, they have no organized character in Ukraine. They are just spontaneous. We fight these crimes all the time, and you can see the proofs in our materials that we provided to you.

As far as the software legalization is concerned, the budget for this year provides for allocation of 100 million grivnas to that purpose. We have drafted a government resolution in this regard which lists responsible agencies. And we anticipate that this resolution will be approved within two or three weeks.

You also request more actions against providers against television networks, radio stations, and so on. And in this regard, I must stress once again that success in this area depends

on applications from copyright holders. Representatives of large majors such as Universal, Warner, Sony are either absent in Ukraine or are passive and don't inform us about such violations. Representatives of movie majors are relatively more active in this area, but they have limited rights. For example, they don't have the right to internet distribution of the movies. And all this means that, as we say, no statement means no offense. If we don't receive complaints, then no offenses are registered.

As far as border enforcement is concerned, we can report that the smuggling through railways has been stopped. At the moment, pirates use more sophisticated tactics. They just send audiovisual products to each other via regular mail. And at the moment, there is no clear recipe to fight this in the world.

As far as the legal reform is concerned, we cannot agree with your comments because the Ukraine is a member of WTO, and our legislative base complies with the provisions of international

treaties in the field of international property.

As far as legislation to fight internet piracy is concerned, the draft law #6523 provides for appropriate amendments to the legislation. It was approved in the first reading by the previous convocation of the Parliament, and it was reregistered in the Parliament under #0902 on December 12, 2012.

MR. McCOY: Let me just interrupt you a moment to say that 10 minutes have elapsed, but because of the time required for the consecutive translation, I'm inclined to allow you to go on for another 10 minutes. So I would invite you to continue. I do have some questions that we have for you. So if you would pause as soon as you are finished with your review of legislation, I'll pose those questions. Thank you.

MR. NALYVAIKO: So we also should not forget that internet providers have strong lobby, too, and not only in Ukraine. Also, there is an ongoing public discussion of the draft law. Some people argue that the draft law would limit the

freedom of speech and access to information for Ukraine. But we keep working in this regard.

You also proposed amendments to Article 176 of the Criminal Code, but it is not quite clear what is the idea behind your proposals because the article already contains the proposed rules.

And as far as the control marks are concerned, we have drafted a new law on the issuance of control marks. It provides for involvement of copyright holders into the process of issuing of control marks. And now this draft law is being considered by relevant agencies of Ukraine. Thank you.

MR. McCOY: Thank you. Let me first ask about the subject of software legalization. You mentioned the commitment of the Government of Ukraine in its budget to spend 100 million grivnas on legal software. There are submissions in the record that indicate that this is possibly 10 or 20 percent of the funds necessary to fully legalize. I wondered if you could respond to that assertion and

also let us know in what time frame the government plants to spend that money.

MR. NALYVAIKO: We had a Joint Plan which provided that Ukraine would spend 100 million grivnas in 2013. That is exactly the figure that we put in our budget. And this exact figure will be funded from the budget in this year, as we agreed.

In addition, we have ongoing stopped taking of software in government agencies to reduce the number of pirated software being used. And also we transfer our operations to open source software.

MR. McCOY: Thank you very much. Another question on the issue of collecting societies. We are aware of serious concerns expressed about the transparency, effectiveness, and fairness of the collecting societies system in Ukraine. And we understand that there is draft legislation that does not appear to fully address these concerns. As a result of comments received during the public comment period, we would like to ask whether this legislation will be revised.

MR. NALYVAIKO: In turn, I would like to

state that the proposed legislation will resolve all problems fully. And we are eagerly awaiting for its adoption for one year and a half. All problems in the system of collecting agencies started when one of the agencies was deprived of the stages. And this decision was not a voluntary decision, but it was based on an order from the prosecution agency. So now we need to approve the draft law in order to identify the designated organization.

In my view, there is a transparency in our system. But as long as we have opposition, they will always claim that there is no transparency. Thank you.

MR. McCOY: Yes, thank you. On that point about the actions of the general prosecutor's office, we would welcome further clarification from the Government of Ukraine. Specifically, we have been told that the general prosecutor's office has informed the relevant collecting society, the Ukraine Music Rights League, that no prosecutorial action was being taken against them. And this appears to be the same organization against which

you indicated that there was an action by the general prosecutor. So I am not sure we are completely clear on the facts here.

MR. NALYVAIKO: Yes, we are speaking about one and the same organization, the Ukraine League of Musical Rights. So from the moment when the league was deprived of the status of authorized agency, the prosecution office stopped its investigation. And at the moment there are no, no claims from the point of prosecution, no prosecution is taken against this organization.

MR. McCOY: Okay. Thanks very much for your time today. And in view of the schedule that we need to continue with, I will move on and invite the next representatives to come forward.

Let me just say as you depart, thank you very much to the Government of Ukraine for your participation in this process. And we look forward to working with you on these issues.

MS. PINHA: Next up, we have representatives from the Government of Paraguay.

MR. McCOY: Welcome. We are pleased to

welcome you here today. And I will give you the floor. And, again, we'll let you know partway through your 10 minutes if we have any questions for you. Go ahead.

MR. BENITEZ: Thank you. For the first time in many years, the Government of Paraguay is present in this public hearing. This gesture in itself constitutes a clear proof of commitment on behalf of my country towards respecting intellectual property rights both in the domestic and international arenas.

Since the last revision of the Special 301, the Paraguayan Government has made important improvements in this area as I will present here shortly. One of the clearest examples is the creation of the National Agency of Intellectual Property through Law 4798 of last year. With this action, the Paraguayan Government upgraded the status of the previous office, which was lately working under the Ministry of Industry and Commerce and now is linked directly to the president.

Other state institutions of the Paraguayan

Government have also shown that attention to this particular subject matter has grown. Such is the case of the Paraguayan Supreme Court of Justice, which only created the Direction of Intellectual Property Rights last year through its internal Resolution 754, dated March 13 of last year.

From that day on, this Direction developed and extended agenda of activities related to capacity training and increasing awareness of diverse aspects related to intellectual property rights to churches, legal clerks, and administrative personnel of the court. And a similar and ambitious agenda of activities has been set for 2013 as well.

A similar case took place in the Attorney General's Office where the specialized unit in charge of prosecuting violations of intellectual property rights was restructured in order to strengthen the institution, thus becoming directly linked to the Attorney General's office, to the Attorney General itself.

Also in March of last year, the Paraguayan Government created a department on a cabinet level

in charge of technology affairs, which now is in charge of preparing a chart for a full implementation of legal software, or either legal or free software.

Beyond the institutional organization and restructuring of the areas related to intellectual property rights, the Government of Paraguay, through its different offices, developed a series of substantive procedures with a goal of deterring violations and punishing offenders, improving control mechanisms, training and improving the performance of officials, and increasing awareness of the importance of respecting intellectual property rights to society as a whole.

These aforementioned measures are reflected in the Paraguayan Government report recently presented. In order to avoid making this intervention any longer, I would like to mention that the initial entities involved in the protection of intellectual property rights are making a major effort with an ever-increasing level of coordination and cooperation between themselves. This made it

possible to seize a relevant volume of merchandize and led to arrest and conviction of an important amount of individuals, which arise to 14 last year convicted who engaged in diverse illegal activities that violated intellectual property rights. The Attorney General Office seized counterfeited merchandize for the value of $11 million, and the National Police of $46 million.

At this point, it is extremely important to highlight the work done by the Attorney General's Office and the local district attorney offices, the National Police, the specialized unit under the Ministry of Industry and Commerce, and the National Customs, and other institutions involved, whose officials worked tirelessly throughout the previous year. All of these actions, however, were carried under limited budget and a short personnel. And this is why cooperating with international actors becomes a crucial task for enabling and securing the success of these projects for both the present and the future.

Finally, the Paraguayan Government would

like to renew its commitment to carry on with these actions, advance and cooperate during the current year, both nationally and internationally, and keep on improving the protection of intellectual property rights. Thank you very much.

MR. McCOY: Thank you very much for your presentation. I'd like to ask on the subject of software legalization that you mentioned, if you could elaborate a bit on the Government of Paraguay's efforts in that area.

MR. BENITEZ: Yes. On March of -- as I mentioned before, on March of last year, there was an agency created and whose main goal is to implement, because until integration of that agency, there was no institution who was legally in charge of that matter. With the creation of that agency, it is settle a path, it is already devising a path for the full implementation, of course. And of the 11, and ministry on the cabinet level, and I think already 3 or 4, I think 4 has already a full legal software implemented in their systems. And the rest are already being charted paths for full compliance.

MR. McCOY: Thank you very much. As you know, Paraguay enjoys an unusual status in the Special 301 Report. Paraguay is listed under Section 306 monitoring reflecting the fact that we have had a bilateral memorandum of understanding to resolve past investigations that resulted from Special 301 Reviews in the past.

We have had government discussions about the way forward on these issues. I think from the U.S. side, the U.S. Government has expressed our willingness to work with the Government of Paraguay to resolve this situation going forward. I'd just invite the Government of Paraguay to comment on your vision of the appropriate way forward and our bilateral cooperation on these issues.

MR. BENITEZ: Yes. First of all, we appreciate the consideration that the U.S. Government provide us in that area and in regard to the MOU itself. And we are assembling a team in charge of, whose task is to present new alternative or a renewal of it. And we accept that there are a lot of measures to be taken by the Paraguayan

Government.

And as you know, we have a new government since June of last year, and we are aware that there are a lot of compromises that haven't been helped by the Paraguayan Government, and we are in the process of compliance of those.

MR. McCOY: Well, I'd like to say thank you very much for your time today, and we look forward to working with you on all of these issues.

MR. BENITEZ: Thank you very much.

MS. PINHA: Okay. Next up, we have our colleagues from the Embassy of Mexico or, sorry, from the Ministry of Economy of the Government of Mexico.

MR. McCOY: Welcome, gentlemen. And we appreciate again the Government of Mexico's participation in the Special 301 process. The floor is yours, and I will again interrupt you partway through your presentation to remind you of the time and let you know if we have any questions. Thank you.

MR. SMITH RAMOS: Thank you very much.

Good morning, Mr. Chairman, members of the subcommittee. The Government of Mexico appreciates the opportunity to appear before you at this hearing and express its views on the 2013 Special 301 Review. For the record, my name is Kenneth Smith Ramos. I am the head of the Trade and NAFTA Office of the Mexican Embassy here in Washington, D.C. And I am joined by my colleague, Mr. Salvador Behar, legal counsel at our office.

Please let me start by saying that IPR protection is a very important issue for Mexico, the reason for which we have participated in various international negotiations in order to advance our IP legal framework. I would like to briefly address specific issues in my testimony related to Mexico's IPR protection and enforcement efforts.

On Mexico's IPR enforcement agencies and their dedication to IPR protection, I will say that since the amendments to Articles 429 of the Federal Criminal Code and 223(b) of the Industrial Property Law, on June 28, 2010, Mexico has made tremendous progress in the prosecution of crime.

Due to these reforms, the Mexican Government has carried out a significant number of actions. In the General Customs Administration, the SAT, as a result of the 2011 actions aimed to detect counterfeit goods at Customs through the implementation of the trademark registration system by the General Customs Administration of Mexico, the agency has now registered 4,000 trademarks in the system.

To combat counterfeiting, the SAT and Mexican Institute of Industrial Property, the IMPI, instituted a pilot program to exchange information through an automated database where Customs authorities can access all registered trademarks. In 2012, the National Institute for Copyright, INDAUTOR, registered 44,464 works, 5,137 contracts, 7,646 exceptions, 3,159 legal consultations, 28,081 ISPNs, and facilitated 1,129 conciliations regarding copyright infringement disputes.

INDAUTOR also participated in more than 116 national and international fora, including courses, workshops, and conferences designed to

disseminate and promote the rights of copyright and related rights. In addition, INDAUTOR entered into 19 cooperation agreements with higher education institutions, international organizations, and copyright offices in other countries.

