BEFORE THE
OFFICE OF THE U.S. TRADE REPRESENTATIVE

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SPECIAL 301 SUBCOMMITTEE
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SPECIAL 301 REVIEW
PUBLIC HEARING

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WEDNESDAY, MARCH 3, 2010
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The hearing convened at 9:45 a.m. in the Hearing Room in the offices of the United States International Trade Commission, located at 500 E Street, S.W., Washington, D.C., Paula Pinha, Chair, presiding.

PANEL MEMBERS PRESENT:

OFFICE OF THE U.S. TRADE REPRESENTATIVE:

PAULA PINHA, Chair
STAN McCOY

U.S. DEPARTMENT OF AGRICULTURE:
OMAR KARAWA

U.S. DEPARTMENT OF COMMERCE:

SUSAN WILSON

U.S. DEPARTMENT OF HOMELAND SECURITY:
SEBASTIAN WRIGHT

U.S. DEPARTMENT OF LABOR:
MAUREEN PETTIS

U.S. DEPARTMENT OF STATE:
JEAN BONILLA
TIMOTHY McGOWAN

PANEL MEMBERS PRESENT (Cont.):
U.S. DEPARTMENT OF THE TREASURY:
TIMOTHY MILLS

U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT:
GEORGIA AMBUNARIS

U.S. COPYRIGHT OFFICE:
MARIA PALLANTE
AMANDA WILSON

U.S. PATENT AND TRADEMARK OFFICE:
MINNA MOEZIE
SUSAN TONG

WITNESSES:

SALVADOR BEHAR, Legal Counsel for International Trade, Government of Mexico
SUZANA VASQUEZ, Ministry of Foreign Trade, Government of Costa Rica
CHAKARIN KOMOLSIRI, Office of Commercial Affairs, Royal Thai Embassy, Government of Thailand

JITTIMA SRITHAPORN, Office of Commercial Affairs, Royal Thai Embassy, Government of Thailand
LILA FEISEE, Biotechnology Industry Organization
SHAUN DONNELLY, National Organization of Manufacturers

RASHMI RANGNATH, Public Knowledge
ERIC SMITH, International Intellectual Property Alliance
EMI MACLEAN, Doctors Without Borders
BRIAN TOOHEY, Pharmaceutical Research and Manufacturers of America (PhRMA)
MICHAEL MELLIS, MLB Advanced Media, L.P.

ROHIT MALPANI, Oxfam America
JAMES LOVE, Knowledge Ecology International

WITNESSES (Cont.):

MATTHEW SCHRUERS, Computer & Communications Industry Association

SHARON TREAT, Maine Citizen Trade Advisory Commission and the National Legislative Association on Prescription Drug Prices (NLARx)

ROBIN LUNGE, Vermont Commission on International Trade and State Sovereignty

SEAN FLYNN, Forum on Democracy and Trade and American University Washington College of Law Program on Information Justice and Intellectual Property on behalf of the AdHoc Civil Society Coalition on Intellectual Property and Access to Medicines

BENJAMIN STERN, Universities Allied for Essential Medicines

ASIA RUSSELL, Health GAP (Global Access Project)

MICHAEL PALMEDO, Program on Information Justice and Intellectual Property

PETER MAYBARDUK, Public Citizen

JOE KARAGANIS, Social Science Research Council

C O N T E N T S

P-R-O-C-E-E-D-I-N-G-S

9:50 a.m.

MR. McCOY: Thank you, Ms. Braxton. Welcome everyone this morning. My name is Stan McCoy, I'm the Assistant U.S. Trade Representative for Intellectual Property and Innovation and to kick off this mornings hearing on Special 301.

It's my privilege to introduce to you Ambassador Mirian Sapiro, the Deputy United States Trade Representative.

AMBASSADOR SAPIRO: Thank you very much, Stan. Good morning everyone. I'm truly delighted to be here and I wanted to welcome all of you, a very warm welcome to the Public Hearing of the Office of the United States Trade Representative on the Special 301 review.

Our objective today is simple, it's to listen and to gather information to prepare the annual Special 301 report. So I will keep my remarks brief.

Let me begin by thanking all of you for coming here this morning and taking the time to share your views with us. I also want to thank the agencies that are represented here today and that will help USTR prepare this report.

And I would be remiss if I did not thank the International Trade Commission for providing this comfortable venue.

As the President has emphasized, economic recovery cannot be driven simply by American consumption. America needs a new growth model going forward, one that is based more on exports and investment than consumption.

We know that exporting jobs grow faster, add jobs faster and pay higher wages. We also know that the protection and the enforcement of intellectual property rights is a critical component for American businesses and entrepreneurs.

Earlier this week, the President

delivered his 2010 trade policy agenda to the Congress.

That agenda makes clear, and I'm going to quote, "That because fostering innovation is essential to our prosperity and to the support of countless jobs in the United States, we will protect American inventiveness and creativity with all of the tools of trade policy."

The President's agenda cites specifically insufficient protection of intellectual property rights as undermining key comparative advantages for the United States in innovation and creativity to the detriment of our businesses, our workers and our families.

It states that we will address insufficient protection of intellectual property rights by negotiating and enforcing effective intellectual property protection in a manner compatible with basic principles of public interest.

The trade agenda also recognizes the importance of transparency and public consultation when addressing intellectual property issues. Today's hearing is one of the ways that we are seeking to achieve this.

We want to ensure that Special 301 decisions are based on a full and complete understanding of all of the complex issues involving intellectual property protection.

Over the past 20 years, the Special 301 process has contributed to the development of the international legal and enforcement infrastructure for the protection of the rights of innovators and creators, and it continues to do so.

I've seen most recently in the recent USTR announcements, successfully concluding separate Special 301 out of cycle reviews for Israel and Saudi Arabia.

This process works largely because the report shines a spotlight on insufficient IP protection and enforcement. That sends a

message to the world, including potential investors, about that trading partner's level of commitment to IPR protection.

The Special 301 process also affords an opportunity to give credit to partner countries that do improve their protection of IPR. Input from the public is absolutely critical to ensuring that we make effective use of the Special 301 process.

As you deliver your statements today, I encourage you to bear in mind the statutory mandate that Congress has given to USTR.

To identify countries that deny adequate and effective protection of intellectual property rights, or deny fair and equitable market access to persons that rely on IP protection.

Your comments will be most helpful to USTR and to the interagency team working on this review, if you can use the time available today for your presentations to direct our

attention to the information that you believe is most important and you want to be sure that we review as we fulfill this mandate.

So I thank you again for coming today and for your participation as we all work together to prepare a full and accurate report. Thank you.

MR. McCOY: Thank you very much, Ambassador Sapiro. Just from the housekeeping side, we've allotted 10 minute intervals for all of the speakers.

The way it will work is that we will have -- this timing light immediately in front of me runs in five minute intervals. So a yellow light will come on four minutes into the initial presentation and then a red light will come on.

And that's the signal that you should finish the sentence you're in the middle of and pause and we will take the opportunity at that point to see if there are any questions from the panel. I will invite

my colleagues on the panel to pose questions.

The timer will cycle again for another five minutes to allow time for those questions. If we run out of questions, we'll just ask you an open-ended question if there's anything you want to add. You can use the entirety of that 10 minutes as Ambassador Sapiro just said.

What we encourage you to do is in the short time available, to direct our attention to those parts of the written submissions you've made or to anything else on the record that you feel is important for the folks here at this table to be looking at as this review proceeds.

That's really the most helpful thing you can do for us. Let me just look around and see if there are any other matters of a housekeeping nature.

As the notice indicated for this meeting, there will be an opportunity to submit post hearing comments if you feel

there's anything you weren't able to cover fully in your comments today.

Post hearing comments are open for a week. So any -- if you feel there's anything that needs elaboration or clarification, you're welcome to go ahead and submit a post hearing comment as well.

With that, I would invite Mr. Salvador Behar from the government of Mexico to come to the front and be our first presenter this morning. We're honored to have you Mr. Behar. If you would please go ahead as soon as you're ready.

MR. BEHAR: Thank you, Stan, Ambassador Sapiro, members of the special committee on 301. First of all, let me thank you for this opportunity to participate in this hearing.

For the first time, Mexico is doing active participation in the process of the review and we are fully committed on IPR rights.

We also understand that this public hearing, as Ambassador Sapiro mentioned, will serve as information gathering for the special committee and present their report to the Congress in 2010.

The government of Mexico wishes to congratulate the decision of the Administration of President Barack Obama to enhance and promote participation of the public on foreign government's as part of the transparency policy government administration since he took office in 2009.

The government of Mexico and the U.S. have developed a strong bilateral cooperation relationship and the high level regarding protection of intellectual property rights, and to strengthen this protection and enforcement in the NAFTA region and abroad.

The government of Mexico recognizes the importance of adequate IP protection regime. We also recognize that piracy and counterfeiting have become

international issue that effects innovation and creativity globally with a severe impact in our stakeholders and government and custom government's human and economic resources.

The purpose of this presentation is to provide, and especially to you, an overview of Mexico's efforts in combating piracy and counterfeit but does not pretend to be an exhaustive list of activities nor efforts from the Mexican authority responsible for IP enforcement.

Mexico has been actively engaged in multilateral efforts to enforce intellectual property rights in various international forum, including, but not limited to the World Health Organization, World Intellectual Property Organization, OECD, WTO, WCO, the Security and Prosperity Partnership, which now we have a group there that will be continue its efforts.

As a clear commitment to protection of IPR national and

internationally, since October 23, `07, Mexico was part of these multilateral engagements with several countries with a negotiation of ACTA.

ACTA seeks to provide a firmware for countries committed to strong IPR protection, to more effectively combat the challenges, piracy and counterfeiting.

Moreover, in January 2010, Mexico hosted the seven round of negotiations of ACTA in Guadalajara with scientific result and getting close to reach an agreement expected to be concluded by the end of 2010.

It is important to highlight that Mexico and Morocco are the only two countries, developing countries participating in these organizations and were Mexico is the only Latin American Country.

The government of Mexico is also committed to transparency and therefore in 2010, the Minister of Economy the Mexican Institute of Intellectual Property and the

Mexican Corporate Office held a joint public consultation process to receive input from the community and the stakeholders concerning ACTA.

Needless to say, this public hearing fully complied with the confidentiality agreement of the ongoing negotiations.

On the 15 in Guadalajara, and the 19 in Vera Cruz, both of October `09, Mexico hosted two sub-regional conferences on IP and Competitiveness of Small and Medium Enterprises in the Agro-Foods Sector in Latin America, respectively. Regarding international corporation of the specialized agencies protecting your rights, we would like to share with you that Mexico incorporation with INTERPOL hosted the fifth congress in counterfeiting and piracy in Cancun during December 1st to the 3rd 2009.

More than 800 delegates representing more than 80 countries met to

support the World Customs Organizations on WIPO, the International Chamber of Commerce through the business action to stop counterfeiting and piracy BASCAP initiative.

The International Trademark Association and the International Security Management Association, government officials and private sector representatives share a proposal for disrupting current worldwide illicit trade and counterfeiting problems.

Mexico currently chairs a group of experts of APEC as well chaired by the Director General of IMPI. Mexico has become also a leader in protection of patents in Central America, launching the support system for management of patent applications for the Central American countries and Dominican Republic.

MR. McCOY: Salvador, can I ask you to pause at this point and we're just picking up on one of the themes that you mentioned that involved cooperation, I believe

that my colleague from the State Department has a question that elaborates on that point. Jean?

MS. BONILLA: Yes, thank you. May I ask, and thank you for appearing for us before us this morning.

May I ask you to comment on the IIPA submission, which indicated that their stakeholders believe that we need significantly better cooperation and participation of local authorities in Mexico in order to more effectively deal with IP enforcement issues.

What are your views on how effective such an approach might be in combating piracy and counterfeiting in Mexico.

MR. BEHAR: Thank you, Mrs. Bonilla. I'm sorry five minutes is too short to explain one or more years of actions in Mexico, but we believe -- we agree that corporation, not only with the state and municipal government's is important, it's also

important among the agencies in Mexico.

We have developed an intergovernmental working group in Mexico where the Attorney General office and enforcement authorities work together and they meet regularly to seek for a better way to enforce IP rights.

I'm glad to share with you, for example, that the power of this action is one member of the Mexican Institute of Industrial Property, by the way IMPI is responsible of 5P enforcement not only for trademarks and patents, but also for corporate, that's why IMPI is an important element for enforcement.

But one member, one detailed person from IMPI has been attached to the customs officers. And there are I think six ports where there's a representative to make more efficient the communication among the agencies.

Also not only in the municipal and state, but also internationally I can tell you

that we have detailed one diplomatic member of the Mexican Embassy to the IPR coordination center.

It's the first time ever Mexico works with the U.S. on that way and we are glad to do it, we are looking forward to expand and the results are there.

There is operation called Holiday Hoax that shows the results. It was a joint operation between the IPR center Mexican offices coordinated from there.

MR. McCOY: Thank you very much. I'd like to give the floor now to my colleague from the Department of Labor for another question.

MS. PETTIS: Good morning. Could you explain in your view how intellectual property protection and enforcement has changed in Mexico since the release of the 2009 Special 301 report?

MR. BEHAR: Well, the enforcement mechanism has not changed. We believe we have

a strong legal framework. We have -- what has changed is the level of enforcement.

We have deployed more officers, we have deployed more actions, we are combating in the flea markets, we are doing raids in customs. We believe one of the most important points where we have to focus in the ports to stop getting into the market.

Once it's in the trade arena, it's more difficult for us to make the job. So we believe that working with customs, working in the ports is one of the important tasks.

Nevertheless, we have deployed, in `09 for example, one camcording campaign, which basically means it was the first time ever we did it.

Basically what we did was an education campaign, we also deployed in the premiers of one movie or so a whole action of cover operation.

There was cover agents inside the theater, agents from IMPI on PGR outside

watching what the people was doing inside the theater, for example.

MR. McCOY: Well, thank you very much, Salvador, for providing such a comprehensive presentation in the short time available.

If there are any additional points that you didn't feel you had an adequate opportunity to make, we would certainly welcome receiving further information from you as a post hearing submission.

And of course you know the government of Mexico is always welcome at USTR and we look forward to our continuing productive engagement with you.

MR. BEHAR: Thank you very much. And as always, it's a pleasure to work as well with you and we look forward to working together.

One minor comment that I couldn't address because of the time concerns, but we do have a specialized court now for IP rights,

which is a huge development for Mexico as well.

MR. McCOY: Thank you.

MR. BEHAR: Thank you very much.

MR. McCOY: If I could now invite the government of Costa Rica, Suzana Vasquez from the Ministry of Foreign Trade to come forward.

Thank you so much, Ms. Vasquez, for honoring us with your presence this morning. We're delighted to give you the opportunity to tell us for five minutes about the IPR situation in Costa Rica and ask a few questions. So please take it away.

MS. VASQUEZ: Thank you very much and good morning, Ambassador Sapiro, the rest of the members of the committee. During the past few years Costa Rica's been in a constant process of issuing and enhancing legislation on intellectual property rights.

We're also a party of several international agreements including the main

WIPO agreements. And as you may be aware of, we're a party of the CAFTA agreement since January 1, 2009.

As part of the implementing process of this agreement, the CAFTA and several Bills and international agreements were approved by congress, both to comply with CAFTA commitments as well as to enhance and improve some additional aspects of the protection of these rights.

These efforts included several amendments to the trademark law, the patent law, the bio-diversity law, the law on disclosed information, the corporate law and the law on intellectual property rights enforcement procedures.

We also issued a new law for the protection of planned varieties and issued several international agreements including the Budapest Treaty, the Trademark Law Treaty and the UPOV Convention.

In addition to these legislation,

the government also issued several regulations to develop some specific aspect of these laws. One of the regulations that's important to mention is the amendments to the regulations on the registration of pharmaceutical products, which it came to develop the procedures for the protection of test data of new pharmaceutical products.

In application of these executive decree during the course of 2009, data protection was granted for four new pharmaceutical products for a period of five years.

Also regarding judicial and any assertive action it's important to mention that at the end of 2008, the general prosecutor appointed the specialized prosecutor on intellectual property, which a main objective is to have a specialized office which in charge of coordinating the procedures on IPR cases that are followed in our courts.

Also it's important to mention

that our municipal authorities have started to take a strong action against IPR violations.

One good example of this took place last September, 2009, when the Municipality of San Jose confiscated and destroyed over 35,000 counterfeit CDs and DVDs with a value calculated in over 35 million colones, which is around $74,000.

This was the second confiscation and destruction of counterfeit products that took place in 2009. And in general, these actions taken by the municipality are undertaken in the framework of their institutional policy against illegal street vendors.

Within these policies in 2008, the municipality has confiscated and destroyed over 110,000 CDs and DVDs. And the main objective of the municipality now is to target and attack the chain of distribution of the companies or the groups that produce these illegal CDs and DVDs.

For this, they have kept a strong coordination with the public ministry, specifically with the unit of quick procedures, which allows them to take very efficient actions.

And it's important to mention that other municipalities from other locations in Costa Rica have started to take these types of actions in their locations, such as in Escazu, Heredia, Belin, Santa Ana, Cartago just to name some.

Also with the objective of strengthening and improving coordination between different government agencies involved in the application and protection of intellectual property rights, the government formally created and appointed an inter-institutional commission for the protection of intellectual property through a decree that was published on December 2009.

The idea of this commission is to create an inter-institutional coordination

body between both government agencies and with the private sector.

Regarding the CAFTA implementation issues, it's important to mention that Costa Rica has successfully accomplished to implement all its obligations that are enforced to this date.

The only issue that's still pending of approval in Congress is the last Bill on intellectual property which includes three minor amendments to three articles of separate laws on intellectual property.

This Bill is in its final stages of discussion in Congress and it's expected to be formally approved in March of 2010.

