BEFORE THE
OFFICE OF THE U.S. TRADE REPRESENTATIVE

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SPECIAL 301 SUBCOMMITTEE
+ + + + +
SPECIAL 301 REVIEW
PUBLIC HEARING

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WEDNESDAY, MARCH 2, 2011
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The hearing convened at 10:00 a.m. in Rooms 1 and 2 of the Office of the U.S. Trade Representative, located at 1724 F Street, N.W., Washington, D.C., Stanford McCoy, presiding.

PANEL MEMBERS PRESENT:

OFFICE OF THE U.S. TRADE REPRESENTATIVE:

PAULA PINHA, Chair
STANFORD McCOY

U.S. DEPARTMENT OF COMMERCE:
SUSAN WILSON

U.S. CUSTOMS AND BORDER PROTECTION:

THERESA RANDAZZO

U.S. DEPARTMENT OF HOMELAND SECURITY:
LAURIE WEEKS

U.S. DEPARTMENT OF LABOR:
MAUREEN PETTIS

U.S. DEPARTMENT OF STATE:
DAVID DRINKARD

PANEL MEMBERS PRESENT: (Continued)
U.S. DEPARTMENT OF THE TREASURY:
WON CHANG

U.S. COPYRIGHT OFFICE:
MICHELLE WOODS

U.S. PATENT AND TRADEMARK OFFICE:
MINNA MOEZIE

WITNESSES:

JITTIMA SRITHAPORN, Government of Thailand, Office of Commercial Affairs, Royal Thai Embassy
KAJIT SUKHUM, Government of Thailand, Department of Intellectual Property, Minister of Commerce
DANIEL KOSTOVAL, Government of Czech Republic, Embassy of the Czech Republic
JOSEPH DVORACEK, Government of Czech Republic, Embassy of the Czech Republic
FABRIZIO MAZZA, Government of Italy, Ministry of Foreign Affairs
SALVADOR BEHAR, Legal Counsel for International Trade, Government of Mexico
SEAN FLYNN, Global Health Organization
JON GELFAND, BeachBody LLC
JAY TAYLOR, Pharmaceutical Research and Manufacturers of America (PhRMA)
RASHMI RANGNATH, Public Knowledge
JAMES LOVE, Knowledge Ecology International

JUDY DREOS (phonetic), Doctors Without Borders
JOE KARAGANIS, Social Science Research Council
ROHIT MALPANI, Oxfam America
BRENDAN HUDSON, Balanced IPR Organization
MICHAEL SCHLESINGER, International Intellectual Property Alliance (IIPA)
PETER MAYBARDUK, Public Citizen

MICHAEL MELLIS, MLB Advanced Media, L.P.

HEARING SCHEDULE

HEARING SCHEDULE (Continued)

P R O C E E D I N G S

(10:02 a.m.)

MR. McCOY: Well, thanks, everyone, for coming. I want to welcome you today to the 2011 Special 301 Review Public Hearing. And, thanks, everyone, for coming.

If there is anyone who doesn't have a seat, we are looking for some more chairs.

Let me just -- let me just mention a few -- a few remarks to get us started here. This is the Second Annual Public Hearing on the Special 301 Process, and we appreciate all of your participation in that process.

We now have all of the interested party and foreign government comments submitted for this year's review, and we are also considering information that we will receive at this hearing, and we will consider any information we receive from all of you as posthearing submissions.

Let me just say, for those of you

who may be less familiar with this process, a couple of words about who the people are at this table and what we have to do.

This body is the Special 301 Subcommittee. It is a subcommittee of the Trade Policy Staff Committee, which is the primary interagency trade policy staff formulation body inside the U.S. Administration.

The Trade Policy Staff Committee delegates to the subcommittee the process of developing recommendations for the Annual Special 301 Review. Those recommendations are fleshed out in the subcommittee and then they are reported up to the full Trade Policy Staff Committee for review and approval.

What we are here to do today is carry out the statutory mandate provided by Congress more than 20 years ago in the Omnibus Trade Act of 1988.

If you would like a description of that statutory mandate and the process by

which it is carried out, you can find that on page 47 of the 2010 Special 301 Report.

I want to say a word about one change -- or, two changes, in fact, in this year's Special 301 Report, compared to the 2010 Report.

First, in the 2010 report you -- there was, on pages 43 through 45 of the report, a section on notorious markets.

As some of you may have noticed, we are now publishing that section separately through the -- through the procedure of an out-of-cycle review under the Special 301 Process.

That new approach was announced in the Intellectual Property Enforcement Coordinator's Joint Strategic Plan for IP Enforcement administration wide.

That Notorious Markets Review is now out. It is -- we don't plan to repeat that review for purposes of the annual process. So, to the extent that you were

planning to comment on a Notorious Markets list to be included in the annual report, I want to make you aware that it is not our plan to do that.

It is our plan to continue doing the Notorious Markets List out of cycle. So, that will be a new opportunity for comment before any new Notorious Markets List is issued in an out-of-cycle review.

The second change I wanted to mention as compared to the Special 301 Review last year is that -- also pursuant to the Joint Strategic Plan, issued by the Intellectual Property Enforcement Coordinator's Office, USTR will use the 2011 Special 301 Report to highlight best practices by our trading partners in the area of IP protection and enforcements.

So, to the extent that -- to the extent that any of you would like to mention, either in your remarks today or in posthearing submissions, particular practices that you

consider to be best practices and that you would like the subcommittee to consider in that regard, we would be very happy to have that information.

If I can now just say a word about how we will proceed today, the -- the hearing is going to proceed with ten-minute increments for each witness.

Last year we interrupted people after five minutes and asked them some questions. We had some feedback that some people found that a rather stilted process. I think what we will do this time is, as you come to the table, I will mention to you what some of the questions were that members of the subcommittee had as they looked at your comments.

You can choose to address those questions during your ten minutes. You can choose to address them in posthearing submissions. You can choose not to address them at all, but we will leave you the

flexibility to use your ten-minute window to talk with us how you want.

If there is a question that arises from the members of the Subcommittee while you are talking, I'll just -- I'll just raise my hand and indicate to you that I'd like to -- I'd like ask you a question.

But, other than that, if you'll just do us the courtesy of doing your best to address our questions, either directly or in your posthearing submissions.

We will be open for posthearing submissions in accordance with the procedures that have been made available, and I don't know if you want to say a word about that, Paula, do we have that covered in our --

Yes. So, in the schedule you have a word about posthearing comments. Let me just say there has been one -- that there has been one change to the schedule that was posted on the internet.

The 11:50 slot for Social Science

Research Council and the 1:20 slot for Public Knowledge, have been reversed. So, Public Knowledge will be going at 11:50 and Social Science Research Council at 1:30.

So, with that, let me just say one quick word about -- about the sorts of general questions we have. One general question that we have for everyone is on best practices.

I have mentioned that already. If you would like to highlight any positive practices you think the Subcommittee should mention, please do that.

And then another -- another general question we have for everyone is -- is basically a reminder to you that we are here to fulfill a mandate from Congress to identify countries that deny adequate and effective intellectual property protection, or deny fair and equitable market access to U.S. person who rely on that protection.

So, we are really very interested in country-specific issues that you feel we

should consider or additional sources of information about specific countries that we should review.

Now, our first several witnesses are going to solve this problem for us because they are representatives of governments and they are going to speak to the situation in their particular countries, and we are grateful for that.

A number of other witnesses later in the day have submitted sort of hearing statements that don't speak in any detail to specific countries. And I will just ask everyone to help this Subcommittee as much as you can with their work by speaking to the mandate from Congress that we have to carry out to make country-by-country assessments.

So that is it for my introduction. They will get an extra chair pulled up at the table here and we will begin the day today by welcoming our government witnesses.

We are grateful, again, for the

participation of several of our valued trading partners in this process. We will have -- the government witnesses will be from the government of the Czech Republic, the government of Thailand, the government of Italy and the government of Mexico.

So, let me just begin the day by inviting the representatives of the government of the Czech Republic to come forward. That is Mr. Kostoval and Mr. Dvoracek.

PARTICIPANT: I think they are in security.

MR. McCOY: Are they? All right. Well, we will just -- we will just invite them to go next.

Are the representatives of the government of Thailand ready to go?

Yes. So the government of Thailand, Dr. Kajit Sukhum and Jittima Srithaporn, please, by all means, come forward and you can start us off today.

Let me say, as you are taking your

seats, that we did take a look at your submission and we are grateful -- we are grateful for that submission.

We were interested in the information you provided about the technology crime suppression division and we received some indications from other -- from other submitters in this process that there are issues surrounding the level of resources that are available to the technology crime suppression division, so we'd be interested in hearing, in particular, about what kinds of resource planning you have going on for your online enforcement efforts.

We are also interested in the positive cooperation that is being developed between public and private sectors, particularly pursuant to the MOU that you mentioned being prepared in September 2010.

So we would be interested in hearing more about how that is being implemented and the types of cooperation that

are developing.

We noted that at least one submitter reported a rise in counterfeit pharmaceuticals in Thailand. So, we are interested in that issue.

And then, we have a continuing interest as we have discussed in the context of the out-of-cycle review and the progress of pending legislation that we know is described to some extent in the submission you made.

So, to the extent that you can speak to those issues, we are grateful for that. Please.

And, may I just say before you begin, that we will -- that Paula is keeping the time and we will indicate when the ten minutes is expired.

MR. SUKHUM: Thank you very much. Good morning, all the panelists. I noted that you have a very wholesome representative of the U.S. Government at the table.

My name is Kajit Sukhum, and an

assistant director general of the Department of Intellectual Property, Ministry of Commerce of Thailand.

I would probably choose to address those questions -- some of them will be during my statement. The others we will submit posthearing replies. Okay.

Now, Mr. Chair, can I ask you the second queries that you mentioned. One was on the resource plan on tech crime.

MR. McCOY: Yes.

MR. SUKHUM: The other is the corporation with the pharmaceutical representatives.

The second one that you mentioned, what was it? I'm sorry. I was --

MR. McCOY: I think the three things I had asked about were on the technology crime suppression on online enforcement, and then second, the public/private cooperation MOU's and so on for including pharmaceutical counterfeiting --

MR. SUKHUM: Right.

MR. McCOY: -- and then, third, the pending legislation.

MR. SUKHUM: Okay. Well, thank you very much. All the three points will be quite apparent after my deliveries of the statement.

Well, I wish to thank the Special 301 Committee for the opportunity to appear before it to present the comment of the Royal Thai Government.

Today, I address before you that compared to 2007, when Thailand was placed on the Priority Watch List, Thailand has demonstrated a commitment to strengthening its intellectual property rights regime.

It has taken substantial and comprehensive steps over its IPR protection enforcement in respond to the concern of the U.S. Government and private sector, and has made significant progress in many dimensions, given that Thailand should be removed from the

Special 301 Priority Watch List for the following reasons:

First, there has been an unyielding political will to elevate intellectual property protection as a national agenda. The National Committee on IP policy has been established and is chaired by the prime minister, in which two subcommittees were set up.

The Subcommittees on Prevention and Suppression of IPR violation chaired by the Deputy Minister of Commerce, Mr. Alongkorn Ponlaboot, and the Subcommittee on IP Policy on Medicine and Pharmaceutical Products, chaired by the Minister of Public Health.

Above and beyond that, in order to educate the public of the value of IPR and its use for protection, the Thai Government has marshaled the creative economy policy to make Thailand a hub of knowledge-based society by the year 2012, aiming to have one-fifth of our GDP in creative sectors.

Second, concrete results have been achieved through strengthened law enforcement and suppression efforts with increased focus on the suppression of IPR violation at all levels, particular focus on major infringement, factories, wholesalers and red-zone areas.

In 2010, a total of 5,610 arrest case occurred, of which 89 were major cases with more than 3.1 million pieces of infringed goods seized.

Large scale infringer was a successful target -- successfully targeted in rates. The average confiscated items per case have grown higher over the last five years.

Ladies and gentlemen, that is equivalent to more than 15 raids per day.

Also, in 2010, other positive development include the rates of search warrants and arrest warrants issued by the IP court, which registered 81 percent of the total 578 requests made.

Court sentencings reflected heavy penalties. The total amount of fines in 2010 amounted to 257 million baht, double that of the total amount charged in 2009. Imprisonment in 2010 totaled 119 cases, compared to 82 cases in 2009.

This is the result of coordinating efforts by the Department of Intellectual Property, the Central IP and IT Court to change the status of the IP Court from being the first instance court to a specialized court in 2008, with longer tenure of senior judges who understand the severity of the matter.

In 2010, confiscated IPR infringed goods in the amount 878,757 pieces, worth more than 2.357 million baht were destroyed on three separate occasions.

During those occasions both the private representative of the U.S. interests, as well as the European interests, as well as the members of the American and European

Embassies were also invited to participate openly.

To facilitate all the enforcement agencies in tracking the status of infringement cases and retrieve relevant information on court decisions and repeated offenses, a project with more than 300,000 U.S. Dollars price tag has been undertaken at the DIP to compile a comprehensive database among enforcement agencies. It is expected to be in operation by the end of 2011 fiscal year.

Third, the Thai government has maintained active and close dialogue with private sector representatives, including those of the pharmaceutical sector on several issues to identify constructive ways and means to ensure continued good working relationship.

The most recent meeting was conducted at the Department of Intellectual Property on February 16th, last. Also, at the meeting were representatives from the Thai

Food and Drug Administration and the U.S. pharmaceutical industry -- sorry, and the Excise Department.

In addition, the U.S. pharmaceutical industry in Thailand has seats in subcommittee on IP Policy and Medicine and Pharmaceutical Products under the National Committee on IP Policy. They are also actively involved with the Thai Government in the Patent Law Amendment Working Group.

A Memorandum of Understanding on the Cooperation on Prevention and Suppression of Trademark Infringing Pharmaceuticals has been signed and activated.

This culminated to the suppression of a large quantity of trademark infringed drugs. Pharmaceutical industry also sent representatives to speak and provide trainings at IPR enforcement agencies to identify infringed pharmaceutical and medical products.

Fourth, the major legislative reforms are now in progress. This includes

introducing the Anti-Camcording Bill, amending the Copyright Law and Trademark Law to include landlord liability, modernizing the Copyright Law to provide better protection in the digital environment, based on international standards under the World Intellectual Property Organization Treaties, amendment of the Customs Law to enable ex officio action to seize infringement goods in transit and transshipment, amending the Patent Law to streamline the patent examination procedures and to be in compliance with the Doha Declaration, and amending the Optical Disc Law to avoid administrative burden to the rights owners and the CD manufacturers.

MR. McCOY: I could say you have about a minute left.

MR. SUKHUM: Okay. Fifth, proactive steps have been taken to strengthen IPR protection. This includes reducing patent examination delays, conducting public awareness campaigns and providing IP education

for students at all levels for primary school, to university, as mandated by the National IP Policy Committee.

Finally, it is noted that the coordination with the IP agents on enforcement, that there has been serious miscommunication between the representatives of the U.S. rightsowners in Thailand and those in the U.S., where praise and commendation has been evidenced in Thailand, the information received in the U.S. differs.

During 2010 raids, we have only -- there have only been one attendance each by MPA and the (inaudible due to accent, hereafter appearing in the transcript as, "IATA") with constant complaint of the lack of funding to participate.

We wish to see more active involvement of the U.S. rightsholder in Thailand.

In conclusion, the Thai government hereby submits that in light of the

significant achievements since 2007, Thailand believes that it is unprecedented and the continuous efforts and sincerity in successes through policy initiatives, enforcement and suppression efforts, cooperation with stakeholders, legislative reform and proactive steps warrants Thailand to be removed from the Special 301 Priority Watch List.

Thailand recognizes that IPR protection and enforcement is an ongoing issue. While much has been done, Thailand is committed and sincerely not denying to be working forward and need support and cooperation from the U.S. and other trading partners to improve the global IP environment.

I would pleased to answer any questions that the Special 301 Committee may ask. Thank you very much again for your time and consideration for this matter.

Thank you.

MR. McCOY: Thank you very much, Dr. Kajit. We are grateful for the input of

the Royal Thai Government on this process, as always, and for our close working relationship with the Government and with the embassy here in Washington, and we are grateful for your presence today.

And if you would like to further address any of our questions in a posthearing submission, we'd be delighted to receive that. And if you would like to provide more information in that context about your efforts to work together with the industries and some of the concerns you alluded to in that process, we'd be open to receiving that as well.

MR. SUKHUM: Thank you very much, Mr. Chair.

I would like to further emphasize the sincerity of our government in order to implement and also provided resources for the IP crime on internet. Okay. The so-called -- the "tech crime."

MR. McCOY: Yes.

MR. SUKHUM: It is noted that USTI and the USPTO will be holding a seminar in Bangkok on the 22nd to 25th of March on how to understand the internet crime and also the online infringement.

This will be hosted by the Department of Intellectual Property. And also we have been working very closely with people from the ICT Ministry, which is the ministry responsible for the operation of the internet and also the online services.

So, secondly, for the cooperation of pharmaceutical industry. During the February 16th meeting there have been discussion between the representatives of the pharmaceutical industries and those of Thai FDA, okay, and also the police, the Royal Thai Police.

It seems that while the Royal Thai Police, their personal and also policy level, willing to go ahead with the suppression of the fake drugs, there are two issues.

The first issue is that there certainly appears to be lack of information on a specific infringement coming from the representatives of the pharmaceutical industry.

That means that the police would not be able to undertake any arrest by any prosecution unless evidence is being given to them.

On the personal level, I have discussed with the Deputy Chief of the police responsible for this section. He said that he has staff and also budget ready to undertake this but awaiting complaint from the representative in Thailand.

MR. McCOY: Thanks very much for that. We are well over time, so could I suggest that we follow up through a combination of any paper you want to submit for the record and, of course, our continuing openness for bilateral discussions with you at any time whatsoever.

MR. SUKHUM: Okay. Well, thank you very much.

MR. McCOY: Thank you very much for joining us today. We appreciate your participation.

Could I ask if the representatives of the Czech Embassy are available. Sure. Thank you very much. I'm sorry. We were -- I'm sorry we held you up in the security procedure a little bit.

I have just been -- as people take their seats, rather than interrupt you with questions, I have been trying to let people know what initial questions we had from review of the materials you submitted.

Please, by all means, take a seat and you can choose to address them now. You can choose to address them in a posthearing submission if you like.