INDAUTOR has focused a great deal of its efforts on educational awareness of IPR in Mexico. This includes the publication of an IPR chapter in the civics and ethics textbook used by all elementary schools nationwide and its organization of 75 courses and workshops for officials and the general public alike.

On the arbitration side, INDAUTOR's conciliation procedures have proven to be effective. Seventy percent of cases were resolved in favor or rights holders.

On the information sharing between enforcement agencies of Mexico and the U.S., this has been a top priority. And after the launch of the Patent Prosecution Highway, PPH, in 2011, IMPI has expanded its network of countries to expedite the patent examination process by using the

substantive examination results of the signatory offices.

Mexico's examination process has decreased from 27 months to approximately 3 months because of the PPH. Collaboration training and increased intelligence sharing among law enforcement agencies of both countries has also been taking place to promote IPR enforcement.

Mexico has been dedicated to international cooperation regarding IPR protection as well. On trade agreements, in 2012, Mexico joined two ambitious free trade initiatives, the Trans-Pacific Partnership agreement with 10 other nations in the Asia-Pacific region, and the Pacific Alliance with Chile, Colombia, and Peru. The three of them also partners in trade agreements with the United States.

Through its participation in these initiatives, Mexico has proven it is committed to establishing high standard protections for intellectual property rights while reinforcing and developing current international norms.

Mexico is committed to combating

counterfeiting and piracy. Last year, Mexico worked with WCO, the U.S., and the private sector to train 727 Mexican Customs officials in identifying counterfeit goods. Mexican Customs also had an active participation in international operatives instituted by WCO and IAPIC (ph.).

Under the auspices of WIPO, INDAUTOR implemented a study visits program for staff of foreign copyright offices in which INDAUTOR welcomed the various director generals of the copyright offices of Guatemala, Costa Rica, Paraguay, Honduras, Panama, El Salvador, and Nicaragua to exchange information and experiences relating to copyright and related rights, as well as strengthen the working relationship between the offices.

From September 24, 2012, to December 17, 2012, a pilot distance learning course in copyright and related rights was organized by INDAUTOR and the WIPO and was overseen by the directors and deputy directors of INDAUTOR, who advised, encouraged, and supported the learning in a digital platform of 90 students.

Currently, at the request of the Ministry of Public Service, INDAUTOR is participating in a contest for public service sponsored by the United Nations for INDAUTOR's work in developing and offering an expedited same-day service for registering of works called Express Author. The project was registered on December 6, 2012, in the United Nations system.

INDAUTOR has also developed other expedited processes to offer to the public such as foreign express, express management, and the implementation of computer kiosks and virtual classrooms in the areas of registration and exceptions. INDAUTOR has also extended the hours of service related to conciliation services, as well as information and consulting services.

MR. McCOY: Can I just interrupt you for a moment to say that five minutes have elapsed, and I wanted to also invite you in the remainder of your time to address two points that came up in last year's Special 301 Report.

One was on the question of overall

enforcement efforts in Mexico and in particular the need for increased resources and more IPR prosecutions and deterrent level penalties. And if that is an issue you could speak to in terms of the enforcement side.

And then on the legislation side, the report cited three points of legislation. One was providing Customs officials with ex officio authority. A second was enacting legislation to strengthen the copyright regime, including implementing the WIPO Internet Treaties. And a third was protecting against unauthorized camcording.

MR. SMITH RAMOS: Absolutely, Mr. Chairman. Let me address the issue on legislative actions first. Legislative actions and administrative regulations are being taken to implement the WIPO Internet Treaties. Mexico has been working alongside the U.S. on draft amendments to IP legislation to ensure that they are in compliance with WIPO Internet Treaties.

There are still issues that require

further attention, such as technological protection measures, RMI violations, and neighboring rights. Mexico is working intensively to address these issues in a bill that is intended to be presented to the Senate in the short term.

On September 19, 2003, amendments were also made to the regulations of health supplies and industrial property law. These amendments require applicants to prove that they are a patent holder or have corresponding license and establish a link between sanitary and IP authorities. COFEPRIS, Mexico's Federal Commission for Protection against Sanitary Risks, has complied with these laws by not issuing registries to generics when a patent is still in effect.

Neither of these amendments explicitly addresses formulation patents. Judicial review was requested, which led to a decision that ordered the protection of formulation patents. In response, COFEPRIS issued no registries of generics where formulation patent was enforced. The above-mentioned confirms how COFEPRIS is committed to

protect the health of the public in Mexico, and at the same time pharmaceutical innovation.

Both COFEPRIS and IMPI are in close communications. Efforts have been made during 2012 to reach out to all interested parties in the private sector in order to identify possible waste to improve the legal framework on this matter.

MR. BEHAR: Mr. Chairman, before my colleague continues, I would like to address a couple of the issues that you have raised. So after that, he can wrap up and conclude with the final remarks and two of the issues that remain important to highlight in this.

Regarding resources, let me remind you that we are having a new administration, the administration of Pena Nieto at present is taking place. And there is -- it is a full commitment to further develop relationships and further cooperation with other countries. That includes also additional resources to the agencies to prosecute and continue with their work, including the Attorney General's Office and Customs

Administration.

Of course, IMPI, the Industrial Property Institute, has also a new leadership which is at present related to the private sector. It is not a government official. It is a person coming from the private sector, and he is also showing new and renewed commitment on the protection enforcement from the IMPI.

Also, as was mentioned before, Mexico is working on a regulation that will be submitted to Congress soon, including reforms to the copyright law and the criminal code.

MR. McCOY: Just letting you know you have one minute left.

MR. BEHAR: And with that, I will let you wrap up.

MR. SMITH RAMOS: Thank you very much. I'll go very quickly. We wanted to touch upon two items on the ACTA. On the one hand, to combat the problem of counterfeiting and piracy, Mexico signed the Anti-Counterfeiting Trade Agreement, ACTA, on July 11, 2012. We are committed toward

strengthening the rule of law and foster economic development along with the other members that have signed this instrument. And the signing of ACTA is a resolute statement of the Mexican Government to continue discussing with Congress the effective protection of Mexican trademarks, invention, intellectual creation, as well as the implementation of the agreement.

As well in 2012, Mexico joined the Madrid Protocol, offering trademark owners the possibility to have their trademarks protected in several countries. And, yesterday, IMPI and WIPO successfully launched operations in Mexico, allowing that very act for the first Mexican country to take advantage of the international system.

I want to just reiterate what my colleague mentioned in terms of the commitment of the administration for intellectual property rights and protection. And for the above-mentioned summary of actions that we have mentioned and have been carried out by Mexico, we formally request to be removed from the Special 301 Report. Thank you very much.

MR. McCOY: Thank you very much to both of you, personally, and to the Government of Mexico for your participation in the process today and over the years. We appreciate it, and we appreciate your remarks today and look forward to continued engagement with you on our mutual interests in these areas. Thank you.

MR. SMITH RAMOS: Thank you very much.

MS. PINHA: Next up, we have our colleagues from the Embassy of Italy.

MR. GALANTI: Good morning. My name is Lorenzo Galanti. I am First Counselor for Economic Affairs, Trade and Science at the Embassy of Italy. Mr. Carlo Villanacci, financial attaché, is colonel of the Italian Fiscal Police, the Guardia di Finance.

Mr. Assistant U.S. Trade Representative and members of the Special 301 Committee, the Government of Italy welcomes this opportunity to reaffirm its growing commitment to intellectual property rights protection and its firm determination to achieve and enhance concrete and

effective IPR protection through actions on the regulatory, judicial, and enforcement front.

The ongoing dialogue between the two governments, as well as legislators from both countries and stakeholders from the private sector, has proven to be particularly intense and fruit-bearing. Evidence of this context is provided by the numerous meetings which have taken place in 2012 between the Italian delegate for Intellectual Property, Professor Mauro Masi, and high representatives from the U.S. Administration, as well as the private sector both in Rome and Washington.

The visit to Italy by Deputy U.S. Trade Representative Ambassador Sapiro in July 2012 and the talks between Assistant USTR Stan McCoy and the Italian Communications Regulatory Authority, AGCOM, in Rome, in September 2012, enabled a fruitful exchange of information on the U.S. and Italian approach to copyright protection.

Representatives of the new leadership of AGCOM pointed out that the draft anti-piracy

regulation is at the top of AGCOM agenda. The AGCOM board of directors ended, as you know, its mandate in spring 2012, leaving the adoption of the new regulation on copyright protection over the internet up to the incoming board. The newly appointed board of directors began its activities in the second half of 2012. It first focused on urgent measures to address an infringement procedure regarding the auction sale of frequencies for the digital terrestrial broadcasting. Subsequently, AGCOM has been monitoring media pluralism and political communication in view of the general election which will take place in a couple of days.

But copyright protection on the internet ranks as a priority in the 2013 work program. As AGCOM's chairman, Angelo Marcello Cardani stated in a public hearing at the Italian Parliament in December 2012, the board of directors will carry out a thorough examination of the outcome of the consultation -- of the consultations, the two public consultations that have taken place, as soon as the aforementioned commitments have been performed. The

board of directors' decision on the draft regulation is therefore expected by mid-2013.

While the draft anti-piracy regulation expects to be finalized by mid-2013, Italy is keeping up the momentum. AGCOM is planning a workshop, to organize a workshop on online copyright protection to be held this spring in Italy involving U.S. authorities. The aim is to share information on different regulatory models such as administrative versus statutory and users versus content focus models, and to compare the existing variety of approaches in the EU and the U.S. and in other countries.

The visit to Washington by Parliamentary Commission of Inquiry on Counterfeiting and Piracy led by the Honorable Giovanni Fava in January 2012 is also testimony of the active relationship and constructive dialogue taking place at all levels. The Parliamentary Commission of Inquiry on Counterfeiting and Piracy established in July 2010 is one of the few existing bodies in advanced countries which comprehensively analyze

counterfeiting and piracy. In January this year, the commission submitted an activity report which provides a detailed insight into the recently improved fight against counterfeiting and piracy.

As has been reported in the Government of Italy's submission, evidence of the efforts by Italian authorities is provided by development both at the level of the judiciary and in terms of enforcement. As to the strengthening online copyright protection ensured by recent jurisprudence, Italy's submission provides detailed information in its Annex 2. Italian courts have recently been issuing a number of judgments, ensuring a timely and effective protection against illegal upload and download on the internet of copyright protected contents, both in civil and criminal cases.

I would like to highlight that a record pecuniary sanction amounting to Euro 6.4 million, which is about $8.5 million, has been inflicted only a few days ago in connection with a case of copyright infringement involving the so-called

ItalianShare network following the seizure of five sharing websites. The manager was arrested in July last year. The network with 300,000 users and 550,000 visits per month posted information and a number of links to illegally download about 31,000 copyright protected contents of an estimated value of several million euros. The online copyright infringement was connected to the violation of privacy law by selling to advertising websites the subscribers' IP addresses and personal data.

Recent Italian judgments have set principles reflecting the same approach as the draft AGCOM regulation. They strengthen copyright enforcement with respect to the inhibition of foreign websites hosting illegal video contents, infringing copyrights, even though they provide hosting services only abroad, illegal broadcasting of soccer matches over the internet, an ISP's obligation to prevent access to illegal websites in compliance with court orders released for the prevention, investigation, detection, and prosecution of criminal offenses.

As far as criminal prosecution of unincorporated professionals for software piracy is concerned, it should be underscored that self-employed professionals possessing and using illegal software programs commit a crime under Article 171bis, Paragraph 1, of Law 633, April 1941. This applies to cases of software piracy for profit. The commercial use is not a necessary requirement for the criminal charge. This was one aspect which is underlined by the private sector in their submission.

MR. McCOY: Let me just interrupt you to say you have about 3 1/2 minutes left, and I haven't interrupted you with any questions because so far you have successfully anticipated all of my questions about internet piracy and software and so on. So I invite you to just continue. Thank you.