With regards to capacity building and institutional strengthening, the National Registry of Copyright and Related Rights and the Industrial Property Registry have undertaken an important process of strengthening capacity building, modernization of IP system and infrastructural improvements.

In this sense, they have appointed several new officers including a five expert examiners for evaluation of patents with which they expect to make a patent examinations more efficient.

Also the Ministry of Justice have started the construction of a new and modern building specifically to host the intellectual property registrations.

And they have also recently installed an electronic system for the processing and application of trademarks and patent, which was hosted by WIPO.

MR. McCOY: Thank you very much, Ms. Vasquez. If I could ask you to pause for a moment and entertain a few questions from us. I'll give the floor first to Ambassador Sapiro.

AMBASSADOR SAPIRO: Thank you very much for that presentation and encouraging report on all that the government has done this past year.

I wanted to come back to the idea of a specialized IP prosecutor and ask you what kinds of resources do you think could be devoted to such an effort and what your view is on where things stand so far.

MS. VASQUEZ: Yes. The idea of the specialized prosecutors office has been there like for a couple of years. And the main constraint for the establishment of this office are financial resources.

This is why the general prosecutor, what he did in the meanwhile was to appoint a specific prosecutor in the like miscellaneous affairs, prosecutors office, which is in charge of, amongst other, the IP cases to coordinate OIP cases in such a matter that they can be attended in a more efficient way.

We are hopeful that with the next government that's starting next May, with the President Chinchilla who actually was a former Ministry of Justice, we can retake this idea

of operating a specialized office.

MR. McCOY: Thank you very much. Could I also ask you, we received a couple of submissions indicating concern that the Attorney General's office had instructed enforcement officials to refrain from intellectual property raids. Is that something that you could clarify for us?

MS. VASQUEZ: Yes. Actually, well we read the submissions from the private sectors stating those allegations. We have consulted with the Attorney General's office and they had informed us they have no specific instruction in that sense.

We do have some possibilities in our criminal procedures regulations that apply to all cases, including IP cases, which allow the judges to dismiss cases that are not considered relevant, but this doesn't apply only to intellectual property it applies to any type of cases.

And I believe this is why there is

some representatives from the private sector have a concern. However, the idea the appointment of this prosecutor office, this specialized prosecutor to coordinate IP cases is basically to make sure that IP cases are followed correctly.

MR. McCOY: Thanks for that clarification. Let me give the floor now to my colleague from the Department of Commerce for another question.

MS. WILSON: Thank you for your testimony. If you've read the submissions then you're definitely prepared for this question, which is related to the other two.

Again, on the issue of prosecution of cases you noted in your submission that your standing by ready to do cases and you just explained that different mechanisms may not be set up for a few more months, Ethiopia cetera, but that you're standing by and that you have resources available, but that right holders aren't taking advantage of what you

have available.

In other submissions that we've received from right holders, they're saying that they're having difficulty getting the attention of enforcement officials of prosecutors, Ethiopia cetera.

Do you have any suggestions of how there could be better coordination between the right holders and the prosecutors and other enforcement officials?

What mechanisms might exist that could facilitate this, what future mechanisms might be put in place, how we could get them communicating better and working better together?

MS. VASQUEZ: Yes. Actually within the Ministry of Foreign Trade after we're finished with CAFTA implementation we thought of other actions we should take and one of them are a capacity building activities involving both the prosecutors office and the private sector to get like better information

and how this resources, the private sector it has according to our legal system a work and how they can be more efficiently used.

And direct from these activities and conversations that they can take place between the authorities and the users of the system, perhaps we can come up with necessary amendments or guidelines by the prosecutors office that can help these resources be taken better advantage of.

Because the reality is that these resources in which the right holders have like an opportunity to help the prosecutors office to follow these cases are not very much used.

So we think it's very important to take advantage of this and have a better communication between authorities and users of the system.

MS. WILSON: So is this something for example that you would be willing to help facilitate through our embassy, you could facilitate such a dialog in capital or --

MS. VASQUEZ: Sure it is, yes.

MS. WILSON: Okay.

MR. McCOY: Let me just say thank you very much, Ms. Vasquez, for honoring us with your presence today, for your presentation and for all the work that I know you personally and the Ministry have put into implementation of the CAFTA and strengthening the IPR regime in Costa Rica, it's very much appreciated.

Of course, the door is always open at USTR for further discussions on those subjects and we look forward to it in fact. And if you feel there's anything you weren't able to cover today that you'd like to add to the record, the record will remain open for that after the hearing for post hearing submissions for another week. Thank you.

MS. VASQUEZ: Thank you very much. Good morning everyone.

MR. McCOY: Thank you. If I could invite the representatives of the Royal Thai

Embassy to come to the table.

Thank you very much for honoring us with your presence today. Very much looking forward to your comments. You have the floor, please go ahead.

DR. KOMOLSIRI: Good morning. My name is Dr. Chakarin Komolsiri. I am the Minister Counselor at the Royal Thai Embassy. I wish to thank the Special 301 subcommittee for the opportunity to appear before it today to present the comment of the Royal Thai government.

Today, I would argue before you that since the January of 2009 under the leadership of Prime Minister Abhisit Vejjajiva and his Deputy Minister of Commerce, Mr. Alongkorn Pollabutr, Thailand has launched an unprecedented effort in its intellectual property right protection with significant success in many dimension.

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 was established and chaired by the Prime Minister himself, we also create the National IP Strategy and proactive plan on prevention and suppression of IPR violations.

Above and beyond that, the Thai government has marshaled, create an economy policy to create Thailand as a hub of knowledge-based society. In the year of 2012, aim to have one-fifth of its GDP in creative sectors.

This endeavor has been praised by Barbara Weisel, Assistant USTR herself, in her lecture to Deputy Minister Alongkorn Pollabutr.

Second, major legislative reform are now in progress. This includes anti-camcorder law, more liability, enhanced border

enforcement and amendment to copyright optical disk law.

Third, among the major legislative reform comes strengthened law enforcement regime. The custom department in search of property rights coordination center has been empowered to create a network linking database to coordinate interagency effort and investigation.

Fourth, seizure and raids in 2009 also demonstrate remarkable achievement in IP violation suppression. Close to 8,000 arrests of IP violator with 5.1 million IP offending good was seized. This enforcing agency destroyed close to $66 million worth of offending good.

Fifth, record of criminal sanctions by the Thai IP court with property penalty could deter right violation resulting in imprisonment in 119 cases in 2009 alone.

And as a result of the supreme court on relation of issuing of search

warrant, search warrant has become more standardized, in fact, close to 500 search warrant were granted in 2009 alone.

Sixth, due to proactive action to combat piracy, there's been a decline in the case of software piracy from 80 percent in 2006 to 76 percent in 2008 as reported by this software alliance.

Seven, CASBAA collaborate with the National Telecommunication Committee to enact a temporary legislation to resolve the problem of cable piracy.

The government also enact the TV and Radio Broadcasting Act, which authorized enforcing agency to revoke or suspend an operator's licence if found guilty of copyright infringement by the court.

Eight, to combat book piracy we introduced the fair use guideline to clarify the exception and limitation to exclusive right of the copyright owners.

Ninth, the government actively is

recruiting participation of the pharmaceutical industry such as PReMA, the sister organization of PhRMA in Thailand, to identify constructive ways and means to ensure continuity of supply related to medicine.

PReMA now are represented and actively involved in both the patent law amendment working group and subcommittee led by the Minister of Public Health. The Thai FDA and IP office also establish a better linkage on the pharmaceutical patent and registration.

Ten, the government realize that -- the government realize importance of expedited patent examination and allocated significant budget of $7,000 to upgrade the patent system to increase the number of patent examiners.

Eleven, to further exemplify Thailand's commitment to accelerate the patent application process. Thailand has exceed through the Patent Corporation treaty, PCT,

which has been in effect since December 2009.

Twelve, the government realize that IPR protection must be inculcated at a very young age. The IPs are now being introduced and created for all level of the education.

This include a trial project in 40 schools before a nationwide expansion and other coordination with the municipal education at Kenan Institute of Asia to create learning material.

In conclusion, the Thai government hereby submit that with our full commitment, sustained efforts and significant success in IP protection, Thailand should be removed from Special 301 priority watch list, with understanding that our off cycle review may be used as a mechanism to demonstrate Thailand progress.

I would be pleased to answer any questions before the Special 301 committee may ask. And thank you for your time in the

matter.

MR. McCOY: Thank you very much for a very efficient presentation. I'll give the floor to Ambassador Sapiro again.

AMBASSADOR SAPIRO: Thank you. Thank you so much. Let me echo Stan's appreciation for that presentation and progress report.

One question is that you noted the pharmaceutical industry is working with the Ministry of Public Health, yet we received a submission from the U.S. Pharmaceutical Industry suggesting that they had not yet had a sufficient opportunity to discuss issues of concern with the government.

Could you elaborate perhaps and give us a sense of what your plans might be for such engagement?

DR. KOMOLSIRI: Certainly, if I may. Right now PReMA, which is a sister organization of PhRMA now, is sitting on two important subcommittees, namely the

subcommittee on promotion of domestic pricing in line with living cost and subcommittee on development of domestic pharmaceutical industry.

These are the major subcommittee sponsored by the Minister of Public Health. Certainly we are now in continuation with consulting with the organization in Thailand and then we have opened our doors, especially at the Thai government, the Department of Intellectual Property to have more dialog with them in the future.

AMBASSADOR SAPIRO: Good. That's very encouraging. I want to turn additional questions over to Stan. Due to a conflicting commitment, I have to beg your indulgence now.

But I'm very grateful for all three governments for coming today and emphasizing the importance of intellectual property protection and enforcement.

And I'm also grateful to everyone coming today. I look forward to hearing about

the submissions and the presentations. And again, appreciate all of your help as we work to fulfill our mandate and prepare a complete and accurate report. So I thank you. Over to you.

MR. McCOY: Thank you very much Ambassador Sapiro for being with us this morning. If I could now give the floor to my colleague from U.S. Agency for International Development for another question for our collaborates from Thailand.

MS. AMBUNARIS: Thank you very much for your testimony and your written submission. Could you please elaborate on the benefits yielded from the creative Thailand initiative for the protection and enforcement of intellectual property rights?

DR. KOMOLSIRI: Well, it's actually a child project of the Deputy Prime Minister himself. Instead of, talk about IP protection without having a real economic benefit, the Deputy Prime Minister think that

we should make it as a real part of a way of living in Thailand.

Meaning, he wanted to make the creation of innovative economy such as Thai film, Thai movie, Thai cooking, Thai folklore knowledge in which people can make a real living.

By all count they believe then they could teach people more how to be more protective of intellectual properties. So that's his own ideas on how want to create the economy.

MS. AMBUNARIS: Thank you.

MR. McCOY: We had some submissions this year noting positive reports of Thailand's enforcement activities along the lines you suggested, I note in particular the submissions from Levi Strauss and from the American Apparel and Footwear Association.

I wonder if you could share more about your government's plans for enforcement against counterfeiting and piracy going

forward.

DR. KOMOLSIRI: I wish to refer to my colleague on this issue.

MS. SRITHAPORN: At present, we have a corporations in coordination with the inter-agencies between the IP office and law enforcement agencies and we are planning to move forward and focus on the suppressions not only in the smallest retailer, but we will focus on wholesales and manufacturing or the manufacturer who produced the infringing goods.

DR. KOMOLSIRI: And also add on to my comments -- my colleagues comment, we have number of agencies who are involved in IP suppression, IP policy and suppression I should say.

The police, the special investigation bureau and we have established, it's called National Intellectual Property Policy which coordinates this interagency efforts.

I mean, one cannot accuse Thailand of lacking of any not agency not enforcing IP. As a matter, I would say there might just be a few of them.

We try to enforce and then to organize, coordinate their efforts together into a more concentrated efforts.

MR. McCOY: Well let me just -- it just remains for me to say thank you very much for a very comprehensive and efficient presentation this morning. We appreciate the efforts of the Royal Thai government to come and provide this presentation, answer our questions this morning.

Of course, our door is always open at USTR for any other points you may want to raise or discussions you may want to have.

We certainly welcome that and would also encourage you, if you feel there's any other information you'd like to add to the public record to take the opportunity to do that. Thank you very much.

DR. KOMOLSIRI: Thank you.

MR. McCOY: Could I invite Lisa Feisee from the Biotechnology Industry Association to make her way to the front. Thank you.

Good morning Lisa, thank you very much for joining us today and the floor is your for your presentation.

MS. FEISEE: Great. Thank you very much. Good morning, my name is -- can you hear me? My name is --

MR. McCOY: And I just said Lisa didn't I?

MS. FEISEE: That's okay.

MR. McCOY: I apologize.

MS. FEISEE: No problem. Common mistake. My name is Lila Feisee and I'm the Managing Director for Intellectual Property for the Biotechnology Industry Organization known as BIO.

I want to thank the U.S. Trade Representative for giving me the opportunity

to make this brief statement concerning BIO's views on foreign countries acts, policies or practices that are relevant to the decision whether a particular trading partner should be identified under Section 182 of the Trade Act.

For a detailed account of countries, please see BIO's written comments to the Office of the U.S. Trade Representative under the Special 301.

BIO's membership includes more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations, most of which are small emerging companies heavily reliant on private equity to fund their investment in biotech innovation.

BIO's member companies turn cutting edge science into health care, agricultural and environmental products that benefit the public and help sustain our planet.

The ability of the biotechnology

industry to obtain necessary private equity hinges on strong and predictable intellectual property, primarily patent protection.

In the health care sector alone, the industry developed and commercialized more than 300 biotechnology drugs and diagnostics that are currently helping more than 325 million people worldwide and has another 400 or so biotechnology products in the health care pipeline.

In the agricultural field, biotechnology innovations are growing the economy worldwide by simultaneously increasing food supplies, reducing pesticide use, conserving natural resources of land, water and nutrients and increasing farm incomes.

Biotechnology companies are also leading the way in creating alternative fuels from renewable sources without compromising the environment. The U.S. biotechnology industry currently employees or supports 7.5 million jobs in the U.S. alone.

These jobs are high paying, the average of which was $71,000 in 2006. This is more than $29,000 greater than the average private sector annual wage.

Approximately 90 percent of our members are small or medium size companies and it has only been in recent years that our companies have begun to look at other countries as viable markets.

Clearly, this expansion benefits not only our companies, but also the global community since our products in the area of health care, alternative energy and agriculture are beneficial to all populations.

As our companies have begun to look to other key markets, we've grown increasingly concerned that the IP environment that is so critical to the sustenance of the biotech sector is less than desirable and in some countries non-existent.

Specifically, we note that many countries provide no protection for the most

basic of biotechnology inventions, plants, animals, microorganisms and genetic materials.

The key to the success of the biotechnology industry across all of the sectors is a business model that is based on taking significant risks to develop truly innovative products.

Specifically, the model is based on making significant investments often hundreds of millions of dollars in early stage research and development with the hope that some of these investments and efforts will yield a commercially viable product.

This model has worked despite the fact that it is lengthy, often taking more than a decade, and that the vast majority of biotechnology are indeed investments in efforts do not result in commercial products reaching the market.

It is only by pushing the boundaries of science in taking these risks that breakthrough inventions are discovered

and converted into valuable products and services for people.

The biotechnology business model requires an environment that as much as possible eliminates unpredictability once a commercial product is obtained.

One important factor in this environment is the guarantee of patent protection. By ensuring that the products or services that may eventually be marketed can be protected from unauthorized copying and use by free-riding competitors, companies can justify taking risks and making significant R&D investments.

Introducing unpredictability by changing the availability of patent right or the conditions under which patent rights can be asserted will adversely effect the business environment that is so crucial to supporting innovation in the biotechnology sector.

MR. McCOY: Could I ask you to pause at that point and interpose a question

from my colleague at the U.S. Department of Agriculture, Mr. Karawa?

MS. FEISEE: Sure. Yes.

MR. KARAWA: Ms. Feisee I would like also to extend my thanks for appearing before the subcommittee.

My question is, in your submission you note that many of your member companies are expanding their sales abroad, but that many obstacles still do remain.

Resolution of which of those general obstacles does BIO feel or consider to be the most economically significant?

MS. FEISEE: In general, the up front investment in biotechnology is generated and fueled by protection on their discoveries. So in order for a biotech researcher or biotech company or biotech innovator to be able to actually move to the next level, they would need to have protection for their basic inventions.

Some countries don't even allow

patents on some of the things that we do here in the United States like transgenic plants, transgenic animals, genetic materials.

And so as a result, the protections for those types of, you know, those types of very basic biotech inventions are lacking in countries that are our trading partners.

So, up front protection is critical because that generates the interest in the development, which I was going to talk about in the next couple of seconds.

But then, of course, you know, investors who are going to invest in the development of biotech would need to know that they can enforce that their investment is secure.

So they would need to be assured that the patent is going to be enforceable and will be -- it is a legal mechanism that will be enforced by the country.

So those types -- those two

assurances, protection up front and then the ability to protect on the other side.

Now in addition to that, one of the things that's extremely important for the biotech sector is more and more of our companies are developing biological products, biological therapeutics, which are extremely expensive to make.

Some of them can cost up to $1 billion to make and the investment is very significant, not only in money, in capital, but also in time.

So, when they do go to other countries, they would like to see that when they, you know, they like to expand their markets for those particular biologicals.

Because they are addressing a lot of the chronic illnesses that countries are dealing with like, you know, diabetes, heart disease, a lot of these biologicals will address those concerns.

When they go to these countries

and submit their data packages, they would like to make sure that those packages are preserved or safe.

And the data exclusivity provisions are extremely important because the investment that's gone up front into developing these products is, you know, is significant.

And so why as a company or as an innovator would you want to go somewhere where you're just not -- your rights are not protected. So that's another very critical part of our, you know, submission that we've made.

MR. McCOY: Thanks very much. Could I give the floor to my colleague from the State Department for another question.