Generally, we are very interested in reporting both on developments in the Czech Republic and on positive best practices, and

you've highlighted some of those in your submission, which you appreciate.

We are interested in the information you provided on internet piracy, particularly in -- if you can let us know more about follow-up enforcement actions, that is of interest to us.

Also quite interested in the future of the National Coordination Group for Digital Media and what sorts of authority it will have. So, that would be of interest.

You've provided some updates in your submission about the efforts with the open-air markets along the Czech border, and that is an area of continuing interest.

And then, we are also interested in the follow-up to some of the information you provided on arrests for copyright infringement and -- and the terms of -- the terms of sentences that might be imposed in the area of copyright infringement.

So, to the extent you can

elaborate in any of those areas, we'd welcome that. But, the floor is yours. Thank you. Thank you very much, gentlemen, for joining us today. We are delighted to have you.

MR. KOSTOVAL: Thanks for the floor, Mr. Chairman.

At the beginning I would like to say that we are fighting IPR infringement in our country because of our interest, not because of the United States but, of course, we are more than happy that the United States are appreciating our effort and see that our effort is also materializing.

Of course, things are to be done in the future as well, and we hope also, in cooperation with the United States.

So, in this statement at the beginning, I would like to draw your attention to four points, that our effort is in four areas, controlling activities, legislation, prevention and education and IPR infringement on the internet.

Controlling activities of the Czech government institutions in recent years have particularly contributed to a significant increment of IPR protection and an enforcement in the Czech Republic.

Czech institutions includes Czech Customs Administration, Czech trade inspection, the police of the Czech Republic and regional departments of the Business Licensing Office.

Numerous controls have been focused on internal market in goods imported and exported goods and on criminal proceedings as well.

The aim of the controls was to minimize the number of counterfeit and pirated goods and to identify vendors. Shortly -- as for the statistics, the total quantity of products detained jumped annually by one million pieces in 2010.

This confirms the trend of decreasing availability of goods infringing

IPR at the Czech open markets and shows that the retail sales should not be further considered as a main distribution channel of counterfeit and pirated goods.

The example of best practices in this regard is collaboration of Czech Customs Administration, Municipalities and the Ministry of Environment on the removal of (IATA) which were used as storage of illegal goods.

Controlling activities of Czech institutions concerns also identification of vendors and revoking the business licenses if IPR violators in 2010.

Identification of vendors is one of the tools, from our point of view, used to control those who repeatedly infringe IPR and enables their prosecution.

When it comes to legislation, concerning the legislative acts, the most important change was the new penal code raising the penalties for IPR-related crimes

came into effect January 1st, 2010.

Further work on other legislation has been done and some acts are to be implemented. New penal code number 40/2009 increases the maximum penalties for IPR-related crimes from two years to eight years' imprisonment and criminalize the manufacturing and storage of counterfeit items.

In general, there has been a significant increase in the number of persons convicted for IPR-related crimes in 2009 and 2010. The details are in the report we have submitted.

Third point, prevention and education activities. Prevention and public awareness play an important role from our point of view in combating illegal practices related to IPR in the Czech Republic.

In 2010, a series of special training seminars, conferences at the national and international level and public awareness projects were held.

As for the actions at national level, we have organized special training courses for controlling stuff, we are educating entrepreneurs, especially from the community of Vietnamese people who are especially involved in those activities, selling in those markets, pirate stuff.

So, we were -- we organized two trainings for those people and Ministry of Culture organized a similar seminar on copyright legislation and its implications in practice for entrepreneurs.

With regard to public awareness, in 2010, there was ongoing work on the project, "I Respect the Original," which continued under the supervision of Intellectual Property Office of the Czech Republic.

Main stakeholders of the project signed a partnership agreement because many, many -- many stakeholders involved, including European Commission, which has international

dimension to it.

So that is why we wanted to have also a signed piece of paper. There is also a newly-established web page, "Respect the Original," and training courses connected to this web page.

When it comes to international cooperation, the Industrial Property Office organized several events on international level, together with Ministry of Foreign Affairs of the Czech Republic.

We organized a conference on IPR enforcement and EU-Asian cooperation because of exactly -- it is coming from Asia -- in May last year, and further, two Chinese delegations visited the Czech Republic and we were discussing protection and enforcement of IPR, and also a special training -- and also a special training for offices from Montenegro and Kosovo were organized by Czech Intellectual Property Office.

Fourth point, infringement -- IPR

infringement on the internet, Czech authorities registered that this pirate business is moving to the internet.

In 2010 we detected that from 80 to 90 percent of all activities were going through the internet, so we are very much focusing on this, improving the legislation, improving the law enforcement activities and also, in accordance with the new state policy on electronic media, the judicial Czech Republic -- it was approved by the Czech government in January 2011, a new controlling body, a national coordinating group for digital media will be established.

One of its tasks will be monitoring and supervising the situation of IPR on the internet.

This new institution will concentrate its activities on copyright enforcement and other issues concerning IPR on the internet, including the improvement of the relevant legislation.

Here I would like to add that we also started detailed discussions with motion picture associations and respective studios based in Los Angeles because there is clear link between increased piracy when it comes to movies on the accessible -- on the internet, which are even not in the distribution, and the impact on Czech business because the studios, then, are not prone to subcontract Czech movie industry and shoot movies in the Czech Republic, despite the fact that we have introduced some incentives, or introduced.

And in talks to cooperate on fighting this on the internet, because it is clearly -- there is clear need to really have international cooperation, and we will have Minister of Interior come into the United States and he will also be focusing on this area.

It is very complicated issue because credit card companies based in U.S. are actually involved, so that is talking to

them. The source of the whole problem is here in the United States because, for example, members of the Academy of -- of Movie Academy --

MR. McCOY: You have about a minute left.

MR. KOSTOVAL: Yes. -- are actually sometimes actually providing those movies to those who are copying and then selling pirate copies.

So, we are really interested in cooperation in this field especially. So, thank you.

MR. McCOY: Well, thank you very much for your efforts and for the detailed submission that you've provided. We appreciate that. And if you should wish to elaborate any further on anything that has come up today or any areas where you feel you would like to provide more clarification, we will be open for posthearing submissions until five p.m. on March 9th.

So, we would certainly welcome that and, of course, we are open to -- to meet with you on a government-to-government basis anytime you would like to do so.

MR. KOSTOVAL: Thank you.

MR. McCOY: Thank you very much for coming today.

Mr. Mazza, Fabrizio, from the government of Italy. Welcome. Thank you so much for coming today, and making the trip. We are, of course, delighted to have you, a valued colleague in many international discussions.

Let me just mention some of the -- some of the thoughts and questions we had as we looked through the valuable information that you provided.

One was on the issue of internet piracy, interested in any concrete steps Italy is taking in that regard. Also interested in -- your comments mentioned barriers toward access to legal content, and we are interested

in your views on what are some of those barriers to access to legal content on the internet and what could be done to better address them.

And then, we were also interested by the fact that on page nine of your submission, it mentioned that there were more that 2,500 people reported to the authorities for audiovisual internet and book piracy and 136 arrests.

So, if you could help us to understand what accounts for the disparity there, that would be educational for us.

The floor is yours. You can speak to those questions as you feel appropriate. You can give your prepared remarks. You have ten minutes and the opportunity of a posthearing submission, should you fell that is necessary.

MR. MAZZA: Well, good morning. I think some of the questions are already answered before and I will make a general

statement now. For others we will have to make a posthearing submission.

Well, I'm First Councilor Fabrizio Mazza and since 2006 I have been the head of the Intellectual Property Department in the Ministry of Foreign Affairs.

Here there is Councilor Vitiorio Ragonesi who is a judge and who is being for ten years a legal advisor of the Ministry of Foreign Affairs for the Intellectual Property, Public Problems.

Now, as you know, this is the first time in many years that Italy participates to the U.S.T.R. 301 hearing, and there is a reason for it.

First, what we want to find out is that the Italian government is highly concerned for the growing of counterfeiting and piracy in the world.

The illegal trade of counterfeit and pirate products in Italy and abroad is a major problem causing significant harm to the

Italian economy.

I'm not going to bore you with a list of foreign products counterfeited and pirated in Italy. Mainly the consumer goods and of the audiovisual sector, and of Italian products counterfeited and pirated in international market.

But we are fully-aware of the negative impact on the economic develop and unemployment in our country and of the high level of cost faced by the Italian economy.

As a consequence of counterfeit and piracy, we observe higher cost for law enforcement activities, increasing control activity at the borders, increasing danger for safety and security of consumers and et cetera.

So, as to say, we are trying, we are taking care in some way of our business, and there have been substantial and comprehensive steps and progress over the last four years.

Effective, for one concern this progress during the last four years, those are at many different level. First, the law number 99 of July 23, 2009 as introduced for criminal association in counterfeiting, the same exceptional sanctions in force for criminal association with the Mafia or terrorists fanatics, like confiscation of money, goods and other assets whose origin cannot be justified.

So, we have now in the criminal court, in Italian criminal court, exceptional sanction which are reserved only for Mafia, terrorist or counterfeiting association.

There is the first very important development, and this law has been enforced for the first time basically in 2010.

Second important development. The section of the Ministry for Economic Development, competent for the fight against counterfeiting is being complete reorganized and substantially enlarged.

The Ministry for Economic Development is now the center of the National Anticounterfeiting Council, which is responsible for coordination of all strategic action undertaken by each agency against counterfeiting.

In their report that we have produced, you can see that the notorious and substantial level of enforcement against infringement of IPR of finance and specialty custom agency has been confirmed by the data concerning intervention during 2010 even if there is a transitional decrees and seizure concerning piracy.

Another dramatic, I would say, development, is that on July 15, 2010, a parliamentary inquiry committee on counterfeiting and piracy has been formed and this committee has recently started ongoing formal hearings with all the relevant institutions and private sector organization.

The hearings started like one

month ago and they are going on very, intensely.

Now, there is a certain separation on the competencies for counterfeiting on one side and for piracy on the other side. For counterfeiting, at the center is the Ministry of Economic Development.

For piracy, the center is the Technical Committee Against multimedia piracy and in the Presidency of the Council of Ministers.

This committee has stepped up its effort and it has, just ten days ago, the committee has set up a task force of national experts. The main target of the task force is to integrate the proposed antipiracy edge com regulation.

The edge com regulation is described in the report by drafting proposal of regulatory measures, identify knowledge for (IATA) initiatives including codes of conduct and self-regulation by ISP and other online

intermediaries, and proposing an educational campaign aimed at raising awareness on the importance of the defense of IP rights.

The official campaign which will be launched at the end of this year by the presence of the Council or Minister.

The most important development, anyway, during 2010, is without doubt, represented by the antipiracy (IATA) regulation described in our report.

As you know, this proposed regulation targets violation of copyright by websites and not by individual users. Now, the possibility of additional measures against individual users, the downloaders, in addition to the ones already existing will be basically dealt by the managing Task Force of the presence of the Council of Ministers, probably through codes of conduct and self-regulation.

Now, we have some reason for excluding from the antipiracy (IATA) regulation, violation by individual users.

We decided they are not adopt the model of the disconnection on the individual internet connection, like in France. This -- the reason of the exemption of violation by individual user are complex, but clear.

Firs, it would be technically difficult to effectively nail down individual users. For example, after the first warning, it would be easy for the user to disguise his or her internet identity. So, the reason, an entire box of technical reasons.

Second, there are some judicial problems. The European Parliament has repeatedly warned directly or indirectly against the administrative order disconnection of the internet is in contradiction with freedom and civil rights.

Moreover, the disconnection, indeed, all disconnection of the internet could also be in contradiction with the disposition protecting essential services especially in the frequent case of phone and

internet joint packages.

Finally, there is another important consideration which is also a little bit delicate. The administrative activities, connection of individual user would be possibly only through the mandatory cooperation of the internet service providers.

One thing is the disclosure of the identity of the individual user by order of the judge already happens in Italy, and a complete different team who did the disclosure of the internet identify by other individual user by the order of an administrative authority.

We think that is a general consideration, and once the neutrality of an internet service provider is broken for the sake of copyright protection, in Italy and maybe in other European countries, it would really be difficult about the legitimacy of (IATA) and jurisdictionally to limit the exception only to the defense of copyright.

On the contrary, it would become easy to open it up to exception in defense of other interests and values, like the right to privacy or the protection against defamation and, as an Italian State, we cannot control entirely these developments because we are executive, legislative and jurisdictional.

In this frame I have to recall the recent fairness of Italian sentence of conviction of the Google and YouTube legal representative for violation of privacy.

We may say that --

MR. McCOY: Could I just say you have about a minute left.

MR. MAZZA: Yes. We have to say we have chosen to stay in a prudent and safe territory. We will not attack the internet connection of the individual user, but at the same time we will not expose the principle of high-speed neutrality to exception in Italy and in Europe might easily be extended beyond the protection of copyright.

So, in this frame, this (IATA) antipiracy regulation represents a very important step toward the effective protection of copyright in the internet.

We hope that this regulation will be approved as a regulation and this time (IATA) and through a law parliament which will be a perfect tool also to obtain other aspect of the protection of copyright, but could require a longer time frame.

Concluding, considering the described improvements in the protection and enforcement of copyrights, we really invite you to consider the removal of Italy from the Watch List, or the opening of an out-of-cycle review during fall 2011, which will be a significant sign of support to our ongoing effort in the field of IPR protection.

MR. McCOY: Well, thank you very much for that information and for speaking to issues where we had questions, internet piracy and so on. We appreciate that.

We appreciate your participation today, and we look forward to continuing our conversation on a government-to-government basis and would be grateful for any further information you want to provide, either as a posthearing submission --

MR. MAZZA: We will.

MR. McCOY: -- or otherwise.

MR. MAZZA: We will.

MR. McCOY: Thank you very much.

MR. MAZZA: Thanks to you.

MR. McCOY: Appreciate it.

If I could not invite Mr. Behar from the embassy of Mexico. Thank you. Than you, Salvador, for joining us today and we are delighted to have you here again with us this year and, as we looked over the submissions received in the process today, one of the suggestions by a submitter related to suggesting high-level national antipiracy plans and coordinations to enhance federal, state and municipal enforcement activities.

We would be interested in your reactions on the question of enforcement at different levels of government in Mexico as well as examples of any issues that the government of Mexico feels need more attention or which can be addressed through further government involvement.

The floor is yours.

MR. BEHAR: Thank you, Stan, it is my pleasure to be here in front of the members of the Subcommittee.

First of all, let me thank the USTR for posting for a whole year my picture in the website. My kids now go to my -- instead of going to my Facebook, go to websites of the USTR. So, I am happy to update it for the next year.

Well, we, of course, appreciate the opportunity to appear before you at this hearing and express our views on the Special 301 process.

For the record, I am Salvador

Behar. I am legal counsel for International Trade at the Embassy of Mexico.

Let me say firstly, that these comments will be cumulative of what I said in 2010. Some -- most of the actions we have done in the past continue. It is a continuous effort. We don't change. We move forward and we accumulate, so I would like you to go back to the files and see my testimony before.

Now, on the intellectual property rights, you know that it is an important matter where the Mexican Government is committed and has been working with the U.S. Government very closely, and the industry.

There is a meaningful bilateral trade between the industries of Mexico and the U.S. because of our geographical proximity.

As our president stated in May 2010, innovation and investment in technology and human capital are keys to sustain economic growth and competitiveness involving Mexico and the U.S., and the protection of

intellectual property rights is important to promote the investments. End of quote.

Our agencies have been working closely to honor this commitment, bilateral commitment.

I would like to address specific issues during my testimony, but I must say that this is just a brevity of the actions and activities related to copyright protection taken by the Mexican authorities.

Most of the statistics will be available upon request by the parties and I will be happy to share in our bilateral meetings, furthermore.

I will say that on the first time, activities by -- in Mexico by enforcement agencies. In 2010, in close coordination with Attorney General's Office, Customs, and the Mexican Army and in collaboration with state enforcement authorities seized more than 146 million counterfeited products and searched more than 1899 properties.

For the last three years the agencies have dismantled more than 877 labs, illegal labs, more than 18,000 raids and arrested more than 3,000 criminals.

With regards to enforcement taken by the Attorney General's Office, responsible for IPR crimes, we have more than 1899 premises, search warrants, 3,000 -- more than 3,000 operations in flea markets and streets, 97 laboratories dismantled just in this year, 16 people in jail time and one -- more than 1,000 people detained.

But we are not only improving the enforcement side, we are also continuing public educational campaigns to raise awareness against piracy.

For example, in September 2010, we launched a full addition of the kids drawing, drawing piracy, with more than 2,300 drawings nationwide, in support of our antipiracy actions.

Moreover, the National Institute

of Copyright has introduced an IP chapter in the civics and ethics textbook, which is a must to be used in elementary schools nationwide.

This chapter is devoted to raise awareness within the general population regarding the respect of IPR at an early stage.

(IATA) has also been recognized with the management improving award for the last two consecutive years and it is important to mention that in (IATA) is the agency responsible of the ISVN and ISSN for the serial number -- standard serial number, aiming to maintain our reliable record of copyrights.

Consideration procedures in the (IATA) interdiction have proven to be an effective alternative use for resolving disputes of rightholders as well, with more than 70 percent of the litigation solved.

Now, to address your question

about coordination and enforcement between our federal government and state and municipal, as well as the private sector, I have to say that as of March 1st, 2011, which I will question the committee whether this still counts towards eleven or twelve, and launch a pilot prosecution highway, which is jointly with the USPTO.

The purpose of pilot project is that the IP Office is can expedite their examination process by using to the maximum extent possible the substantive examination results obtained by the signatory office.

The pilot prosecution highway reduces the substantive examination period. What was used to be done in 27 months now can be resolved in a period of three months. This is only one example of cooperation between two agencies that work very closely and effectively.

Collaboration, training and increasing intelligence-sharing among law

enforcement agencies of both countries has been taking place to enforce IPR rights more effectively between the U.S. and Mexico.

Since early 2010 the government of Mexico has designated an attache officer in the IPR Coordination Center in order to share information and promptly act when IPR infringements are detected.

This coordination has proven to be effective. At least two cross-border operations have been carried out. Last summer a joint operation between DHS and Mexican officials called "Safe Summer," took place.

This operation was coordinated by the U.S. Intellectual Property Copyrights Coordination Center. The operation "Target Health and Safety-Related Items," smuggled through international mail branches and express career courier facilities in both countries.