MR. GALANTI: Thank you very much. I am about to finish. A comprehensive reform of civil justice, Law 27, dated March 2012, has led to the establishment of 12 specialized sections with specific competencies on intellectual property and

corporate law in Italian courts, concentrating litigations in a limited number of courts, also with a view to preserving existing IP expertise among judges.

Finally, several examples provide evidence of Italy's commitment to the enforcement of domestic and EU laws and regulations. Fiscal Police, Postal and Telecommunication Police, and the Customs agency are actively conducting activities and operations to fight against counterfeiting in the area of physical goods, as well as copyright protected audiovisual works.

As an additional piece of information with respect to the submission by the Italian Government, I would like to point out that the Italian Fiscal Police, in its fight against copyright infringement in 2012, has conducted 1,871 inspections, referred 1,653 persons to justice, arrested 44 persons, and seized 2.1 million products, including 45 websites and more than 1.9 million CDs, DVDs, videocassettes.

The government eventually expects that Italy's position be thoroughly assessed in light of

its consistent and coordinated commitment in the area of the protection of intellectual property rights. Thank you very much.

MR. McCOY: Thank you very much for your comments and for your efforts. As I said, you have anticipated our questions, which were mostly around the issue of internet piracy, which you know is the first issue highlighted in the Special 301 Report last year. Thank you very much for your update on the status of AGCOM's consideration and your up-to-the-minute update on enforcement actions and including very recent ones. So appreciative of both your efforts, and I hope you will convey our regards back to your colleagues in Rome, who as you noted we have had some government-to-government interactions with this year.

So unless you have anything further, I will just make up for my failing to welcome you when you sat down and say thank you very much for your participation in the process, and we look forward to continued engagement with the Government of Italy on our shared interests in this area.

MR. GALANTI: Thank you very much. And we also look forward to continuing this collaboration.

MR. McCOY: So I think we are scheduled for a 10-minute break right now. We'll resume at 11:25. Thank you very much.

(Off the record.)

(On the record.)

MR. McCOY: Thank you everyone for helping us to restart promptly. Let me just say we have been joined on the panel by one more interagency representative, who I will invite to introduce herself.

MS. BLEIMUND: Hello, good morning. My name is Emily Bleimund. I am with the Department of Health and Human Services, Office of Global Affairs.

MR. McCOY: Thank you very much. And without further ado, we'll get right back into the schedule. Paula, if you will start us off?

MS. PINHA: Great. Our next testimony is from the American Society of Composers, Authors and Publishers.

MR. McCOY: Hello, welcome. And we'll

follow form from earlier. You have 10 minutes, and I'll let you know midway through how you are doing on time and whether we have questions. Thank you.

MS. McGIVERN: Members of the 301 Committee, thank you for allowing me to testify on behalf of the American Society of Composers, Authors and Publishers, otherwise known as ASCAP, and its more than 450,000 songwriter, composer, and music publisher members.

Our members come from a variety of backgrounds, but they are overwhelmingly individuals whose livelihoods depend, are built upon writing music, as a result upon the revenues we collect on their behalf and distribute for them.

Our ability to guarantee the collections come from countries where American music is enjoyed has a direct impact on the revenues and personal incomes of our members. That is why your assistance is needed in collecting the paychecks owed to hundreds of thousands of U.S. citizens from foreign markets that to date have failed to respect one of our most important and valued exports, our

copyrights.

To ensure that our members receive fair payment for the public performance of their musical works they create and own, ASCAP grants licenses to a wide variety of music users in the U.S., such as television and radio broadcasters, hotels, nightclubs, and so forth.

A unique feature of the system is ASCAP's reciprocal relationship with foreign performing rights organizations, or PROs, all over the world. These foreign PROs collect royalties for the performances of American music in their territories and send it to ASCAP for distribution to our members. In turn, we do the same for their members based on their members' U.S. performances.

Because of this reciprocity, we know that when foreign PROs collect for our members, those foreign PROs are also collecting for their local members and thus benefiting their local members. Conversely, when foreign PROs are unable to collect for both U.S. music creators, those local creators also suffer.

Meager collections in certain countries, as documented in our business confidential filing, distinctly correlate with countries whose governments are well known for their censorship practices. I won't elaborate, but it is detailed in our filing.

As the U.S. seeks to further foster freedom of expression around the world, we must not neglect the vital importance of ensuring that when people express themselves, whether foreign or U.S. citizens, by composing music that is publicly performed, they all have a right under international legal norms to be paid for those performances.

From several Caribbean nations and from China in particular, ASCAP has been unable to receive the full royalties that our members are owed, despite years of negotiations and litigations and efforts quite frankly to resolve it within the International Trade Association framework. And it has only been in recent years that we've been raising these issues with the USTR because we have hit such roadblocks.

ASCAP and its members also face obstacles in a number of other countries in collecting royalties as also detailed in our submission. These challenges of collecting royalties and enforcing rights for musical works are neither intractable nor insurmountable as some of the other problems that have been raised with you.

Caribbean governments, for example, can solve these challenges by enforcing the laws in place that are applicable to broadcasters and cable operators. They can revoke the cable operators' licenses or suspend them. The Chinese government can set fair rates of compensation for performances, and it can account for years of unpaid royalties, almost a decade's worth in the broadcast area.

Hundreds of thousands of American creators speaking through ASCAP urge our government to press these governments to take these modest and, as we said, doable steps without further delay.

If time allows, I can say a few more words on the Caribbean and China or answer your questions.

MR. McCOY: No, that's a perfect

anticipation of the questions I was going to pose. If you could start off on China, one issue we are interested in is how do our challenges in China compare to other major U.S. trading partners around the world in terms of the reliability of your relationships there and ability to collect on behalf of your members in China?

MS. McGIVERN: In China, we are wholly beholden to the Musical Society for Copyrights there. That society or PRO, in turn, is wholly beholden to the government. The only way that our rights can be represented is through that government-designated agency. And the only way that government-designated agency actually sets rates is when the state council allows it to set rates.

So I would say, again, it is documented in our business confidential filing. ASCAP is not only uncompensated, but grossly under-compensated for the performance of music broadcasts on broadcast channels, in commercial venues such as hotels, and are not compensated at all in the case of theatrical exhibitions of movies.

And in the latter case, they presently have as a proposed change to their copyright law that the musical performance be made the responsibility of film producers instead of the collecting society. We have sent letters to the Chinese society specifically from major movie studios around in the U.S. that they do not want this responsibility. That is not the global practice.

The global practice is for the movie studios to rely on the local performing rights organizations to collect for them, because the movie studios assign their publishing rights to their publishing arm. And, therefore, they also benefit from the collection of public performance through the exhibition of movies in those countries. So the Chinese law or proposed change as we understand it is directly contrary to what American movie studios want. And there is no mechanism, organized or otherwise, for film producers to undertake to do these collections and identify who the money is supposed to go to.

I guess the other thing I wanted to mention is China's first adopted broadcast rates did not come into force until January 2010. And they are exceedingly low by any objective standard. And not a penny has been paid for broadcast performances since 2001, when China acceded to WTO in 2009.

And then, finally, China's policies of censorship drive consumers to great amounts of pirated content for which no compensation can be collected. These unpaid royalties are largely due to songwriters and composers who are independent entrepreneurs and SMEs. As explained in more detail in our filing, the publishing money tends to stay in the territory of the local PRO, to the extent that publisher has a relationship with the American publisher. Some of those monies may be remitted, but by and large the monies we get from overseas, and we receive about $5 to $6 for every one we pay out, go to individual songwriters.

MR. McCOY: You have about 4 1/2 minutes left. I wonder if you could spend that time elaborating for us on the problems in the Caribbean

that you detailed in your submissions and maybe highlight for us what you see as the main drivers or concerns there.

MS. McGIVERN: And HBO also commented on some of the problems at a far greater scale. In the case of our struggles with the Caribbean, the amounts that we estimate to be due may seem minimal, and we try to be very conservative on that front, and we were only estimating what might be due to ASCAP members. And as I said, we're talking about individual songwriters and composers.

There are two other PROs in the U.S. We did not include estimates for them, but you could probably easily double it, so it would be more on the order which is business confidential, but it would be double what I put in our papers.

In Jamaica and the Republic of Trinidad and Tobago, cable operators have refused to negotiate with the local PROs. In the case of Trinidad and Tobago, they commenced an action in court, in 2002, and it is now 2013, and they still haven't settled. They were able to obtain a

judgment. That cable operator sold its assets to another cable operator and therefore became judgments-proof. That new cable operator is called Flow Trinidad, which is part of a broader operation called Columbus Communications, which operates throughout the Caribbean. And all you have to do is look up the map of ColumbusCommittees.com, and you will see that it has got tentacles in almost every country in the Caribbean and parts of Central America.

I should also add that through other arms of Columbus Communications, they receive FCC licenses, which actually enable their other arms to steal signals, as HBO documented, and not pay local PROs. It's difficult to connect all the dots, but it does show that it is a complicated problem.

Similarly, leading TV and radio broadcasters throughout the Caribbean, and notably in Barbados, refused to pay for the public performance of music. And their courts have similarly been incapable of enforcing the public performance right to the detriment of both local and

U.S. music creators.

I should have added in the case of Jamaica, which also Flow Jamaica is another subsidiary of Columbus Communications, prior to 2007, the Jamaican Society was able to license the cable operators. But once Flow Jamaica started acquiring local cable operators, they stopped paying the local PRO.

Non-compliant broadcast and cable operators have also caused notable difficulties in Antigua and Barbuda, Saint Vincent and the Grenadines, Grenada, Dominica, St. Lucia, and Belize. All these countries export goods to the U.S. duty-free under the cable [sic] Basin Economic Recovery Act, a program that requires them to respect U.S. copyrights. These countries continue to enjoy these trade benefits, but they shirk from their obligations under the program, in effect taking money out of the pockets of songwriters and composers.

MR. McCOY: Well, thank you very much for your written submissions and for coming to speak

with us today. We very much appreciate your participation in the process.

MS. McGIVERN: Yes. Thank you.

MS. PINHA: Next up, we're going to hear from the American University Washington College of Law, Program on Information Justice and Intellectual Property.

MR. McCOY: Welcome. And, again, you have the floor for 10 minutes, and I'll interrupt you partway through to let you know how you are doing on time and if we have any questions.

MR. FLYNN: Great, thank you. I appreciate that. So my name is Sean Flynn. I am the Associate Director of the Program on Information Justice and Intellectual Property at the American University Washington College of Law.

So first, Emily, thank you for coming. I think this is the first time in the last four years that an HHS representative has come. It has been a constant refrain among the public interest advocates that HHS should be here, and so I think you'll hear today that we are happy to have you. So thank you

for coming.

So as I stated in my written remarks, PIJIP has been attending these hearings and bringing up several themes that are repeated in our submission this year, that the 301 process fails to implement stated U.S. policy promoting balanced intellectual property policy; that the reports take one side of intellectual property policy, promote that side, but do not reflect the balances promoted by limitations and exceptions within intellectual property policy; that the definition of what is adequate and effective intellectual property protection should include that definition of balance that exists in current U.S. law.

And, in addition, in looking internationally at what is adequate and effective, the 301 process and U.S. policy more generally should not follow a one-size-fits-all policy. I think the first year that I came, I cited some of the economic evidence that shows that intellectual property monopolies and monopolies in general have a much more invidious effect in poor countries of high

income inequality. It creates more exclusionary pricing practices in medicines and textbooks for other goods. And, therefore, the goal of U.S. policy should not be to export exactly the four corners of U.S. policy.

And where it does on the protection side, again, it must also be looking at the limitations and exceptions side to ensure that other countries have adequate flexibilities to respond to those very real problems. And, again, as came up in our previous submissions and in the CCIA's submission this year, that those limitations and exceptions have impacts on U.S. businesses, as well as U.S. and foreign consumers. So this is a trade issue.