MS. BONILLA: Thanks Stan and thank you, Lila. Your submission stated that BIO was concerned that the compulsory licensing regimes in some countries are not TRIPS compliant. Could you please elaborate

on that statement?

MS. FEISEE: Well I mean I think this is something that is probably being discussed and debated. We think that the TRIPS provisions that pertain to compulsory licensing were meant to be used very, very sparsely and, you know, under a very, you know, unusual circumstances and for very specific reasons and diseases.

And so from our perspective, you know, the spirit of it anyway. And so from our perspective, you know, compulsory license, anything could be considered a public health issue, anything could be considered a public health emergency or a public health concern.

And so, you know, in that sense, if you're an innovator and you are looking to expand your markets and go into places where, you know, where the product is going to be necessary, you know, to help treat the population and you feel that maybe, you know, they view your products as being useful for

addressing public health concerns and that falls within the scope of the TRIPS agreement it just to me it seems as though, you know, the spirit of the treaty, the spirit is not being met in some countries.

I can understand why. There's certain, you know, countries have significant problems, health related problems and absolutely there are ways to deal with it without breaking patent rights or ignoring patent rights.

And clearly there are ways that, you know, companies are very interested in trying to work with governments.

So I just -- breaking patent rights is something that we would not encourage and in fact we would like the USTR to make sure that that's something that just doesn't happen. Thank you.

MR. McCOY: Thanks very much for your presentation today. We appreciate it and I apologize again for massacring your name

at the outset.

MS. FEISEE: That's okay.

MR. McCOY: If there's anything you'd like to add to the record following the hearing, you're very much welcome to do that.

MS. FEISEE: Great. Thank you very much.

MR. McCOY: Thank you again. Could I invite Shaun Donnelly from the National Association of Manufacturers to come forward please.

Ambassador Donnelly, thank you very much for your presence today. We are honored to have you. You have the floor.

AMBASSADOR DONNELLY: Thank you Mr. Chairman, members of the committee. The National Association of Manufacturers is our nation's largest and oldest industrial trade association representing small and large manufacturers in every industrial sector and in all 50 states.

I want to emphasize one key point

and that is the importance of intellectual property rights for manufacturers across the board.

It has sometimes been alleged that intellectual property rights protection is somewhat of a niche issue of concern only to a few sectors like entertainment and pharmaceuticals and software.

I want to refute that. This is a mainstream issue from manufacturers large and small in every industrial sector. Fighting counterfeiting and piracy must be a pillar in an overall U.S. strategy for economic growth, competitiveness, export and jobs.

Fighting counterfeiting and piracy is also of course about protecting consumer health and safety.

The NAM and our member companies large and small plus our workers, shareholders, communities are very grateful the strong efforts at USTR and the other agencies have been making, but we feel there

is much more that needs to be done.

We are strong supporters of the effort to negotiate a high standard anti-counterfeiting trade agreement. We commend that agreement to get a gold standard agreement. We urge that that be carried forward.

The NAM is stepping up our own efforts on intellectual property rights. We are creating a taskforce among our member companies.

In our Special 301 report this year we highlighted a number of issues, strong customs enforcement at the border, particularly important with our immediate neighbors, Canada and Mexico who are OECD members and NAFTA partners. We should expect a high standard there.

We're concerned about lax enforcement around the world on counterfeit products, transshipment including in free trade zones, that is a priority issue.

We believe it is absolutely critical that the U.S. Government resist efforts by some trading partners to negotiate international compulsory licensing provisions on green technologies. This is a real threat to American industry and to American jobs.

Here at home we remain concerned about an effort that our own customs and border protection personnel seem to be operating under instructions that limit their ability to cooperate with rights holders in terms of identifying and sharing identifying information.

We hope that that policy can be corrected administratively or legislatively if necessary. We urge special attention to the concerns of small and medium size manufacturers.

They need more support, they need more outreach. You've seen our Special 301 submission, we've identified China as our number one country of concern for

manufacturers.

We want to -- we think that the vast majority of the counterfeit products that found in our country and around the world seem one way or another to trace their way back to China.

We recommend that China be put on the priority watch list with an aggressive out of cycle review with real teeth in it. And we'd like to work with the committees.

We've identified a handful of other countries that are important. Canada, we believe is overdue to deliver on some high level promises on enforcement and updating legislation.

Ecuador and Venezuela, which where you have Chief of State of these government's leading sort of anti-IPR or anti-business, anti-American efforts we think needs a very close look.

We are concerned about the Brazilian government's efforts to press ahead

and for cross retaliation to bring long-standing IPR rights in Brazil under assault to settle an unrelated agricultural dispute. We think that that needs very high attention.

We look forward to working very closely with the IPR enforcement coordinator with the USTR with all the agencies that are here.

We believe that American manufacturing cannot grow, we can not double exports, create good new jobs, strengthen communities, fund R&D and create a culture of innovation without much improved IPR environment around the world. Thank you very much.

MR. McCOY: Thank you very much, Shaun. For a question let me give the floor to my colleague from the Department of the Treasury.

AMBASSADOR DONNELLY: Okay.

MR. MILLS: Thank you again for your testimony. You note in your submission

that border enforcement in the Czech Republic remains a challenge and you recommended that they be moved, the Czech Republic be moved to the priority watch list.

We received another submission from another different industry group recommending that they actually be removed from the watch list entirely based on positive reports of engagement, including an MOU with the Czech customs and significant results on anti-piracy border enforcement.

So first, were you aware of these developments? And second, how would you suggest that we balance in our review these two contradictory recommendations?

AMBASSADOR DONNELLY: Well I think you should listen to us. No, sorry. No, I don't think the reports were coordinated and I can't claim to you that we have perfect knowledge. But the best information we have is that these open markets right on the German and Austrian borders remain concerned.

And frankly, when we talk about a country like the Czech Republic, they are a member of the European Union, they are -- we have very high expectations in terms of variability to deliver.

So my understanding is that this issue remains a concern for the European Union, for other partner countries there and we believe it continue to deserve priority attention.

We're certainly welcome to getting, you know, updated information and so on, but it's just such an obvious front.

And I believe there may -- one theory I have heard is that there has been progress on a certain particular kinds of products that may have been for sale, but I believe the markets themselves are still there and they continue to offer non-IPR compliant products. So we don't think the issue is solved.

MR. McCOY: Let me give the floor

to my colleague from the Department of Commerce.

MS. WILSON: Thanks. Like many, China is your primary concern and China has been a concern and China will continue to be a concern. Have you given any thought, and we've used the 301 process for over a decade now to address the issues with China.

Have you given any thought to how we might use the process in a new and creative way, the process that report to address these issues?

Have you given any, you know, we've read your submission, we've listened to the testimony, we've read everyone else's submission, have you given any thoughts to how we might use this process, us this report in a different way to bring more something, to do something?

AMBASSADOR DONNELLY: Well, in my government days I had the privilege of working with some of you --

MS. WILSON: Which is why we're asking the question, because you've seen it from both sides.

AMBASSADOR DONNELLY: And I'm not sure we found the answer, the answer when I was sitting on your side of a table. I don't say that I have a solution, I would just, at a somewhat high level of generality.

So I think one lesson in terms of dealing with our friends in China, it takes a somewhat sophisticated approach. I think you have to -- it takes what I would call a carrot and stick, but the stick needs to be substantial.

And I think that's -- there's been a lot of carrots, there have been a lot of efforts by many of your agencies working with the Chinese, training, capacity building, exchanges, industry has been involved and China is such an important partner, but I think people are prepared to do it.

I honestly believe personally that

what we really need is something that convinces our friends in China that failure to really move forward on this aggressively just to deliver results, not just cooperation, not just dialog, not just capacity building, but concrete results is going to have consequences.

And that's where I think you have to figure out what those are. But I think China is such an important player in the world, they're in the G-20, they're a major voice on how the world economy is being run in the WTO and elsewhere.

And I think we have to make clear that we hold them in the IPR and many, many other issues, to a much higher standard. That they need to, you know, step up and deliver improved performance and failing to do that, will have concrete consequences.

We would like to work with you, I'm sure there are people in the Congress and other industry groups and other stakeholders

who would like to participate with you.

But I would urge that, that's why we think an out of cycle review, I think there's really two parts to it, one is engaging with the Chinese and the other is really a very intensive effort here at home to figure out what a strategy, what the benchmarks, what the implications of failure to deliver on benchmarks are.

I don't have those answers. I'd like to be part of working with you to see if we can find some.

MR. McCOY: Well thank you very much for your presentations today. It's been helpful. We appreciate your participation and as I've said with the others, if there's anything more that you feel ought to be added to the record, you're very welcome to do that. But we're grateful for your participation.

AMBASSADOR DONNELLY: Good. Thanks Mr. Chairman.

MR. McCOY: Could I invite Rashmi

Rangnath from Public Knowledge to come to the table? Thank you.

So thank you very much for being here. We're delighted that you've honored us with your presence. And please go ahead, the floor is yours.

MS. RANGNATH: I want to thank the committee for inviting me and providing an opportunity for Public Knowledge to testify at this hearing.

The Special 301 Review Process is a powerful tool to ensure protection for U.S. intellectual property interests. Unfortunately, we feel like the tool has been used in the past to enact -- to force enactment of unbalanced IP laws and force countries to exceed to international treaties that are not necessarily in the interest of the country's citizens.

Further, past review processes have not provided a clear justification for why a country has been placed on a watch list

or a priority watch list.

All of these factors have harmed the credibility of the process as a means to secure U.S. IP interests both in this country and abroad.

In order to remedy these shortcomings, we urge the USTR to first be mindful of the importance and balance to U.S. copyright law and to promote this same balanced system abroad.

Not to use the Special 301 Review Process as a means to force countries to exceed to implement treaties, and three, to introduce greater transparency into the review process.

U.S. copyright law maintains a delicate balance between the rights of copyright owners and users. This balance has been responsible for fostering learning, creativity and innovation within the U.S. and many U.S. industries have relied on the copyright systems limitations and exceptions

to bring their products into a system market.

For example, copyrights fair use doctrine has facilitated the proliferation of devices like VCRs, TiVO and Sling Box.

The presence of a similarly balanced system of limitations and exceptions is vital to provide this industry's great ability to export their products and services to foreign markets.

Therefore, we urge the USTR to promote this balanced system and not to be swayed by rights holder assertions that limitations and exceptions in foreign law amount to a denial of protection for IP.

During the 2009 Special 301 Review Process rights holder representatives such as the IIPA even objected to limitations and exceptions similar to our own, for example, Israel's fair use exception or India's personal non-commercial use exception claiming that such exceptions are similar are narrower than U.S. exceptions would violate the Berne

convention and TRIPS.

Such assertions are not consistent with U.S. law and the Trade Act certainly does not mandate a reading of IP protection that is inconsistent with principals of U.S. law.

If exceptions such as fair use for personal copying are permitted by the U.S., they cannot constitute a denial of protection in other countries.

This is so even the details of how the exceptions operate vary from country to country. The corollary of the system of balance is a country's decision not to ratify or exceed to certain treaties.

Many countries have legitimate and lawful concerns the provisions of treaties would not promote a balanced IP system in their country. Therefore, the USTR should not place countries on watch lists for failure to exceed to a treaty.

In particular, the process should not be used to pressure countries to exceed to

a possible ACTA in future.

Finally, we urge the USTR to employ data transparency in its Special 301 Review Process. Special 301 reports have often failed to clearly indicate the basis on which a country has been placed on a watch list.

Often, the reports have contained general statements such as the need to improve enforcement without providing further explanation of what that meant.

A clear understanding of what the USTR considers a particular country's enforcement standard to be lax could only be obtained by reviewing the rights holder comments.

Such vagueness leaves very little basis to evaluate the reasons why a country was based on a watch list, it also gives no indication of whether the country is being cited for a failure to enforce laws on its books or to enact new laws the delegations of

limitations and exceptions or increase penalties.

Another concern with respect to transparency is the USTRs reliance on unsupport and unverified rights holder assertions.

The 2009 comments contain several assertions of counterfeiting and other practices in particular countries, with no citations to any authoritative source.

In addition, many experts have questioned the validity of industry loss numbers and the methodology used to compile them. In view of these concerns, we urge the USTR to first make transparent the set of factors and standards it uses for evaluating countries in each U.S. Special 301 process.

Second, 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 offer an out of cycle review.

And third, arrange for independent external verification of country data and statistics submitted by rights holder groups before making factual determinations based on these assumptions.

Finally, we request the USTR to provide an opportunity for public to find comments in response to this comment process. Thank you.

MR. McCOY: Thank you very much. I'll give the floor to my colleague from the U.S. Copyright office for a question.

MS. WILSON: I'd like to ask a question about the first topic you raised, the balance in a country's copyright law and other intellectual property laws.

And I know that you cited the example of Israel and the private use exception there and you have stated in your statement that Israel's come under criticism for that exception.

But I'd like to know if you have

any other examples where a particular country you feel is not receiving and appropriate treatment of that balance. And, you know, of course this is something that we'd be interested to hear in more detail from in a further submission.

But if you have thoughts right now, keeping in mind the, you know, the existence in our international agreements that countries are free to determine their exceptions and limitations just as we've done here in the United States in the fair use doctrine.

MS. RANGNATH: I cannot think of example off the top of my head. I remember reading a lot of them in the 500 plus page report, but we'll be happy to get back to you with more examples of more countries.

MS. WILSON: Thank you.

MR. McCOY: Just a question from -- a question of my own it relates back to what Ambassador Sapiro said at the outset about our

focus being on our mandate from the congress here to identify countries that deny adequate and effective intellectual property protection or fair and equitable market access to U.S. persons who rely on that protection. That's what the statute calls for, that's this committee is set up to do.

I appreciate your country specific comments on Israel and India, I guess beyond that are there other country specific issues that you feel that we need to look at or look at from a different perspective as you suggested, or would you like to elaborate on your earlier comments about additional sources of information that we might be able to consider about specific countries in terms of enhancing this review?

MS. RANGNATH: Do you mean in terms of understanding what their laws are or what additional sources of information in addition to rights holders information?

MR. McCOY: Yes. You indicated

there might be some further steps that the government could take to gather and verify accurate information about what the IPR situation is in countries.

And of course that's something we very much want to do so we're open to your suggestions for good ways of doing that.

MS. RANGNATH: Okay. I think a greater time period between the first round of comment submission by rights holders and others who are interested in contesting some of the assertions is useful.

Second, an independent review of the study submitted by rights holder groups presenting loss numbers would be useful especially if other economists can review the methodology used in arriving at these loss numbers.

Also an opportunity for civil society in other countries to present an alternative highlighting the need for balance in the kind of expectations that are placed on

them is also useful.

MR. McCOY: Yes. It was really -- you got the end there to what I was asking about, which was not so much the having an iterative comment process here, but standing -- if you were standing here in the shoes of the government often, you know, we get good information from the people who submit into the process and what are the other sources that we ought to be looking to.

MS. RANGNATH: The helpful thing is even those who submit into the process can be required to provide some citations of sources.

For instance, in our comments we've highlighted how there are allegations of I think educational textbooks being sold in India for a very low price, there's no citation to a source or any authoritative source.

There are several allegations which some of them are probably true, but a

lot of them don't cite to any source of information, which makes it easier to provide unverified claims.

If these are claims of a basis for decision making, then those who make those assertions should be required to cite to sources, authoritative sources more effectively inform the USTR how they get this information.

MR. McCOY: Thank you very much for being here today and sharing your comments with us and answering our questions, we appreciate it and we appreciate the time you've invested in providing your comments into this process. Thanks.

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

MR. McCOY: Could I invite Eric Smith of the International Intellectual Property Alliance to make his way to the table.

MR. SMITH: Thank you Madame

Chairman and Stan and everybody. I wanted to thank every agency on the committee and all of you for the fantastic work you've done over the last 25 years to enhance protection for intellectual property.

IIPA is a coalition of seven trade associations representing over 1,900 U.S. companies that depend on adequate and effective copyright protection and enforcement by our trading partners.

Special 301 has been critical to growing the U.S. economy, jobs and exports since its passage by congress in 1988. This mechanism has focused the spotlight on the massive problem of piracy and counterfeiting that undermines economic growth and job creation in all countries including the U.S.

It brought regular and persistent attention to the need for countries appearing on Special 301 list to improve and enforce their IP laws as part of a mature trading relationship with the U.S. and the rest of the

world.

Special 301 also spurred the development of binding multilateral rules in the WTO TRIPS agreement that obligated countries to improve their laws and enforcement systems to protect trade in IP-based products.

Special 301 also contributed to the successful conclusion of the WIPO internet treaties in 1996, which established the global legal infrastructure that would govern the protection of content in the digital age.

These treaties, the WCT and the WPPT now have 88 and 86 members respectively and their key obligations have been implemented in over 100 countries, most of which are developing countries.

In the 1980s, many countries had no copyright laws and little or no enforcement. As a consequence, piracy rates were 90 percent or greater.

Today, as a result of your efforts

and Special 301 attention and the impact of multilateral rules, virtually all countries have significantly improved their copyright legal regimes and most have enhanced their enforcement systems.

These improvements over the last 25 years have made our copyright-based industries among the most productive and fastest growing sectors of our economy. They have also resulted in significant growth of the creative sectors among our trading partners.

The core copyright industries contributed over one-fifth of the total real growth of the U.S. economy in 2007.

These industries and the upstream and downstream sectors that are critically depend on the output of the core creative industries, employed 11.7 million people and generated over 11 percent of U.S. GDP in that year.

Exports and foreign sales of the

core creative industries increased to over 126 billion in 2007 and led other key sectors of the economy. But much remains to be done.

The President has called for the doubling of U.S. exports in the next five years. Our industries could be at the forefront of this achievement if piracy, the most acute trade barrier our industry has faced is reduced.

To accomplish this, we need the help of our government and other governments worldwide.