In the U.S. the operation resulted in more than 800 seizures were estimated in

several hundred millions of dollars, and in Mexico it resulted in the seizure of more than 300 tons of counterfeited goods.

Now, let me talk about international cooperation. In June 2010, (IATA) signed a cooperation agreement with the OAS, the American Organization of American States, on intellectual property, trade and innovation.

Mexico reaffirmed its commitment to protect IPR internationally. We are an active negotiator -- we were an active negotiator of the ACTA which was agreed to last fall.

We look forward for a signature and internal process for approval by our respective legislators and parliaments, as the case may be.

In the world and -- the world Intellectual Property Organizations sign a cooperation agreement to implement and increase activities related to human

resources, training and education for professionals in Latin American region, to promote and disseminating the importance of IP protection.

It is also important to highlight that MPB is the first government agency to be awarded the IP productivity, security and transparency certificate by the Business Software Alliance.

After our conclusion of the audit made by BSA, MPB became the first administrative authority worldwide that audits its IT platforms in terms if IP and, thus, use of legal software.

This is a first step of the program launched by BSA in Mexico in the "Ejemplo Empiezs En Casa," "The Example Starts at Home."

The Mexican Customs Office has also made exceptional and consistent progress in the protection of IPR. The office has been recognized by the World Customs Organization

presented the Yolanda Benitiz Award to Mexican Tax Agency, SAT, in recognition of Mexico's successful efforts to fight circulation of counterfeited goods and expired medicines.

In 2009, the government of Mexico conducted more than 460 operations in which 48 -- 38 million pieces of counterfeited goods were confiscated. The program will have generated approximately $220 million in the black market.

MR. McCOY: You have about a minute left.

MR. BEHAR: Four representatives of SAT have been certified by the World Customs Organizations as experts in IP. These are the first Latin Americans to reach that achievement.

For ten training courses to 595 government officials will perform in customs, the keynote of the series was based intellectual property practice to achieve maximum deterrents at the border with the

support of the U.S. Government and WCO, the Customs organization.

Mexico was also part of the Jupiter Operation led by Interpol to crack down on piracy. Last week Mexican enforcement agencies initiated a training seminar to share best practices for detection and deterrents of piracy.

On the legislative actions, you may be aware, Mexico has made important reforms to IPR regulations to strengthen the protections including the ex official authority to PGR, raising criminal penalties.

In 2010, general rules of foreign trade were published to more expeditious and assertive detection of pirated goods in the suspension of the list of importance of companies involved.

We are also establishing a trademark recordation system where (IATA) and Customs will provide rightholders with additional tools to protect IP against

infringing goods at the border.

The amendment in the Customs law is submitted to Congress and the agencies continue working with the IP systems to implement such a program.

MR. McCOY: You would be welcome to submit the rest as a posthearing statement if you would like.

MR. BEHAR: I have one line to say and I am done. The recordation system will provide enforcement officials the following tools: Cargo logs; security kits; access to programs and databases; and, access to the Philips database for DVD's, CD's and so forth.

For the above-mentioned, we formally request Mexico (IATA).

Thank you very much.

MR. McCOY: Thank you. Thank you very much, Mr. Behar. We value our cooperation with the government of Mexico and the Mexican embassy tremendously, and we are grateful to you today for providing a summary

of some of the elements of that cooperation, and we look forward to continuing to work with you and discuss with you on a bilateral basis how we can build on that cooperation.

So, thank you very much for being here today.

MR. BEHAR: Thank you very much. And Mr. Amigo is here and is coming today for the APEC meeting which we share the IG. Thank you.

MR. McCOY: Thank you. Thank you.

So, we had foreseen a break, but we have run a bit over time, so I'm just going to forge ahead until the lunch break.

We have next BeachBody LLC for ten minutes. Could I ask the representative of BeachBody LLC to join us at the table.

All right. If they're not ready, then I'll ask the Global Health Organization's representative to join us at the table. Is that Sean? Yes.

So, quickly, in terms of the -- in

terms of your submission, you talked at one point about promoting best practices in innovation policies and we'd be interested in hearing more of that in line with our mandate to look at best practices in the Special 301 process this year.

And we also noted on pages 23 and 24 of your submission that you had talked about the Special 301 report in 2010, encouraging countries to adopt ex officio border enforcement of patents and we would be interested in, if you can explain where you perceive that encouragement as existing in the -- in the 2010 Special 301 Report.

With that, the floor is yours for ten minutes.

MR. FLYNN: Sure. Thank you very much.

I have to say I was very much looking forward to seeing who BeachBody LLC was, but --

MR. McCOY: We will have to wait.

We will give them another chance to come back in the room.

MR. FLYNN: It is you. I thought so.

Thank you again for having me here and thank you for having this hearing again. I personally and, we generally think that this is a positive change in 301, hence we are happy that you are continuing it.

So, I do want to take up particularly, that issue of best practices. I'll refer to the specific, you know, page numbers you asked for in an off-the-record -- or sorry, in postrecord comments, if that is okay.

So, I have given you a handout today. I think what I wanted to use this time for was to reemphasize, I think, a significant and early point of departure between our comments and the pharmaceutical industry's comments that are before you today.

And that is the comment from the

pharmaceuticals' entry submission that intellectual property, particularly patents and related medicine-related intellectual property are not a barrier to access to medicines, they're actually the driver of access to medicines, and therefore it is consistent to drive trips-plus policies on access to medicines without infringing upon the U.S. commitments to the Doha Declaration.

And I want to explain why that is not true, and I think the rest of the specific comments we make in our written submissions follow from that and I think you'll get opportunities to hear from others today about some of those specifics.

So I have handed out to you a series of graphs, and this is meant to summarize and explain the different impacts of intellectual property in rich countries versus middle-income countries.

So here I'm specifically talking about, for instance, Thailand, Brazil, India,

some of the major targets for the pharmaceutical industry within the 301 paradigm, within the 301 program.

So patents are designed to promote incentives for research and development and implies a tradeoff. It purposefully raises prices on goods in order to create research and development incentives, but the amount that those prices are raised are different in middle-income countries and more wealthy countries. And the reason is the inequality within income within those countries.

So, the first chart is a hypothetical country with just a flat demand curve. And the idea is that the patent in that demand curve would promote higher prices, but it is not necessarily unreasonably high prices because, even in an monopoly market, there is a restraint. The restraint on pricing is a function of the demand curve.

The company can only raise prices so much as the decrease in additional sales

because of the higher prices will not result in a decrease in overall sales and, therefore, profits.

Now, where exactly that point takes place -- it seems to be going on and off. Is this fine?

Where exactly that point takes place is a function of the shape of the demand curve, and the shape of the demand curve is very different in more wealthy countries than it is in middle-income countries, especially, and that is the rest of these charts.

So, the charts compare, for instance, Norway, the most equal distribution of income in the world, with Brazil, the most unequal distribution of income in the world.

And if you look at the profit-maximizing behavior in these two charts, in Norway the profit-maximizing behavior is to continue to decrease prices until you hit about 80 or 90 percent of the population, then the social system is going to have to kick in

and provide for the remaining 10 or 20 percent.

So, the dead-weight loss in economic terms in a country like Norway is about 10 percent of the market.

It is the reverse in a country like Brazil. Because there is a very small portion of the population that makes equivalent to "first world" incomes is a very small portion, five, 10 percent that are wealthy even by European and United States standards.

The profit incentive in those markets is to actually price to that segment, and ignore the long, low tail of the other side of the market that is the poor majority of the population.

So, instead of the dead-weight loss being 10 percent of the market, the served segment of the market is 10 percent.

This is the fact that led to the creation of what we call the global access to

medicine movement. When AIDS drugs came out in 1996, two years after the TRIPS Agreement was signed, these new products were sold at the same price in every country in the world and that wasn't a market flaw, that was the market.

The profit-maximizing incentive, if you have a new drug that everybody needs is to serve the majority of the rich countries and to serve the small sliver -- the small sliver of rich people in all the poor countries.

Now, that is the problem that leads to the rest of our submissions. Every time you take action in 301 or a trade agreement that increased intellectual property standards on medicine, especially in middle-income countries with large income inequality, you are impeding access to medicines. You are promoting incentives to price to that highest sliver of the population.

So you need on the back end, if

you care about these problems, policy tools. You need what we call TRIPS flexibilities. You need flexibilities like "And here is the best practices," right?

India, Section 3-D of their patent law limiting the amount of patents they grant to a different level than we were given in the United States. But, a different level is reasonable because they have a different income distribution in that country.

You want stricter patent laws in middle-income countries than you have in wealthy countries. That is a best practice. It might not be a best practice if implemented in the United States, but in India it is absolutely a best practice.

Or pricing mechanisms, straight-up price controls, or using government purchasing to maximize your negotiating power and minimize prices is what you want, especially in developing countries.

You have to have policy tools on

the other side to address the pricing problem, or you will price out 90, 95 percent of the country from access to their goods.

Now, what Joe will talk to you about this afternoon is that this is actually not just a medicines problem. It is also a copyright problem.

So, what we see in copyright protected movies and DVD's and CD's in middle-income countries is that they price them at the same exact price as in the United States.

So, if you adjusted those prices for purchasing power, the latest version of the Dark Knight DVD -- and Joe will give you these figures -- it costs about $700, the equivalent in India, if you adjusted the purchasing power.

So, they're not looking to serve the whole market, they are looking to serve this sliver of the market that has high incomes, and that causes the rampant counterfeiting and piracy on the other side.

So, the best practices are not just to ramp up enforcement, they are to deal with the pricing problems. If you want to universalize monopolies on medicines and copyrighted goods, then you need to have policy tools on the other side to deal with the economic incentive you've just created to price out the majority of the population.

So you should be researching those. If you think that everybody should have an equally-enforced copyright law, patent law around the world, what are the other policy tools that you want to promote to make sure that those companies serve the entire market.

We want all of -- all people, all countries to be able to consume our movies and music, but they won't do it if you price everyone out. And that is the economic incentive that the strict monopoly laws are creating, both in copyrights and in patents.

I'll stop there for a minute. I

haven't been watching the time, but I know I'm going right into the next segment.

MR. McCOY: Yes, you have about a minute left.

MR. FLYNN: Okay. I'm happy to take any questions or I'm happy to pause for a moment and then go in, because I think I'm up next, on pricing programs, and I want to raise -- I'll just kind of go into that.

MR. McCOY: If you want to just -- do you want to just -- I think you are -- I think what you are alluding to is that you are the next one we have on our -- the next one we have on our schedule is Forum on Democracy and Trade, and you were going to talk there about the -- I think we had had another representative for that, but you are going to -- you are going to take that spot and talk about something else, I hope.

You know, the subcommittee rather frowns on people just using multiple headings to talk to us, to talk to us for longer blocks

of time.

So, if you can -- if we can ask you -- if you are addressing something appreciably different on behalf of a different group, that is fine.

MR. FLYNN: It is a different issue on a different group, yes.

MR. McCOY: Okay. Do you want to go ahead and --

MR. FLYNN: So that is the -- so I think that is the summary of the global health concern. All the specifics around specifics on data exclusivity, specifics on linkage programs, specifics on the statements in 301 that seem to look down upon pricing programs, et cetera, our concerns are motivated by that first principle.

And I want to switch now and talk from the perspective of the Forum on Democracy and Trade, and I'm also just going to, here, take the National Legislative Association on Prescription Drug Prices who is scheduled this

afternoon, but this is the same testimony for them, so I'm just giving up the afternoon slot, if I may.

So, from -- so that problem with creating a monopoly on essential medicines causing higher prices, it causes extra problems in developing countries, but it causes problems here, too, right.

So the United States spends over twice the OECD average on medicines every year. The expenditures on medicines in this country increase at multiple times the inflation rate despite the amount of medicines not changing dramatically, and that indicates ever-increasing shifts in the United States towards the purchasing of higher and higher cost brand in medications.

The medicine expenditure problem in the United States -- and we perceive it as a problem -- is driven by the patented medicine problem, the branded medicine problems.

Our generic prices are actually often lower than many of our competitors, but our branded prices are much higher.

Now, the exception is, within Government purchasing. Within our Medicaid program we pay prices that are equivalent to or even less than Canada and many of the other trading partners, and the reason for that is we use the same tools as foreign countries to negotiate lower drug prices through pooling our purchasing power.

So, Medicaid programs use formularies called "Preferred Drug Lists," and those formularies consider a price. They look at price and efficacy of drugs and they place the most cost-effective treatments on preferred lists, and that drives purchasing towards those preferred lists.

Now, these are the same tools that have been targeted for the last several years in the Special 301 Program as being "unfair," -- quote/unquote -- and it is the same tools

that are targeted in the 2011 PhRMA 301 submission this year which, it seemed like when I kind of skimmed through it, most of this mission is actually about pricing programs, not about intellectual property.

And so, our message is this: And this goes within the TPP Agreement that's now being negotiated. It is a criticism that's been leveled at the Korea Free Trade Agreement and the Australia Free Trade Agreement, which is that USTR and our trade policy, more generally, should not be pushing standards abroad that we don't live according to here at home.

So, in the Korea Free Trade Agreement, for example, there's a provision that Korea should provide appeals for pharmaceutical companies that are dissatisfied with the reimbursement prices they received with the public --

MR. McCOY: Could I ask you to focus on the Special 301 process. I

understand there are many witnesses who have many concerns about aspects of trade policy beyond our mandate today.

MR. FLYNN: I'm particularly talking about within Special 301. There is a section last year. There was a section in 2009 that identifies programs for having unfair reimbursement programs.

Now, I'm assuming from this that you are using the standards that you are pushing in your FTA agreements, which is why I raised that standard.

It is often couched in vaguer terms such as "transparency," or "adequately valuing patented medicines to promote incentives to innovate," et cetera.

But we don't provide those same kind of standards in this country.

MR. McCOY: Do you think those terms mean something else? I'm sorry.

MR. FLYNN: Do they mean something else?

MR. McCOY: I'm interested in what the specific criticism is because we are here to try to make the report better, and if you can identify, you know, specifically what it is about the -- about the report, and I understand you said, "quote/unquote unfair" at one point, and then -- but then you said the report actually used terms like "transparency," so I'm -- I want to be clear about it.

MR. FLYNN: Great. So, Stan, that's an excellent point. So, I have no idea what you talked about when you say that something is unfair.

We look at those programs and we see programs that operate the same way as programs in the States. So, I'm trying to use, for instance, your free trade agreements to give some meaning to that, but I'd rather you actually gave meaning to that within the section itself.

So, what do you mean when you

target France, for instance, a having unfair reimbursement programs or not having sufficiently transparent practice?

Thailand, last year, came up and sat in front of you and said that, in response to your advice they put pharmaceutical representatives on pricing committees in ways that would violate State conflict of interest laws.

We think that you should not be pushing other countries to do things that would violate conflict of interest laws in the United States.

MR. McCOY: If you could let us know in your posthearing submission where it says that France has an unfair reimbursement policy or what -- I'd really be interested in what --

MR. FLYNN: Page 14 you include "Industry has expressed concerns regarding the policies of the following countries, Finland, France, Italy" -- you know you don't say that

you agree with them, but I think the implication is, when you list France that you are targeting France for something that's unfair about that policy.

So, you should explain what's unfair about it. You should explain how it is different than what we do in our own country, or you should get rid of this chapter.

Now, we also make an argument that, actually having this chapter violates your own statute. There's nothing in your statute that allows you to go around calling "unfair" other countries' pharmaceutical pricing programs.

If they are discriminatory, you should say what's discriminatory about them, as you do with respect to Poland, but you don't any anything discriminatory about the operation of these programs in Finland and France and Italy, Japan, Korea, New Zealand, Taiwan.

What's the discriminatory aspect?

What's the aspect that violates a trade principle?

Now, the market access clause within the statute that you are enforcing has a specific definition. It says it has to be a discriminatory non-tariff barrier. It can't just be a pricing program that pharmaceutical companies don't like.

You have to point out what's discriminatory about it. So, in the next report we ask you to do that.

MR. McCOY: You have about three minutes left if there's anything further you want to --

MR. FLYNN: I think I'm done. I'll take questions.

MR. McCOY: Okay. Well, if you want to elaborate on any of this -- I mean, my question is the one I articulated. It seems to me that you are -- it seems to me that you are -- the sentence you were just citing says "U.S. industry has expressed concerns

regarding the policies of several industrialized trading partners, including" -- and then it proceeds to list several countries on issues related to innovation in the pharmaceutical sector and other aspects of health care goods and services.

And then it goes on to give examples of Japan and Poland in a bit more detail.

I'm not sure I understand the connection between the comment you just made and what it actually says in the report. It seems to me you are doing a considerable amount of reading between the lines.

If you can clarify that for us, either in the remaining two minutes or in a posthearing submission, if we are saying things in the report that are wrong, we want to fix that.

MR. FLYNN: So, on page -- so I'm not sure what it means when you list countries in response to industry concerns in a written

report, and then I hear you coming back to me and saying, "But that doesn't actually mean anything. We just mentioned those countries."

If it doesn't mean anything, don't mention the countries. If it does mean something, then please explain what it means.

But, here on page 13 and 14 is expressly what I'm disagreeing with. For example, "Government practices including unreasonable regulatory approval delays and potentially unfair reimbursement policies can discourage the development of new drugs and other medical devices."

That sentence is not in compliance with your statute. There's nothing in your statute that says that you can target countries based on unreasonable, unfair reimbursement policies that discourage the development of new drugs," it is not what 301 is about.

It is not a drug development rule. It is to identify discriminatory non-tariff

barriers. That's what the market access definition is.

So, you should explain how these pro -- how unfair reimbursement policies are different than the reimbursement policies that the U.S. implements, and therefore, unfair. That's my definition of unfair. If you have a different one, then we'd like to hear that.

And how these reimbursement policies are discriminatory, A; and, non-tariff barriers, B. That's what your statute says. I don't see anything in here that indicates that these pages, 13 to 14 comply with your statute or comply with good policy which we define as not adopting international standards that, if applied in the United States, we would not follow today.

And that's within Medicaid. That's within State reimbursement policies. That's within Veterans Administration purchasing. That's within GSA purchasing.

MR. McCOY: Okay. Thanks, Sean.

Time is expired. We appreciate your participation today, and you can -- you are at liberty to provide any further information you would like as a posthearing submission.