We have commented in the past and we have commented this time that the process for this 301 hearing has improved marginally by the inclusion of this open hearing. And we continue to welcome this open hearing. However, it is still not a fair and adequate process for reaching effective and efficient decisions on the many factual and legal disputes that you have before you.

One of the primary flaws in the process is that as of yet there has been no effort to respond to the conflicting statements that you get before you within the report itself. That's a basic function of administrative law is to show that administrative agencies are applying their minds to differences in fact and law and policy, and respond to those differences within the report itself. And I continue to encourage you to do just that, to respond not only to the submissions you agree with, but to the ones you do not.

And, finally, we have raised over and over that the 301 Report itself should explain the relation of the continuation of the Watch List process with the advent of the World Trade Organization and the dispute settlement process. There should be an explanation of whether you will continue to entertain listings on the Priority Foreign Country list. And no WTO member to my knowledge has been listed on the PFC list before. You have the perfect opportunity to address that this year with the substantial dispute over whether

Ukraine should be listed as a Priority Foreign Country, even though it is now a WTO member.

But let me focus the rest of my comments today on the balance point. So we continue --

MR. McCOY: Could I just interrupt you. You have about six minutes left, so plenty of time. And I was just going to invite you to address one other question, if you could, in addition to that point which was as you sort of alluded to, yours was one of a couple of submissions that pointed out different concerns about exceptions and limitations around the world. You in particular mentioned an issue about quotations in Germany, and we got another submission on that. I'd be interested in any elaboration you have on the facts around that situation. But with that, go ahead. Thank you.

MR. FLYNN: Great. I will return to that point. So the first point which I think I have covered, but I just think it bears repeating, that within the statute itself, you have statutory commands to list countries that deny adequate and effective protection of intellectual property and

deny fair and equitable market access to those who rely on intellectual property protection.

It is our assertion that those words, intellectual property protection, includes the affirmative rights for users of protected content as well as it does those who are rights holders of protection itself. So someone who relies on fair use, for instance, is a right holder that is protected within the four corners of the statute protecting copyright, as well as the person who holds the right to exclude themselves. Same would go with patents and trademarks, etc.

That is a basic point. It is canvassed in longer fashion in our statement. But I would just say that this is a point that I think if there is a disagreement with your own interpretation of the statute, we encourage you to explain that within the 301 Report itself.

We have included, as Dan mentioned, listing of Germany and other countries that appear to us who have a lack of sufficient balance specifically within their copyright systems. We

have -- now, by we, myself and some of the other professors that I work with at American University, our submission was signed by other organizations, but I am testifying in my own capacity today so as to not attribute my statements to them. But we, those other professors, have commended USTR for coming forward within a TPP negotiation, and asserting that a mandatory duty to have balanced copyright should be one of the mandatory provisions within the international rubric.

And that, we see, or we interpret that as a policy change, and that policy change should infuse this process as well. So there are now U.S. policy promoting mandatory balancing efforts at least on the copyright side, and those should influence how the 301 process goes forward.

The principles that that statement endorsed included an endorsement of the hallmark of the fair use doctrine, which is its flexibility to interpret to new situations over time. This is particularly key to technology industries. So very few, and we actually have done a survey in some of

our research, there are no countries that we know of with closed systems of limitations and exceptions that have anything that would be applicable to the transformation of content by users on a service like YouTube, for instance, a service that is provided by U.S. businesses and is important for U.S. trade. You need some element of flexibility to incorporate protections for those.

As I said, we have a longer list. Let me address the German question and a couple of others as well. Before I get to Germany, let me just mention Panama and Colombia. So two countries that within the last year have amended their copyright laws to make them less flexible, to make the limitations and exceptions less effective, to make their systems more onerous to consumers and to businesses in this country and abroad that rely on those kind of limitations and exceptions.

If you look at the Panamanian submission with us, I think this was a perfect statement for what is wrong with the current system and was expected by other governments. On the first page of

the Panamanian letter, they assure this process of a strong commitment to protect IPR in a constant, effective, and inflexible way. Inflexible? Inflexibility? Is that what we are promoting in this process? And I think that Panama, through its legislative reform, has indeed enacted one of the most inflexible copyright laws that we know of today.

It used to have a fair use provision, and it amended its law to take away that fair use provision. It inserted to comply with its FTA requirements protections for temporary copies on the internet. But it has no commensurate protections, no fixation requirement, no exemption for transitory copies. So it leaves the impression that it is applying copyright to areas that we do not apply in the United States, making it a much worse law than the United States for user rights and technology companies.

Combine that with a kind of bonus system allowing the enforcement agencies to profit themselves through a bonus system for their

employees for enforcement of its laws and in addition a requirement that all limitations and exceptions be strictly interpreted.

MR. McCOY: Let me just say your 10 minutes are up, so if you could wrap it up?

MR. FLYNN: Quickly, Colombia has passed a similar law in regards to its temporary copies and etc., but I would also point out that one of the things that this process looks like is -- looks at is process. So we heard that with regard to Ukraine today, encouraging a more transparent process. Colombia's law has been stricken down by a constitutional court for having rushed through their amendments without an adequate process for consumers and others to engage in that process.

As it goes forward, we think you should make a comment on Colombia, both on process and substance, on substance to have adequate limitations and exceptions, especially in the digital environment, and on process, encouraging them to have a more open and transparent process where all stakeholders can intervene.

And finally on Germany, a much fuller explanation of the German problem is included in the CCA submission. Those are actual technology companies that are affected by that. So I would go there for the fuller story.

But the short story is that Germany is considering a law that would give exclusive copyright ownership to the quotation of news materials that appear in internet snippets. So, essentially, this is targeted at Google search engines that show snippets from the pages that they show in the searches. It would give an exclusive right to those pages to exclude those kinds of snippets, to be monitored by a collection agency that would then exact fees.

This appears to be the most direct violation of the Berne quotation right that I have ever seen. I have not seen that argument on the other side. But to the extent that this forum is to assess and warn countries about violation of international law, I think that's a prime one and, again, one that you can move forward and make a

statement showing that this is a balance process and that you are looking at both lack of limitations and exceptions or users rights, as well as lack of protection.

MR. McCOY: All right, thank you for your participation in the process and your comments today. We appreciate that very much and your time.

MR. FLYNN: Thank you.

MS. PINHA: Next up, we'll hear from the representative from the Health Global Access Project, Health GAP.

MR. McCOY: So welcome, and thank you very much for your participation. The floor is yours for 10 minutes. And I'll let you know partway through how you are doing on time and whether we have any questions. Thank you.

MR. KAVANAGH: Thank you. My name is Matt Kavanagh. I'm the Senior Policy Analyst for Health GAP, Global Access Project.

As some of you know, Health GAP is a network of activists, lawyers, doctors, and academics dedicated to eliminating the barriers to

HIV treatment for people living in the global south, Africa, Asia, and Latin America. It is our contention that the Obama Administration is currently violating both the spirit and the letter of the Doha Declaration in this Special 301 process. In fact, it is a matter of life or death for millions of people around the world living with HIV.

To repair this, the Administration should remove the following low and middle income countries from the listing based on pharmaceutical policy. Each is compliant with TRIPS, and further U.S. demands are inappropriate. That includes Argentina, Algeria, Chile, China, India, Indonesia, Pakistan, Thailand, and Venezuela from the Priority List. From the Watch List, Brazil, Dominican Republic, Ecuador, Egypt, Lebanon, Mexico, Peru, Philippines, Tajikistan, Turkey, Vietnam, and Paraguay.

HIV is a catastrophe for communities around the world, especially in Africa. It is still the leading cause of needless death among women of reproductive age. And the economic impact of HIV is affecting countries, and it is staggering.

But the past two years have actually presented stunningly good news in the science of HIV, perhaps the best since the advent of triple-combination antiretroviral therapy in the mid-1990s. Studies now have confirmed what many of us have long believed was biologically true, which is that antiretroviral HIV treatment is also HIV prevention. And an NIH study recently showed that people on HIV drugs were 96 percent less likely to transmit HIV to their partners.

This finding has the potential to revolutionize the response to global HIV. Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, wrote in *Science*, quote, "The fact that treatment of HIV-infected adults is also prevention gives us the wherewithal even in the absence of an effective vaccine to begin to control and ultimately end the AIDS pandemic."

And, in fact, just a few days ago, President Barack Obama in the State of the Union committed the U.S. to, quote, "Realizing the promise

of an AIDS-free generation, which is within our reach." But to do so we need affordable medications.

The Doha Declaration signed in 2001 by the U.S. said, in part, the TRIPS Agreement does not and should not prevent members from taking measures to protect public health; it should be interpreted and implemented in a manner supportive of WTO members' rights to protect public health and in particular to promote access to medicines for all. And yet when countries do exactly that, when they use the flexibilities specifically articulated, they end up on the Special 301 Watch List. That needs to change.

These provisions include essential flexibilities that more, not fewer, countries should be making use of. And the Commission on HIV in the law recently noted this in their major report that included representatives of the U.S. Congress, presidents from around the world, and major U.N. officials.

Key elements of that include compulsory

licenses. Article 31 of the TRIPS Agreement specifically allows for the issuance of compulsory license, providing a way for governments to compel patent holders to grant non-exclusive use of patents to governments or generic producers in exchange for a royalty when the matter is life or death. The Doha Declaration agrees that this is important. So then why is Thailand listed on the Special 301 list in reference to its compulsory licensing? Why is India?

Data exclusivity has also been deeply contentious. The TRIPS Agreement requires that undisclosed tests or other data be protected against unfair commercial use. The U.S. has tried to interpret this as essentially creating a property interest in the data itself and requiring governments to grant a period of exclusive us.

But this specific proposal was actually rejected during TRIPS negotiations, as you all know. We find nothing in TRIPS that prevents government use of data for registering drugs as safe and effective. This has nothing to do with unfair

commercial practices.

On linkage, in TRIPS, there is no obligation for countries to link marketing approval with patents. And, in fact, there should be no formal burden on the often under-resourced drug regulatory agencies of countries that are charged with protecting health and safety to check patent status before granting approval of drugs.

Recently, however, this has been a major demand of the U.S. within the Special 301 process, creating a major non-patent barrier to the introduction of generic medicines.

Unskilled patent ability. The ability to define what constitutes an intervention -- an invention has been an important flexibility to limit the over-patenting and is the right of countries within WTO. If the scope of what can be patent is narrowly tailored, then we can assure that only true inventions are granted monopoly rights, and yet the U.S. stands opposed.

And, finally, opposition mechanisms. Countries are allowed under TRIPS to set up

mechanisms to allow generic companies and all other interested parties, which we would note includes often patient groups in countries with high HIV rates, to challenge whether patents meet the standard of a country's laws and to prevent improvident granting of patents. It is unclear why the U.S. would oppose this measure in negotiations and in the Special 301 List.

So this matters. The cost of HIV drugs globally has fallen from over $10,000 per patient per year in 2000 to $119 for the WHO-recommended first-line. But this has only happened because of the use of the flexibilities that are actually targeted in the Special 301 report as violations or somehow problematic. The less dramatic but still important path of artemisia in combination therapy used to treat malaria is also documented in what I have submitted to you, and it follows the same path.

To understand how these price reductions came to be, we have to look to India. Today, India supplies over 20 percent of the world's generic medicines and 80 percent of the generic

antiretroviral drugs. Most African nations are largely or completely reliant on the robust Indian generic sector for affordable medicines for HIV. In developing countries outside Africa unable to access versions of the same set of medicines due to patent barriers, the costs have remained approximately 10 times higher.

And it is important to note that the U.S. PEPFAR program and the Global Fund to Fight AIDS, Tuberculosis and Malaria also relies on Indian-produced generics fully legal under WTO to assure that U.S. taxpayers get value for their dollars.