The failure of many of our trading partners to provide adequate and effective protection of U.S. copyrighted materials harms our economy, deprives us of high paying jobs, lowers U.S. exports by damaging commercial opportunities for legitimate products and adversely affects our path to economic recovery.

In its 2010 submission, IAPA has highlighted progress and remaining

deficiencies in the copyright regimes in 39 countries or territories, persuading them through the Special 301 process to improve their copyright protection and enforcement and to eliminate unfair trade barriers to market access is a critical element in meeting the President's goals and harnessing creativity to drive our economic recovery.

This year we ask the U.S. Government to pay heightened attention to countries where enforcement is inadequate and non-deterrent.

We should ask our trading partners too, first, undertake more criminal actions against piracy of software in the corporate environment, against growing online and mobile device piracy of music, motion pictures, software, video games and books and journals, against continuing piracy of optical disk products and the unauthorized printing and commercial photocopying of books and journals and against the manufacturing and trafficking

and circumvention devices.

Second, to dedicate sufficient enforcement resources and training and power enforcement authorities in a manner commensurate with the scale of the problem.

Remove onerous and unnecessary procedural barriers to the judiciary acting in civil and criminal cases. Impose deterrent penalties in criminal cases and adequate and deterrent damages and remedies in civil cases.

The U.S. Government should also ask our trading partners to encourage cooperation of ISPs with all content owners including workable and fair notice and takedown systems and graduated response mechanisms to deal with repeat infringers online.

Direct government agencies, contractors and educational institutions to use only legal software and legal copies of textbooks and to ensure that their networks and computers are not used for infringement of

any copyrighted content.

Enact and enforce laws against camcording motion pictures --

MR. McCOY: Eric, could I ask you to pause at that point and entertain a couple of questions. First, let me give the floor to Jean Bonilla U.S. Department of State.

MS. BONILLA: Thanks very much, Stan. Thanks Eric for appearing this morning. I wanted to follow up on the comments in the previous testimony about sources of information. And I wonder if you could elaborate on some of the sources that you draw upon in preparing your submission for this 301 process.

MR. SMITH: Sure. Each of these association members of IIPA in the countries that we're talking about have people on the ground or people in the region.

We follow, our association members and IIPA follow -- have followed for the last 25 years in almost all of these countries the

development of IP legal reform and enforcement.

Those people on the ground intimately cover raids, sentencing, law reform and over the years we've grown quite expert in what's happening in each of these countries and the resources primarily are our own members and companies who operate on the ground in those countries and are intimately familiar with how piracy operates within that particular country.

We also cite, on occasion, secondary sources and studies which bear upon issues that are of concern to us.

MR. McCOY: Another question from my colleague at the U.S. Patent and Trademark Office.

MS. FERULLO: Thank you, Stan. Eric, as you mentioned President Obama has set the goal of doubling U.S. export by 2012 and the copyright industry being in the forefront.

In IIPAs view, which market do you

see us having the most potential for increasing copyright industry exports and what may be some challenges that you may likely face in those markets?

MR. SMITH: Of the countries that we've talked about in our submission, I think I'd have to mention first China and second India. These are the largest countries in the world.

These are markets that, in particularly in China, where levels of piracy and various onerous market access barriers have prevented our companies from effectively doing business in that market.

If those circumstances were to change through, in the case of China, lowering of market access barriers, and of course some of those were the subject of the WTO case that just concluded, and those need to be implemented, lowering those barriers to allow companies into the market would have an incredibly positive effect on the U.S.

economy.

There is tremendous demand in China for these products that our members produce. Right now, market access in China is available to pirates, but not to our own companies.

India is another country where very difficult enforcement problems have kept piracy levels very high and if we could get improved enforcement in India, not only would it help our industries, but it would help even more the very large copyright industries that exist in India, which of course is an English speaking country.

MR. McCOY: Thank you. I'd like to call on USAID for a question now.

MS. AMBUNARIS: Thank you Mr. Chairman. Thank you for your testimony and for your extensive submissions.

Given that you mentioned that piracy is an acute trade barrier and given that you've cited 39 countries in your chart,

in your submission, could you please elaborate on your concerns about internet piracy and again, discuss the specific countries that you see as most significant in this regard and whether they're the same that you've mentioned in the copyright area.

MR. SMITH: Well over the years, you know, members of this committee dealt with physical piracy for 15 of those 25 years and today internet piracy and use of digital content and file sharing of digital content has become one of the most significant areas of concern to our industries.

Physical piracy continues to remain a problem, but increasingly for most of these industries, the internet has taken over as the means to distribute content and the piracy issues which were brought under control in many respects due to the effectiveness of Special 301 and other mechanisms have not yet gotten control of the problem of internet piracy, which is spiraling out of control in

many countries.

China is one of them, there are 750 million mobile device users in China. Broadband has been introduced, as of January, 3G. That, unless something is done soon to establish the legal enforcement infrastructure in a country like China.

But it's not only China, all of the countries that we identify, virtually all of the countries we identify here, we speak to the specific issue of internet piracy and the creation of the legal infrastructure and enforcement infrastructure that will permit countries to bring that piracy under control, not only to benefit U.S. industry, but to benefit their own industries.

MR. McCOY: Thank you very much, Eric. I know in the short time available we've only scratched the surface of a very long submission that IIPA provided. Trust that we've received it, we're studying it and we appreciate your input into the process.

MR. SMITH: Thank you, Stan.

MR. McCOY: At this point I think we've reached the time for our break. Let's try and make it a short break and reconvene now at 11:30. That will make us only 10 minutes behind schedule, which I think is a signal achievement for the morning.

(Whereupon, the foregoing matter went off the record at 11:21 a.m. and resumed at 11:33 a.m.)

MR. McCOY: Ms. Maclean, thank you very much for honoring us with your presence today. I appreciate your being here and sharing your perspectives with us. The floor is yours.

MS. MACLEAN: Thanks. And forgive the speed, I'm going to try to make it through without interruption. Medicines Sans Frontieres or Doctors Without Borders is concerned about the impact of IP barriers on access to medicines.

People in developing countries are

dying because medicines do not exist due to inadequate incentives for their development or because they're unavailable due in part to patent barriers and high costs.

This hearing is an opportunity to invite the alignment of U.S. trade policy with U.S. global health policy. What's more important however, is an end result that furthers access to medicines for all in developing countries as required by the Doha declaration.

Currently, U.S. trade policy has the effect of undermining U.S. global health policy. First, the U.S. IP agenda hampers the efforts of developing countries to purchase affordable medicines.

Second, it drives up the cost of medicines for the U.S. bilateral AIDS initiative, PEPFAR, and the multilateral Global Fund for which the U.S. is the biggest contributor.

The sustainability and

effectiveness of PEPFAR and the Global Fund are dependent on continued access to affordable generic medicines.

Third, U.S. IP policy does not encourage innovation of new medicines needed for diseases of the poor, like neglected tropical diseases, a priority of President Obama's Global Health Initiative.

The problem with access to medicines extends to any new drug, diagnostic test or vaccine and to all diseases. Yet AIDS continues to serve as a powerful example of the potential provided by price reducing generic competition.

AIDS also unfortunately serves as an example of the persistent and increasing barriers to medicine access imposed by heightened IP measures.

Today, 4 million people are on antiretroviral therapy or ART. This is only possible because generic competition caused annual first line drug prices to plummet from

over $10,000 to under $80 today.

MSF could not provide treatment to 140,000 people in more than 30 countries without generic competition. The U.S. Government acknowledges the significance of generic competition in its own global AIDS contributions.

PEPFAR has reported savings up to 90 percent through the purchase of Indian generic medicines.

Along side the tremendous progress in AIDS treatment remains tremendous need. Ten million more are in immediate need of first line treatment. Drug prices matter dearly for these people.

There's also an approaching treatment time bomb, increasingly patients will need to switch to newer drugs for long term survival. There are deadly costs to not transitioning out of a failing first line regimen.

A recent study found that the

mortality rate was three times higher for those remaining on a failing regimen. But the price difference is massive between the cheapest first line medicines and improved first line, second line and salvage therapy.

These newer drugs are more expensive because they're often patent protected in all countries with pharmaceutical manufacturing capacity.

For second line treatment, the difference in cost is a factor of 8 to 12. For salvage therapy, far more than that. Essentially drug costs will increasingly limit patient options.

Because of a lack of access to the right drugs and sufficient funds, many people will not appropriately transition to more effective regimens with deadly consequences.

Still, the cost of patients transitioning to newer drugs will quickly swallow health budgets unless there are dramatic price reductions of the kind seen

through generic competition.

AIDS is only an example of what we can expect or already see for other diseases, but this need not and cannot be the case. The U.S. is bound by the Doha declaration and the global strategy and plan of action to support an agenda that encourages innovation and access to affordable medicines in developing countries.

TRIPS flexibilities are critical in ensuring that newer drugs, including future AIDS treatments can be within reach. MSF is particularly concerned about USTRs challenge to the rights of developing countries to define patentability criteria, issue compulsory licenses, define data protection provisions, avoid so-called patent linkage and define enforcement within the context of TRIPS.

I will briefly identify the use of Special 301 to undermine the rights of countries to define patentability criteria and

to issue compulsory licenses.

Countries have the right to determine patentability criteria, yet Brazil and India, among other countries, were named in the 2009 Special 301 report in part because of their establishment of entirely legal limitations on patentability.

Brazilian and Indian safeguards serve to prevent unnecessary and improper patenting of medicines. India's section 3D for instance, prevents patents unless there is a medical benefit over existing medicines.

Relying on section 3D, India rejected a patent for a Nevirapine syrup used to treat pediatric AIDS.

Because India is effectively the pharmacy of the developing world, this was a critical decision for HIV positive children in India, but also for all children in low and middle income countries who rely on Indian generic AIDS drugs and who cannot wait.

Just because Australia grants a

patent on the wheel does not mean India and Brazil must also.

Countries also have the right to issue compulsory licenses. Despite the U.S. use of compulsory licenses, the USTR has consistently challenged developing countries aiming to do the same.

The TRIPS agreement includes no restrictions on the conditions for the use of compulsory licenses, only processes to follow.

The Doha declaration affirmed that countries have the freedom to determine the grounds upon which such licenses are granted.

And I quote, "Yet PhRMA and BIO again this year tried to invent restrictions that do not exist within international law and to compel developing countries to accept them through U.S. trade pressures."

The importance of compulsory licensing can be illustrated by the Thai example. There were particular needs for compulsory licensing in Thailand, including

concerns regarding the price, appropriateness and reliability of supply of ARVs.

Thai compulsory licensing had dramatic effect. The AIDS drugs, efavirenz, for instance, experienced a 50 percent price reduction allowing Thailand to increase coverage by 20,000 people.

At the time, USTR was forced to acknowledge that Thailand had acted within its legal rights. Nonetheless, the USTR has unacceptably kept Thailand on the priority watch list.

Such inclusion puts pressure on Thailand, but also signals to other countries to be wary of using legal means to ensure a sustainable supply of life saving and health improving medicines.

MR. McCOY: Can I interrupt you at that point. You almost made it.

MS. MACLEAN: Last paragraph.

MR. McCOY: Go ahead.

MS. MACLEAN: The Special 301

report must no longer be used to encourage TRIPS plus IP measures not required by international law. The Special 301 report must no longer threaten developing countries for acting within their rights to ensure access to medicines for their populations.

Rather than using the Special 301 report as a bully pulpit to impose a heightened IP regime on developing countries, the U.S. Government should use its laws, policies and financial resources to ensure that R&D is needs driven and encourages innovation and to ensure access to medicines through all the full exercise of TRIPS flexibility.

So my question to you is, is this something that the USTR under the Obama Administration will commit to.

MR. McCOY: Thank you very much. I want to pick up on the comments in your submission about the treatment of low and middle income countries in particular.

Is it appropriate in your view, and given that you've just talked a bit about country-specific issues in Brazil and India, which are not the lowest income of all developing countries mentioned in your comments, is it appropriate in your view for the U.S. Government to have different expectations of trading partners based on their having low, middle or high income levels?

And if so, on what issues would you suggest that we draw what kinds of distinctions?

MS. MACLEAN: It is acceptable for the U.S. Government to expect developing countries to adhere to TRIPS with the limitations that they're allowed within TRIPS as well.

Beyond that, it should be within the freedom of the developing country, whether it is low or whether it is middle income to respond to what their population needs are

with regard to intellectual property.

If the U.S. feels that there is a violation of the TRIPS agreement, that's something that the U.S. can obviously take up with the World Trade Organization, but there should not be excessive pressures imposed on low and middle income countries, especially in ways that are detrimental to access to medicines.

This is a violation of the Doha declaration and as I mentioned it's actually inconsistent with what the U.S. global health interests are as well.

I mean I was surprised, for instance, that the USAID representative didn't ask Thailand about the compulsory licensing issue given that that is something that should be within the interests of USAID that Thailand used appropriately in order to ensure that there's access to medicines for their populations.

MR. McCOY: Could I give the floor

now to my colleague from the Department of Labor for a question.

MS. PETTIS: Thank you for your testimony. I have a concern about counterfeit medicines, could you address that? How would you approach this concern, counterfeit medicine?

MS. MACLEAN: Our particular concern in that area is related to substandard medicines, which is actually medicines that don't -- that are inappropriate and they can be either medicines that are generic medicines, it can be medicines that are patented medicines, it can be medicines that are counterfeit medicines.

And one of our concerns about U.S. enforcement measures right now is that there's a conflation of substandard medicines and counterfeit medicines.

And if there's a real interest in the U.S. Government in challenging substandard counterfeit medicines as well as substandard

patent medicines and substandard generic medicines, the effort should not be within the IP realm, the effort should instead be in trying to support the drug regulatory authorities in developing countries.

MS. PETTIS: Thank you very much.

MR. McCOY: You don't think trademark counterfeiting should be a tool for approaching the problem of substandard medicines?

MS. MACLEAN: We have very strong concerns with the way that that's been implemented and there are some very clear examples of what can happen with excessive use of IP restrictions to try to counter this problem.

We've seen in Europe over the course of the last year and beyond the interruption of completely legitimate legal generic medicines being exported from India to Nigeria and Brazil and other countries, including some medicines that were purchased

by the Clinton Foundation.

It's a really serious concern and it's something that we don't want to deter within the transport of generic medicines.

MR. McCOY: Were those trademark counterfeiting cases or patent infringement cases?

MS. MACLEAN: Our concern is more that when that -- when IP is used in this way it becomes excessively used. There are other mechanisms to try to respond to those issues, not the mechanisms that the U.S. is suggesting.

Although I have to say our concern, I think there's a reference here to some of the conversations that are happening around the anti-counterfeiting trade agreement.

It's really hard for us to be able to determine whether the language that is being proposed within that would be detrimental to the legal export of generic

medicines, which is our real concern here because it is entirely secret.

And so if there's a real interest in transparency from the U.S. Government, we would hope that that would be made publically available so that can be discussed and so that we can really determine whether the measures that are being proposed are going to be detrimental to the legal export of generic medicines.

MR. McCOY: Well, on that let me say thank you very much for joining us today and for providing the comments you just provided.

We appreciate it and I will say again as I've said with others, that if there was anything further that you'd like to put in the public record, we're open to doing that as a post hearing statement.

Thank you very much for joining us today and participating. Could I ask Brian Toohey of Pharmaceutical Research and

Manufacturers of America to come forward. Thank you. Brian, the floor is yours.

MR. TOOHEY: Great. Good morning, Mr. McCoy and good morning members of the 301 committee. My name is Brian Toohey representing the Pharmaceutical Research and Manufacturers of America. I appreciate the opportunity to appear here to day to discuss our 301 submission.

The Special 301 process was established to ensure the adequacy and effectiveness of intellectual property systems around the globe for U.S. business.

The process is central for industries such as the U.S. biopharmaceutical industry, which relies on robust intellectual property protections in this essential driver of the U.S. economy.

PhRMA member companies are leading biopharmaceutical innovators who are devoted to developing medicines that allow patients to live longer, healthier and more productive

lives.

Our membership ranges from small research firms to large corporations that employee tens of thousands of Americans and encompass both research-based pharmaceutical and biotechnology companies.

Our sector is one of the most knowledge-intensive in the U.S. economy responsible for 80 percent world's global health care biotechnology research and development, totaling more than $65 billion in 2008, of that roughly 70 percent was invested right here in the United States.

Our sector supports high quality U.S. jobs, investing almost 10 times more per employee in research and development than other manufacturing industries.

In 2006, our industry supported more than 3 million U.S. jobs and contributed 88.5 billion to gross domestic product, more than triple the average contributions of other sectors.

As a result, many U.S. states and trading partners abroad are actively competing to attract the U.S. biopharmaceutical sector.

These figures highlight the critical importance of work undertaken by U.S. trade negotiators to open foreign markets, encourage the adoption of policies that do not discriminate against foreign-based companies and promote innovation in the global trading regime.

Moreover, this data underscores the need for enhanced vigilance on the part of U.S. trade officials as the United States struggles to recover from one of the worst global recessions we've ever faced.

Our industry has by no means been immune to the global recession. From January to October 2009, 58,000 industry jobs were lost compounding earlier contractions in 2007 and 2008.

Without the enforcement of intellectual property laws around the globe,

including through this 301 process, biopharmaceutical jobs in the U.S. and elsewhere will continue to be at risk.

Furthermore, without robust enforcement of these laws and concerted effort to combat market access barriers that continue to merge in our trading partners, the United States will likely fall short of meeting President Obama's State of the Union goal of doubling U.S. exports over the next five years.

To foster continued economic expansion, drive growth and exports and high quality U.S. jobs as well as delivery the breakthroughs that will save lives and lower health care costs, our sector relies on public policies that promote and protect innovation, including patents and regulatory data protections.

These mechanisms not only stimulate the early stage discovery and development in new medicines, but also

safeguard the sector's ability to carry out the clinical investigations that are essential for ensuring those medicines are both safe and effective.