MR. FLYNN: Thank you. And again, we really thank you for this opportunity to have an open hearing. I think it is a great improvement.

MR. McCOY: We thank you for coming. Thank you.

Is BeachBody ready? BeachBody LLC. Please come on up to the table. Make yourselves comfortable.

What we have been doing is, rather than stop you five minutes through and switch to questions, just try to let you know if we have any general questions, and then -- and then we will interrupt you if questions come up during the presentation.

But, in your submission you provided some interesting statistics about

seizures in China. We are interested in hearing more about your interactions with Chinese enforcement agencies and where they're positive and where they're not so positive.

We are also interested in your experience with Chinese Auction sites. You elaborate on that a bit in your submission, but that's something that's of considerable interest to us if you want to elaborate on that further today.

MR. GELFAND: I will, for sure.

Well, Mr. McCoy, members of the Special 301 Committee, on behalf of BeachBody LLC, we are based in Santa Monica, California, I want to thank each and every one of you for the opportunity today to testify.

My name is Jonathan Gelfand. I'm senior vice president of business development and general counsel for the company.

If you don't know BeachBody's a health and wellness company based, again, in California, our core purpose and corporate

mission to help individuals achieve their goal and enjoy fit, healthy-living lives.

BeachBody's core offerings are in-home fitness DVD's, so they include brands like P90X, Insanity and TurboFire, which are advertized on infomercial and direct response mediums as well as direct person-to-person sales.

All of our products include DVD's, calendars, peer support, diet and nutrition guides, an entire wellness program so that in six weeks, 90 days, you can begin your personal wellness journey.

In addition to our core in-home products, we also now have a network of peer-to-peer person distributors. On the multilevel marketing network we have over 55,000 Americans that distribute our products.

The company's growing due to the success of our fitness products. Last year, alone, in a challenging economy, we employed 138 new Americans, bringing our total up to

over 400, so we are very proud that we are continuing to grow.

As our success has grown, unfortunately, so has piracy. Piracy is running rampant right now in our DVD programs. Counterfeiting is such a problem of massive consequence that I have tripled my team in-house, and being a small-to-medium enterprise, this kind of expenditure, we spend well -- close to a half a million dollars just in enforcement and legal fees and translation on international enforcement.

For a small company, these costs are astronomical. In addition, frequently, despite our best efforts, the piracy is continuing unchecked. No matter how many auction sites we take down, no matter how many websites we can take over through URDP actions, how many seizures we are doing through Customs, through CBP and ICE and FBI-coordination, the piracy is continuing to grow and grow.

I know that many people are speaking to you today, and I know the committee, itself, has noted this growing problem so I don't want to spend too much time on that, but I really want to stress the direct impact to a small-to-medium enterprise is significant.

I don't have the stature of a Disney or an IP to go in front of all senators whenever I need to and really highlight this issue yet, at the same time, the direct economic impact can wipe out a small company.

We have estimated by putting up websites similar to the piracy websites. We have put up a lot of websites for a six-month test period to collect which orders, and we also traced activity going to some of the more popular pirated websites out there, and the annual revenue exceed $70 million on our product alone.

This $70 million in product that was being sold through our dummy websites --

and we were sending them real products. They must have been thrilled -- as well as the pirate websites.

That $70 million does not include the Chinese auction websites which I could spend some time on for your question.

The webs -- the auction sites, DHgate and Taobao and Alibaba, as well as iOffer, eBay, are extremely problematic. This is where the majority is traded.

Ebay has been largely responsive. I know people have different feelings, but the VeRO program is working for us. The problem, of course, is it is so easy to come up with another user name and to pop back up that, as many as we take down, many more pop back up.

Now, on outside of eBay, on some of the foreign auctions sites, take-down are much slower. A two-week take-down process means they can be transacting hundreds of thousands of dollars of business before they come down.

And, when we track some of them, they are up within an hour. So, despite we spending a lot of time and resources to take sites down and to take auction users down, they come right back up frequently, and that is a significant problem impacting small biocenoses.

In addition, while Ebay, we will frequently see sales of one to ten, on iOffer and some of the other sites, we have seen lots of 1800 units at P90X be sold for a cost of about $6 each.

We sell P90X for $120. So these obviously aren't coming in under "for sale doctrine," or anything that's legal. These are pirated products.

Before we commence enforcement action, we do purchases to ensure that they're always pirated product. We are very, very cautious and careful not to take down any kind of legitimate sale, especially when dealing with U.S. auction sites such as eBay.

You also asked about Chinese enforcement activity. Our largest problematic country is still China. We are spending a considerable amount of time chasing a lot of the websites that come up.

They register websites using our domain name, p90xstore.com, p90xworkoutdvd.com and the wonderful name about domain names is they're virtually unlimited.

We can spend weeks and tens of thousands of dollars to take down an ISP, to remove a payment processor, and then to eventually do a UDRP action and physically take a domain name.

And they've replicated our entire website. So, it already exists for them. For us to spend weeks-upon-weeks while they're conducting hundreds of thousands of dollars in revenue and sales, for them to simply add a one or P90XX Workout DVD, it takes them seconds, which takes us tens of thousands of dollars and months-upon-months.

A lot of these websites that come up are rings, meaning that as soon as we take one down another one will pop up and look identical.

Once you go into their contacted or terms of use it will just reference the old site, and you realize there's 10 to 20 websites that are all working in concert, capturing orders, selling for very similar prices, masquerading as the company itself.

They copy everything including our terms of use, our privacy policy and this is leading to not only direct company harm, it is leading to direct consumer harm.

This is another large thing I really want to stress. Like many companies, BeachBody takes its customers and its product extremely serious. This is all we are.

All we are is as good as our word. We have an A-plus rating with the Better Business Bureau, and it is a company that does millions of transactions. Maintaining that A-

plus rating is a challenge and we do that by making sure that our customers are always treated as just that. They are what make our life blood as a company.

When a consumer buys a pirated DVD, it is frequently defective. It stops working midway through. This leads to considerable consumer confidence damage.

These people are very vocal on blogs and through attorneys general and the various sites that we sell them defective goods. When they contact us, that raises a very large customer service problem, again, for a small company, it is a lot harder to absorb that.

If you make the customer happy and send them a legitimate product which they didn't pay for, do you take care of the customer or do you use that as a learning tool for that consumer. And this is a problem that many companies are facing time and time again.

We do have a lot of people that

come to us who were simply duped into buying defective goods.

In addition, there's been increasing reports of people that have had problems when they've bought defective programs, everything from hard drives being replaced, identify theft, these are real world problems which are now striking, whether it is through physical DVD's placed into a laptop when they want to do a workout of watch the latest movie or through the torrent and the different downloads which are running rampant right now.

Based on our experience and our every single day of trying to enforce and protect our intellectual property as a small company, we have several main recommendations for improving IPR internationally.

First, we really are asking -- we have a need for increased use of criminal enforcement tools to create greater deterrents. Right now there simply isn't a

great enough deterrence, especially internationally, to prevent piracy.

My simile is, it is like as if you were caught driving 90 miles an hour on the freeway and you only received a $10 speeding ticket that didn't go against your insurance.

At that part it is a cost of driving, doing business. It is a toll road. And right now that seems to be the problem that we are facing.

Internationally, the penalties seem grossly inadequate. The cost to a small company to conduct a raid in China or another international territory such as Russia, are extremely high.

It is a huge pain point. It takes weeks-upon-weeks of hiring investigators, of making sure you do everything right. You have to, then, convince local police which can sometimes be a challenge, to put it mildly, to take up a case against their local factories.

And, even when you spend all that

money, the amount of the penalties that at least we are seeing handed out are inconsequential compared to the money they make by continuing their illegal behavior.

Domestically, a frequent problem that we receive is when we go to prosecutors and we want somebody to take up a criminal case, we are told that because of resources and because of funding, unless it is a humongous case --

MR. McCOY: You have about a minute left.

MR. GELFAND: Okay. -- we are seeing prosecutors not willing or able to take it.

Our second recommendation is we need better coordination, communication among the USG bodies, CBP, ICE, the FBI. The more we work together the more we are able to operate correctly and efficiently.

The third is the need for Customs and other enforcement authorities to provide

IP owners with earlier and more substantial access to the information we need if we need to pursue our own investigations. Greater information is critical for us.

And the last one is the need for greater transparency regarding the results of when the Government is taking up a matter and knowing where that is so that we know how to act as private actors.

Any questions? Any details I can fill in for the group?

MR. McCOY: Thank you very much for that. We appreciate it. We appreciate your written submission --

MR. GELFAND: Thank you.

MR. McCOY: -- spelling out some additional concerns. I know time was short today.

MR. GELFAND: Yes.

MR. McCOY: Thank you for speaking to our -- to the particular questions we had. We appreciate that and, if there's anything

more you feel you would like to elaborate on, we are open for posthearing submissions until March 9th. But, we are certainly delighted.

Any -- Susan is just mentioning it would be certainly helpful to us as we look to design effective U.S. Government responses to the situation in China.

The more sort of written details you feel comfortable providing us about your experiences with different enforcement authorities in China, your experiences using the legal takedown mechanisms that are available, your experiences using takedown mechanisms that are available for different types of IP, those kinds of things provide us with a lot of insights and help us in our interactions with Chinese enforcement authorities to --

MR. GELFAND: A hundred percent. I'll start sending that in. We understand this isn't the Government's job to do this for us. It is a two-way street. We need to work

together to tackle this humongous problem. So, the more data we can provide, we are more than willing to do that.

So, thank you for all your help and your efforts.

MR. McCOY: Thanks very much. We really appreciate you coming and joining us.

Next on the list is Pharmaceutical Research and Manufacturers of America.

And, let me say, just as you are taking a seat that, you know, we have looked at your submission and some of the things you highlighted.

You may have heard my interaction with Mr. Flynn on behalf of the Global Health NGO's. Let me be -- let me give you kind of the other side of the coin on that.

We had a discussion, Mr. Flynn and I about -- about the information that's in the Special 301 Report right now on pricing and reimbursement systems, and potential problems they can cause.

We have seen, from your submission that PhRMA would like us to go a great deal farther in raising concerns about various pricing and reimbursement systems.

You just heard a number of concerns about why we shouldn't do that. What do you have to say about your views on that subject?

MR. TAYLOR: Would you like me to start by answering that or --

MR. McCOY: You can -- it is -- the floor is yours. You can start by answering that or you can roll right into your prepared remarks and answer it when you feel like it.

MR. TAYLOR: I think I'll close by tackling that issue. It is one that is very serious to us.

Thanks very much to the panel for the opportunity to appear in front of you this morning. My name is Jay Taylor, representing the Pharmaceutical Research and Manufacturers

of American, known in short as PhRMA.

PhRMA's member companies exist to create medicines that help save lives, fight disease and enable patients to live longer, healthier lives.

To accomplish these goals, biopharmaceutical companies invested over $64 billion in new research and development in 2009, with almost $45 billion invested directly by PhRMA's member companies.

In his recent State of the Union Address, President Obama offered an ambitious agenda focused on bolstering the economy and job growth, including the central themes of innovation and American competitiveness.

The President emphasized that medical innovation will continue to play a critical role in these efforts. PhRMA's member companies make enormous investments in our future, in our employees and in our economy, in part, because they can count on the United States' longstanding history of

strong intellectual property protection.

The result has been significant research and development investment by our members in the Unite States over the last 30 years.

These investments, in turn, have led to numerous cures and treatments for American and global patients, strong export performance and support for 3.2 million U.S. jobs.

At the same time, PhRMA member companies are actively engaged in solving the health problems of the developing world. Indeed, America's pharmaceutical companies are one of the largest contributors of funding for innovative treatments for diseases affecting developing regions in Latin American, Asia and Africa.

In the last decade, our companies have provided over $9.2 billion in direct assistance to health care for the developing world, including donations of medicines,

vaccines, diagnostics and equipment, as well as other materials and labor.

This highlights why the Special 301 process is so critically important to the biopharmaceutical sector, patients globally and America's economy and health care sector.

Intellectual property protections fuel investment in America's biopharmaceutical research and manufacturing sector, thereby permitting our companies to play a critical role in the nation's economic recovery.

Our industry supports 3.1 million American jobs, 650,000 directly. At the same time, our industry continues to be a core driver of U.S. exports. These jobs and exports exist for one reason. Our companies' invested in developing new medicines in the United States.

These benefits to our health care system and economy exist in large part because the United States respects intellectual property and the Special 301 process helps

encourage our trading partners to both respect the value of intellectual property and to live up to their trade obligations.

Review of PhRMA's individual country submissions demonstrates that many countries have failed to meet their obligations. The actual protection and enforcement of the intellectual property rights of these countries falls far short of the standards contained in the WTO agreement on trade-related aspects of intellectual property rights, as well as obligations under several U.S. free trade agreements.

In order to facilitate the protection of rights of U.S. businesses and foreign markets and foster innovative cures for the world's patients, we recommend that the United States first, reduce the number of U.S. trading partners that fail to enforce IP rights.

Second, assist countries to fully implement and enforce international IP

obligations.

Third, advocate at international organizations to defend and strengthen IP rights.

And finally, engage on foreign government price controls and cost containment measures that undermine IP and impede market access.

In closing, I would stress that we cannot continue innovation and progress in the medical sciences without strong enforcement of intellectual property rights.

Today we have a long history of securing appropriate protection for innovation and intellectual property.

America's patients and economy are better for it, and in order to secure these benefits for the future, we must remain strong and steadfast in our protection of intellectual property.

Thanks. That was our opening remarks. I'll now turn to the pricing

reimbursement question, Stanley, that you posed at the beginning.

We have raised pricing and reimbursement issues over the years in our Special 301 Reporting, and consider that those issues fall squarely within the statutory mandate of the Special 301 process.

In fact, if you look at the language of the statute -- give me one second. Section 301-D3-F2 of the Trade Act of 1974 expressly includes restrictions on market access related to the use, exploitation or enjoyment of commercial benefits derived from exercising intellectual property rights.

As our industry tackles many, many cost containment measures around the globe, we find ourselves caught in a situation where, due to issues like therapeutic reference pricing, international reference pricing, our prices are falling generally, particularly as they get lumped in the baskets with generic products, and this essentially devalues the

intellectual property that our companies have invested in these products.

I think we all know that generic products would not exist without the innovative products that preceded them, and the notion that our products, when they are -- you know, make it overseas, are then finding themselves in these situations where companies are no longer able to reap the benefit, recoup the large investment cost that goes into developing these products.

It creates a situation that we feel fits squarely within Special 301, and the process that this committee oversees.

Yes, I think, as all of you may be aware, the average cost of developing an innovative pharmaceutical is about $1.3 billion. Only one product makes it through out of several tens of thousands of products at the outset of development.

And so, what you end up with at the end of the day is a very important product

to our members, very important product to the world's patients, and this notion of pricing reimbursement and cost containment overseas is a real threat to those products, and it does truly undermine the value of IP.

Now, in terms of the comment about Medicaid programs and pricing and reimbursement of what the U.S. Government is doing as it looks forward to the Trans-Pacific Partnership and other agreements, as the panel is probably well-aware, both the Australia and Korea FTA' squarely, expressly separated out anything other than central government pricing program in a footnote in the pharmaceutical chapter.

And, in fact, in Korea this was even made more expressed by noting that Medicaid was not a central government program, making clear that those agreements in no way intended to encompass Medical programs, I think, discussed by one of the previous speakers.

So, I think there is a threshold matter. You have a very clear expression that those programs are not included in that discussion.

Secondly, when you deal with Medicaid, you are dealing with a very small population in the United States, as opposed to the systems we face as an industry, which are government-wide.

The governments tend to be our single payer. They are our single customer, and these systems affect the entire population, the entire market for our companies as they look overseas.

So, when you compare the magnitude, the scope of Medicaid to these giant programs that dictate market access for our companies globally, it is a very imbalanced comparison.

But I think more of a threshold issue, Medicaid simply is not included in USFTA's to date and, clearly, that would be

the case going forward with the TPP.

Sorry. I'd be happy to answer any other questions.

MR. McCOY: Well, just bringing it back to the -- how this translates into the Special 301 Report, then I take it, from having looked at your submission and the recommendations in there that you think we should expand our listing of countries for the pricing and reimbursement reasons?

MR. TAYLOR: Yes. I think the pricing/reimbursement fits squarely within the statutory mandate of 301 insofar as for industries like ours that rely so heavily on intellectual property, when you have a single payer system that is devaluing that intellectual property, that ultimately comes back to roost here in the United States with our companies and the investments that they're making in the products.

MR. McCOY: Okay. Thanks very much for your remarks. I was going to tell

you you have about a minute left, but if you are done, there's no need for us to use the time.

MR. TAYLOR: Thanks very much to all of you.

MR. McCOY: Thanks very much for joining us today. We are delighted you were able to join us and share some of your views and elaborate some on your written submissions.

Thanks, Jay.

Next we have Health Global Access Project. It is Matt Kavanaugh. Are you here?

(No response.)

MR. McCOY: Public Knowledge? Do we have Public Knowledge here?

You are actually welcome. I mean, I remember last year that we had a little colloquy about specific countries and our concern there, so I won't reiterate at great length except to say that it is, again, the mission of this panel to look at sort of

country-by-country issues and, to the extent you can identify ways to help us with that, that's probably of the greatest assistance to us.

MS. RANGNATH: Right. Let me start by answering that question.

First of all, thank you for inviting me to testify here and we appreciate the --

MR. McCOY: Thank you for coming.

MS. RANGNATH: So, the point about country-by-country reports, the point of our testimony is to provide input from the public interest perspective about how country-by-country comments provided by rightsholder groups should be evaluated.

We think that taking our perspective is important as the USTR looks at comments provided by rightsholder groups. So, that is the context in which we are providing comments.

So, although we don't identify

particular countries, we feel like when you evaluate particular countries for their -- under the report, you need to look at making sure that values that are held within the United States copyright system are reflective within the report, as well as the need to ensure that developmental needs of countries and the need for balance within intellectual property laws are taken into account as you evaluate countries.

So, that is the angle from which we come. So, with that, I am going to deliver my prepared comments and look forward to your questions.

So, the Special 301 Review process is a powerful tool to ensure protection for the U.S. intellectual property interests. We urge the USTR to use this tool to secure trade interests of all U.S. constituencies and not merely and narrow set of stakeholders.