MR. McCOY: Could I just take the opportunity to interrupt you for a moment. You have a little less than four minutes left, and maybe in that time it would be helpful to the committee if you would clarify what your request is with respect to the Special 301 Listings. Is it your assertion that countries like China, etc., should be removed from the Priority Watch List entirely, or is it more based on the emphasis or selection of issues? If you can clarify that for us, that might be helpful.

MR. KAVANAGH: Certainly. I'll do so just at the end. Just briefly, the case of lopinavir/ritonavir is an important one to look at. It is a key second-line AIDS drug, and it is available because India has limited scope of patent ability, pre-grant opposition, and no data exclusivity, that's all WTO compliant. Should PEPFAR stop providing people with this drug? These are exactly the provisions that are opposed in the Special 301 List that you're asking be changed. Has the USTR done a costing study of what this would cost U.S. taxpayers and how about in lives?

The Thai case is also instructive. When Thailand issued a TRIPS-compliant compulsory license on this exact drug, they ended up on the Special 301 Watch List because of it, and there it remains. We see that there are references to the Doha Declaration there. And, yet, the country remains, and vague language continues there.

So we have looked at whether the Obama Administration has actually changed policy at all or whether the policy has changed since the Doha

Declaration. And suffice it to say that in what we have submitted to you, we see an increase in the number of countries that are the Special 301 List for specific TRIPS-complaint measures that are fully within their rights to do under WTO, and yet they find themselves specifically listed under pharmaceutical issues. And that's the request here.

These countries, it's not that they should be removed entirely per se. That's another submission. But instead in each of the countries we have listed, they are listed specifically for TRIPS-compliant pharmaceutical measures. Those references should be removed from the Special 301 List.

It is also notable that I, going through the entire Special 301 Listing, could not find a single example of a country that was previously listed that was removed from the list because the U.S. acknowledged its use of TRIPS flexibilities to protect public health. As far as I can tell, it has never happened. And I wonder about the section of the report that goes into detail about the U.S.

support for Doha, when in fact it has never actually acted on it in the areas that matter.

Finally, in a few points here, we find ourselves right now at a kind of breathtaking possibility when it comes to global health scientists, heads of state, civil society groups. We're all talking about the end of AIDS. Our President is talking about the end of AIDS. And yet we still continue to list countries and to advocate for policies that I'm telling you and experts have told you for years will in fact drive up the price of antiretroviral medicines dramatically in the world.

On that basis, the countries that I listed should be removed from the list when it comes to pharmaceuticals. There should be under all of those countries no listing that asks them or demands that they implement TRIPS-plus provisions.

On a final note, we would note that very important policy questions currently face the Obama Administration when it comes to low-income countries, when it comes to least developed

countries. The TRIPS council with U.S. support is extending the deadline to implement TRIPS for countries designated at the U.N. as least developed countries. It extended it to this June, as you know. The LDCs have formally requested a further extension. And countries should not -- we argue that countries should not have to implement TRIPS until they are no longer LDCs.

I'd remind the USTR that the LDC designation comes from the U.N. to indicate the poorest countries in the world with low GAP and human capital, countries like Bangladesh, Haiti, and Swaziland. By definition, they have little ability to implement an IP system, and implementing TRIPS would be inappropriate, halting development, and hurting public health. If the Obama Administration is serious about health and development, it should support this proposal, and I ask that you do so.

Finally, the risks -- what the Administration risks right now is looking completely disingenuous. When the President stands up and says that he is for the end of AIDS, and the USTR

continues to put out a report that actually asks countries to implement policies, especially those in countries like India that would cut off the flow of generic medicines, we know that that's disingenuous. We will not see the end of AIDS if that happens.

I'm glad to see HHS here and also the State Department here. And I would ask are you reviewing the impact? Have you done an analysis of the impact that this would have not only on people's lives, but also on U.S. taxpayer dollars. Thank you.

MR. McCOY: And thank you very much for your participation today. I am sure the whole committee appreciates both your time and your engagement with the process. Thank you very much.

MS. PINHA: Next up, we have the U.S. Chamber of Commerce, the Global Intellectual Property Center.

MR. McCOY: Hello, and welcome. The floor will be yours for 10 minutes, and I'll interrupt you partway through to let you know how you are doing on time and whether we have any specific questions for

you.

MS. VETERE: Excellent.

MR. McCOY: Please, go right ahead.

MS. VETERE: Thank you. Well, good morning. My name is Gina Vetere. I'm the Executive Director of the U.S. Chamber of Commerce's Global Intellectual Property Center, also known as the GIPC. On behalf of the U.S. Chamber, I would like to thank this committee for giving us the opportunity to testify today and for your ongoing hard work in support of intellectual property worldwide.

The U.S. Chamber is the world's largest business federation representing the interests of more than three million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations. We are also home to the largest international staff within any business association, providing global coverage to advance many of the policy issues of pressing issue to our members.

In 2007 the Chamber established GIPC to

lead an effort to champion intellectual property rights as vital to creating jobs, saving lives, advancing global economic growth, and generating breakthrough solutions to global challenges. The Chamber's GIPC and international division welcomes the opportunity to submit joint comments on this year's Special 301 Review in order to provide greater attention to the challenges faced by our innovative and creative industries that are exporting or seeking to export overseas.

Our submission highlights systemic concerns that span across sectors and provides an assessment of the challenges and opportunities posed by the IP systems in seven different countries. We look forward to working with this committee and our trading partners to secure meaningful IP policy improvements that produce economic benefits in the U.S. and also in these countries.

As demonstrated by recent studies, intellectual property is critical to driving U.S. job creation, economic development, and competitiveness. Intellectual property intensive

companies account for more than 5.8 trillion of the U.S. GDP, drives 74 percent of U.S. exports, and support 55.7 million direct and indirect American jobs. Sound intellectual property policies are vital not just to the U.S., but also to promoting innovation and creative economies around the globe.

The Special 301 Report is a vital tool for elevating attention to and respect for adequate and effective intellectual property rights amongst our trading partners. It is also for us a valuable resource for businesses seeking to operate globally.

Late last year, GIPC created an intellectual property roadmap for countries seeking to facilitate the creation of jobs, continued innovation, and access to new technologies. The result is GIPC's 2012 International IP Index called Measuring Momentum. This index is a first of its kind empirical assessment of the strengths and weakness of 11 economically and regionally diverse countries. We have submitted a copy of the index for the record with our Special 301 submission, and we refer to it where appropriate throughout our

submission.

The index not only provides a useful snapshot of the current IP systems of those countries included in the index, but it also serves as a useful comparison of the IP laws and practices across countries on a like for like basis. Overall, while the index demonstrates a number of instances of countries seeking to craft effective IP rules and dedicate greater resources to combat IP theft, it also shines a spotlight on a number of challenges to securing effective implementation and enforcement of IP laws and practices.

I'd like to take this opportunity to highlight a few key points in our thematic concerns and also our country-specific concerns.

First, the overarching IP challenge is addressed in our submission. With that, the first is the erosion of intellectual property rights. Intellectual property provides an incentive for individual innovation and serves the public interest by facilitating the creation and dissemination of knowledge and culture. We are concerned about any

efforts that limit innovators' ability to protect their property rights of their inventions or the scope of what can be protected absent the careful balance that already exists in our laws.

We urge the U.S. Government to use all available means to oppose efforts to impose unwarranted exceptions to patents, trademarks, and copyrights to the detriment of innovation, growth, and global well-being.

In this context, our submission highlights examples such as India's issuance of its first compulsory license to allow for generic manufacturing of a patented anti-cancer drug and Australia's passage of legislation that stripped trademark owners of their ability to use their brand on tobacco products. Such actions establish a dangerous precedent for the protection of IP for all industries.

Second is the importance of bilateral and regional trade agreements. The Chamber supports the negotiation, conclusion, and enforcement of bilateral, regional, and multilateral agreements

that advance global intellectual property standards, including in the currently ongoing Trans-Pacific Partnership negotiations.

Third is the particular challenge posed by the internet. The internet has developed into the greatest marketplace of goods and ideas, but online theft of intellectual property is massive and growing. Protecting intellectual property is as important on the internet as it is in the brick and mortar world. It is therefore critical that law enforcement has the tools, resources, and will to fight theft in both the online and physical environments.

We commend USTR for recognizing the challenges caused by online theft through its Special 301 out of cycle, notorious -- reviews of notorious markets. We urge the subcommittee to factor the notorious market review findings into this year's annual Special 301 Review, and to make action by foreign governments to address any notorious markets in their jurisdiction a priority.

MR. McCOY: Let me just interrupt you to

say you've got about five minutes left. And I think you have partly anticipated the question that we had, which was going to this IP index that the Chamber has developed. Of course, as a committee charged with developing an annual report that lists countries at different levels, we are very interested in the challenges you have grappled with in trying to make those assessments. So any insights you can share on how you have developed that index and what you see as key benchmarks is, I'm sure, helpful to the committee.

MS. VETERE: Great. Thank you. Absolutely, we did append a copy of the index to our submission. It looks at 25 factors that are indicative of an IP environment that promotes innovation, growth, job creation in all countries. So it is not meant to be a comprehensive list of every factor, but of those that go across sectors. That's what makes it unique is that it does go across sectors.

So, of course, we did have to go through some challenges. You know you have to try to -- we

didn't weight them. We made everything one point because we think it is important to show this from a broad picture and across sectorial, and to also be able to highlight trends where situations are improving, but also trends where situations are becoming more challenging.

And I think overall, as we called the report Measuring Momentum, we think there is a lot of countries seeking to make improvements. And we hope that this index, which we plan to continue and produce on a regular basis and to expand, will be able to help benchmark and track those improvements going forward.

And going back to the last systemic concern is the need to improve enforcement efforts and resources in the U.S. and overseas. It is important the U.S. continue to work with foreign governments to promote the enforcement of existing FTAs. In many cases, there have been significant improvements. However, we have also seen considerable setbacks. The Chamber is also particularly concerned about the trans-shipment of

illicit goods, including counterfeit products and the process by which these goods are destroyed once seized.

In addition to the systemic concerns, we wanted to highlight some particular challenges in the systems of Brazil, Canada, China, India, Mexico, Russia, and Ukraine. We chose to divide the submission this way because as a broad-based industry association representing a wide variety of issues across sectors, we felt that categorizing as Priority Watch List versus Watch List was better left to other sector-specific associations that were in a better position to provide a broad assessment of the IP issues in those countries that present the greatest opportunities and challenges for our members.

For today's purpose, I wanted to highlight just a few examples from each country. For Brazil, while we commend the economic policy agencies of the Government of Brazil for recognizing the important role that higher IP protection plays in fostering innovation and growth, our submission and the index

also set forth a number of areas where greater progress is needed.

For example, we highlight concerns with ANVISA acting beyond its congressional mandate when reviewing patent requirements and pharmaceutical patent applications filed with the Brazilian National Industrial Property Institute. We also note several bills related to the internet and copyright protections that are pending. And it is imperative that these initiatives not erode or limit the ability of rights holders to enforce their IP.

Canada. While the U.S. welcomes -- the U.S. Chamber welcomes Canada into the TPP negotiations wholeheartedly, we are concerned about Canada's inadequate level of intellectual property protection and enforcement. Canada's laws and enforcement mechanisms are in need of sufficient modernization for the digital age. Our submission highlights concerns, for example, with recent decisions by the Canadian federal courts which have imposed an onerous test for utility that is inconsistent with both its past practice and its

international obligations.

And while we commend Canada for its passage of Bill C-11, which went a long way toward implementing the WIPO treaties, we urge Canada to do more to combat intellectual property theft particularly online.

In China, we continue to see progress made to protect IP rights through certain amendments in the copyright, trademark, and patent laws, and in the recently concluded judicial interpretation on internet liability. Nevertheless, while we recognize and commend this progress, we continue to have serious concerns about the size and scope of IP infringement in China. We strongly urge more efforts by the Chinese Government to advance the development of new medicines, including to the establishment of effective regulatory data protection.