PhRMA member companies continue to face significant challenges of discovery, development, testing, production and ability to commercialize new treatments.

Protecting intellectual property both within the United States and outside is an essential economic prerequisite to the continued medical advances against the most challenging and costly diseases.

Encouraging the safeguarding -- encouraging and safeguarding this innovation is not only essential to workers and patients in the United States, but also in the developing world.

Our member companies continue to tackle numerous health challenges in the world neediest markets by, among other things, building health infrastructure and researching

neglected topical diseases.

These efforts would be impossible without a secure global environment that encourages innovation.

In conclusion, brining new life saving and life improving products to patients around the globe is a central role of our member companies.

Because intellectual property is critical to carrying out this mission, the Special 301 process is in turn essential to innovative U.S. industries such as ours.

PhRMA very much appreciates the continuing efforts of all the agencies represented on this committee to promote compliance with international obligations abroad.

We commend your efforts to open overseas markets through vehicles such as the Special 301 process and look forward to working with you on these matters of great economic importance to the United States.

Thank you very much for your time. I'm happy to answer any questions.

MR. McCOY: Thank you very much. Let me give the floor to my colleague from the U.S. Patent and Trademark Office, Susan? Sorry, Minna.

MS. MOEZIE: Thank you for your comments. With respect to Thailand and several other countries, your submission mentioned industry efforts to engage constructively with foreign governments. Could you please elaborate on why you consider this important?

MR. TOOHEY: Well, we think a constructive engagement on the part of our industry -- we consider ourselves part of the health infrastructure in the country and it's critical that we have an open engagement to be part of that infrastructure, have the ability to both have access to foreign government officials to have our fair field in no favor, but also to have a continuing dialog.

And where we have these types of dialogs in countries like Japan over the course of decades, we found that it both contributes to public health in the country as well as appropriately awards innovation.

MR. McCOY: Let me give the floor to my colleague Susan from the Department of Commerce for a question.

MS. WILSON: Thanks. We've received several submissions focused on issues related to pricing and reimbursement. And in the past, certainly your organization and your members have expressed concerns related to these issues in foreign countries.

Do you still consider this to be an important issue for your membership or what are your views on this at this time?

MR. TOOHEY: Oh, absolutely. Along with strong IP protection and a science-based regulatory regime it's central to our efforts internationally.

In many countries around the world

we have one partner, one customer if you will, the government and while having a firm intellectual, a secure intellectual property environment is a critical prerequisite ensuring that we have a pricing reimbursement system that is appropriate for that country and that rewards innovation is absolutely critical.

Without an appropriate pricing and reimbursement system, intellectual property is really of no value in some countries. So it's an absolute critical part.

We also think it's a critical part of our market access in these countries, and market access is a central part of what the Special 301 statute outlines as enforcement not only for market access and intellectual property for IP intensive industries.

So we absolutely consider it a critical issue, it takes different forms in different countries, but it's central to our mission.

MR. McCOY: Let me give the floor to USAID for another question.

MS. AMBUNARIS: Mr. Chairman, thank you for this opportunity. Thank you for your testimony Mr. Toohey.

I'd like to just state for the record that we at USAID regarding the proceeding and the current testimony that we really welcome the opportunity to enhance medicine's quality assurance systems, especially in developing countries.

And we look forward to the opportunity to work across the government. And in this regard, we welcome views by our -- from our partners on how we can work with you to work on and assure quality safety and efficacy of medicines in the countries we work in.

And specifically with regard to PhRMA, may I ask what are your opinions, sir, is the most effective way to address the distribution of counterfeit medicines through

the Special 301 report?

And is there any way in terms of information that you can suggest that we examine concerning problems in free trade zones as well?

And then finally, in your experience, what intellectual property and market access issues are the most influential when companies in your sector are considering investing in foreign markets?

So you can take those in any order or submit, make submissions for the record.

MR. TOOHEY: Sure. And well, thank you, those are very important questions and we welcome the opportunity to provide a more detailed a response, I know the time is limited.

First let me just say we absolutely share your concern of counterfeit drugs in many developing countries, it's a major problem on the ground and many countries in Africa where almost 50 percent of the

medicines are counterfeit or substandard.

It's a huge concern, a huge public health issue and we're already working in many countries to try to address that proactively with regulatory officials. I'd be happy to follow up with you and provide you more information on that.

It's critical that it be an important part of U.S. global health policy and U.S. intellectual property protection, because it does no good for anyone to take substandard or counterfeit medicines.

And maybe switching to your second question real quickly here, what are the most important elements of intellectual property. Well, the key element is obviously patent protection, ensuring a stable and -- insuring our surety of our patents in any country.

But also ensuring the protection for our test data, which are linked, but very separate intellectual property protections, as well ensuring enforcement.

Now, it's often referred to as linkage in many countries, but essentially linkage is enforcement of a patent and those are sort of the three key elements that our companies look to, to ensure the protection of intellectual property in foreign markets.

MR. McCOY: Well, thank you very much for your statement and for efficiently addressing our questions today. We appreciate very much your participation and of course you're welcome to submit any further information should you feel it's necessary to do so.

But thanks very much for your participation today.

MR. TOOHEY: Thank you very much. Appreciate the opportunity.

MR. McCOY: Could I ask Michael Mellis of MLB Advanced Media. Can you move from the on deck circle to the batter's box, Michael and the floor is yours.

MR. MELLIS: Chairman McCoy,

members of the committee, on behalf of Major League Baseball I would like to thank you for the privilege of addressing you this morning.

My name is Mike Mellis and I'm Senior Vice President and General Counsel of MLB Advanced Media, which is Major League Baseball's internet and interactive media company.

Under the leadership of Commissioner Allan H. Selig MLB has developed highly successful diverse and innovative sports media businesses.

On television our game telecasts are distributed nationally through DirecTV, ESPN, Fox in Demand, the MLB Network, TBS and Verizon, locally through broadcast television stations and regional sports networks and internationally to over 200 counties and territories and the U.S. Armed Forces overseas.

On the internet we have been a pioneer. Our first live game webcast occurred

in 2002. Today, our MLB.tv service is the world's most successful and comprehensive live video service of its type on the internet, distributing thousands of live games each season to a global audience of baseball fans on personal computers and iPhones.

Clearly, rights owners like us can be adversely impacted by telecast piracy. And right now there's an emerging type, unauthorized streaming over the internet of live television programming of all types including live sports telecasts and related programming.

The number of sites and services involved in this phenomenon is significant and has grown rapidly. Many are open doors permitting any type of television programming to be streamed live persistently and globally without authorization from copyright owners.

This can be accomplished through the use of this $70 device and some software. 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 bases, tens of thousands of hours of live television programming from networks around the world are being pirated.

Included is significant piracy of U.S. sports telecasts and other U.S. television programming.

In our rights enforcement efforts through the past several years, during which we have identified and logged thousands of piracy incidents, the dominant pattern we have seen is piracy occurring through a streaming over peer-to-peer services based in China.

Approximately 75 percent of the pirated retransmissions of our games -- telecast, excuse me, have occurred through offshore sites and services and approximately 50 percent of the total through Chinese sites

and services.

Our domestic copyright law is clear that this is copyright infringement. However, litigation in the United States is a remedial tool available to U.S. exporters of television programming only in limited circumstances.

This is because the piracy is a global phenomenon often involving sites and services that operate entirely offshore and 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 interests and legal obligations for the United States and its trading partners to work cooperatively to curtail this problem.

USTR should be commended for identifying this matter in its 2008 and 2009 Special 301 reports and we very much value the

dialog we had with USTR about this matter.

Since the problem has continued to grow, USTR should continue to identify it in the 2010 301 report and give it priority in trade negotiations.

We ask that you please be aware of two recent developments. First, on December 16th of last year the House Judiciary Committee held a hearing on the piracy of live sports broadcasting over the internet.

Second, early in 2009, the OECD published a report entitled piracy of digital content, which includes a case study about internet piracy of live sports telecast.

The House Judiciary Committee hearing record and the OECD case study are significant new sources of information about the problem from which USTR and the Special 301 committee can draw.

We have provided relevant documents in our submissions to you. 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 for the privilege of addressing you this morning.

MR. McCOY: Thank you very much for your statement and we appreciate it. And let me ask my colleague from the U.S. Copyright office to take the first question.

MS. WILSON: Thank you Stan. Mr. Mellis your submission to USTR indicated that the sports coalition members have devoted quite a bit of resources to addressing digital piracy.

I was wondering if you could detail some of the efforts and some country specific examples if you have them or if you'd like to just describe some of the resources that your members dedicate to addressing digital piracy.

And I'm also interested to know if any of those efforts involve working closely

with governments and if you could provide some examples of public/private partnerships to that.

MR. MELLIS: Sure, I'd be happy to. In our office we have a team of dedicated employees who monitor the internet for piracy incidents. We monitor hundreds and hundreds of sites and services and we log and we catalog each one, we develop data in that way.

We also use it for our rights enforcement efforts which involves the sending of cease and desist letters, wherever we find the problem.

So we have gotten to the point where we have hired full time employees just for this purpose and everything that surrounds that.

My understanding is from some of the other sports leagues to the extent that they don't do that work in house, they either contract out with vendors who do similar things for them and there is expenditure,

significant expenditure being applied across the board.

With respect to government outreach, which you asked about, there is a broader group that we are a part of called the Coalition Against Online Video Piracy and that groups efforts have included informal discussions with the Chinese government, specific agencies in the Chinese government.

All the sports coalition members in our 301 letter are members of the Coalition Against Online Video Piracy, although that is a much larger group.

MR. McCOY: I'll give the floor to my colleague from the State Department, Mr. McGowan.

MR. MCGOWAN: Thank you. In your submission you mention a number of places where how much money your losing, the industry is losing through copyright infringement and piracy.

Do you have or does any of the

other organizations you work with have any cost estimates or estimates of the amount you're losing?

MR. MELLIS: We don't. There are a couple of reasons why. One of the recency of the problem. The second is that the extent -- the unknown part of it, there's much that we don't know about it.

We can track sites and we can track incidents and we can produce data with respect to that, but that's only one piece of a much larger puzzle in terms of what the audience size is, who was involved beyond what we can find out through our own limited means of figuring that out, patterns of piracy and the like.

Our perspective is one about threat of harm. I think it's easy to extrapolate if this problem were to continue to grow into the future, you know, the type of economic harm that it could have, but we don't have those cost estimates and we're looking

much more in a proactive way toward this problem.

MR. McCOY: Let me give the floor now to my colleague Mr. Wright from U.S. Customs and Border Protection.

MR. WRIGHT: Thank you Stan and thank you very much for your testimony. What IPR market access issues are most influential when companies in your sector are considering investing in foreign markets?

MR. MELLIS: Well, I can speak from the perspective of, you know, my company, MLB Advanced Media and we're probably advantaged in that respect because we're an internet company.

We do sell into foreign markets. We do, for example, have foreign language website, we do sell MLB.tv to customers around the world.

I'm not aware of any particular barrier to entry that we've experienced in those efforts. I'd say that the barrier is

more one that is negative in the sense that the piracy probably has an adverse effect on what people otherwise might do in those countries with respect to coming to our websites or purchasing subscriptions.

MR. McCOY: What tools do you find most useful in combating internet piracy?

MR. MELLIS: Well, since it's a worldwide problem, I think the answer depends on where we're talking about. You know, in the United States the reactions tended to be more robust and our results more effective.

Abroad, there are some countries, China in particular, where we routinely send cease and desist letters and notices and make attempts to contact these sites and services, which, you know, are known services there and they are, with one exception, with one site that we had a successful outcome with, they're ignored.

So it depends. Publications like the Special 301 report and like the OECD

study, which the Department of Commerce was very helpful in approving, are very important tools and we can use to supplement and raise awareness of the issue, about the issue, excuse me.

MR. McCOY: Well, thank you very much for joining us today and for your presentation bringing these issues to our attention. We appreciate it very much and the record remains open following the hearing if you want to add anything further.

MR. MELLIS: Thank you.

MR. McCOY: Let me invite Rohit Malpani from Oxfam America to step into the batters bock for the next one.

MR. MALPANI: You got the pronunciation right.

MR. McCOY: Yes, I hope I didn't mess that up too badly.

MR. MALPANI: It's perfect. Thank you for the opportunity to present the views of Oxfam America. Our organization welcomes

the new and more open process that the USTR has instituted.

We hope your office will continue to solicit broad input in the Special 301 report as well as other areas of trade policy making.

Oxfam America is an international development organization working for lasting solutions to poverty and social injustice.

We joined with several other non-governmental organizations to submit comments for the Special 301 review that request the U.S. Government to respect its obligations under the Doha declaration on TRIPS and public health, which calls for the primacy of public health over the protection of intellectual property for medicines.

The submission also asks the U.S. Government to stop pushing developing countries to adopt intellectual property provisions for pharmaceuticals that exceeds TRIPS requirements and jeopardize access to

affordable medicines.

I also submitted a statement for the hearing on behalf of Oxfam America that focuses primarily on the treatment of a few countries in past Special 301 reports.

My testimony today will focus on two of these countries, Thailand and India. Both countries were placed on last year's priority watch list.

In 2009 20 developing countries were placed on the priority watch list or the watch list due in part to their unwillingness to adopt TRIPS plus rules for pharmaceuticals.

The U.S. should not place any of these countries on either list in 2010 due to their IP rules for medicines. This includes Ecuador whose system of compulsory licensing is WTO compliant.

Thailand, which I think goes to this question between countries that are very poor and that are sort of poor has been criticized by the U.S. Government for its

enforcement of government used licenses to treat HIV and AIDS, cancer and heart disease and for its decision to not introduce TRIPS plus rules.

This criticism relies on two erroneous arguments offered by the pharmaceutical industry. I would like to offer our reasons why these arguments are unjustified and should be discarded.

The first erroneous argument, Thailand is not sufficiently poor or underdeveloped to avail itself of TRIPS flexibilities and safeguards, particularly compulsory licensing.

Well TRIPS flexibilities are available to all countries regardless of their level of development, that's a key TRIPS principal which the U.S. Government must respect.

Furthermore, Thailand is a developing country with 10 percent of the population earning less than $2 per day. Many

other Thais above the poverty line struggle to meet their family's basic needs and rely mostly on government provided health care.

They cannot afford to pay for medicines out of pocket and the Thai government cannot afford to pay high prices for essential medicines if it is to maintain basic free health care for all Thais, including treatment for HIV and AIDS.

Compulsory licensing ensure the future sustainability of Thailand's HIV and AIDS treatment program and expanded treatment for cancer and heart disease to thousands of poor and middle class Thais.

The second erroneous argument, noncommunicable diseases, such as cancer and heart disease are not public health problems on the order of communicable diseases like HIV and AIDS and therefore TRIPS flexibilities do not apply to these diseases.

The Doha declaration states that every country can use TRIPS flexibilities to

the full in order to protect public health and is free to determine the grounds upon which to grant compulsory licenses.

This includes the use of TRIPS flexibilities to treat cancer and heart disease which are two of the leading causes of death in Thailand.

Over 80 percent of all deaths from noncommunicable diseases already occur in developing countries according to the World Health Organization and Thailand is no exception.

As lifestyle shift, the burden of noncommunicable diseases will grow in poor countries and in other developing countries.

Instead of using Special 301 report to obstruct developing countries like Thailand that us TRIPS safeguards to improve the health of its citizens, the United States Government should acknowledge that public health priorities in developing countries now must address a broad range of diseases and

these priorities must be set independently by public health officials.

Finally, I would also like to offer Oxfam's views on the approach USTR should adopt towards IP protection in India. India's IP market is fully consistent with its WTO obligations, crucial to protect global public health and vital to encourage innovation.

Low cost generic medicines manufactured by Indian companies enable affordable health care for millions of poor people in India and millions of people in other developing countries.

Without competition in the Indian marketplace, steep price reductions for antiretroviral medicines preceded the global expansion for HIV and AIDS treatment would have been impossible.

Treatment for other diseases also would not be possible. Any suggestion that calls upon India to strengthen its IP system

jeopardizes tenuous public health systems in dozens of countries across Asia, Latin America and especially Sub-Saharan Africa.

It would also undermine U.S. foreign policy objectives in many countries hard hit by the HIV and AIDS crisis. Today, over 80 percent of all antiretroviral medicines purchased by the U.S. Government's global AIDS treatment program are exported from India.

Strengthening India's intellectual property regime would undermine U.S. Government treatment goals especially as patients switch to newer antiretroviral medicines.

Stricter IP rules, particularly revisions to section 3D of India's patent law would also harm innovation. Section 3D excludes patent protection for new forms or new uses of already patented medicines, a permissible limitation under TRIPS.

By narrowing the scope of

patentability, the Indian government has prevented pharmaceutical companies from abusing the patent system via evergreening, that is by introducing medicines that are only second forms or indications of older medicines that are neither novel nor innovative.

If India were -- I'm almost done.

MR. McCOY: Okay.

MR. MALPANI: Thanks. If India were to modify section 3D, it would encourage pharmaceutical companies to engage in run seeking behavior in lieu of increasing innovation.

Thank you for the opportunity to speak today and we hope that the U.S. Trade Representative does a better job of balancing the need for adequate protection of pharmaceutical company inventions with the public interest and ensuring that these benefits reach millions of people in developing countries.

MR. McCOY: Thanks very much.

Could I ask you, essentially the same question I asked to MSF which is given this, I mean your submission too makes this observation about the needs of low and middle income economies and you've just talked a bit about India which is not the lowest of the low income developing countries.

I'm curious where you come out on this notion of whether our expectations should be different depending on income levels from high to low and in what ways they should be different.

MR. MALPANI: Well again, the first thing to recognize is that all countries have the right to set their own levels of intellectual property protection and as my colleague from Doctors Without Borders mentioned, the Doha declaration invites all countries, and especially developing countries to make full use of safeguards in order to protect public health.