For instance, the past few years have seen an increasing correlation between

the USTR determinations and IIPA requests, escalating from 83 percent in 2007 to 91 percent last year.

In doing so, the USTR, we think, has ignored the interests of internet and consumer electronic industries. In addition, we urge the USTR not to cause countries to provide for IP protections beyond the requirements of their international obligations.

To the extent that the USTR seeks changes to domestic policies of other countries, the agency should do so through diplomatic engagements rather than trade pressures.

This approach would foster better economic ties with U.S. trading partners. In order to secure these objectives, the USTR should, first, be mindful of the importance of a balanced copyright regime in protecting the interests of IP owners and users.

Second, not use the Special 301

process as a means to cause countries to accede to or implement treaties such as the anticounterfeiting trade agreement.

Third, introduce greater transparency into the review process. A balanced copyright system that secures rights for the benefit of owners and limitations and exceptions for the benefit of users has been the hallmark of U.S. copyright law.

This balance has fostered the development of creative industries such as film making as well as innovative industries such as the internet and consumer electronics industries.

These industries rely on copyright limitations and exceptions to make and market their products and services in this country and abroad.

Absence of this balance in other countries would harm the ability of these industries to export their products.

Therefore, we urge you not to be

swayed by rightsholders' assertions that limitations and exceptions in foreign/domestic laws amount to a denial of IP protection.

Such assertions are neither consistent with the U.S. copyright law, nor required by the Trade Act.

Countries should not be forced to accede to treaties such as the WIPO internet treaties and the anticounterfeiting trade agreement.

As we stated in testimony last year, countries may not accede to certain treaties out of concern that their provisions would not be conducive to national interests.

For example, in 2009 comments, Israel questioned the relevance of technological protection measures in copyright and, therefore, decided not to accede to the WIPO treaties.

Similarly, developing countries may consider ACTA provisions burdensome. For example, they may find ACTA's enforcement

obligations too onerous on their limited resources.

Decisions not to accede to particular treaties are the prerogative of sovereign nations and must be respected.

If the USTR deems particular policies of countries inconsistent with those countries' international obligations, it should engage with those countries diplomatically.

This approach is particularly prudent in today's world where emerging economies are growing in strength and offer attractive market access opportunities for U.S. producers.

Pressuring these countries to adopt particular IP provisions may push them to refuse to engage in trade with the United States.

The Special 301 Review process should be transparent. As we stated last year, the evaluation criteria used to list

countries on the priority watch list and watch list are vague.

Often reports have contained general statements such as the need to improve enforcement without further explanation of what that means. A clearer understanding as to why a country is cited can only be obtained by reference to the rightsholders' submissions which often complain against countries for including copyright limitations and exceptions within their laws.

In addition, the Special 301 Report seems to rely on rightsholder assertions -- on unverified rightsholder assertions and discredited methods of estimating losses, caused by intellectual property infringement.

In order to address these shortcomings, we renew our calls to the USTR to, one, make transparent the set of factors it uses for evaluating countries in each U.S. Special 301 Report, provide a clear written

explanation stating the basis for identification of a country in the Special 301 report and placement on watch list or priority watch list or for an out-of-cycle review and, finally, arrange for independent, external verification of country data and statistics submitted by rightsholders before making factual determinations based upon it.

Thank you, and I look forward to your questions.

MR. McCOY: Thank you, Rashmi.

You know, we did wrestle a bit with this question that you and others had posed last year of the desire to understand the criteria for placement as we work within the statutory mandate given to us by Congress and that mandate is what it is, and we -- but we do want to try to be clear and transparent in expressing the concerns of the U.S. Government through this process.

In an effort to shed some light on this question, we included in the 2010 Special

301 Report, on page two, a section on country placement that elaborates a bit on the Special 301 decisionmaking process.

I'm sure it doesn't answer all of the questions that you've posed, but I'd be interested, either now if you have immediate thoughts, or in some posthearing interactions and your thoughts about that explanation.

MS. RANGNATH: Well, the Trade Act calls for the USTR to identify countries that deny adequate and effective protection of intellectual property rights. Those are broad criteria.

And within those broad criteria, what particular issues do you look at? For example rightsholders' submissions have complained about, say, not signing onto the WIPO Treaties, and when countries do sign onto the WIPO Treaties, there are proposed law amendments to bring them into compliance with WIPO Treaties not going far enough.

For example, I think this year's

submission, and even last year's, complaints about proposed law amendments in India that says that the technological protection measures provisions are not sufficient because they allow for circumvention to accommodate for lawful users.

Now, when the report comes out it says India is placed on priority watch list because, among others, you need to improve enforcement.

What does that mean? Does it mean that you have considered those law amendment provisions adequate or inadequate? Does that factor into the decisionmaking process?

Things like that are useful for civil society and, for the countries themselves, it signals how agencies of the United States Government are thinking about copyright policies and we also urge you that while you are making these decisions you have to be aware of balancing provisions within U.S. law. So, that's -- right.

MR. McCOY: In that same spirit, Rashmi, we would be interested in any examples that you would care to provide, either now or in a follow-up submission of where the Special 301 Report has treated the existence of a limitation and exception in foreign copyright law as a trade barrier.

MS. RANGNATH: I will -- thank you for providing the opportunity for posthearing, and we will try to see if we can sift through that.

But, the point is that the report does not specify a lot, so it is hard to find those places where you've actually said that a limitation and exception is a trade barrier.

The point is that there is not a lot of explanation about what factors about -- what complaints of the rightsholders have you taken into account versus what you have not.

For example, agencies like the Federal Communications Commission, when they give their report and order lists the

discussion, this public comments, list what comments they took into account and what they did not and why they came -- arrived at a particular response at a particular decision.

Something like that that highlights "This complaint is valid, and this is why we think adequate enforcement is lacking," is important.

So, to look for specific examples where the USTR has cited a country for lack of limitations and exceptions might be hard because they are not cited. They should be.

MR. McCOY: Okay. Thanks very much for your input.

We have now reached noon, and it is time for us to take our one-hour lunch break. What I would propose at this point is that we start again after lunch and we pick up, if the representative of Health Global Access Project is available, then we can slot that presentation back in, but otherwise, we will pick up with Knowledge Ecology

International after lunch.

MS. RANGNATH: Thank you so much for having me.

MR. McCOY: Thank you very much for joining us.

(Whereupon, the meeting recessed for lunch at 12:02 p.m. until 1:04 p.m.)

MR. McCOY: All right. If we are all ready, should we get started?

I think our first presentation of the afternoon comes from Knowledge Ecology International.

Mr. Love, do you want to step up. Thanks for joining us today. I don't know if you were here for the intro, but rather than interrupt you at five minutes and do questions, which some of the participants found a little artificial last year, we have just been letting people know up-front what the questions are, if any, and letting them use the whole ten minutes and speak to questions as they like, and we will interrupt

if there are questions that come up during the presentation, but I think most of the back-and-forth this morning went pretty smoothly.

In regards to the information that you've provided, I think probably the most pertinent thing I mentioned earlier was that we are, of course, always most interested in country-by-country information or criticism, since that's a particular focus of this review.

So, you know, if there are particular statements about particular countries that are incorrect or need further explanation, we are always happy to look at that.

But, the floor is yours for ten minutes. Thanks very much.

MR. LOVE: Thank you. And before I launch into bitter criticism of U.S. trade policy, I'd like to stop by complimenting USTR, in general, and Stan, in particular, for being so accessible to us over the last --

well, the entire time that Stan's been working for USTR, and compares very favorably, in our opinion, to lots of dealings we have with other agencies and I just want to make sure that he understands that we are grateful for that.

Now, I will shift to the other gear.

MR. McCOY: Thanks. You can skip the bitter criticism, though. We just did ten minutes of that.

MR. LOVE: All right. Okay. Well, you know, one thing we had in our comments is that we noticed in some areas that the 301 list over the years has had areas where it doesn't seem to be about the enforcement or even protection of core U.S. interests, but it sort of seems to be overreaching about trying to promote certain policies.

One is the term extension on copyrights, just as an example. I can't

imagine that the U.S. is well-served by an endless copyright term, and it has created all kinds of problems about access to orphan works and things like that, and it doesn't really benefit anyone that's alive, obviously.

And so, it is weird for us to see things like that in the 301 list. I just don't think it belongs there. You have bigger fish to fry than trying to get 95 years of protection for some dead artist or something. I just think that maybe you should, you know, prioritize that.

The other thing is that there was this reference in last year's list to heat -- patents in India on heat stabilized drug and as if it was a bad thing that India wasn't granting any patents on processes that relieve the heat stabilization of medicines.

And I would have to say that getting appropriate delivery mechanisms on cheap generic drugs in developing countries is a super high priority for people that deal

with public health problems in developing countries.

A lot of places, as you know, and is actually mentioned in the 301 list don't have refrigeration goods -

The U.S. claims to be very concerned about the quality and safety of drugs, so I think you should recheck the idea that, you know, that you want to have super strong patent protection on things that make drugs more safe.

MR. McCOY: Can I interrupt you on that one for a second?

MR. LOVE: Yes. Yes, sir.

MR. McCOY: If I'm remembering correctly, the reference in the report was to sort of point out that it might be desirable to provide an incentive to invent not only things that, you know, enhance the efficacy of the compound, but also to provide incentives for inventions that might serve the needs of developing countries, such as temperature

stabilization.

MR. LOVE: I think that is wrong, and I think that it is -- yes, there is an incentive effect of providing strong patent protection on heat-stabilized formula in Bangladesh and Indian and Nepal and Thailand and places like that.

I don't think it is a very significant incentive, and I think that the harm you have from creating problems -- the first time you ran across this was the area of DDI when Bristol-Myers got a patent in Thailand on the enteric coating of DDI that wasn't even granted in the United States.

And, as a result of the patent, you know, the government there dispensing DDI in powder form, so you can imagine in Thailand every day AIDS patients taking DDI in a powder form and then mixing it before they take it, as opposed to taking it -- enteric coatings, like when you go to a drug store and you get like a nice coating on an ibuprofen or

something like that, which is how it is taken in the United States, I just thought that was really a bad outcome.

And most people involved in treatment thought it lowered the compliance and led to bad health outcomes.

So, this is like not a minor issue. It can't be a core U.S. interest to promote strong IPR protection on heat-stabilized drugs and, you know, you should think about that.

Another thing is, on data exclusivity, we raised the issue of what happens in some countries, because they get sort of pressured into having exclusive rights on data exclusivity, they don't even have compulsory license on data protection, whereas they have on patents.

So, data becomes like a stronger form of IP protection than a patent does. So, one way countries have done it is the data protection is related to drug registration.

So, what some countries do, they actually just don't even bother to register the drugs, or they claim they are on a clinical trial or something like so they basically kind of route around a policy because they wan access to cheap generic AIDS drugs where they may be able to resolve the patent issue, but they can't resolve the data issue.

I just think that's really not what you want. I don't think because you are -- you know, you say you care about the safety of drugs. You don't want people bypassing drug regulatory. If anything, you want to have stronger regulatory things in place that people actually use and respect.

I wanted to make a point, that really cover our comments, but that's not -- the relationship between a democracy uprising throughout the world and access to information, in general, I think a lot of what's been shocking and surprising in a very

pleasant way, this absolute great awaking about democracy that's taking place in so many countries right now is people have access to information.

They have access to Facebook, to Twitter, but you know, basically the, you know, the internet, they're sharing information, and the reaction of the governments to these things has been to short of shut down the internet, and to do these things of surveillance and, you know, kind of police state things.

So, a lot of these technologies are running parallel with what the copyright industry is doing on protecting copyright.

So, I just think what you need to do -- I don't think there's anything you need to do to protect copyright owners. It can be done with more sensitivity to the effect of repression and surveillance by dictators and things like that.

So, I just think, as your work

program going forward, you may want to at least have somebody take a look at this issue and see if there's sort of least restrictive in terms of the dictator route that can be done in terms of your enforcement things as it relates to the internet.

And also, recognizing that sometimes some of these personal affair use things result in very big political changes which are in the United States' interest and reflect our values.

On the issue of data, I think there that the issue for us is, in addition to being super strong, there's this ethical problem on clinical trials. It has been addressed in the WHO global strategy.

There's a -- there was a bill introduced in the Congress last year that will be reintroduced this year. You may think, well, it is not a lot. It's just a bill and things like that, but I predict that, as has happened in Europe on the area of the animal

testing, where now animal, you cannot duplicate trials on animals because the animal rights lobbyists succeeded in changing that and the EU is putting this into a trade agreement with respect to animal testing.

As relating to Canada, that human beings will start to achieve some of the same rights that animal have in testing in the United States and Europe, and I think, just looking forward, you should think about alternatives to exclusive rights and still protect legitimate interests of people that invest tens of billions of dollars in clinical trials, because I think they have legitimate interests, I just don't think that exclusive rights is the only way you can protect those rights.

The last thing I'm going to say right now is that if this becomes the best practices about the way to design the list, what we recommend is that you have a cutoff for countries based on their per capita income

where you don't really hassle them on the IPR issues as it relates to medicine and that it be some objective standard.

We thought, okay, if the United States makes four or five times as much money per capita as a developing country, I think you should leave them alone on the medicines issue.

If they go past that threshold, you know, I think they should participate more fully in the system of rewards for people that develop new drugs.

But I think you should sort of deal with that, and it is not just whether or not you like China or you like India or whatever, I think what you should really be focusing on is the per capita income of the country.

Or, you could also look at a metric like the percentage of the population that lives at less than two dollars a day or something like that. I mean, just sort of

drive into the process.

The LDC definition, which the U.S. tariffs used in the past was welcome, but it's kind of limited. As you know, it doesn't cover countries like Kenya or most of -- you know, a fair amount of Africa is not covered by that definition.

Only one country in the Western Hemisphere is covered by that definition. Haiti. And, you know, it's a fairly limited thing, and I think it's also a fairly political definition in itself.

That concludes my oral testimony.

MR. McCOY: I was about to say you've got about a minute left, so your timing is good.

David's just pointing out to me that we are not aware that we have any submissions this year nominating Sub-Saharan African countries for consideration for the list. I'm not aware that we have had Sub-Saharan African countries on the list in the

last couple of years.

That is not to say that, you know, that's not to say that's hard and fast, but --

MR. LOVE: Appreciate that.

MR. McCOY: Yes, go ahead, David.

MR. DRINKARD: That is not to say that there aren't any IP issues in Africa, and the embassy in Kenya has been actually involved in combating counterfeit pharmaceuticals as well as establishing an IP working group.

And there is an IPR working group at the embassy in Legos as well that's focusing on not only counterfeit pharmaceuticals, but other IP issues within the country.

So, the embassies are engaged on these issues within Sub-Saharan Africa, even though there aren't any submissions against them, but we don't have any nominations for Africa.

MR. LOVE: As you know, there's

quite a bit of controversy over the Kenya counterfeit legislation, as being --

MR. DRINKARD: Our efforts have been around public awareness.

MR. LOVE: Thank you.

MR. McCOY: Thanks, James.

MR. LOVE: Thank you very much.

MR. McCOY: The next on our list is Doctors Without Borders. Medecins Sans Frontieres.

MS. DREOS (phonetic): Thank you so much. Merci beaucoup. My name is Judy Dreos (phonetic), and I am the U.S. manager of the Access to Medicines Campaign of Doctors without Borders.

I would like, before my intervention today, I would like to just make sure that I'm mistaken, but I believe there is nobody representing DHHS at this hearing today.

MR. McCOY: I am not aware that there is. They are participants in the

Special 301 and the Trade Policy Staff Committee process that makes these decisions.

MS. DREOS (phonetic): I just would like to reiterate, for a second year we have a public hearing. We welcome the public hearing, but we regret that DHHS is not attending the meeting, as a medical organization within DHHS should be listening to what we have to say and what others have to say so we will basically reiterate our emphasis that DHHS should be sent -- should receive a copy of this testimony, but also should participate in further meetings.

And now I will start my intervention. Thank you for this opportunity to speak about the 2011 Special 301 Review Process.

Medecins Sans Frontieres, Doctors Without Borders is an independent international medical humanitarian organization that delivers medical care to patients in over 60 countries.

Our projects focus on the medical needs of poor people living in developing countries where medical needs are often the most neglected.

We seek increased access to affordable live-saving medicines, vaccines and diagnostic tools in developing countries and to stimulate the development of urgently-needed better tools for our field teams and the people in countries where MSF works.

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

Through the release of the Special 301 Watch List every year, the U.S. Government is trying to drive countries to implement

intellectual property standards above requirement for international law.

We urge the U.S. Government to abstain from threatening developing countries with trade sanctions simply by trying to respond to public health needs.

The problem of access to medicines extend to any drug that are not (IATA) of vaccine needed to treat, detect or prevent a range of diseases affecting the people MSF treats in developing countries.

The problem of access to medicine is not limited to HIV-AIDS and other communicable diseases. The global burden of noncommunicable diseases is increasing worldwide with the heaviest burden facing the low and middle-income economies.

However, the magnitude of the HIV-AIDS pandemic has highlighted the fact that millions in the developing world do not have access to medicines needed to treat the disease or alleviate the suffering because

their governments or they cannot afford them.

It has also shown the benefits that generic competition can have on the cost of treatment. Today five million people are on antiviral biotherapy. This is only possible because generic competition costs are not first-line direct prices to reduce from around 10,000 U.S. Dollars to under 80 U.S. Dollars today.

MSF could not provide treatment to 160,000 people in more than 30 countries without generic competition. The U.S. Government has also acknowledged the significance of generic competition in its global AIDS contributions.

PEPFAR, for example, has reported savings of up to 90 percent through the purchase of generic medicines.

Alongside the tremendous progress in AIDS treatment it remains a tremendous need. Ten million people more are in immediate need of treatment and increasingly

patients will need to switch to newer drugs to ensure their long-term survival.

MSF data shows how this will impact the cost of treatment programs. The WHO recommended second-line treatment is around 4.4 times more expensive than the most affordable front-line regimes, and extended third-line regimes are estimated to cost about 2,200 U.S. Dollars for one-year treatment.

That cost will increasingly limit patients' treatment options unless there are important price reductions of the kind seen through generic competition.

HIV-AIDS also serves as an example of the persistent and increasingly barriers to medicines access enforced by heightened IP measures.