In India, while the Chamber commends the government for recognizing the importance of IP and their national IPR strategy, we are also concerned we have not seen demonstrable progress in advancing

robust IP policies. In fact, on the GIPC's IP index, India ranks last out of all the countries we examined.

India issued its first compulsory license this year and followed it with patent revocation of a drug that is patented without challenge in 90 other countries. The Chamber will also be watching closely the case regarding Section 3(d) as an important marker in determining whether the Indian courts are going to continue to erode IP via the judicial system.

In Mexico, we commend the government for advancing intellectual property protection such as by implementing ex officio authority for law enforcement. But we urge them to also do the same for their Customs officials. Our submission also highlights several other concerns such as the need to provide greater clarity that the June 2012 data protection guidelines also cover biologic medicines. We urge Mexico to fully input the WIPO treaties.

MR. McCOY: And you're at 10 minutes, so if you could wrap it up.

MS. VETERE: Okay, last is in Russia, we also urge them to address copyright piracy, which we see as a significant problem, to make amendments to its laws, to provide effective copyright enforcement on the internet.

And in Ukraine, we are also concerned that regulatory agencies are not implementing their IP commitments and are concerned about the piracy rates being the highest in Europe.

Adequate IP is really important to us, and we look forward to working with you to continue to improve the situation and our trading partners. Thank you for the opportunity.

MR. McCOY: And thank you for your time and your participation. We very much appreciate your engagement with the process today and on an ongoing basis.

MS. PINHA: Next up, we'll hear from the International Intellectual Property Alliance.

MR. McCOY: And let me just say while you are making your way up, again you have 10 minutes. I'll interrupt you partway through to let you know

how you are doing on time. In terms of questions, there have been a couple of allusions directly or indirectly to IIPA's recommendation on Ukraine. So make sure to spend some time on that. Thank you.

MR. SCHLESINGER: Good morning, chairman. Michael Schlesinger and Eric Schwartz. We appear before you on behalf of the International Intellectual Property Alliance, a coalition of seven copyright-based trade associations, representing over 3,200 companies in the software, motion picture, music and sound recording, entertainment software, and book and journal publishing industries. We appreciate the opportunity to weigh in on the 2013 Special 301 process.

In our 2013 Special 301 Report, we document online and physical piracy of copyright materials, market access barriers, and other developments in 48 countries and territories. IIPA recommends the designation of Ukraine as a Priority Foreign Country under the Special 301 statute as a result of severe legal and copyright enforcement problems.

IIPA also recommends that seven countries remain or be placed on the Priority Watch List and that 25 countries remain or be placed on the Watch List for denial of adequate and effective IPR protection or fair and equitable market access.

IIPA further advocates solutions to address the copyright industry's initiatives and challenges for 2013. Our country and territory surveys aim to bring focused attention to the problems of piracy and market access barriers and can, with the help of all the agencies that sit on this committee, increase respect for intellectual property globally, open markets, and thereby generate real economic growth and jobs. We also take note of important progress made in certain countries in our report.

Special 301 remains an important trade tool to identify countries wanting attention for lax copyright protection or for maintaining onerous market access barriers. The notorious markets process has also been very helpful in identifying specific piracy markets, both online and physical.

Special 301 also fosters a sound approach to setting IP policy objectives for the year to protect our nation's creative industries to the benefit of creators and consumers worldwide, to boost U.S. exports, create good high wage U.S. jobs, and contribute to U.S. economic growth. The U.S. core copyright industries remain important drivers of the U.S. economy, contributing 6.4 percent to the U.S. economy, over 5 million workers, and $134 billion annually in revenue from foreign sales and exports.

While these statistics amply demonstrate the contribution of copyright-based industries to the economy, they do not reveal the massive costs imposed by overseas piracy and market access barriers to U.S. copyrighted products and services. Content industries are forced to face unfair competition from those who engage in piracy as a high profit, low risk enterprise.

Today, legitimate businesses built on copyright are facing increased threats as they must compete with the massive proliferation of illegal services unencumbered by costs associated with

either producing copyrighted works or obtaining rights to use them. Independent studies estimate the value of digitally pirated music, movies, and software in the tens of billions of dollars.

In many countries in the IIPA submission, rampant piracy not only impedes the evolution of legitimate channels for distribution, but also threatens to damage permanently or displace existing or authorized distribution channels which are unable to compete with infringing business models.

Some of the cross-cutting initiatives and challenges summarize actions that governments must execute to reduce copyright piracy, open markets to legitimate U.S. copyright exports, and ensure that adequate legal structures are in place to address piracy in all its forms and lower piracy levels. And these are basically providing adequate laws and to turn enforcement responses to copyright piracy in all its forms, which are laid out in more detail in our report, but also ensuring full implementation of our trade agreements and dismantling market access barriers.

We urge the U.S. Government to use all its tools to uphold U.S. trade laws to achieve these initiatives and meet these challenges. And we thank all of those in the U.S. Government who work steadfastly throughout the year to ensure that our trading partners respect U.S. intellectual property and open their markets to our products and services.

We look forward to our continued work with USTR and other U.S. agencies on meeting the goals identified in the IIPA submission. My colleague, Eric Schwartz, would now like to say a few words about Ukraine before we take your questions on issues or countries that are mentioned in our report.

MR. McCOY: Sir, you have about 4 1/2 minutes left. Go ahead.

MR. SCHWARTZ: Thank you.

MR. McCOY: Sorry, you have about 5 1/2 minutes left.

MR. SCHWARTZ: Even better. Thank you. I will, as my colleague Mr. Schlesinger said, focus on the Ukraine and try to respond to some of the issues

both raised in our filing, in the written submission by the Government of Ukraine, and some in the question and answer this morning.

It has been seven years since the IIPA last recommended any country be designated for a Priority Foreign Country. We recognize this is a very serious recommendation, and we recognize the serious consequences, and made our recommendations only after consideration of those consequences. But we think that both the designation as a Priority Foreign Country and the withdrawal or suspension of GSP benefits is warranted in Ukraine for a number of reasons.

First, exceedingly high piracy rates, both digital and hard copy piracy. We note that there is the Petrovka Market in Kiev, for example, is on the Notorious Markets designated list in December of 2012.

Second, there has been little meaningful engagement between rights holders and the Government of Ukraine both on enforcement actions and on transparency as the legislative reforms Bill 6523,

and now in the new section, same bill renumbered 0902. There are a number of notorious websites hosted in Ukraine, served by Ukraine ISPs that export piracy, and there has been little effective enforcement. We note as one example the Ex.ua case of a service that was taken down for only a few days. It is back in full operation. The equipment was returned to the operators. No criminal charges have been filed against the operators of that service.

I would also note surprisingly that in the written testimony by the government, there was no mention of the 2010 action plan. It was mentioned this morning by my colleagues from the Government of Ukraine in their opening remarks, but no details given about the implementation of that plan, which was supposed to focus, as you all well know, principally and primarily on internet enforcement.

With regard to software legalization, the government has mentioned the budgeting of U.S. dollars, approximately $12.3 million. There are several points on that. One is the question of

whether those monies will actually stay in the budget when the budget is revised in the first quarter of this year. Two is whether those monies will actually ever be spent. And this is to implement a 2003, now 10-year-old, regulation and pledge to implement the legalization in government ministries which the Government of Ukraine has acknowledged in several key ministries.

It is estimated, by the way, that the 10 to 20 percent figure that the $12 million might address is actually high. It is estimated that to fix the problem would probably require spending in excess of $200 million. As well, the government mentioned that there is a 40 percent piracy rate in government ministries, which is itself very high. But from best I can tell, I believe what they have done is written off older PCs and software, so they wrote off about 20 percent of the software and computers in government agencies to come up with that statistic.

On the collective administration issues, we would just, to repeat a longstanding dispute, it

is unfortunate that this has been such a long and arduous process to properly accredit the legal collecting rights societies and to allow the unauthorized societies to continue and to effectively legitimize piracy.

One thing of note, in the written testimony by the Government of Ukraine, ULASP, the one non-licensed rogue society, mentioned the licenses that they have, for example, from Universal Music. And we are in receipt of a letter dated January 30th, which was received by SIPSU, so before their testimony was prepared, that notes Universal Music gave no rights to this collecting society.

I would just say that -- oh, one other point, excuse me, from this morning. On the notion of illegal camcording, it is I received information this morning just to confirm that there have been 22 forensically matched audio takes of motion pictures in Ukraine in 2012, and there was one camcorded entire movie from a multiplex in Donetsk.

MR. McCOY: Sir, your 10 minutes is up, so if I could ask you to wrap up.

MR. SCHWARTZ: Yeah. I just wanted to respond to some of the issues that were raised this morning and just to say that there is not adequate and effective protection and enforcement in Ukraine. And we think that they are undeserving of the GSP benefits.

It is a safe haven for criminal syndicates. These activities are not, as the government observes, spontaneous activities but very well-organized activities. And that we do believe that it is proper to both designate them as a Priority Foreign Country and to withdraw their benefits. And be happy to answer any questions that you have on any of the 40-plus countries that we filed on.

MR. McCOY: Thanks very much. We are in receipt of your submission, and so we won't dwell on the additional countries. Appreciate your detailed response to our question about Ukraine. And you give me an opportunity to advertise by mentioning various new facts, that we are open for post-hearing submissions whether from you or from any other

participant in terms of supplementing the record based on what you have heard today or things you feel need to be responded to. So that opportunity does exist, and I will mention the details again at the end. So thank you very much for your participation and your time today.

MR. SCHLESINGER: Thank you very much.

MS. PINHA: Next up, we'll hear from Public Citizen.

MR. McCOY: So welcome. Thanks for being here today. The floor is yours for 10 minutes. And I'll let you know how you are doing on time and if there are any questions partway through.

MR. MAYBARDUK: Thank you, Stan. It's good to see some familiar faces here today. Thanks everyone for this chance to testify.

Public Citizen is a nonprofit consumer advocacy organization based here in the nation's capital. We have 300,000 members and supporters and a 40-year history of working for the public interest in a variety of fields, consumer interest litigation, trade agreements, pharmaceutical safety

and efficacy. I am the Director of our Global Access to Medicines program. For the past six years, I have provided technical assistance primarily to developing countries, but really public agencies, as well as civil society groups around the world that are interested in using the TRIPS flexibilities to promote access to medicines for all, among other issues. And we can have conversations about anti-counterfeiting policy the next time that comes up at your agencies as well.

In this capacity, and, well, some of you will remember that in past years I presented extensively on Ecuador's compulsory licensing protocol and gone over the individual elements of it and how we advised them on implementing a TRIPS-compliant policy, and so on.

And in this capacity, doing this work with developing countries has occasionally been quite frustrating for me to come up against U.S. trade policy seeking to place obstacles in the path of countries' rights. In the case of Ecuador, there were WikiLeaks cables showing that U.S. Embassy

personnel worked to organize OECD countries against that TRIPS-compliant policy. So part of what we'd urge is to, you know, for this not to be a TRIPS-plus process, not be putting impediments in the way of countries' rights to promote public health.

So I note in the -- I have prepared some largely informal comments. Page 19 of the Special 301 Report from last year, I believe the standard language that's being used for the 301 Reports is to the effect that the United States respects the rights of trading partners to issue compulsory licenses and support these health rights that countries sometimes exercise.

And this is a very, it is a very important guarantee. These rights are an essential part of the intellectual property system. They do not derogate IP rights. They do not take away from IP rights in any fashion. They are part and parcel of the system. They are part of the essential balance ensuring that public interests are met, access to medicines among other national interests can be met. So I'd urge you not to see these -- I'd urge you to

live up to that guarantee and not see the exercise of TRIPS-compliance compulsory licensing as anything that should be noted in the 301 List or that in anyway takes away from intellectual property rights of the intellectual property system.