When you look at a country like

India though, 500 million people in India still lack basic electricity. That's more people total in the European Union today.

It's very difficult when you look at developing countries whether they have very high levels of poverty or specific islands of poverty to suddenly try to select and choose these countries as ones that do not merit full use of the public health flexibilities under TRIPS.

For the pharmaceutical industry, including in countries such as Thailand, they still have the ability to sell their medicines at very high prices in the private market to the tiny elite who normally do not use the public health care system.

So in a sense, you're able to segment the market between those who are very poor and those who need to get medicines for free or at very low prices subsidized by the government, versus those in the private sector who can pay a much higher price and I think

are the market that the pharmaceutical industry and the U.S. Government is trying to reach.

But I think it's very difficult to start drawing lines between differing developing countries, again when you look at the high levels of poverty not only amongst the poorest, but again amongst those in the middle class who are not like the middle class in this part of the world and who often have to spend massive amounts of resources in order to provide for their own public health or to provide for health of family members.

MR. McCOY: Thank you. Let me give the floor to my colleague from the Department of Labor for a question.

MS. PETTIS: Again, thank you for your testimony and I have a similar question for Doctors Without Borders to you. What views do you have on the issue of counterfeit medicines?

MR. MALPANI: I think to add on to

the testimony that was already provided, counterfeit medicines and the way in which they are dealt with under the TRIPS agreement should remain and this is the standard that has already been set.

This has to deal with willful trademark infringements. The problem has been around trademark infringement as was alluded to is when it deals with it for unintentional trademark infringements or, sorry, for non-willful trademark infringement.

And the example that came from the European Union, for instance, was for amoxicillin, which was ceased in Germany even though this is a medicine that has been off patent for many years and that was on its way from India to another developing country.

But the real problem again is with substandard medicines and this is outside of counterfeit medicines, except that some counterfeit medicines can be substandard.

And in order to deal with

substandard medicines in all countries and substandard medicines again are both branded and generic medicines, it's important to invest in the drug regulatory systems in developing countries to improve good manufacturing practices for all manufacturers and to ensure that developing countries themselves contest the adequacy and safety of medicines.

And this is the real problem. And the concern is when you hear the pharmaceutical industry talking about it, they want to group together counterfeit medicines and substandard medicines and imply that intellectual property enforcement through patents will be the way of dealing with substandard medicines.

MR. McCOY: Let me give the floor to my colleague from the Department of the Treasury for a question.

MR. MILLS: In your submission in your testimony you state that the Special 301

report is often used to pressure developing countries to abandon measures needed to achieve affordable health care.

How do you feel that the Special 301 review process can balance incentives for development of new medicines with the need of countries to be able to provide that affordable health care?

MR. MALPANI: Well the first thing you would have to do is probably have somebody from Health and Human Services actually be on your committee.

You know, when Stan talked about earlier in one of his questions that he wanted to make sure that all intellectual property rules are being enforced, I find it surprising that we're not talking about how to enforce public health safeguards and flexibilities that exist under the TRIPS agreement.

There's many, many provisions within there that provide for this balance. The fact is, is the TRIPS agreement, even if

people feel that it's imperfect, does provide for this balance between protecting innovation and promoting the public interest.

And it's allowing developing countries to be able to find what that adequate level of protection of intellectual property and promotion of public health is what is necessary.

And the Special 301 process instead of focusing on real violations of intellectual property laws, often is acting on behalf of the pharmaceutical industry and other industries in order to push developing countries to not find this adequate balance.

The fundamental precept is developing countries are going to have to create different levels of intellectual property protection that both responds to the needs for innovation within the country as well as to protect the public interests.

And we think it's important for this process in the future to be able to

identify individuals within the U.S. Government who can help find that right balance and who can make sure that the views of public health officials in developing countries, as well as within the U.S. Government are adequately represented.

MR. McCOY: Thanks very much for your comments. Let me just say as a point of order that HHS is a participant in the interagency trade policy process. I don't know if they'll be able to join us today or not, but I appreciate your comments very much.

Thank you for joining us and the record remains open should you want to add anything further.

MR. MALPANI: And I would like to just say one more thing. I will have some comments to add on and I think I wanted to say that, you know, some organizations or civil society groups from developing countries and especially Thailand and India were unable to participate in this process today.

I think they had asked to speak via telephone and I think given that we are in the world's most advanced technological society that we would be able to provide for that opportunity in the future.

So I do hope in the future that given these are the people that are affected by the decisions that are being made in this room today and subsequently, that we will provide an avenue for them to speak on their own behalf. Thank you.

MR. McCOY: Thanks for your suggestion. Could I ask the next speaker to make their way forward. That's James Love from Knowledge Ecology International.

MR. LOVE: Thank you for holding the hearings this year. I think this is helpful. I'm going to kind of speed read through my talking point here.

We're not happy to see that some groups are asking that the use of open source software open standards is somehow represents

something that should put a country in the 301 list.

And I think that no country has generated more jobs and had more income from open software and free software and open standards than the United States.

The internet's based on that and I think you'd be hard pressed to find a more important sector in the last several year of the U.S. economy than that. So I think it's a mistake to attack open software and open standards.

On the issue of the counterfeit drugs, I agree what MSF and Oxfam have said and lots of people say this all the time, the problem that developed countries have is substandard drugs.

The solution to substandard drugs is better drug regulation. It's not really an IPR problem, it's usually some company you've never heard of before that just has crappy drugs or some non-existent regulatory system

in some country.

The co-mingling of the substandard and the counterfeit drugs together is designed to push up the numbers on the counterfeit.

Actually, counterfeit is an important problem. I think people who counterfeit drugs should go to jail for a long time and it can kill people. And even if they didn't kill people, they should still go to jail.

But I think that to mix it with the substandard thing really offends people and also to mix it with infringement offends people.

There's so many cases in the United States where companies are sued for infringement and companies like Abbott and Pfizer get sued for infringement by people.

That doesn't mean that they're counterfeiters, it means there's a dispute about some patent issue. And it doesn't help to throw everything in one bucket like that,

so unpack those things.

I agree about these issues about the coherence of the Doha declaration, the World Health Assembly resolution 6121, the WIPO development view should coherent with that. You shouldn't say one thing there and another thing here.

One thing on that development chain is that people are saying that stronger exceptions in the area of copyright they think could be lenient to stronger enforcement of copyright.

I mean you might have problems enforcing copyright because you have the wrong laws in the country, maybe you need different laws for people that make less than your kids make delivering newspapers.

So, if there's really huge differences in income that maybe that's the reason why you have problems on enforcement. And so kind of different kinds of law may be more realistic to enforce. In the WIPO

development agenda there's like an attempt to try and explore those issues.

I haven't heard anyone talk about the 2007 deal between the Democrats in the White House, but now the Democrats are running things, should think that they'd be a little prouder of that deal they made in 2007.

But it focused on linkage, data exclusivity and patent extensions. And I think that what was done in that 2007 deal should be applied to all developing countries.

In terms of the middle income countries and the sustainability, I'll talk a bit about briefly the sustainability of AIDS treatment, you cannot meet your commitments to treat people with AIDS unless you deal with the intellectual property issues.

You can't do it without generic drugs. And the newer drugs, the second generation drugs, the patent protection is pretty extensive and they cost not $100 a year for a cocktail, but like far different numbers

from that.

So that's a life or death issue. The U.S. is the biggest purchaser of generic drugs right now in the planet when it comes to AIDS.

Now, the way that market got started is Brazil, which is a middle income country, bought generic drugs to treat their own population. They were the first country in the developing world to provide triple therapy for poor people.

And it was their purchases of generic drugs which created the economies of scale out of Africa later to benefit from that.

If you separate middle income countries from lower income countries, what you end up doing is you get the market so much that they really can't really make it work in terms of those countries.

Now the last thing I want to add, because I think I'm running out of time here,

is on pharmaceutical test data. One of the biggest objectives of the 301 list asks from the pharma is to push exclusive rights for the pharmaceutical test data.

A lot of people have focused on the problem of the intellectual property issue, the fact that, you know, it creates a barrier for generic drugs, it drives up the price of drugs, it creates a monopoly in that arena.

And certainly for the U.S. trying to provide AIDS treatment, if you have generic drugs, you can't sell them in a country because of that exclusivity issue, you're going to be really stuck, tax payers will be stuck, we'll be stuck or we'll just have to just basically back away from our commitments.

But, there's another issue and that's the ethical issues. The World Health Assembly, as I elaborate in the statement, they adopted a statement that the requirements for drug registration should follow the

declaration of Helsinki and other appropriate texts on the ethical principles for research involving humans.

Now the issues is the following, and I guess this is the last thing, the clock's out, is if you know what the result of an experiment is on a human, you're not supposed to repeat that experiment, that's unethical.

And when you say that you can put a drug on the market if you repeat the experiment that's already been done by somebody else, you're forcing the generic drug company to do something which violates medical ethics.

The solution is to explore other ways to protect the legitimate interest of people in clinical test data, which is an important issue through something other than exclusive rights. Thank you very much.

MR. McCOY: Thank you very much. Let me give the floor to my colleague from the

U.S. Patent and Trademark Office for a question.

MS. MOEZIE: Thank you for your comments. You've highlighted the issue of pharmaceutical data protection.

I wonder could you comment on the relevance of the obligation in TRIPS article 39 to protect tested against unfair commercial use as well as other international obligations that you view as relevant.

MR. LOVE: Yes. We spent a lot of time on this issue over the years and including the point when U.S. complicated a case against Argentina in this issue.

And I think it's everyone's conclusion that if there was a case to be made that the TRIPS provision obligated countries to have exclusive rights of the test data, the U.S. would have brought a case against some country on the planet and they wouldn't have to do this hand-to-hand combat with the 301 list.

Now, you don't have a legal case, that's why you don't bring it to the WTO. That's why you throw into the FDA in these TRIPS plus provisions.

I think the better way to respond to this is to look more generally and this is also about the pharmaceutical pricing issues. That's not really an IP issue either, that's just basically demand by the domestic industry for higher prices everywhere.

I think we should have to look at is what is the global system for supporting R&D, who's going to pay for new drugs. All the LDCs in the world have this same GDP as Denmark so it's not just the low income country, it's really a country north and south.

We think there just has to be adult conversation about what the expectations are of countries of different incomes to contribute to R&D, but it doesn't all have to be through high drug prices.

The WHO says to explore the de-linking of incentives from drug prices. The NIH is not a high drug price, it's a $30 billion investment by the U.S. tax payers to support medical R&D. Other countries don't do what we do. They could do a lot more than what we do.

And issues about procurement and a lot of other things come into the play. I think the problem is, is that you just -- it is perceived throughout the world that this agency and this committee is just advocating on behalf of the pharma and bio submissions and they're not really proactively engaged in a process the WHO started with the Intergovernmental Committee on Intellectual Property Innovation and things.

I think you need to have a more holistic approach that looks at both de-linking incentives and also public sector research.

MR. McCOY: Thank you James. Let

me give the floor to my colleague Paula Pinha, the Chair of the Special 301 process at USTR.

CHAIR PINHA: Thank you Stan. Mr. Love, thank you for your testimony. As Ambassador Sapiro said earlier, we are here to seek to fulfill our mandate from Congress to identify countries that deny adequate and effective intellectual property protection or deny fair and equitable market access to U.S. persons who rely on that protection.

In your opinion, are there country-specific issues that you feel we should consider or additional sources of information about specific countries that we should review?

MR. LOVE: I think in our community people were astounded that Thailand was put on the -- that the citation for Thailand in 2009 made reference to the compulsory licensing case, particularly as it relates to these issues of transparency.

I don't think anyone has been as

transparent as Thailand in its compulsory -- they published a book about it, they briefed Congress, they held press conferences, they had teachings up in Geneva to negotiators, delegates.

They've answered every question, they've given a million press interviews. It's just like nothing compared to that in any other country, and that was something was cited.

So I think that that should stop. In fact any country that just goes by the promise that you made in 2001 in Doha that you can issue a compulsory license to protect health, they should never be put on the list and certainly the references to Thailand is one that really stuck out with people.

I also think, and I agree with Public Knowledge and the earlier comment on this, that some of these references about things that deal with the pricing of books and copyrighted material are really misplaced as

well.

I see that in the Philippines as it relates to textbooks in the past, I see it in India, I see it in different places. People can't afford things in a lot of countries, they are poor.

If you want them to abide by the law, don't tell them they have to have high prices and not infringe. They can infringe less if they have low prices.

I think the bigger struggle you have is to get them to actually take the copyright laws seriously in the first place, not to go after somebody that's trying to go legitimate bonafide effort to basically make something affordable.

MR. McCOY: Well, let me say thank you very much for joining us, participating, sharing your views today. And the record remains open if you should want to add anything further by way of post hearing submissions.

But we very much appreciate your presence and your participation today.

MR. LOVE: Thank you very much.

MR. McCOY: Thank you.

MR. LOVE: And also I encourage you to do a telephone hook up for developing country people next time as Rohit mentioned.

MR. McCOY: Could I ask Matt Schruers from the Computer and Communications Industry Association to step up to the plate now and take the unenviable slot of being our last speaker before the lunch break.

MR. SCHRUERS: To continue the metaphor, I guess I'm batting clean up. So I'll be brief since I stand between you and lunch.

So I appreciate the opportunity to speak today on behalf of the Computer and Communications Industry Association, which is a trade association of internet communications and technology companies.

CCIA has been a long supporter of

free trade and to that extent recognizes a Special 301 may be an appropriate process for securing markets overseas to U.S. companies.

That being said, just as adequate protection of rights is important to certain creative industries, clear and enforceable substantiative limitation on rights are a necessary to information and technology companies that depend on those limitations to the copyright laws to export information, goods and services and create jobs here at home.

A study commissioned by CCIA in 2007 following a WIPO methodology found that industries which rely on one form or another on limitations to copyright contribute to $.2 trillion in value-added to the U.S. economy, employ 17 million Americans and so on.

The point therefore is that using Special 301 to move the substantive boundaries around our intellectual property rights will not necessarily have the same economic

benefits as using Special 301 to improve enforcement overseas.

To adjust the boundaries we may simply be shifting around benefits between U.S. companies picking winners and losers and find that while we might have improved the economic benefits for rights holding constituencies overseas, we have impaired U.S. companies that are depending on limitations and exceptions when operating overseas and are in fact increasingly being subject to liability in foreign markets for doing things that are permitted under U.S. law.

So, committing ourselves to focusing on the enforcement of existing Berne-like norms, is an activity that will likely have far greater positive impact on the U.S. economy.

As our written comments discuss further, Special 301 being used to pursue issues unrelated to adequate and effective protection of rights also cannot only

undermine economic interests of the U.S., but undermine the credibility of the process.

Because when we place IP respecting nations on lists based on substantive policy agreements, we actually undermine the gravity of the Special 301 scarlet letter when it's implied to countries that actually do fail to provide adequate and effective protection.

Our written testimony focuses on the example of implementing anti-circumvention rules similar to the U.S. Digital Millennium Copyright Act for purposes of complying with the WIPO internet treaties.

And CCIA's view is the disputes over how to implement these controversial and arguably in many cases unsuccessful international treaties which post date 301, Special 301 are not quote, "onerous and egregious acts, practices or policies with respect to rights related intellectual property," as should be understood under the

trade act.

TPM protection, as I said, post dates Special 301, it extends far beyond the section 106 rights, it extends Berne and in fact RDMCA extends well beyond the WIPO internet treaties. So for those reasons Special 301 should not reach TPM protection issues.

Similarly a country's disinclination to adopt the notice and takedown regime is also not in our view a Special 301 issue. Our notice and takedown has been in many situations subject to abuse.

Surveys suggested that more than a third of takedown claims are not based on not valid copyright -- not invalid copyright claims, excuse me, and more than half were actually submitted to -- by companies targeting their competitors.

So, again, that's a difference of a situation where we're fighting about the underlying substantive technical norms as

opposed to actual enforcement.

And finally before I want to take questions from the committee, let me just second KDI's statement that criticized IIPAs statement that developing countries interest in open source licensing models promotes piracy.

IIPA submissions says that various government's endorsement of greater open source deployment quote, "encourages a mind set that does not give due consideration to the value of intellectual creations."

This is utterly false. The importance of copyright to open source licensing models is just as important to the importance for closed source licensing models and whether you support a open or closed source policy preference in your procurement doesn't have anything to do with Special 301.

And in fact, open source licensing models were largely pioneered by U.S. software developers.

And so suggesting that something that U.S. software developers are doing as a licensing preference, which increases U.S. exports and creates U.S. jobs somehow undermines IP norms is not only wrong, it's probably irresponsible.

So, I won't say anything more about that and I'm happy to take questions.

MR. McCOY: Thank you very much. Let me give the floor first to my colleague from the U.S. Copyright Office for a question.

MS. WILSON: Thank you Stan. Thank you for your very full statement and I wanted to ask you a little bit of a question about what you touched upon regarding -- and you also mentioned this in your submission that some countries lack the adequate and effective copyright exceptions.

I appreciate the example that you're given that pertains to the TPMs and your position on our treaties on that point.

Do you have any specific examples

of your members experiences pertaining to the exceptions that would illustrate for us, you know, how those exceptions need to be preserved in those countries that are extended according to your position?

MR. SCHRUERS: I'd be happy to. There's more examples than I have time to discuss. We put out a paper on this a few years ago, which I'll be happy to submit for the post record -- post hearing record.

But one example that's noted in our submission is that the Berne norms that have existed for years create a mandatory access right to quotations.

And that is not always recognized in countries overseas and the U.S. information service providers have been held liable for providing what are essentially quotations of compilations which I would say are adequately protected by a mandatory exceptions stated in the Berne convention.

And a violation of that long

existing access right is equally relevant to Special 301 as is violations of endorsements of -- the failure to provide proper enforcement for section 106 like rights.