The USTR continues to undermine both PEPFAR and the Global Fund and treatment providers such as MSF by threatening trade repercussions against countries that use the flexibilities in international trade law that

all for generic competition to continue.

In our 2011 submission we have highlighted the importance of the following three flexibilities, the rights to developing countries to define patentability criterias, the issue of compulsory license, the right to define the protection provisions and the right to define enforcement regimes.

We provide examples of Brazil, India and Thailand as developing countries that were included in the 2010 Special 301 Report for using these flexibilities. Using data exclusivity.

This is one of the most burdensome TRIPS-plus provisions because it creates a parallel monopoly with incremental effects in generic competition and ethical implications to repeat clinical trials, that recently the Obama Administration recognized the effect of the exclusivity on the cost of health care and included a proposal in its 2012 budget to reduce the damage of the exclusivity for

biologic projects and increased competition in the U.S. market.

The announcement for the prospective savings of 11 billions over the next ten years for the U.S. Government.

I have a point on -- also on patentability criteria. We are especially concerned also as Knowledge Ecology International, with a reference including the 2010 Special Report to produce stable forms of drugs or new means of drug delivery in reference to Section 3-D.

In our 2011 submission we have highlighted also the importance of the Brazilian and (IATA) area that has given a role to the National Health Surveillance Agency and Visa in the review of pharmaceutical patent applications to have determined whether patentability criterias are met.

Public health implications and access cost, monopoly protection in developing

countries be preserved and reserved only to truly innovative products, and the ministers of health are given a say in the review of the patentability criterias.

It is also important that developing countries rights to ensure and to issue compulsory license and to define the appropriate levels of performance, enforcement are respected.

Today, more than 3,000 people living with HIV-AIDS from all over Asia have rallied in India alongside the United Nations Special Rapporteur for the right to health, to protest TRIPS-plus measures that have been included in a trade agreement negotiated between the India and the European Commission.

If some of the provisions in the agreement go forward, India's capacity to remain the pharmacy of the world will be in danger.

With this testimony we join in solidarity with the protestors in India and we

urge the U.S. Government not to ignore their voices by pushing for similar standards.

The United States demands not only directly undermine the commitment made by the U.S. Government under the Doha Declaration and TRIPS Agreement on public health. Under WHO global strategy and plan of action on public health innovation and intellectual property, but they create a fundamental contradiction between U.S. trade policy and the U.S. Government commitment and priorities on global health and development.

We urge USTR to align themselves with better access to medicines policies pursued by the U.S. Government. For example, during the January 2011 Executive Board of the World Health Organization, the U.S. Government made a very strong statement in support of generic competition to lower the price of HIV-AIDS treatment in developing countries, recognizing the pharmaceutical price discounts do not always have as much an impact on

bringing prices down as robust generic competition does.

It urged companies to join the recently created Medicines Patent Pool in order to increase generic competition for newer HIV-AIDS drugs.

The U.S. presents a Special 301 process a tool to protect innovation. MSF recognized the importance of innovations and the need to finance research and development.

We are a humanitarian medical organization that needs and welcomes biomedical innovation to better treat our patients by seeking greater and higher intellectual property norms in developing countries, however, the U.S. Government, through USTR is perpetuating a business model that links innovation cost to high prices, and that's not addressed the innovation needs of developing countries.

There are better and newer ways the U.S. Government could protect and promote

innovation and they are currently being piloted and under discussion at the World Health Organization and other forums, ways that could combine innovation and access by the linking the cost of research and development from the prices of the products.

The Special 301 Report must no longer be used to incorporate TRIPS-plus measures to not require by international law. The Special 301 Report must no longer threaten developing countries for acting within their legal rights to ensure access to medicines for the populations.

Rather than using the Special 301 Report will not unilaterally impose a heightened IP regime on developing countries. The U.S. Government should lose its law, policies and financial resources to ensure the research and development, and encourage innovation and to ensure sustainability, access to medicines for all.

Thank you.

MR. McCOY: Thanks very much. I don't know if you were here. I had this back-and-forth with James already about something that came up in your submission as well which was this idea of Section 3-D of the Indian Patent Law and I want to thank you for citing particular examples in the report of language that troubled you, rather than just generalities.

I think, you know, -- I think in your submission you mentioned that -- that the U.S. Government was encouraging the patentability of known practices. I think if that was the impression that was given, that was certainly not the intention.

The U.S. Government supports the international standard of patentability, including the requirement of novelty.

I think the point that we were trying to make in the report at a point -- I'm getting to a question here. I promise. Its point -- a point that I'm wondering if you

have concerns about is that if the patent system is there to incentivise innovation, shouldn't it also incentivise innovations that would -- that would help to address concerns that affect drug delivery, in particular, relating to problems of developing countries.

Now, we can always debate whether a particular invention meets the test of being truly inventive or not, but as a general matter, I mean, do you have a -- do you have a view on that, and I ask that because it might help us to better articulate that point in the future.

MS. DREOS (phonetic): Yes, just before I try to answer your question and I will be happy to further answer your question in writing if that's useful.

When you talk about generalities, yes, we tried very hard in our submission to be very specific and to give you language, wherever we find it's very problematic, but I have to be honest with you, it's been very,

very challenging because we find the Special 301 list to be full of generalities, and to be very lacking of specificity.

So, I will encourage you as a best practice in next year to be much more specific what you mean and what you want from countries when you are citing them.

On the patentability criterias, the language is completely unclear and very general, but even in compulsory license, when you are criticizing Thailand and without saying it, for using compulsory license, and you are asking Thailand -- the Thailand government to incorporate pharmaceutical companies, you seem to be asking Thailand government to incorporate pharmaceutical companies and their deliberation process in compulsory license.

If that's not the case we will appreciate it if you were very clear on what you mean when you are putting countries in the lease and what ask, because it's challenging

for us to respond if not.

And on your specific question, I completely agree with the James Love from KI has responded. I think we basically will -- would like to make the point that he has made.

For us, as I explained in my testimony and in my oral submission and in my written submission is that we believe that intellectual property right systems has a role to play to protect innovation with a balance and within context.

We don't believe that pushing countries like India to protect the patents, products like heat-stabilized products and new means of delivery. They are not genuine innovation because they don't really have a therapeutic benefit. They have a -- they basically have improvement and they facilitate the treatment of our patients, but we don't believe this is the kind of innovation --

MR. McCOY: That was my question. I think you've answered it.

MS. DREOS (phonetic): Okay.

MR. McCOY: You don't think inventions should be patentable just because they're -- they don't have --

MS. DREOS (phonetic): If they don't have a genuine therapeutic benefit, no.

MR. McCOY: So, if it's an invention of, you know, that avoids the need for -- that helps to, you know, deliver the drug in the body or -- or, you know, make it heat-stabilized or whatever the case might be, you don't think --

MS. DREOS (phonetic): I think you have to differentiate between the needs of incentives and the need to patent that incentive, that invention. I mean, you could think of an incentive to the -- to innovate in that direction, but I don't think that's necessarily linked to a need for a patent on that invention.

You can think about other kind of incentives that don't create a monopoly.

MR. McCOY: We are over time. That's my fault. Thank you very much for joining us. Thank you for all the good work of MSF around the world.

Social Science Research Council. Okay.

MR. KARAGANIS: Thank you for giving me the opportunity to address you today. Just to preface, I want to say a couple of words about procedural reform of the Special 301 process, this is a subject we addressed in more lengthy comments last year and just repeated briefly in this year's submission, and then talk a little bit about the organization of software markets and the role of piracy within them because software losses are something that are referred to repeatedly in the Special 301 Reports over the years, and there have been some fairly significant changes in how the industry describes losses and these should be incorporated into future 301 Report, and we

think have implications for how the Special 301 Report handles questions of software enforcement.

We think there's a need for, you know, brighter lines around the kinds of requests that Special 301 places on other countries with respect to software enforcement.

And also by way of preface, I just want to note that when I was up here last year I said that we had a report that was almost ready to come out. This year it is still almost ready, but much closer, as you can see.

This is a proofer copy. There will be -- the full launch of the report will take place on Monday of next week. I wish I had had copies for all of you today but, in any event, most of my remarks today and in previous comments are backed by work that we have done over the last four years and now published in this report.

So, if these comments interest you

I will encourage you to take a look at the report.

So, broadly, on the question of procedural reform, I'd just like to note that, you know, the nature of the process has really changed over the last 20 years.

You know, the recent reforms around comments and, of course, in the holding of public hearings are a very good start and responding to what is really a kind of expansion of the range of stakeholders that understand the importance of trade policy and IP policy and feel a stake with -- a stake in the process.

This is a relatively new development. We think it's only beginning because of the range of issues that IP policy and TRIPS policy increasingly impinge on. The Special 301 process has begun to address that but, ultimately, I think we will have to do much more to expand the range of stakeholders that it listens to in composing the Special

301 Reports.

So, just to, you know, set an example, we have never seen consumer-oriented IP policy addressed through Special 301 Reports. We have never seen calls for greater exceptions and limitations to copyright to make other countries more congruent with U.S. standards or, for that matter, calls for public access to Government-produced research in other countries which is the norm in this country.

Those things would have clear public benefits, both for consumers and companies. This is something the KEI has hit on in the past. I think it's very important as we move forward.

The advisory groups to the Special 301 process still compose largely of the dozen or so industries that helped found Special 301 20 years ago. Why aren't there consumer groups as part of those advisory committees? Why aren't there other kinds of organizations

with a constructural voice in the process?

There's nothing in the statute, the 301 Statute, that requires the current composition of the advisory groups to be, you know, essentially the same stakeholders that created the process.

And the last two years have really begun to demonstrate how much more interest there is and how much broader the stakes are, as the process begins to open up and provide opportunities for people to be heard.

I'll just refer back to my earlier comments, my written comments if you want to learn more about that, and procedural issues are something we addressed at some length in the report.

And just to speak a little -- say a couple of words about software piracy and the organization of software markets, Special 301 Reports talk repeatedly about software piracy. In fact, it's probably fair to say that over the last ten years debates about

copyright enforcement and industry losses have been driven by software industry claims.

Certainly the software losses reported by the BSA of $53 billion in 2009 dwarf the claims by other industries by an order of magnitude.

The assumptions underlying these claims of losses have been widely criticized, especially the equivalents drawn between parted copies and lost sales, the rough -- the one-to-one equivalents.

As many people have noted in the past this was a more or less absurd assumption in developing countries where price-to-income ratios are very high and open-source alternatives to many of these software tools are widely available.

So, last year something rather significant happened in the evidentiary discourse that underlies software industry loss claims in this regard.

The IDC dropped this one-to-one

assumption and stopped characterizing losses in any terms at all. It now refers only to the commercial value of unlicensed software.

Losses have dropped out of the picture as far as the software industry is concerned.

So, given that, what happens to a decade of USTR policy that's been built at least partly around the incorporation of those loss claims?

I'll say, on this Special 301, I think judiciously backed off the use of numerical estimates of losses by industry a number of years ago, reflecting what has turned into a fairly broad-based critique of the methodologies used to produce those loss numbers.

This is, you know, a good step, but still makes -- and it's still framed by assumptions of massive losses that are just -- just characterize the discourse overall and no longer appear to need specific loss claims to

be repeated and reiterated in industry -- in Government documents and Government reports.

So, in the software context, again, I -- I'd like to emphasize that I think the USTR plays a -- has a pretty judicious stance toward what kinds of requirements it places on other countries, or what kinds of demands it places -- it makes on other countries, especially it plays an appropriate role when it encourages other countries to legalize the software in the public sector, and when it encourages enforcement against commercial pirate vendors under the TRIPS Agreement.

So, those are entirely appropriate roles, I think, but really, that's as far as the evidentiary basis goes in terms of harms, and at the edges of USTR language in the Special 301 Reports, there are a number of other kinds of vaguer hints about the appropriate behavior of other countries vis-a-vis software piracy that really suggest

alignment with the much stronger efforts to criminalize software piracy that BSA would like to see that IPA would like to see.

So, you know, I think it's important to step back briefly and look at how software markets are organized and to see that, you know, the software market --

MR. McCOY: I am sorry to interrupt you, but you've got about three minutes left.

MR. KARAGANIS: Sure.

MR. McCOY: But I'm wondering -- I was kind of expecting a "for example," there on what -- what are the -- you mentioned a couple of examples of asks that you think are on one side of the line.

MR. KARAGANIS: Sure.

MR. McCOY: I'm wondering what is the ask on the other side of the line.

MR. KARAGANIS: On the other side of the line, the criminalization of end-user organizational piracy is entirely addressable

through civil means.

The -- you know, something that appears in the industry literature, but not in Special 301 Reports is the push-back against Government procurement mandates for open-source software.

So, open-source is often evoked by other countries as a means of combating piracy. IPR reports in the last couple of years have begun to include criticism of these types of mandates as a restraint on trade on the basis of the claim that open-source software is less favorable to the respect for intellectual property rights than commercially-produced software, commercially-licensed software.

These sorts of things -- again, just in the spirit of drawing brighter lines around what the USTR is asking around software piracy, the criminalization of end-user piracy is a very poor policy object to include and this does pop up in some of the USTR country

language.

The Romania -- criticisms of the Romania government were tempered by positive language about criminal convictions in software -- in and around software piracy with the implication that if countries adopt stronger criminalization of end-user piracy, use of software by businesses, that this will bring them into closer alignment with what the USTR wants.

MR. McCOY: You've got about a minute left.

MR. KARAGANIS: Okay. So, just to summarize very briefly, piracy is part of the software business model in developing countries. This is not a controversial statement at this point. It's a form of price discrimination that the software companies use very successfully to lock in market share, to acquire 95 percent of market share or more in most of the countries under consideration, almost entirely through piracy.

Calling piracy a dead loss to the software industry, calling it theft just doesn't characterize how the market works.

The software business, the legalization which we fully support in these countries, proceeds through institutional licensing so the major software vendors generally cede the retail market to piracy in part by pricing retail software at Western prices which are totally unaffordable to most developing country publics.

That market is effectively ceded to piracy. Software companies then to in and enforce against public institutions, large businesses, and then that enforcement frontier is against -- is really built around enforcement against medium and small businesses.

And in my view and the view of the work that we have done in this report, it really shouldn't be the business of the USTR to help the software industry shift the cost

of optimizing its business model to public bodies in other countries.

That's -- it's a poor use of Government resources. It's legitimately criticized when those other countries object or prove to be recalcitrant in adopting those kinds of enforcement measures.

MR. McCOY: Okay. Thanks very much. I think our time is up, but that we appreciate your presentation. We appreciate your coming down here today and your participation in the process. Thank you.

MR. KARAGANIS: Thank you. I'm Joe Karaganis. I'm a program director at the Social Science Research Council in New York.

MR. McCOY: So next we have Oxfam America. Go ahead. Welcome.

MR. MALPANI: Thank you. So, it's Rohit Malpani for Oxfam America, which is an international development and humanitarian agency working on poverty reduction.

Before I start, sort of following

up on Doctors Without Borders' comment. There's nobody from HHS, but I was also wondering in terms of representation from USAID or from the Global Health Initiative, as well as the Food and Drug Administration, and just wondering as to whether or not there had been thinking about having either of those attend.

The Food and Drug Administration has done really good work and I have attended a couple of meetings with them where they really parse out the difference between, you know, counterfeits and substandards and falsified and generic medicines.

So, I think it would just benefit this hearing and, in general, as well as the Global Health Initiative which is trying to take more of a hold of government approach.

Any thoughts around that or --

MR. McCOY: The USAID wasn't able to make it today. They do routinely participate in the --

MR. MALPANI: It's a big agency, though. They even opened a policy department. Are they that busy?

MR. McCOY: I don't make those decisions.

MR. MALPANI: Maybe I can get a job there --

MR. McCOY: Similarly, FDA and HHS are both -- are both part of the TPS process--

MR. MALPANI: FDA is a really big agency, too.

MR. McCOY: Well --

MR. MALPANI: Just thinking that if you could have everyone else from these other departments you could probably spare even four hours, maybe they could just do the afternoon with all the public interest groups.

MR. McCOY: You are welcome to let those departments know of your --

MR. MALPANI: I'm not in the Government, though. You are.

MR. McCOY: Concerns of what --

MR. MALPANI: You are the chair of the -- you probably have more influence than I have, respectfully.

MR. McCOY: Go ahead.

MR. MALPANI: Okay. So, our submission this year focused on two interrelated topics, our views on the 2010 Special 301 Report and our concerns with the existing U.S. approach to evaluating the intellectual property framework for medicines in developing countries.

And I suppose I'm going to speak a bit more in generalities, but I'll try to link it back into specific countries, but apologies if I'm not fulfilling that.

So, I guess, first around the 2010 Report. We had hoped that the 2010 report would integrate key public health principles and tried on the Doha Declaration, and we acknowledge in the introductory language to the report that it does mention the Doha Declaration and the right of developing

countries to use key safeguards such as compulsory licensing to protect public health, but we were disappointed that, in practice, the U.S. continued to push for strict interpretations of key intellectual property rules that would limit access to medicines, while continuing to raise vague procedural concerns with the use of key TRIPS safeguards and especially compulsory licensing, and this would be especially in reference to Thailand, and I think I have had separate discussions around this where, you know, if you want to talk about transparency, then it would be helpful if you put out some indicators and criteria instead of just putting that in general, especially since the Government had, I think, issued three 100-page white papers that talked at length about the consultation process.

And I'm not sure -- if that's not transparent enough then perhaps nothing is.

With the remainder of my testimony

I'd like to outline three reasons why the 2011 Special 301 Report should do more to respect the right of all developing countries to adopt public health safeguards and flexibilities to the fullest, and I'll just conclude with some brief recommendations.

So the first reason, strict intellectual property rules that exceed WTO obligations, in our belief, do not lead to additional innovation, especially on behalf of patients in developing countries.

With the Special 301 Report, the U.S. Government is employing an approach to IP protection that contradicts the approach that the U.S. and other developed countries employed for their own national development.

Historically IP legislation is often followed development. As countries grow richer or wealthier, so does their IP framework evolve from imitation. And as they evolve from imitation to innovation, they have introduced more stringent intellectual

property laws.

Developing countries have faced an entirely different approach to IP over the last two decades. You could call it a double standard.

Instead of promoting innovation, we believe that ever stricter IP rules prevent developing countries from imitating, and thereby cultivating innovation-based cultures that can contribute to economic development and a broader public good.