Now, the problem with the guarantee as listed is that every recent use of compulsory licensing for pharmaceuticals as has been listed in the 301 Report has been criticized in some fashion. And even after taking a series of meetings, inner-agency meetings to talk about Ecuador's licensing protocol before the first license was issued, I was then quite disappointed to see that Ecuador is nevertheless listed for issuance of its first license and under language that was to the effect that USTR would continue to monitor activity in this area. But that itself can be quite detrimental to a public health policy of that sort and was quite disappointing.

So essentially what I'd like to do is offer an opportunity to USTR and to the other agencies here to demonstrate that this expressed

guarantee in the report is meaningful. It is not, these are not simply words, but that there are compulsory licenses that can be issued, that a TRIPS-compliant compulsory license will not be mentioned in the 301 Report, will not be subject to this form of light sanction.

I think TRIPS compliance would be a pretty good standard for this. And I'd like to say that we are always available to discuss any concerns that anyone on this panel might have regarding whether a particular license in a particular country is TRIPS-compliant or not, because if all compulsory licenses are listed, I guess how can we give that guarantee credence? How can we assure ourselves that the U.S. Government is living up to the health commitments that it has made and that trade policy does not need to conflict with health policy.

For those of us who work in the health policy field, it really does seem to be a zero sum game that if a country exercises its rights, it will be listed in spite of that language on Page 19, and that's all there is to it. So we would really like

to see some evidence to the contrary. I think it would help restore some faith that this is not a biased process.

Three countries this year, at least by my count, have issued compulsory licenses for pharmaceuticals. In every case, it has been exceptionally important to the health interest of those countries. I'll make a few quick comments on those countries and licenses.

MR. McCOY: Can I just say before you go on that you have five minutes left. And, second, on Ecuador, can you just identify if there is specific language about Ecuador in the 2012 Special 301 Report that you have a concern with?

MR. MAYBARDUK: I think this goes back to 2011, because the last license was issued in 2010. So I'll have to --

MR. McCOY: The language you have a concern with is saying that we are monitoring?

MR. MAYBARDUK: Yes. It is any mention of licenses at all, because that functions, I mean we're all familiar with diplomatic speak. That

functions as a light sanction, and we see it as detrimental. So we'd like to see that sort of language omitted in the future.

But so three countries this year. Ecuador issued a license for HIV medicines called abacavir plus lamivudine. Second-line HIV/AIDS treatment follow the same protocol that we have outlined before. I'd be very happy to go through the details at a later date, if there is a need. This is a license destined for public non-commercial use.

Indonesia issued seven licenses, well, its government, making government use essentially the patents for seven licenses for HIV/AIDS, as well as Hepatitis B. And it is very -- this is very -- to the licenses from Indonesia. It's a difference between being able to provide standard of care HIV/AIDS treatment to their population or not.

This is a very large country, relatively low GDP. And they have largely had to rely on older drugs. They are not up to date in the treatment regimes. They are not able to provide adequate treatment to people who have developed resistance.

And this policy could really make the difference in that particular area. We have a policy brief on that could provide, talk more about the medical need for it.

I noticed in one of the, in the submission to the 301 process this year from one of the organizations here today, there was a reference to an Article 31(a) concern under TRIPS. This was not licensing on a case-by-case basis but rather as a group. There is not a guarantee in TRIPS for case-by-case basis licensing, but the language refers to authorization on its individual merits.

These are seven licenses issued on their individual merits. The mere fact that they were included in a single order does not mean that each license is not individually justified by the medical need or considered on its merits. In fact, we know that the Ministry of Health and other agencies there, in their inter-agency process, were considering what are the licenses that are truly going to benefit us in this case and so on. So we don't see any Article 31(a) problem, though we're

happy to follow up on that in more technical detail after the fact.

MR. McCOY: I think we would welcome that. There is some lack of clarity around what exactly is going on. So if you have more details and want to make them part of a post-hearing submission, you are more than welcome to do that.

MR. MAYBARDUK: We'd be happy to do that. Generally, what would really help us is having some sense of what are the particular, again, TRIPS compliance issues that are being considered in your inter-agency process. I mean we don't, you know we're just going to disagree about meeting TRIPS-plus standards.

But if it is an actual question about meeting the requirements in TRIPS and in Article 31 in these cases, I'd be very happy to answer particular questions. Sometimes it's a little difficult for us to try and spend a lot of time. We are pretty low resource organizations anticipating your concerns, and we see a bit of a process problem to simply replying to the concerns of industry

groups.

So I have given you my card. It would be very helpful if you have particular concerns to just ring me up as you are going through this consideration. We could talk about it. Happy to provide a brief on any particular issues.

Finally, India, and I am not in the weeds on the India case the way -- there are great many people paying attention, of course, to that compulsory licensing case. And I don't want to comment extensively on it because I have not been one of the participants. But sorefinib license for liver and kidney cancer quite important because only two percent of patients, as I understand it, needing that drug are getting it. The price has been very expensive.

There are tremendous price reductions promised. There are several criteria available under the Indian Patents Act, Section 84, for compulsory licensing. I know that some concerns have been raised about at least one of those grounds, and that's being litigated. But I really,

you know, I'd note that any one of the grounds would, any one of the grounds in which a license was issued would satisfy Indian law. Moreover, simply the price and reasonable affordability ground works with the TRIPS requirement, which ought to be the concern of this panel. So in the case of these three licenses, I don't really see -- or these three sets of licenses, I don't really see a 301 issue.

And, again, I would like to just offer that opportunity to say we'd like to see compulsory licensing on its TRIPS-compliant omitted or otherwise very specific TRIPS concern being noted so countries know what they can do about it and know how to remedy a process. These are part of the intellectual property system. They are a part of countries' essential rights. And it would really help us, I think, in our interactions with the U.S. Government to know that the words of these rights are respected, have some meaning, and have some practical consequence in the world.

MR. McCOY: Okay. Well, thanks very much for your participation today and your time. Your 10

minutes has elapsed, but we are grateful for your engagement in the process, and I reiterate, as I have with others, the opportunity to make a post-hearing submission to follow up on any details.

MR. MAYBARDUK: Thank you.

MS. PINHA: Great. Next up, we are going to hear from Knowledge Ecology International.

MR. McCOY: Welcome, and thank you for your engagement with the process. The floor is yours for 10 minutes. And I'll let you know how you are doing on time partway through.

MS. COX: Okay, thank you. Good afternoon. My name is Krista Cox, and I work as an attorney for Knowledge Ecology International, KEI, a nonprofit, nongovernmental organization that searches for better outcomes, including new solutions to the management of knowledge resources, particularly in the context of social justice.

From the outset, I'd like to say that we are very happy to see a representative from the Department of Health and Human Services this year. We noticed your absence last year, and we are very

glad to have you.

We offer the following comments on the 2013 Special 301 Review. First, we have deep concerns regarding least developed countries. I would like to follow up on some comments that were made by my colleague from Health GAP.

We suggest that any requirements or pressure for least developed countries to implement TRIPS standards should not be placed. And we, therefore, strongly urge the United States to support the grant of an extension of the transition period under Article 66.1 of the TRIPS Agreement for least developed countries.

The currently extension period for least developed countries runs through July 1, 2013. And Haiti, a least developed country, in fact the only least developed country in the Western Hemisphere, requested an extension of this period. And we ask that the United States support Haiti's request in granting extension to all least developed countries.

In granting such an extension, no conditions should be placed on least developed

countries. And we strongly support Health GAP's statement that these countries should not be forced to implement TRIPS standards until they are no longer least developed countries.

In its 2012 Special 301 Report, the USTR noted, quote, "In December 2011, WTO Ministers decided to invite the TRIPS Council to give full consideration to a duly motivated request from LDC members for an extension of the TRIPS Agreement transition period. The U.S. supports this decision and looks forward to continuing to work with LDCs and other WTO members in this regard," end quote.

We call on the United States to fulfill its support for least developed countries and work to grant the requested extension. As we just heard from my colleague from Public Citizen a moment ago, we would really like to see USTR give meaning to the words that it puts into its Special 301 Reports.

Should WTO members fail to approve an extension, we request that the United States exempt least developed countries from any scrutiny under the Special 301 process in the future. And USTR

should not -- I'm sorry, USTR should continue to recognize the particular challenges faced by least developed countries and not place them on the Special 301 List.

Aside from the extension for LDCs, we urge USTR to recognize the number of flexibilities preserved in the TRIPS Agreement. And such flexibilities cover a wide range of areas, including for example compulsory licenses. Again, we just heard from my colleague from Public Citizen -- some of them, and we object to the practice of USTR of placing countries on its Special 301 Watch List for issuing or threatening to issue a compulsory license.

Although the United States claims to support the sovereign right of states to grant these licenses, USTR has repeatedly placed countries on its Watch List for exercising this right, including over the years Ecuador, Thailand, and India.

We note, for example, our concern over last year's report, which singled out India's compulsory license for the patents on Nexavar or

sorafenib, a community cancer drug that was priced at $68,000 per year in India, a price that is well beyond the reach of the vast majority of patients in the country. This number is 41 times the projected average per capita income in India, which in 2010 was $1,330 a year.

Placing countries on the Special 301 List for granting compulsory licenses appears to me to be hypocritical. Consider the known practice in the United States of granting judicial compulsory licenses after the Supreme Court held in the case *eBay v. MercExchange* in 2007 that injunctions are not automatically granted in all cases of IP infringement. Where the United States commonly grants judicial compulsory licenses, it seeks to limit the rights of others to exercise its flexibility.

And with respect to access to medicines, pressuring states not to grant compulsory licenses can severely and detrimentally impact the public health of its citizens, particularly when medicines are priced grossly out of reach of the majority of

its population. We believe that the India compulsory license is fully TRIPS-compliant. And we have been actually involved in that case. We have several briefs available on our website showing that those licenses are fully TRIPS-compliant.

In last year's Special 301 Report, several countries were cited for issues relating to the linkage of drug registration and patent status. Patent linkage is a controversial concept which is considered inappropriate in many contexts, including in high-income countries such as those in Europe, in part because of the extensive evidence of abuse such as where weak or non-germane patents are asserted in the linkage process.

We note that the May 10, 2007 agreement made regulatory patent linkage optional rather than mandatory, which we believe is a superior alternative to what the United States has proposed in the leaked text for the currently negotiated Trans-Pacific Partnership Agreement. And the United States should not retreat from its May 10th deal and should not place countries on the Special 301 Watch

List for choosing not to implement the system of patent linkage. In addition, we object to --

MR. McCOY: You have about five minutes left. Can I ask you a question on India?

MS. COX: Please.

MR. McCOY: So flip through the report to find the statement on India that you've cited as a concern. I think the one you may be referring to is the sentence on Page 35 of the report last year that says the United States will closely monitor developments concerning compulsory licensing of patents in India following the broad interpretation of Indian law in a recent decision by the Controller General of Patents while also bearing in mind the Doha Declaration on TRIPS and public health found in the intellectual property and health policy section of this report. That's the statement that gives you concern for KEI?

MS. COX: Yes, it does.

MR. McCOY: Can you elaborate on what that concern is?

MS. COX: Sure. I think my concerns echo

on the concerns that Peter from Public Citizen mentioned, that the fact that you are mentioning these compulsory licenses in the context of the Special 301 Report, you are putting these countries on the list to monitor them. And expressing these concerns, notwithstanding the reference to the Doha Declaration, seems to suggest that there is something wrong with the compulsory license, that you need to monitor it, that you feel like perhaps it is either not TRIPS-compliant or not appropriate for them to grant these licenses.

We understand that in other fora, the United States has raised some concerns about compulsory licensing of non-HIV/AIDS, malaria, and TB drugs. There seems to be sometimes a little bit of discussion or confusion over whether that is appropriate. We note that both the Doha Declaration and the TRIPS Agreement reserve the right to issue compulsory licenses, and states have the right to grant compulsory licenses and to determine the grounds upon which those licenses are granted. It does not require it be limited to a specific set of

diseases, nor does it require an actual emergency or public health emergency.