MR. McCOY: Thank you. Let me give the floor to my colleague from USDA for another question.

MR. KARAWA: I also thank you for coming today. My question is related to internet piracy in Canada. How do you propose or what would you consider the way to address this problem with the difficulties to copyright holders?

MR. SCHRUERS: So the Canadian situation is interesting because there is now essentially an informal inter-industry agreement about notice and notice forwarding in Canada. It's my understanding is that's the current state of the law.

There's been some proposals to codify that, which CCIA would probably support depending what language comes forward.

That's not what we do here in the U.S. We do notice and takedown under section 512, which was part of the Digital Millennium Copyright Act.

And as I mentioned, the takedown method is subject to abuse and inaccuracy, the fire and forget type notices often miss their mark.

And in a lot of ways we've seen the notice in notice model is more effective in Canada and it's also indicated in the fact that notwithstanding notice and takedown here in the U.S., rights holders are in the U.S. privately negotiating with ISPs in an effort to get them to adopt something that looks a lot more like notice and notice.

So the fact that we were contracting around the U.S. model doesn't necessarily suggest that we should foisting it on to other countries and we should recognize that there are different roads to reach better IP enforcement.

MR. McCOY: Thanks Matt. Last question is kind of brining us back to the theme that we've mentioned several times today of the Congressional mandate to assess the adequacy and effectiveness of IP regimes abroad and fair and equitable market access.

I appreciate that you've provided some comments about Canada. Are there country-specific issues that you want to call our attention to or are there other sources of information that you feel this committee should be looking at with respect to specific countries and the question Congress has asked us to explore of whether they provide adequate and effective protection of IP.

MR. SCHRUERS: Well, let me just be a little bit difficult and quibble with what 2242D2 says is adequate in effective protection of rights related to intellectual property, which is why, for example, I feel comfortable making that Berne article 10 argument that I made.

So, and that language is different from protecting intellectual property rights holders rights of authorship which is used elsewhere in 2242D. Congress' use of different language there suggest that they meant something different.

With respect to Canada, our focus in the statement that we submitted was on Canada, that's certainly true. I think that was more a useful example of how certain submissions in this process have suffered from a sort of mission creep growing from disputes about enforcement to disputes about what ideals, substantive technical intellectual policy would look like.

And so I'm not prepared to give, you know, a list of other examples today. Indeed it is merely exemplary of a process which we should not continue to engage in.

MR. McCOY: Well, thank you very much for your comments. It's now 12:40, what I would suggest is that we break for lunch

now, but return here promptly at 1:40, not 1:30 as scheduled.

But let's keep 10 minutes behind schedule and resume at 1:40 with Sharon Treat of the Maine Citizen Trade Advisory Commission. If that's acceptable, then we'll see you all at 1:40. Thank you very much Matt.

(Whereupon, the foregoing matter went off the record at 12:42 p.m. and resumed at 1:45 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:45 p.m.

MS. TREAT: Okay. Good afternoon. Thank you very much for this opportunity to testify. I am Sharon Treat, I'm a Maine state representative and a member of the Maine Citizen Trade Policy Commission.

We have also submitted a written letter signed by the chairs of the commission and I want you to know that this was a unanimous vote of our bipartisan commission to come and testify here today.

We were established by the legislature in 2003 to assess and monitor the legal and economic impacts of trade agreements on state and local laws and on working conditions in the business environment and to provide a mechanism for citizens, legislators and others to voice their concerns and recommendations and to really interact with USTR.

As I mentioned, we're bipartisan,

we have membership from a wide variety of interests including the representation of a health professional.

And we have been involved in health issues really from the inception of the commission being established. We've previously written letters regarding the impact, potential impact on Medicaid policies to the USTR and to Congress.

We have written with respect to the Korea Free Trade Agreement and we are very interested to read the Special 301 report, particularly because we feel that our advocacy, there were some ears listening to our advocacy before when the special footnote was added to the Korea Free Trade Agreement, specifically carving out state Medicaid programs.

Yet, despite this advocacy and that response, it seems that USTR is still moving ahead with many of the policies that concern us, and we see these here in the 301

report as well.

We rely, as many states do, in fact at least 40 on an evidence-based reimbursement approach to pharmaceutical pricing in our Medicaid program and also in several other programs that we have, Maine Drugs for the Elderly is one, we have a discount drug program called Maine Rx that we were actually sued by the pharmaceutical industry and won a lawsuit, it went all the way up to the U.S. Supreme Court, which requires discounts from the drug industry.

In our Medicaid program, we're actually getting one of the best prices in the United States, about 50 percent off of the average wholesale price as a result of very aggressive evidence-based negotiations to get rebates and different pricing reductions.

I can just tell you that given right now we're faced with a budget situation where we're trying to cut -- we tried to cut basically a third of our entire state budget

for a two-year cycle in the last year and we're going back for more cuts this year and on the chopping block is in fact our Drugs for the Elderly Program, cutting that back.

So anything that is done anywhere that's designed to keep drug prices high and that directly focuses on activities that states use, such as preferred drug lists, is of serious concern to us.

And we are very concerned by what we see happening here. I just mentioned that the 301 report specifically mentions the policies in Japan, Canada, France, Germany, New Zealand and Poland saying that they're unreasonable using reference pricing.

Reference pricing is something that is basically what we're doing in the state of Maine and many others states around this country. So to see that language in the report raises a grave concern in our mind that states may be the next country targeted in the 301 report for not complying with the kinds of

policies that you would like to see.

Finally, we're very concerned that it seems that there's a real collision course here between the policies of the USTR expressed in 301 report as well as other places and the drive for national health care implementation across this country by our own President.

And certainly the states have been partners in that effort to try to get access to health care, we don't want to see anything that would really price health care out of the marketplace and that is in fact what we are concerned we are seeing in the Special 301 report.

So I think I'll stop there. I cut out a lot of my comments so that I wouldn't be interrupted. And I'd be happy to go back to any of them or answer any questions that you have at this time.

MR. McCOY: Thanks for that. Let me give the floor to my colleague from the

State Department. Go ahead.

MR. MILLS: Thank you Stan. In the 2009 special report -- I need my glasses, it's afternoon.

MS. TREAT: I do too, I had to switch during the hearing.

MR. MILLS: Cites concerns about transparency in some countries, pharmaceutical pricing and reimbursement policies. Do you have a view on the importance of these issues?

MS. TREAT: Yes, I do. Actually one of the things that most concerned our commission was the language in the Korea Free Trade agreement, which under the guise of transparency in pricing really put in place mechanisms that if they were applied to state Medicaid programs would pretty much put our preferred drug list out of business.

They would have lengthened the process, they would have added pharma appeals to the process, they would have added pharma representatives to the process. This is not

how we run those programs.

They have to be nimble, they have to be responsive to, for example, a drug going onto generic, being able to switch to a generic version of something under short order.

And so transparency in this manner where we're having public hearings, which I think are fantastic and it's a great innovation on the part of the USTR to do that, that's one thing.

But policies that are under the guise of transparency that actually tie our Medicaid directors in knots and we did some meetings with Medicaid directors around the country who were very concerned about that language in the Korea Free Trade Agreement.

So we would not like to see that kind of so-called transparency moving forward. Pricing transparency of a different nature, which is really like posting that information, focusing on -- and this isn't your bailiwick,

but what PBMs do in the kind of pricing they have, that is of more interest.

And we do have a law in Maine that requires the pharmaceutical industry to really back up what it says average wholesale price is so that we know whether in fact that's accurate. That kind of transparency I think would be very helpful.

MR. McCOY: Maybe I should follow up on that question and say I believe that your larger comments, isn't it a good thing from the perspective of the larger health care discussion that you alluded to?

If there is greater transparency and greater opportunity to recoup research and development costs that they may currently be borne disproportionately by the U.S. health care system and the U.S. consumer review the appropriate schemes, what were your -- what were your thoughts?

MS. TREAT: Well I have two thoughts. One is that I think that it's

disproportionate cost to the U.S. needs to be established. Because I think that what's going on is that -- I mean I just don't buy into that premise that we necessarily disproportionately fund that research.

And so that the only way to continue that research is to keep drug prices high. So that would be the first concern that I would have on that.

The second is that, you know, Medicaid is really the safety net for this country. We need access to those drugs just like every other country. We're not here to simply impose regimes on other countries that don't apply to us.

This is international trade, the agreements whether it's Korea, it's a bilateral agreement or if you're looking at a multilateral agreement, those same agreements can be imposed on us.

We look at this and say, we're not at all assured that by going after other

countries, these same policies aren't going to be enforced against us by them.

We look at what happened on the gambling issue where states were told don't worry, you don't need to worry about your regulations, this has been carved out. It turned out that the ruling was it wasn't carved out.

And we saw in our state that that came back to our state in a proposed solution to that which would have offered up regulation of liquefied natural gas off our cost of Maine, which was of high interest to our fisherman.

So, you know, these kinds of issues, the complexity of them, are the reason that we have a trade commission in the state of Maine to try to educate members of our legislature and our administrative offices as well, the executive and try to get ourselves involved with what you're doing to make sure that you're fully aware of the implications

for us at the state level.

MR. McCOY: Thank you for being involved in what we're doing and making your presentation today. I did see that you're on the schedule to come back shortly on behalf of another group.

MS. TREAT: Yes. Our budget was cut, we're trying to downsize our --

MR. McCOY: So, we have next Sean Flynn on behalf of Forum on Democracy and Trade. Sean, you're welcome to take a seat there and the floor is yours.

MR. FLYNN: Great. Thank you very much. I'll be speaking here on behalf of the Forum on Democracy and Trade but we submitted a joint submission with Sharon's group as well which is the National Legislative Association Prescription Drug Prices.

And our program at American University, which is a clinical type research and advocacy program serves as council to both groups. And so you will have me to sandwich

in between Sharon's two comments and I'm sure we can trade back and forth.

I'm going to try to leave most of the technical questions to Sharon, since she's the actual state legislator and focus on some of the legal questions that were raised in our submissions and perhaps reflect back on some of the policy information as well.

So first just to set the background, so you know, the reason these pricing issues popup into 301 is the link between patents on pharmaceuticals and high drug prices around the world, but including the U.S. is I think that Sharon very forcefully documented.

So when you have patents on essential good and service, it crates an extremely strong forum of market power unlike a substitutable good no one will choose to not purchase a medicine that's needed for their health.

And so we see the very extreme

pricing in developing countries that submissions like MSF today have very forcefully advocated.

It's commonly recounted, for instance, that drug prices for first line AIDS drugs were priced about $12,000 a year in every country around the world in 1999 regardless of income level of that country. And we also see extreme drug prices in this country as well.

Now one of the most effective tools to counter monopoly pricing of an essential good and service is to pool purchasing, is to pool a consumer side of the equation and then to negotiate drug prices between a large buyer and a single seller. It's countering a monopoly with a monopsony.

And that's what states do through Medicaid, it's what the VA does through their purchasing list and it's what foreign countries do with their preferred drug lists as well.

It's what Australia does through the program that's regulated by the Australia/U.S. Free Trade Agreement. It's what Korea does by the program that's regulated by the U.S./Korea Free Trade Agreement.

Now the one big difference, of course, between the U.S. and other countries is that we have -- other developed countries, is we have an extremely large population of uninsured people who actually face unpooled prices at the retail markets.

And it's those people who pay prices that are between 100 and 500 percent higher than the prices in other countries. But government programs in this country pay the same and often lower prices than countries like Canada, Germany, Japan and many of the other countries that are singled out in the last 2009 301 report for having unreasonable pricing policies.

And that's why you see states like

Maine and Vermont before you here today, the Forum on Democracy and Trade, which represents states across the country and trade officials that are worried about trade agreement effects on state programs around the country, and the National Legislative Association Prescription Drug Prices, which Sharon will just talk about which represents 12 or 13 stats across the country.

So the message is this, the kind of programs that 301 has been targeting in foreign countries as being unreasonable are the same programs that are being used effectively in the United States. That is an unreasonable use of Section 301.

And now let me put the cap on it. I think it's also illegal. You are implementing a Congressional statute. That statute demands that you look at other countries intellectual property practices, adequate and effective protection of intellectual property and then market access

issues.

But the phrase market access has a definition. It says that unreasonable market access issues are either market access problems that violate an international trade agreement, and the pharmaceutical chapters of 301 never mention any international trade agreement that's been violated, or that constitute a non-tariff barrier.

Now, a non-tariff barrier is a term of art in trade law and I've never seen it applied to a non-discriminatory price regulation.

So when you use 301 to target a price regulation without demonstrating how it is discriminatory, how it treats different countries products differently, you are breaking new legal ground in international trade law, you're doing so without Congressional authority and you're doing so in a way that harms interests in this own country.

So we are asking you to remove that section from 301, to stop using Special 301 to target non-discriminatory price control mechanisms on pharmaceuticals that do not violate any other trade agreement. To do otherwise, is to violate your statutory mandate.

MR. McCOY: Thanks very much for your comments. We'd like to revert back to the discussion that we just had with the previous speaker on transparency.

Is transparency in how these pricing schemes are operated, is that not a great thing, should not maybe opportunities for the affected industries to understand how the schemes function (Inaudible due to faulty in-house sound).

MR. FLYNN: Yes. So let me answer that in two parts. First of all, the statute that you're implementing does not mention transparency.

It does not mandate that USTR go

around the world and define transparency provisions within other country's regulatory schemes, just as they do not do so here.

The statutory phrase is market access. Transparency doesn't give you market access, it's not a market access term, it's not a statutory term that empowers you to do so.

Now I believe to paraphrase what Sharon just said, and I think you can ask her this question again, do U.S. programs provide the type of transparency that you're requiring either through 301 or through Free Trade Agreements abroad?

And the answer is, no. When states create pricing boards to help them create preferred drug price lists, and that's the mechanism that's used in the states, states create a list of drugs that are preferred within their reimbursement programs, one of the factors that's included is price and that creates an incentive for

pharmaceutical companies to lower their price in order to gain access to that purchase list.

They don't include pharmaceutical companies on the board, which has been requested in past 301 decisions and was actually brought today by the Thailand example as a reason they should be taken off because they actually have two government pricing committees with pharmaceutical representatives on the committee.

That's one of the definitions that USTR has used for heightening transparency. That's not done in any state in the United States. There's at least 40 states that have preferred drug price lists and none of them include pharmaceutical representatives on the bodies that make those decisions.

You can challenge court -- pharmaceutical companies can challenge those decisions under normal administrative process rules, but there are not special rules for any of those lists that give pharmaceutical

companies the right to appeal specific listing decisions, other than under due process norms, or that include them in the determination of pricing or that give them seats at the table or that even have a notice and comment process beforehand.

So you are requiring procedures abroad that we don't follow at home.

MR. McCOY: We received several submissions talking about whether or not we should consider issues of so-called TRIPS plus standards protection.

And since you've been talking a bit about the Special 301 statute, I wonder if you have a view on the fact that the Special 301 statute states that countries may be determined to deny adequate and effective IP protection even if they're in compliance with the TRIPS agreement.

In that light, do you think it's appropriate for us to limit this review to such compliance?

MR. FLYNN: So I'm going to, like Sharon, you're going to have me twice and I'm actually going to have a whole other submission on behalf of Global Health Organization. So I'll answer that briefly, but I'm going to have a lot more to say on it.

So the short answer is, you're very right, the statute itself says that compliance with TRIPS itself does not mandate a finding that that country has adequate and effective intellectual property.

However, the counter is also true. It is left in your discretion. It does not say that compliance with TRIPS is not adequate and effective intellectual property.

If this administration and this panel decides, to take a not random example, that developing countries on access to medicine issues compliance with TRIPS is adequate and effective, there's nothing in the statute that would say that's a wrong determination.

That is a policy choice that this administration is making. And I'll put a cap on it.

This is really, in our opinion, the first 301 report that's being drafted under this new administration and that is frankly why you've had 700 or so submissions in this process when last year there were 55. You've had over 30 NGOs submit into this process when in the past four years there's been one.

So people are interested in seeing policy change and they're interested in seeing policy change on particular areas that the Obama Administration campaigned on, that the Obama Administration has made public statements on.

And one of the key ones is on the access to medicines issue. And I'll follow that up in my next comment which will be focused on global health care.

MR. McCOY: Thanks very much.

MS. TREAT: Thank you.

MR. McCOY: So we'll hear from you again on behalf of someone else. Let me just address the fact that the AIDS Access Foundation, look around the room and see if there is anybody here who's authorized to speak on their behalf.

I don't see that that's the case, so I'll just say that this is covered by the people who mentioned a phone connection as possibly appropriate for another hearing.

So I think Sharon Treat, you can go back again now on behalf of National Legislative Association on Prescription Drug Prices.

MS. TREAT: Thank you very much. I am Sharon treat and as I said, I'm a state representative. In Maine we have a part time legislature and so we almost all hold other jobs and my other job is as Executive Director of the National Legislative Association on Prescription Drug Prices.

This is an organization that was founded back 2000 by a group of state legislators that were focused on drug pricing in the United States and ensuring access to prescription drugs.

Even then, prices were considered extremely high and these legislators got together to figure out what mechanisms they could employ at their state level to try to reduce drug prices.

Part of what our organization has done is try to focus on the trade issue and we have a working group of legislators and we've also had some attorney general representatives and others from around the country to participate in our meetings.

That working group is co-chaired by Arizona Senator Meg Burton Cahill and Connecticut Representative Kevin Ryan. I'm here today to speak on their behalf.

I just want to say specifically that we oppose any expansion of the 301 report

into the realm of disciplining countries for implementing effective and non-discriminatory pharmaceutical pricing policies.

We also oppose the recent trend of the U.S. Trade Representative to use trade agreements in negotiations to develop new international standards restricting the use of the most effective programs to restrain drug prices.

As I already have testified, we believe these programs will directly and negatively effect the capacity of states to provide health care and pharmaceuticals to their residents through existing Medicaid and state funded programs and will cripple the ability of states to expand access to health care in the future.