Our own research in the last few years has shown that stricter IP rules, in fact, have done little to nothing to stimulate local innovation or to channel foreign direct investment that could improve innovation in developing countries.

For example, Jordan, which introduced TRIPS-plus rules in 2001 as a condition of a U.S. free trade agreement and their accession to the WTO, derive few benefits from stricter IP rules.

Local drug companies have not managed to increase their local innovative capacity and multinational pharmaceutical companies do not channel any new foreign direct investment into the local economy to stimulate innovation.

And, in fact, our study also showed that in Egypt, for instance, which had no IP protection until 2005, multinational companies had channeled $223 million of FDI into the generics industry because it's a big market, both within Egypt and regionally.

So, just to day that often this idea that you can draw a straight relationship between the two is a bit false.

Furthermore, stricter IP rules in developing countries do not alter the calculus that multinational companies employ when deciding where to invest limited R&D resources.

Developing countries, even after recent economic growth, still only represent

in total approximately 15 percent of global pharmaceutical demand.

Stricter rules in a few countries may generate greater profits for pharmaceutical companies, but it does not lead to additional innovation that would meet the public health needs of those countries.

And I'd also like to remind this panel that, alongside meeting minimum obligations under TRIPS, many developing countries are sharing the global burden for research and development through other means and this is something that's being discussed at the World Health Organization.

But, this includes, you know, serving as low-cost centers for manufacturing through government finance, research and development, which we can all agree there needs to be more of, and as a preferred site for drug industry clinical trials which enables drug companies to drastically reduce their costs, to test the medicine's safety and

efficacy.

There's a great piece in Vanity Fair from this January that talked a lot about this movement towards developing countries and it was talking more about the safety concerns, but it's also interesting in terms of the cost-per-patient actually goes down quite a bit for pharmaceutical companies.

And, you know, in the end, the benefits don't go to the same patients on which the medicines were tested on. And, as we were talking about data exclusivity, in fact, we are almost encouraging generics companies to test those patients again, instead of providing the benefits of medical research.

The second reason is, second, strict intellectual property rules in middle-income countries have negative public health impacts upon poor people in middle-income countries as well as upon patients in least-developed countries.

We are concerned that the Special 301 Report, in assessing appropriate levels of IP protection, ignores the high rate of poverty in middle-income countries.

While these countries have often experienced strong top-line growth, there remains enormous income disparities. A recent study published by the Overseas Development Institute calculated that approximately 1.4 billion extremely poor people live in middle- and low-middle-income countries out of a total of 1.7 billion worldwide.

So, while the tiny elite in these countries can pay high prices for medicines in the private market, the vast majority of people, and especially the poorest rely upon the public sector to provide affordable medicines.

High prices charged by pharmaceutical companies limit the coverage the public sector can provide and thereby limit access, especially to the poorest.

And this is often what we have talked about, again, with respect to Thailand and even countries like the Philippines or India. The Philippines has the second-highest medicine prices in Asia and the measures that they've taken in the last few years to actually introduce TRIPS flexibilities that exist in many other developed countries, you know, I think should be welcomed by the United States and not criticized, given the lack of access to medicines in the public and the private sector.

And I'd also like to say, when generic production is delayed or limited in middle-income countries, it directly impacts access in the world's poorest countries.

This is, as you know, because the least-developed countries have little or no manufacturing capacity to produce pharmaceuticals and must rely upon generics produced in middle-income countries and especially India which, as other people have

said, is popularly known as the pharmacy of the developing world.

And we believe that solution, such as the Paragraph 6 Amendment, which often the U.S. talks about, have failed to deliver upon its promise and have been views as a solution wrapped in red tape.

Our believe is, in the foreseeable future, only generics produced and exported from developing countries with viable generics industries can ensure access to medicines in the world's poorest countries.

Thirdly, strategies employed by the pharmaceutical industry to promote access to medicines -- and I'd just like to say donations are broadly criticized by civil society groups and multilateral organizations, and I believe even by PEPFAR.

They are not sustainable. They interfere with the generics markets and they can have very bad impacts on public health systems.

So, when you hear a presentation about donations, that's not a good thing, and that's something which even the WHO has strictly said, except for elimination of neglected diseases, has very bad impacts. So, let's not cheer about donations of drugs.

But just to say, other strategies used by multinational companies, including differential pricing and voluntary licensing have been insufficient and inadequate, especially when compared to the benefits bestowed by generic competition.

I would remind the panelists that the inability of multinational drug companies' to ensure access to medicines has been reaffirmed by the U.S. Government, as mentioned at this January's executive board meeting of the WHO.

The director of the U.S. Global -- U.S. Office of Global Health Affairs stated, "Recent studies have demonstrated that differential pricing does not always have the

impact on the pricing of medicines that robust generic competition does."

In addition, we would also note that pharmaceutical company strategies are often restricted to a few high-profile diseases, are entirely dependent upon the whims of a pharmaceutical company's charity, and are often limited in geographic scope.

In particular, while drug companies have shown limited response in its concerns about the high prices of first-line AIDS medicines, few companies have addressed the high prices of medicines to treat noncommunicable diseases such as cancer, heart disease and diabetes.

In the developing world, these diseases are the major cause of death and disability, and in many of the countries which you criticize on the 301 Report, the World Health Organization estimates that 80 percent of all deaths from noncommunicable diseases occur in the developing world today.

So this is a real problem. It's a big focus this year at the United Nations, for instance, and strategies to address this sort of burgeoning epidemic of noncommunicable diseases.

And finally, I'd like to reiterate that the provisions that exceeded those established in TRIPS should not be demanded of developing countries through this Special 301 Report.

MR. McCOY: You've got about a minute left.

MR. MALPANI: Okay. Of particular concern to Oxfam from previous 301 Reports are date exclusivity, patent extensions, patent linkage and expansion of the scope of patentability, and we think that it should not criticize countries for using compulsory licensing.

And finally, that the 301 Report should not be used to either introduce new IP enforcement obligations related to

pharmaceuticals or to expand or modify the definition of a counterfeit medicine so that it is confused with either generic medicines or substandard of falsified products.

Then finally, just to say that, you know, we have applauded the efforts of the Administration to develop and implement the Global Health Initiative which seeks to introduce the whole of Government approach to improving access to health care in developing countries.

It its deliberations, we hope this panel and others who cannot be here today do not take actions that would undermine the efforts that the U.S. Government, other donors and poor countries, as well as poor people are taking to tackle diseases that afflict the world's poorest people. Thank you.

MR. McCOY: Thank you for joining us today, and thank you for the work your organization does around the world.

MR. MALPANI: For the record,

Rohit Malpani from Oxfam America.

MR. McCOY: And our next speaker is from Balanced IPR Organization. You'll want to press the button right in front of you there. Welcome.

MR. HUDSON: There we go. Thank you. Thank you for the opportunity to be with you today. My name is Brendan Hudson with Balanced IPR Organization.

I have had about 12 years of experience in IPR enforcement efforts, and that's the issue that I want to talk with you about today, the USTR's role in that.

I formerly worked with the U.S. movie industry. I'm no longer associated with them, to be clear, and have had experience in running or supervising IPR enforcement programs in at least 20 countries and two different continents.

I have also had about 12 years of experience with the 301 process and I would like to say thank you for all of the work that

you've done over the last 12 years. It has been a very effective leverage for us in improving IPR enforcement for U.S. companies and U.S. products.

I would also like to mention, completely off-topic, that a 95-year or more extension of copyright is not a little fish to fry. It's rather a very cute little mouse to protect, so I hope you would continue to do that.

It is my hands-on experience in those countries that brings me to talk with you today about an issue that I also consider to be a very big fish for you to consider and fry, and that's corruption.

Corruption, piracy and counterfeiting all go hand-in-hand. It's been my experience that the underlying problem in IPR enforcement really has much more to do with corruption than any other issue that I have come across.

Corruption and ineffective IPR

enforcement goes hand-in-hand, and corruption in the inability for American companies to properly sell their product in foreign markets goes hand-in-hand.

Corruption is a fundamental impediment to effective achievement of U.S. trade policy and trade law objectives. Anticorruption, on the other hand is a fundamental policy, a fundamental principle of U.S. foreign policy.

It is an issue that, at the very highest levels from the President to the Secretary of State, to the Attorney General, has been stated as a commitment and priority of this Administration.

So, it's really our purpose today just to take a few minutes to encourage you to make sure that anticorruption and trade policy, particularly as it affects IPR enforcement, go hand-in-hand.

We believe that USTR can have an immediate impact on improving IPR enforcement

in a number of markets where we have problems, simply by addressing this issue.

Now, it's kind of unusual, I think, that you -- for to bring the issue up saying that IPR can address it and specifically can address it by bringing up the issue with U.S. companies.

But that not only is consistent with comments that the U.S. Attorney General and the Secretary of State have made, it's also very much consistent with reality.

If we take a look at how IPR enforcement works in foreign countries, it really is the private sector. It is U.S. companies that run it. It is -- in nearly every country where there are IPR enforcement efforts, 75, 80 percent of all enforcement is done in coordination with the U.S. private sector or their foreign agents.

I managed millions of dollars in various countries that we used to contract agents, foreign agents to do our work. You

rarely see a U.S. Government official actually doing the hands-on antipiracy or IPR enforcement, it's the U.S. private sector, either directly or through associations.

Now, the problem really is this, is that there are millions of dollars that are used to hire foreign agents. They have incredible financial incentives to get results for U.S. companies.

They work in an environment that's corrupt. It's just basically corrupt on almost every level in a lot of countries, and they often have very little control, and certainly no awareness of U.S. position on anticorruption.

So, concerning USTR's role and the role of 301, I had mentioned previously that 301 actually does have an important aspect, an important impact in leveraging IPR enforcement in a lot of countries and I have used that, myself, and have had other people use it.

Seen from the U.S. point of view,

you know, sometimes people just kind of raise their eyebrows at the 301 list, but the truth of the matter is, we have used that, that listing and admittedly has been our PR effort.

It significantly impacts public opinion and the opinion of governments in those areas. And, you know, the problem with that is that -- what that does is it, then, gives a certain amount of credibility to the local effort.

It is almost -- it is very difficult sometimes determining where U.S. influence stops and where foreign agents that work for U.S. companies begin.

And for enforcement officials it is -- it can lead to some difficult situations, particularly when there is not sufficient controls.

Given that, what we have done -- and I hope you will take a few minutes to read the submission that we had. We would like USTR to take at least three specific actions

that we do believe would have an immediate impact.

The first is discussing any new 301 Report, and discussing it as a serious position consistent with the seriousness that it's been given by the President, by the Secretary of State and by the Attorney General, at least.

Second is working with the U.S. Intellectual Property Enforcement Coordinator, who -- I am not sure his -- I believe he is not here today, but as I understand, USTR will be working with the IPEC to come up with action plans, and we would encourage that those action plans include anticorruption efforts. It could be education, awareness and especially for reporting.

And third, and to include that in your -- on going forward annual reports to the Ways and Means Committee and to the Senate Finance Committee as a way of showing how we have -- how you are addressing that issue.

And, given that, if you have any questions.

MR. McCOY: We appreciate your input on this. A couple of questions, thoughts. One is, are there particular countries where you feel this needs to be addressed?

I recall, in past reports, we have talked about local protectionism and corruption as an IP enforcement issue in China. So, it has come into the picture from time to time before.

I think it is an interesting suggestion that we do this more -- more comprehensively, but one thing that would be helpful to us is your thoughts on where there are particular countries you would like us to look at or if you are more asking us to look at other efforts that are already undertaken to assess corruption overseas and sort of incorporate those into our thinking?

MR. HUDSON: Well, specifically

for those countries that you are going to list and for those countries for which you will have an action plan done with IPEC, that it should be included in every single one of those.

Now, it is difficult to say that only third-world countries have corruption. The truth of the matter is, you can go from northern Europe to Southern American, to Asia, and you are going to have those problems for the reasons that I have given you.

There are extreme financial advantages and incentives and a lack of control. So, I would say included in every country that you list.

MR. McCOY: Okay. Thanks very much. If you would like, as a matter of, you know, posthearing submission, to provide us any more details on particular countries and how the -- how the anticorruption issue has concretely impacted IP enforcement in those countries, that's always welcome.

I know we have received considerable input from our folks in China on that, but should you want to expand that out a bit, by all means, please do so.

MR. HUDSON: Thank you. Thank you for your time.

MR. McCOY: Thanks for joining us today. We appreciate it.

The next speaker on our list is International Intellectual Property Alliance.

Michael, welcome. I wanted to -- I wanted to ask you the -- first, thanks for your highly country-specific recommendations.

We -- most of our questions, as we read through your submission, related to particular countries where your perspective has changed in one way or another from last year, so I might just ask you a blanket question.

If you can take advantage of your remarks today to mention a couple of the most prominent countries where you feel the

circumstances have changed, and make sure we are apprised of the change in circumstances that you feel is relevant, I think that would be of greatest interest based on the feedback I have received from the members of the Subcommittee.

MR. SCHLESINGER: Certainly, Stan. Thank you very much. I will try to do so. To the extent that I fail, you can remind me again at the end.

Well, good afternoon. I'm Michael Schlesinger. I'm counsel to the IIPA. I'm appearing before you on behalf of IIPA, a coalition of seven associations, 1900 companies which make up the major sectors of the U.S. copyright industries.

We appreciate the opportunity to weigh in on the 2011 Special 301 process, and we thank you for your time and want to thank you for your efforts here in Washington and around the world.

In this year's Special 301

submission, IIPA has identified 40 countries that deny adequate and effective protection of intellectual property rights and/or deny fair and equitable market access.

By denying such basic protections and access to their markets, these countries' practices harm our creative content businesses that bring movies, music, software, video games and books to the world.

These businesses remain critical to the future growth of the U.S. economy, provide millions of jobs and help expand exports in line with the Administration's goals.

It should, therefore, be a critical part of the Special 301 process to define concrete plans of action for the year ahead and longer term, to improve copyright protection, reduce global piracy levels and open markets to U.S. copyright content around the world.

There are massive costs

attributable to piracy, market access barriers, investment barriers and discriminatory treatment to U.S. firms.

Unfortunately, today, not only physical piracy, but more than ever, internet and mobile piracy threaten businesses built on copyright protection.

Legitimate online business models, while growing in number and size, are still dwarfed by and have significant difficulty competing with the massive proliferation of illegal services.

IIPA's filing seeks to help the U.S. Government define and seek implementation of concrete solutions. We do this through identifying key copyright industry's initiative and challenges for 2011.

We first address the overarching need for deterrent enforcement responses to copyright piracy through passage and implementation of good TRIPS-compatible and WIPO internet treaties, WCT and WPPT-

compatible laws and enforcement procedures to deal with specific problems.

We discussed the enormous challenge posed by internet and mobile piracy, including the need for a multifaceted approach, a strong legal framework, appropriate levels of responsibility for online infringements that foster cooperation among all stakeholders involved in the online supply change for creative content and strict enforcement by governments against online theft of copyright.

As one example of this problem, the entertainment software association study found that in 2010, ESA vendors detected more than 144 million connections by peers downloading illegally only some of ESA members titles.

The top five countries in that study were Italy, China, Spain, Brazil and France.

We also point out the independent

and Envisional study which concluded that almost 24 percent of all worldwide internet traffic is copyright infringing.

The IIPA submission also addresses the unauthorized use of software within businesses, enterprise and user software piracy, the principal and most damaging form of infringement to the business software industry today.

More than $55 billion worth of unlicensed software was used globally in 2010, including more than $32 billion of U.S. vendor software.

This problem requires a specific enforcement response, including deterrent level civil and criminal actions, inspections, audits, and ensuring legal software licensing practices ensue among corporate entities and governments, thereby setting a good example for the populace-at-large.

And, if I have time at the end I would love to respond to the statements of my

colleague at SSRC.

We talk about the critical nature of technological protection measures, TPM's, which are used to foster new business models for distributing creative content and also use to ensure that works made available in the digital and online environments are not easily stolen.

We highlight the need to address the ever-increasing threat from those who build their business models around providing devices, tools or technologies to gain unlawful access to our content, including our video games and defeat these TPM's.

Examples include mod chips, game-copiers, softmodding. These are just some of the sophisticated techniques used to ravage the console-based video game market, as an example.

Redress illegal camcording by which 90 percent of newly-released movies that are pirated can be traced to those who use a

digital recording device in a movie theater to literally steal the image and sound right off the screen.

One thousand major motion pictures were stolen this way in 2010, causing dramatic harm to the markets for those motion pictures.

This harms U.S. films, but it also harms the local film market. For example, we had 52 detections of Thai films that were stolen right off the screen in 2010, illegally camcorded. We also show a 48 percent increase in 2010 in illegal camcords in Thailand.

The motion picture industry urgently needs help to address this problem through adequate laws, training of cinema personnel and strict enforcement.

Submission addresses both piracy, large-scale photocopying of entire books, commercial print piracy and increasing unlawful digitizations or online copying of published materials.

This form of piracy also needs

governments to recognize the extreme harm, and we need help to set a good example in the education sector.

Redress game cartridge counterfeiting which is essentially a Chinese export, damaging the world's markets for those games. We also discussed physical optical disk piracy and signal theft of pay TV content.

India accounts for more than $1 billion in value in unauthorized pay TV content through individual tapping into systems illegally, illegal distributions and underdeclaration.

The IIPA submission also draws out the direct relationship between piracy and market access barriers and calls upon policymakers to recognize and draw on this relationship to help make the reduction of market access impediments a key component of ongoing efforts to combat piracy.

Simply put, if we can't bring in,

publish, show, sell, promote creative products in countries due to artificial barriers, we cannot do business there.

Such barrier is an additional burdensome, discriminatory requirements such as censorship on foreign titles, such as we experience in China or undue costs, such as unusually high customs valuations, as is being introduced in Indonesia, act to subsidize pirates who do not have to deal with such barriers.

Such barriers also stifle the growth of local creative communities since they discourage creative collaborations.

Recognizing all these challenges in each country report, in our submission, IIPA has sought to identify specific priority actions, short-term goals with expected real commercial returns as well as medium and longer term systemic changes.

There are commonalities in the report that are highlighted there, and you can

take a look at them, but I think I'll stop here to leave a couple of minutes for any additional questions.