If I may continue my comments on exclusive rights over test data, we echo some of the comments made by Health GAP, and we also object to the unilateral pressure placed on states to adopt TRIPS-plus measures. We note that exclusive rights in the test data are designed to delay entry of generic medicines into the market. And they require the investment of unnecessary, unethical clinical trials. Exclusive rights are not required under TRIPS, and international standards require only protection over such data and not exclusive rights.

Other more efficient and ethical models exist, such as cost-sharing models of protection, and they have in fact been implemented for test data over agricultural products. Pressuring countries into adopting data exclusive models treads on the policy's base reserve to determine the best methods for protecting such regulatory test data.

I just want to turn now to a couple of copyright issues that concern us. We note first

that technological protection measures, known as TPMs, are not required by the TRIPS Agreement. And those standards that the United States often pushes for with respect to TPMs where countries have adopted the WIPO Internet Treaties, that is the WCT and WPPT, go well beyond the requirements of international law.

The WIPO Internet Treaties require the protection of TPMs only in connection with exercise of rights protected by copyright law. And U.S. efforts to adopt circumvention of a TPM as a separate, independent cause of action, such as is included in the leaked proposal for the TPPA, go well beyond these international requirements. The Special 301 Report cited several TPP negotiating partners, including Brunei, Chile, Mexico, and Vietnam, as not implementing adequate measures to protect TPMs.

And we note that there are a number of ways that a state can implement its obligations under the WCT and WPPT, if it has acceded to and ratified these treaties, and the U.S. model can be

an inefficient and unfair system that should not be pushed on other countries.

The TPPA proposal is a controversial one, even within the United States. The U.S. Court of Appeals for the federal circuit has considered that making the circumvention of a TPM a separate and independent cause of action apart from copyright infringement to be an absurd result.

The United States should not pressure countries to strengthen their own anti-circumvention measures or adopt standards that are not uniformly applied within our own country.

Similarly, the United States notice and takedown procedure under the DMCA has been heavily criticized and should not be exported to other countries, either through the inclusion in free trade agreements or the pressure by USTR in the Special 301 process. In the United States, the notice and takedown system has been criticized because of abuses, including the negative impacts on free speech, flawed takedowns from non-infringing content, or inappropriate use targeting a business

competitor.

Notices for takedowns have increased exponentially over the last year -- Google has some interesting graphs on that -- and represent a costly and time-consuming process. Surveys of some small internet service providers reported tens of thousands of invalid or illegitimate notices.

MR. McCOY: All right, your 10 minutes are up, so if you don't mind wrapping it up.

MS. COX: Sure. Because of the expense in evaluating these notice claims, some internet service providers have stated the policy of taking down all content when receiving a notice in order to avoid any liability. And these processes are unfair.

Other models for complying with the WIPO Internet Treaties exist and may prove to be better models than the DMCA. Alternative processes such as notice and notice or procedures that require judicial oversight promote fairness and safeguard against potential abuses by right holders.

We ask that USTR question the Special 301,

what the Special 301 Report is intended to achieve and what value it provides. The 301 process unilaterally pressures countries to adopt TRIPS-plus measures which are often poor models for the domestic situations. The TRIPS-plus measures encouraged by USTR through the Special 301 process and through free trade agreements create patent and non-patent barriers, increase IP rights across both patent and copyright sectors without also ensuring proper balancing provisions, and negatively impacts public health and access to knowledge. Thank you for your time.

MR. McCOY: Thank you for participation and engagement in the process today. We appreciate that.

MS. PINHA: Last but not least, we'll hear from the Biotechnology Industry Organization, BIO.

MR. McCOY: So, welcome. We'll do this, as we have all morning, with 10 minutes, and I'll let you know how you are doing on time partway through.

MR. DAMOND: Thank you. Good afternoon.

My name is Joseph Damond. I'm Senior Vice President for International Affairs with the Biotechnology Industry Organization, or BIO. I am accompanied this afternoon by Roy Zwahlen in our legal department. Thank you for the opportunity to testify about IP problems facing the biotech industry.

BIO represents more than 1,100 companies, most of them small, most of them still in the process of developing their first product for the market. Currently, there are more than 400 biotech drugs in clinical trials, targeting more than 200 diseases. In agriculture, there are more than 13.3 million farmers around the world using ag-biotech processes in crops, grown on more than 2.3 billion acres of farmland worldwide.

In industrial and environmental biotech, we can now harness microorganisms in new and exciting ways to manufacture polymers, vitamins, enzymes, or transportation fuel, which will help us move from a petroleum-based economy to a bio-based economy. America leads the world in biosciences,

employing 1.2 million people directly, supporting another 5.7 million jobs in affiliated industries.

Most biotech companies face a difficult situation from inception, no product to sell for 10 or 15 years, high risk of failure in the development process, a dire need constantly to find new funding. For example, to develop an innovative biologic drug, a typical startup requires an average five rounds of investment funding.

Startups must entice this investment with the strength of their technology, the strength of their management, and the strength of their IP portfolio, for only two-thirds of new drugs in development are being pursued by these small firms, often in partnership with academic institutions. All of these elements are necessary to ensure success. And that's why a weak global IP situation requires the attention of the industry, the U.S. Government, patients without cures or with insufficient treatments, citizens needing a cleaner environment, and the poor who need a sustainable food supply.

BIO requests the U.S. Government and other governments, including those of course that have prioritized the development of their biotech industries, consider IP policies carefully for the impact they may have on the development of innovation systems and access to tomorrow's technological advances.

Overly restrictive limitations on patentable subject matter, departures from international norms on patentability standards, multiple and arbitrary pre and post review procedures, ineffective judicial review and enforcement, weak protection of the expensive clinical trial data required by regulatory agencies, and compulsory licenses negatively impact the complete biotech ecosystem.

These deficiencies have a particularly large impact on our companies in large emerging markets such as China, India, Brazil, Mexico, Russia, and Turkey. Ironically, many emerging markets routinely state their desire to increase their innovative capacity and dedicate significant

government resources themselves towards these efforts. Yet, we find sometimes that policy-making in these governments is less than coherent and that IP policies undermine these broader economic development goals, both impeding the incentives for innovation locally and the ability of our members to do business and partner in those countries.

The U.S. Government can help make it clear that weakening the global IP system makes it even harder and riskier than it already is to develop new projects. And most of these projects do fail already, not just in the U.S., but anywhere. Less development of these new products means that more of tomorrow's cures, fuel, and food will remain in the lab where no one will have access to them.

BIO understands many criticisms of IP in our industry are founded on the principles of public health. We apply the selfless efforts of many of these organizations that, for example, purchase their own medicines to deliver directly to the world's poor. However, an overemphasis on the supposed failures of the IP system distracts from

the real barriers and complexity of access for the poor.

Ninety-five percent of the medicines of the WHO's Essentials Medicines list are not patented. However, about a third of the world's population still doesn't have access to these essential medicines. Similar trends can be found in key developing countries. None of the drugs on India's Essential Drug List are patented. Notwithstanding that, the WHO states that the drugs on the EDL in India are affordable to only 20 percent of the Indian population.

BIO notes with interest the recently released Promoting Access to Medical Technologies and Innovations jointly released by the WTO, WIPO, and WHO. And we applaud the holistic approach to understanding relevant public health issues, discussing non-IP barriers to public health, which include inadequate regulatory systems, trade barriers, and taxes.

And I note that all of these countries that were mentioned, or most of them, despite their

interest in supposedly providing cheaper drugs and medicines, have extremely high tariff barriers at the border and very high taxes internally, which just makes them much more expensive for patients. It seems inconsistent with a policy of -- with access policies internally. I believe the U.S. Government has made very little success in dealing with any of these trade barriers that they unilaterally impose on their own patients in trade negotiations.

MR. McCOY: Just to say you have about 4½ minutes left, and I would encourage you to move to some of the specific country issues that you'd like to highlight.

MR. DAMOND: Okay. I do want to focus on some broad issues. I want to say that it is worth noting that -- I was referring to the Joint Report just issued. It is worth noting that if the U.S. had been better consulted, incorrect and mainly misleading claims such that the U.S. itself, it widely issues compulsory license, could have been corrected prior to its publication. We understand

that those claims which are incorrect are being looked at by those organizations.

The broad point I want to make this afternoon is that there is a broad global consensus that the sources of inadequate access to medicines are numerous and complex. In our view, a careful study of the work that has been done on the issues shows clearly that the IP issues are not even near the heart of the problem.

Moreover, proposed solutions that focus on weakening IP have a consequence of undermining incentives for drug development and innovation. While there are other solutions which would not have this impact, indeed, putting the burden of paying for medicines on the very industry that is trying to develop them seems quite wrongheaded.

Our industry stands ready to find ways for improving access to medicines and ways to keep this country's second-to-none engine of biotech innovations sustainable and flourishing. And for those reasons, we ask that USTR carefully consider the priorities enumerated in our submission. Not

only do the jobs of hundreds of thousands of Americans hinge on impact or improvement of global IP, but to do so, so do the needs of patients and families globally.

I make one more point from the trade policy perspective, and that is that the ultimate sanction in a lot of these cases presumably would be a loss of GSP benefits for countries if they were designated a Priority Foreign Country, very serious offender. Even that step, keep in mind GSP itself is a WTO-plus treatment. Nothing in the WTO requires the United States Government to grant GSP to any beneficiary. It is in fact greater than the benefits that we granted to countries who are fully compliant with the WTO benefits.

I just mention this because the other options that are listed by USTR fall short of considering denying a country their GSP benefits, which is in itself a WTO-plus treatment. That might be a useful comment in the context of some of the other statements that were made about TRIPS compliance.

The final point I would just make about compulsory licensing, since so much was spoken about it today, is that without getting too much into the technical details, it seems to us that the consequences of what some of us advocated this morning is that there is no recognition of any effective limits, wherever, whenever, on a compulsory license on any product whatsoever. That means there is no guarantee of any intellectual property rights because the state can define what it grants a compulsory licensing on in an arbitrary manner.

Secondly, countries have significant resources to deal with health issues if they so wish. I'm not going to go into detail, but let me just note that several -- most of the countries on the list spend multiples of the amount that they spend on health on their defense, on their national defense systems. In effect, the U.S. industry is being asked to subsidize that because the states themselves do not place a high enough priority on health. These are the public policy questions in

the context that this has to be viewed.

And, finally, this is one sector in which the U.S. still leads the world. And given the global opportunities to expand and grow that, and working with foreign countries, most of whom want to partner with the U.S. biotech industry if given the chance, there are, as I said, close to 2 million jobs directly in the U.S., and we have an opportunity to expand that.

In the absence of that, what you are going to see is jobs being exported to these countries. And I am not sure that that is the proper focus of U.S. trade policy. Thank you.

MR. McCOY: Thanks very much, appreciate your engagement today. You are right at 10 minutes, so I'll just say thanks very much for your participation and engagement and for the participation and engagement of everyone who has been involved in the process today.

I wanted to reiterate the opportunity for post-hearing comments. Post-hearing comments are optional and may be submitted until 5:00 p.m. on

February 27th, 2013. Post-hearing materials should be sent electronically via www.regulations.gov, Docket Number USTR-2012-0022. Submissions should contain the term 2013 Special 301 Review in the type comment field on www.regulations.gov.

If there is nothing further to add on the part of any of the other committee members, I will thank them for their significant investment of time not only in doing this for one morning and into the afternoon, but in doing many, many other inter-agency meetings in order to complete this rather arduous process. So thank you to all of you. Thank you to all of you for your participation in and engagement with the process, which we very much appreciate. And we are adjourned.

(Whereupon, at 1:00 p.m., the meeting was adjourned.)

C E R T I F I C A T E

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

SPECIAL 301 REVIEW PUBLIC HEARING

February 20, 2013

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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ED SCHWEITZER

Official Reporter