MR. McCOY: You've got exactly a couple of minutes, and I think what would be of greatest interest to the subcommittee is if you could mention a couple of countries that you think are particularly notable where something has changed, causing you to change your perspective.

I think the one that stood out to the Subcommittee was Saudi Arabia where a year ago I think IIPA had recommended favorably on their removal from the list and this year your view has changed, but we would be open to hearing about others as well.

MR. SCHLESINGER: Well, sure. Very, very briefly on Saudi Arabia, obviously we are talking about the largest potential market in the Middle East, in the Gulf.

The other countries in the Gulf have effectively addressed their -- most

intellectual property concerns, not all, but Saudi Arabia is the one market where we still face difficulties.

We note in the report that legitimate revenues in the UAE are actually greater than the legitimate revenues that we received in Saudi Arabia, notwithstanding the exponentially larger size of the potential Saudi market populace.

We also note that gains that we expected to see in the criminal enforcement process were not achieved in 2010, and thus, we are asking for USTR, once again, to note Saudi Arabia and to watch the developments there.

A couple other markets, just to mention, ones where we have recommended an elevation from previous years. In the Philippines we have not seen sufficient progress on implementing the new anti-camcording law.

We also have a situation where,

frankly, the court system is so unreliable with respect to the issuance of search warrants and quashal of the search warrants, that it's very hard for us to devote significant resources into a system where we don't know whether we will get any justice at the end of the day or actual protection.

So, those are just two reasons. In Costa Rica we saw a roll-back in copyright protection, in particular, with respect to phonograms and performers.

In Viet Nam and in Spain we see the rapid increase in the internet piracy problem, proliferation of online access. Viet Nam doesn't like to hear it, but they are going down a very similar road to China in terms of relying mainly on administrative enforcement mechanisms and not having any effective criminal enforcement mechanism place or one that is arguably in violation of their BTA obligations. You could --

MR. McCOY: Let me say, just thank

you very much.

MR. HUDSON: Sure.

MR. McCOY: A quick highlighting, and I also want to thank you for what I'm sure must have been a considerable effort to streamline your two-phone-book-sized submission into a one-phone-book-sized submission. Those of us who have to read them all appreciate it greatly.

But, thanks for your remarks today. If there's anything that you needed to say that you weren't able to say, we welcome a posthearing submission, but we have got your submissions and we are pouring over them.

MR. HUDSON: Thank you very much. I would certainly like to clarify some of the SSRC's statements that have been made today and we may do that in writing. Thank you.

MR. McCOY: Thank you very much.

The next speaker we have is Public Citizen. Welcome. Thanks very much for coming. Thanks very much for coming, Peter,

and we are looking forward to your presentation. The floor is yours for ten minute.

MR. MAYBARDUK: Thank you, Stan.

Thanks, everyone, very much for holding this hearing. My name is Peter Maybarduk. I'm the Access to Medicines program director at Public Citizen, a nonprofit consumer advocacy organization based here in Washington, D.C. We have 80,000 members, 200,000 members and supporters.

In my hearing statement I offered to yield my statement time for questions regarding Ecuador's compulsory license issued in April of this year and their Access to Medicines policy.

As some of you know, Public Citizen has provided technical assistance to Ecuador in the Access to Medicines area, assisted in the development of the policy and ensuring its TRIPS compliance.

So, I'm more than happy to answer

any questions that you have. In the absence of the questions at the outset, I can walk you through some of the documents I have just handed you, if that would be for the best.

MR. McCOY: I think we would welcome that.

MR. MAYBARDUK: Okay. Okay. Well, as a threshold matter, I think it merits saying that Public Citizen does support many of the criticisms articulated today regarding the 301 process.

But we would like to focus in on one country that is making use of its public health rights under WTO rules and the Doha Declaration.

We have been working with the government of Ecuador for several years, not in any paid capacity, but consistent with our mission to improve access to medicine worldwide.

And we have maintained a dialogue during that process with U.S. Government

agencies and with the U.S. Government, the U.S. embassy in Quito regarding any updates as a part of the compulsory licensing Access to Medicines policies out of Ecuador.

I'd like to have a look real quick at the 2010 Special 301 Report and note some language on page 13 which we appreciate. Consistent with these views, the United States respects our trading partners' rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement and encourages our trading partners to consider ways to address their public health challenges while maintaining intellectual property systems that promote investment, research and innovation.

I would contend that Ecuador's process, certainly consistent with the provisions of the TRIPS Agreement and it will be important in terms of demonstrating the veracity of this statement in the 2010 report to not list, to make any reference to Ecuador

for compulsory licensing policy in the 2011 report.

In your packets here, the comments that we submitted to the 301 process, narrative brief review because these hold true, and the compulsory license, itself, is included both as a -- both in the official Spanish and an unofficial translation. For any legal questions, please refer back to the original Spanish.

But on October 23rd, 2009, Ecuador's president, Rafael Correa, issued Decree 118 declaring access to priority medicines affecting the health of the Ecuadorian population to be a matter of public interest.

Although not required by TRIPS, the decree satisfies an Andean Community Proviso enabling Ecuador's Patent Office, in cooperation with the Ministry of Health, to receive compulsory license requests and issue licenses case-by-case on public interest

grounds.

Since that time, in April of 2010, Ecuador issued its first compulsory license for the HIV-AIDS medicine Ritonavir, which is an essential component of the Kaletra second-line AIDS treatment, say the terms of the license, as I said, are included there.

It's a license for public use satisfying -- and now we have biddings between Abbott and Cipla, which is represented in Latin America by ESKEGROUP to help reduce costs in that treatment.

So, I guess, just to highlight some of the ways in which it's a TRIPS -- you know, in which it's a TRIPS-compliant policy and a transparent policy, the patent office in Ecuador has met at least twice with the American embassy in Quito. Probably several more times by now, as well as with the patent-based pharmaceutical companies' trade association, IFI in Ecuador, which issued a public statement accepting the decree.

The compulsory license policy adopts many TRIPS terms verbatim, nonexclusivity, predominant supply of the domestic market, adequate compensation patent holders, license review and termination.

Interagency agreement is required for the issuance of public interest licenses, so there is a process and there is a case-by-case evaluation.

The royalty payment system -- well, actually, at this juncture probably merits turning to earlier this year when Ecuador's trade preferences were being reviewed there was a submission by the Emergency Committee for American Trade to USTR, which put forward several what we would characterize as -- well, certainly unsupported claims regarding that policy.

And in there you have our submission clarifying the truth behind some of these questions. ECAT stated that TRIPS provides countries with the right to use

compulsory licensing when there's a national health emergency but, of course, under WTO rules, countries have the freedom to determine the grounds upon which such licenses are granted.

ECAT stated that Ecuador appears to be basing licensing findings on the presidential "degree" rather than making individualized decision, but it does require -- but, in fact, the decree requires licensed applicants -- that license applicants, each require that a license request be evaluated according to the supported circumstances of each case, must be reviewed case-by-case by the patent office and the Ministry of Public Health.

ECAT accuses Ecuador of failing to promptly notify rightholders and asserts that patent holders are denied the ability to participate in a meaningful way but, in fact, Abbott was notified of ESKEGROUP's license request within days of admitting the completed

license application for consideration, and five weeks before the compulsory license was granted on April 14th and so on.

So, we considered some of the criticisms that have been put forward of Ecuador's policy. While they are unsupported, it's very hard to find any evidence for the claims.

In last year's 301 Report, on page 31, Ecuador is cited in the realm of compulsory licensing as follows: "The United States will continue to monitor recent developments concerning compulsory licensing of pharmaceutical and agricultural chemical products in Ecuador, bearing in mind the discussion of the Doha Declaration on TRIPS and public health in Section One of this report."

With the license issued since, what we would like to see this year, as articulated also in last year's comments, "USTR should not cite Ecuador for any matter

related to that country's TRIPS-compliant protocol for the compulsory licensing of pharmaceutical patents in the public interest.

"USTR should also not sanction Ecuador's compulsory licensing protocol indirectly, for example, through imprecise references to alleged IPR protection failings in Ecuador through otherwise unwarranted elevation in Ecuador's Watch List status."

So, to return to the point, if, indeed this language from the 2010 report on page 13 holds true, that the United States respects partners' rights to grant compulsory license consistent with the TRIPS Agreement, there's a perfect opportunity here to demonstrate the truth of that claim by omitting any reference within the 301 context to Ecuador's compulsory licensing policy.

And given that great pains have been taken -- and I'm happy to elaborate on that -- to ensure TRIPS compliance of that policy, I think it would be very difficult to

support any -- to support any other treatment in the report, any mention whatsoever of Ecuador's licensing policy in the report without coming into a contradiction with the language on page 13 with the assurance about respecting partners' rights to protect public health under WTO rules.

I suppose that's my submission. I'm very happy to answer questions about this policy. Last year there were -- you know, I also offered to answer questions about the interagency process on counterfeit drugs. There were a number of questions for public health groups last year on that set of issues.

MR. McCOY: I think it has been a really helpful drill-down for us on the situation in Ecuador if we have -- you know, if we have questions on this going forward. As folks on the Subcommittee study the materials, we will know where to find your but, for the time being, we appreciate the input and your time today to educate us

further on the work Public Citizen has been doing in Ecuador.

MR. MAYBARDUK: Yes. Let me add one addendum, actually. That occurs to me -- we gathered that some of the concern around Ecuador's policy was related to a perceived issue that this could be -- that no one knew where the boundaries were, this could be an entirely open-ended policy.

No one knew sort of what would happen next. And, given that there has been one compulsory license granted, and given that -- because I was in Quito three weeks ago, and I can say that there's actually -- you know, there have been license requests, at last one license request staid, basically denied, and multiple times, you know, in this license that was issued as well as the new public request that's been put forward, those requests have been sent back to the license applicants for amendments, basically for failure to dot their I's and cross their T's.

I mean, they actually have pretty exacting requirements on this in Quito and be happy to dialogue separately about that.

MR. McCOY: Okay.

MR. MAYBARDUK: Thank you.

MR. McCOY: And I think next we have Mike Mellis from MLB Advanced Media.

Hi, Mike. Welcome.

MR. MELLIS: Hi.

MR. McCOY: We are -- I don't know if you were here at the beginning, but rather than, you know, rather than interrupt you at the five-minute stage, we are just going to let you take your full ten minutes here and I'll let you know, at the outset, some of the questions or thoughts we had in looking at your submission.

One was that just wanting to better understand the types of efforts that you are undertaking on sports broadcast piracy around the world and any examples you've encountered of sort of best practices on

public/private cooperation on this issue.

One of the things we have been asked to do by the Intellectual Property Enforcement Coordinator in the Joint Strategic Plan is to use this year's Special 301 Report to spotlight best practices.

So, that's one thing that you could do today that would be helpful to us. Another thing would be to go in a little more detail to a couple of things that you mentioned in your submission.

One was the situation in China, the example of TVants is one that was mentioned in your report. Another is the example of Israel and some of the concerns there. Those are both situations of continuing interest to the Subcommittee.

But, you have the floor for ten minutes. You can address those questions to the extent you would like, or you can give your prepared statement or you can follow up with a posthearing submission if you would

like to do that.

MR. MELLIS: Okay. If I might, could I just read my statement and then -- I have taken some note and I think I could try to answer your questions as best I can.

MR. McCOY: By all means.

MR. MELLIS: Mr. Chairman and members of the Committee, I would like to thank you for the privilege of addressing you this afternoon.

My name is Mike Mellis and I'm senior vice president and general counsel of MLB Advanced Media, which is MLB's internet and interactive media company.

Under the leadership of Commissioner Selig, MLB has developed highly-successful, diverse and innovative sports media businesses.

On television our game telecasts are distributed nationally through direct TV, the ESPN, FOX, IN DEMAND, the MLB Network, TBS and Verizon locally through broadcast

television stations and regional sports networks and internationally to over 200 countries and territories and the U.S. Armed Forces overseas.

On the internet we have been a pioneer. Our first live game webcast was in 2002. Since then our mlb.com TV Subscription Service which distributes thousands of games each season to fans on personal computers and wireless devices has served more than one billion live video streams.

Clearly, rightsowners like MLB can be adversely impacted by telecast piracy and, as we explained in our past letters and testimony to the Committee, there is an emerging form of telecast piracy now, the unauthorized internet streaming of live television programming of all types, including live sports.

The number of rogue sites and services involved is significant. Many are open-doors, permitting any type of television

programming to be streamed live, persistently and globally, without authorization from copyright owners.

In our recent letters to the Committee we have identified rogue sites and the nations where they are located.

The threat this poses to the U.S. televised media sector must be taken seriously. Although there is much that remains unknown about this problem, particularly with respect to its offshore aspects, it is clear that on an annual basis thousands of hours of live television programming from U.S. networks are being pirated, included, a significant piracy of live sports.

In our rights enforcement efforts, the dominant pattern we have continued to see is piracy occurring through offshore sites and services and, in particular, streaming over peer-to-peer services based in China.

In the recent out-of-cycle review

of notorious markets in the 2010 Special 301 Report, USTR identified one of the latter services, a streaming over peer-to-peer network called TVants, based in Shijiazhang, China as a notorious internet market. Another is called Stream Torrent, also located in Shijiazhang, China.

Our copyright law is clear. This is copyright infringement. As ICE's recent seizures of rogue site domain names show, it can also be a crime, however, domestic copyright enforcement is a remedial tool available only in limited circumstances.

This is because the piracy is global, often involving sites and services that operate offshore, outside the effective reach of our courts.

We therefore believe that international cooperation must be improved. Most nations are both exporters and importers of television programming, so we see common ground, both in terms of shared economic

interest and legal obligations for the U.S. and its trading partners to work cooperatively to curtail this problem.

We would like to commend USTR for identifying this matter in its 2008, 2009 and 2010 Special 301 reports and in its recent out-of-cycle review of notorious markets.

Since the problem is continuing, we recommend that USTR continues to identify it in the 2011 Special 301 Report and gives it priority in trade negotiations.

As we develop more experience in this area we look forward to the opportunity to make additional recommendations to you.

Once again, thank you very much for your interest in this matter and the opportunity to address you this afternoon.

Okay, Stan, to dive into your -- to try to answer your questions: Number one, what do we do in terms of rights enforcement? What we at mlb.com have an in-house rights enforcement team.

We have had to hire people to deal with this problem. We are now in our -- we will enter our fifth season of comprehensively monitoring the internet for incidence of live game telecast piracy.

You know, we have quite a few games, over 2,400 games a year. It's a big task to monitor literally hundreds of different sites and services that we are aware of where this problem has manifested and document what we see.

We think it's important to create a data set, you know, where are we seeing problems, how often, and the like, and that's one reason why we do it.

Another reason why we do it is, obviously, to try to stop it from happening where we can, and that involves cease and desist correspondence and, in some cases, specifically in the United States where some services have automated take-down tools, we can click and get streams blocked almost in

real time.

So, it depends on the level of cooperation of the site or service provider. But with respect to the offshore aspect of the problem -- and let's talk about China for a minute, and a site or service like Stream Torrent, which is a peer-to-peer network, they are unresponsive and our efforts to contact them and other rightsholders that I know of are just ignored.

We have not litigated this matter yet, but others in the sports community have. The Premier League has filed a number of lawsuits in Scotland, in England, in Israel, UEFA, the Dutch Soccer League. Erevidisie has had several lawsuits in the Netherlands.

So, there has been, you know, litigation taken up by sports leagues out of their home bases to try to address this problem, but we -- we have not been engaged in that exercise yet.

MR. McCOY: And can you tell us a

little bit about the situation in Israel?

MR. MELLIS: Yes. The situation in Israel is that the Premier League started a lawsuit several years ago against a service that was persistently and chronically pirating their soccer matches.

They did not know the -- they do not know the identity of the people or the entity behind it, so the case is captioned "Premier League versus Anonymous."

And in the Tel Aviv District Court there were two opinions issued. The first opinion which was not given any legal effect was that the matches were not subject to copyright.

That is obviously an incorrect decision as a matter of U.S. copyright law and under Israeli copyright laws we see it under treaties.

The judge, then, kind of retracted that decision and the decision that is now up to appeal at the Israeli supreme court held

that it's a fair use to retransmit live the entirety of a Premier League soccer match or, I should say "matches," because it just goes on and on.

And, like I said, that's up on appeal in the Israeli supreme court, and I believe the oral argument -- the argument before the court is next month.

The Israeli government has taken a public position against this decision at the district court level. The Israeli government advisor, which I understand is their equivalent of attorney general or solicitor general here in the U.S., filed a memorandum of law arguing why sports telecasts deserve copyright protection as much as any other cinemagraphic work and why and how if, if these rights were not enforced in this case, Israel might run afoul of its treaty obligations.

MR. McCOY: Well, very good. Thank you very much for making the trip today

and for sharing with us your perspectives on this problem.

As I -- I don't think you were here when I mentioned this at the outset, but because you mentioned the notorious markets list, I'll just repeat that the notorious markets list that came out yesterday, our intention is not to duplicate that list again in the report that comes out at the end of April, but to continue the process as an out-of-cycle review, so that would mean we would do a new request for comments later in the year with a view to a new out-of-cycle review in the period between Special 301 Reports.

But, thank you very much for your input today. It's much appreciated, and your insights. And I believe, Mike, that brings us to the end of the schedule for today.

MR. MELLIS: Thank you all very much.

MR. McCOY: Thank you.

So, we have nothing further by way

of announcements here except to thank you all once again for your participation in this process, and to let you know that the chair of this Special 301 process and the organizer of today's hearing, Paula Pinha, is sitting immediately to my left, and she can be your -- she can be your target for all praise and complaint.

But I want her to be, first, the target of my praise for her considerable efforts in putting together this hearing today. Thank you very much.

Thank you to all the members of the Subcommittee for your time and attention today, and taking time out of what I know are very busy schedules, to hear from members of the public about the important process before us.

And, thank you to all the members of the public and representatives of industry organizations. I will remind you one more time that posthearing briefs are completely

optional.

They may be submitted until five p.m. on March 9th, 2011. Your posthearing briefs should be sent electronically via www.regulations.gov, Docket Number USTR-2010-0037.

Please put the term "2011 Special 301 Review" in the typed comment and upload field on www.regulations.gov.

Thank you very much and have a good day.

(Whereupon, the meeting was concluded at 2:38 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Special 301 Hearing

Before: U.S. Trade Representative

Date: 03-02-11

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

Court Reporter