I'm going to go off message just a little bit to talk about that transparency issue. We actually consider a best practice to have conflict of interest policies applied to any preferred drug list committee that's

making up those decisions to ensure that there is zero pharmaceutical industry representation on those preferred drug list or DUR committees.

And in fact, the District of Columbia has passed a law restricting any funding or gifts to those people and indeed Vermont and Massachusetts and others have gift, more broad gift ban provisions anyway. So those would clearly violate the Korea agreement and other proposals.

I want to also mention that we -- this is an issue, if you go to the written submission that we worked with Professor Flynn to put together, you might want to take a look at the footnote on page 6 through 7, footnote 14.

It details at least eight letters that have gone from legislators as well as chief executives.

The Governor of Washington State, for example, Governor Granholm focusing on --

I mean Gregoire, Christine Gregoire, writing to either USTR, to members of Congress expressing concern about the free trade agreements language as well as other initiatives of the U.S. Trade Representative over the last several years. So you can take a look at those that are mostly posted online.

Medicaid costs topped $350 billion in 2008. It's the single largest state government expenditure after education and I really wish there was the HHS representative sitting on the panel right now because it is really our signature program at the state level for health care.

I just want to point out some of -- I mentioned Maine's success in using the preferred drug list and other mechanism to reduce prices. Here's some other statistics.

Iowa has saved $100 million between 2005 and 2009 savings equal to 34.7 percent of its total drug budget. Oregon saved 40 percent per prescription due to

generic uptake because of its preferred drug list.

You know, discounts negotiated by private companies for Part D, which did not use the same mechanisms, were substantially higher, 30 percent higher than what states have previously been spending for the Medicaid population that then was moved to Part D under the Medicare Part D.

So that's an indication, that 30 percent figure is an indication of sort of a minimum amount nationally that is being saved right now using these pricing mechanisms.

Again, I want to end with the concern that this approach and these policies are really on a head-on collision with other policies of this administration; policies that I, as a state legislator and that many legislators around the country, are very much in support of, which are about expanding access to health care across this country, affordable health care.

And we hope that you will take into consideration those policies as well as you try to navigate your direct requirements here.

MR. McCOY: Thanks very much. And we will not be surprised to learn the questions we have based on the National Legislative Association on Prescription Drug Price submission, were again, very similar on this question on the transparency and merits of encouragement of transparency in systems overseas (Inaudible due to faulty in-house sound).

Is there anything else that you would like to say on behalf of this group, on that?

MS. TREAT: Well I'm not going to go into those legal argument, but I'll just tell you that someone I work with who works on these prescription drug issues went to the meeting on setting up a preferred drug list in Maine and she said she was amazed to find that

it was a room sort of the size of this that was completely filled with representatives of the pharmaceutical industry.

Clearly, it's being done in a transparent manner, but it does not meet the definition of transparency that has been used in, for example, the Korea Free Trade Agreement.

And we actually were very concerned about that language. I'll leave it to Professor Flynn to say whether or not you're allowed to define, you know, those things are part of what your responsibility is.

But clearly the kinds of requirements that have been put into these agreements are very much inconsistent with what states are doing.

And we, I've been told directly by state Medicaid directors that they could not do their job, they could not do these preferred drug lists the way they do and

comply with those requirements, which would delay for in many cases for several years, the actual putting something on to a list, for example.

They need to be nimble so they can take advantage of, as I mentioned before, if a drug suddenly goes on to a generic list, you know, becomes generic after it's been an incredibly expensive drug, something that is taken by, you know, thousands or millions of people.

State Medicaid directors need to be able to move quickly to change their drug lists to, you know, get those reduced prices.

And so, you know, we are very concerned and we don't see the trend -- I guess what's disturbing is that these are issues that we have been raising for, you know, many years, four or five years.

And it doesn't -- it just seems like instead of going -- really considering them, I mean this footnote was put in the

Korea agreement, but instead of really understanding it, there seems to be an even greater effort to focus on this whole area in a way that clearly would have repercussions for us at the state level.

MR. McCOY: I'm interested in what you mentioned about the open meeting. Would I be correct in understanding that to mean that the state policies are transparently run in the sense that folks who are affected can know when decisions would be made and provide information to decision makers, the process is transparent in that sense.

And would you agree that foreign government processes should be similarly transparent?

MS. TREAT: I'm not here to pontificate about what foreign government should do. My concern is what the effect is on our state.

I do care about access to health care for people all over the world as an

individual, but as state legislators what we're focused on is policies being played out at the federal and international level that have an impact on access to health care in our states and so that is our concern.

MR. McCOY: That's understandable. Thank you very much for making the trip here and sharing your views.

MS. TREAT: Thank you. I appreciate it.

MR. McCOY: So I think Robin Lunge from Vermont Commission on International Trade and State Sovereignty. Robin did I pronounce your name correctly?

MS. LUNGE: You did.

MR. McCOY: Thank you.

MS. LUNGE: Good job. It's a rarity actually.

MR. McCOY: The floor is yours, please.

MS. LUNGE: Thank you. My name is Robin Lunch I work for the Vermont Legislative

Council's Office which is the non-partisan legal and policy staff for the Vermont Legislature.

I'm here today on behalf of the Vermont Commission on International Trade, which was created in 2005 by state law. Our commission has eight members, it's a bipartisan commission.

We have two legislative members, a representative of the Attorney General's office, our Secretary of Commerce and four members appointed by our Governor including a representative of labor, environmental interests and two representatives from business one of whom is from IBM, which is one of our largest employers in Vermont, the other of whom represents the interests of small exporters in the state.

So just a little bit about us. Our statutory charge is to look at the balance between promoting trade as a vital economic interest for Vermont and a way to increase our

economic development potential with maintaining the state's ability to determine its own policies recognizing that there are certain areas that are specific to state sovereignty under the 10th Amendment of the United States Constitution.

So why should you be interested in state pharmaceutical policy? I think that's an obvious question for you to be asking yourselves.

And the short answer to that, I think you've already heard, which is when you apply international standards to other countries, which could then become memorialized in a reciprocal trade agreement, it's vital for you to understand if that policy is in conflict with something that a state or other locality or domestic policy issue here.

So I want to talk to you a little bit about Vermont. Vermont has been a leader in health care reform. And one of our state

senators talks about the health care reform in Vermont as a three-legged stool.

We like three-legged stools, you use them in milking, probably a lot of you don't milk a lot of cows, but we do that in Vermont.

So and our three legs are access, quality and cost containment. And cost containment has been a vital piece of our health care reform because without cost containment, there's no way that we would be expanding our coverage to the numbers of folks that we do cover in Vermont.

We have 93 percent of our population covered, the majority of that is through some state funded program either through a Medicaid expansion program, state employees or teachers.

Ninety-seven percent children in Vermont have health insurance. So we've achieved nearly universal access without a mandate as Massachusetts did.

This started a long time ago with Former Governor Dean creating a children's health insurance policy called Dr. Dinosaur. The other thing that we've been doing for a long time is providing affordable access to pharmaceuticals for low and middle income elderly and individuals with disabilities.

Our state programs go up to 400 percent of poverty, which is higher than what the Federal Government is currently considering its subsidies in the national health care reform.

We provided access to pharmaceuticals through state only pharmacy programs and then after the Medicare Part D, because Part D was worse than the coverage that the state offered through a wrap-around program for those individuals.

So, we recognize the importance of pharmaceuticals as being vital to people's health and a necessary part of our health care system.

In fact, we're focusing now on a program called the Blueprint for Health, which focuses on the prevention and management of chronic disease largely through pharmaceutical management. So drugs are important to us and having access to drugs is important to us.

But we would not have been able to achieve that level of coverage or to put it in a different way, the pharmaceutical company wouldn't have the market penetration in Vermont if we had not also pursued cost containment.

In terms of our prescription drug cost containment, it's important to note that Vermont has achieved a negative spending trend in pharmaceuticals in our Medicaid program.

In addition, through the implementation of our preferred drug list, we saved $3.8 million within the first eight months, which for many people is not a lot of money, but in Vermont $1 million is a lot of money.

In addition, we've saved over 10 percent of our prescription drug benefit for state employees by restructuring our benefit to include a preferred drug list. So this has been a vital tool.

Our preferred drug list in Medicaid includes an evidence-based process focused on clinical efficacy and cost. There's also a focus on generics. We include generics on our preferred drug list.

And we use the preferred drug list as a mechanism to negotiate additional rebates from drug manufacturers. We also do both purchasing with other state Medicaid programs to increase our buying power.

This is not all that different from what other countries do in terms of managing their drug costs.

So I would just close by saying that the Vermont Commission is very interested in having you focus on whether it's necessary to look at pricing and reimbursement

strategies and reeling it in light of the importance it has to states.

MR. McCOY: Would you help us with this question of transparency that we discussed with the last couple of speakers. I'm particularly interested in whether that you could consider that Vermont runs its program in a transparent way with open meetings?

I don't know what the state statutes are in Vermont on that score, but would you consider that you have transparency in the process there and would you consider that it's appropriate to seek that kind of transparencies from foreign entities?

MS. LUNGE: Sure. I'll address that issue. I should just provide a caveat, which is that the Vermont Commission on International Trade has not specifically discussed transparency issues.

So in speaking now, I'm speaking really more as a general health policy person

for the state of Vermont and not specifically for the commission, because they haven't considered that question.

Our state statute establishes what's called the drug utilization review board, which is a board made up of state Medicaid officials, pharmacists, doctors and other clinicians.

There are no consumers on that board, there are no industry representatives on that board.

In fact, I feel confident in saying that my health committees would probably see it is a conflict of interest to put industry on that board because we are purchasing from -- we don't usually put people that we're buying things from on the board setting up how we're going to procure the items.

The meetings are subject to our open meeting law, there are minutes. However, a couple years ago we actually changed the

state law to provide the ability of that board to go into executive session.

We did that in part in response to the pharmaceutical industry indicating that they did not want information about the price negotiations to be held in an open meeting.

So, they certainly, the pharmaceutical company is able to attend the open meeting, but the meetings do go into closed session when they discuss price negotiations and when they're actually choosing which drugs to put on the list because they were trying to be sensitive to the assertion that the prices they negotiated were subject to trade secret.

So, I think in terms of transparency you can't have it both ways. Either it's open information or it's a trade secret and you need to kind of sort through do you want to have the ability to keep some of that information confidential for the protection of the industry as well as have an

open process.

Now similarly, consumers can't go to the closed meetings either. Consumers and industry have the same rights of appeal either way, neither of which is specifically specified in the DUR board statute, it would be through our other state rules and statute.

I did compare our process to the transparency provisions in the Australia agreement a number of years ago and we did not -- we weren't 100 percent in alignment with those requirements.

I don't remember the details off the top of my head, but I'd be happy to see if I can dig that up and provide you with that specific comparison of whether or not our statute met the transparency requirements in that agreement. So I hope that's helpful.

MR. McCOY: That is helpful, thanks very much. I think that was the main area of questions that we had on this course. So unless there's anything else that you want

to elaborate on, I'll just say thank you very much for your participation.

MS. LUNGE: Thank you.

MR. McCOY: Can we squeeze in one more before the break and invite you back again? Are we having problems with both mics now? Right, I don't know if these are doing any good. We're going to go to the break and see if we can get microphones. Thank you.

(Whereupon, the foregoing matter went off the record at 2:28 p.m. and resumed at 2:36 p.m.)

MR. McCOY: You are now speaking on behalf of American University Program on Information Justice and Intellectual Property on behalf of AdHoc Civil Society Coalition on IP and Access to Medicine. So the floor is yours, please go ahead.

MR. FLYNN: Okay. Thank you. So as I mentioned previously and as you just did, this submission is on behalf of the joint submission of the global public health groups,

some of whom are testifying in their individual capacity today, but this was the joint submission that was signed by a number, I think it was 12, global health groups.

I intend to, you know, follow up and answer some of the questions that Stan was asking and hit upon some other points as well.

And this is my longer submission, so I'm going to have to cut through and hit to a bunch of points and hope you'll give me the opportunity to expand in question and comments.

So first of all, in considering your mandate, I think it's important to consider from an administrative law standpoint what it is your doing.

So from an administrative law standpoint, this is an adjudication, it's backward looking, not forward looking, you're not making a rule, you are looking, you're implementing a statute and interpreting that statute and applying it to facts as they come

before you and you're adjudicating those facts and making factual findings at the end.

And I introduce that way to say that we have procedural concerns with this process. We want to thank the committee for opening this process significantly more than has been the case and I think that was at least in part to some submissions from many of the people who signed this joint submission asking for a more open process to hear from public interest concerns.

But it's still not a very adequate process for the determinations that you need to make both on facts and law. Some of the submissions that we've been making both in our written submissions and that I'm submitting to you today are legal disputes.

We have disputes with the way that the 301 statute has been interpreted and implemented particularly over the last eight or nine years.

The expansion of 301 into

pharmaceutical pricing is one such issue and the expansion of 301 to put pressure on developing countries to implement TRIPS plus intellectual property policies on access to medicines is another.

And that's the one that I want to focus on now. There's a series of procedural suggestions that we make in the submission.

I think you can sum them up by saying that you should be following the procedures that would be required by the administrative Procedure Act in a process that's required by statute to be done on the record after a hearing.

I'm not arguing that you're legally required to implement that rule, because I don't think you are. I'm arguing that as a matter of policy to adopt best transparency and participation practices, those are the standards that you should be implementing in the future.

Let me return to the question that

Stan left off with which is that doesn't the statute, I'm paraphrasing wrongly, does the statute essentially require us to look into enforced TRIPS plus standards because of the provision in the statute that says compliance with TRIPS does not mandate that something be considered adequate and effective intellectual property.

You do have to give meaning to that phrase within the statutes, but you also have to interpret this statute against the background of the other United States and administration commitments that promote access to medicine specifically and that have turned against past policies of using TRIPS plus intellectual property requirements on access to medicines, and they just list those.

You should be interpreting the mandates against the background of the TRIPS provisions that address and emphasize the importance of balance and national discretion, which include Articles 1, 6, 7 8 and 40.

You should be interpreting all of your statutory mandates against the background of the WTO accords, which mandate multilateral, unilateral adjudication of trade disputes.

This is a pre-WTO statute and actually my legal opinion is that this process violates the WTO.

You should be interpreting all of your access to medicines intellectual property standards against the background of the 2001 WTO Doha declaration, which has been extremely narrowly misinterpreted by the past administration to include only public health crisis and that's not what the declaration says.

And specifically, the declaration affirms the rights of every country to use all TRIPS flexiblities in full, quote, unquote, "in full."

And that specific phrase within the WTO Doha declaration has been attacked

essentially by the U.S. over and over again in the Special 301 process in the past, including in the 2009 report, as exhaustively demonstrated in our written submission.

You should also be adhering to U.S. commitments in the WIPO development agenda. You should be adhering to the ethical guidelines of the declaration of Helsinki, which James Love mentioned.

You should be adhering to the Obama Administration's expressed policy to quote, "increase access to affordable drugs in developing countries," including through support for, quote, "the rights of sovereign nations to access quality assured low cost generic medication to meet their pressing health needs under the WTOs declaration on trade related aspects of intellectual property rights."

And you should also, I submit, be interpreting your mandates against the background of international human rights

obligations including documents the U.S. has not signed and including common international law that promote the rights of all countries to access to health care and have been specifically interpreted by the Special Rapporteur on the Right to Health, who requested to submit comments by telephone today and was not made available.

That in position of TRIPS pressure on developing countries violates other country's citizens rights to health. That should be the normative and legal framework guiding your determinations on all access to medicines to principals.

MR. McCOY: Can I give the floor to my colleague from the State Department for a question, please.

MR. FLYNN: I'd be happy to answer a couple questions that I have for myself if you don't have --

MR. McCOY: Excuse me, my colleague from the Copyright office. Let me

just give the floor to Susan then, go ahead would you.

MS. WILSON: Thank you very much for your presentation. I believe there's more to come. We've tried to get at this particular question a couple of times today and heard, I think very clearly the opinions of some of your colleagues on this issue of counterfeit medicines versus substandard medicines, so I won't ask the question in the same way.

But I think one of the things that we're trying to get at in the medicine space from an enforcement perspective since there's clearly disagreements about some of the policy issues surrounding medicines.

But in the enforcement space, one thing that I think is very important to all of us in this room, regardless of where we are on some of the other issues, is the fact that there is a tremendous amount of counterfeit medicine and truly counterfeits, packaged,

trademark bearing, false, dangerous ingredient counterfeit medicines circulating in the market place globally.

How, and one of the things that we've done as the U.S. Government is used Special 301 to highlight that issue and to draw attention to the issue and to get enforcement resources focused on the issue in the United States and also use that -- used it to focus foreign government's on the issue.

And one of the things that we've tried to do, and I think under some circumstances less successfully than under others is enlist the NGO community or try to, to help us.

And maybe we haven't used the right words and we haven't approached in the right way or maybe years of being on opposite sides and other circumstances have led to less than the kind of relationship you need to work together under these circumstances.

But one of the things I think that

we're looking for is how can we work together in this area in which we all agree there is an enormous problem, we may not have the contacts that you have, I know we don't, with the people who are in the first line, in the trenches distributing medicine, you see it all the time where as close as you are.

How can we work together, what suggestions can you give us on tackling this problem on getting a hold of the true counterfeit problem?

Not using IP to get at, you know, substandard drugs, not using IP as a shield for trying to disrupt what are otherwise valuable humanitarian efforts, but really tackling this menace, this scourge. We all know where it's coming from, we all want to do something about it and we haven't been able to and it's growing by leaps and bounds and it's killing people.

And what suggestions do you have, and I'm posing that question not only to you,

but for everyone else who takes the microphone for the rest of the day, what can you tell us, how can we help each other on this issue.

MR. FLYNN: I mean I think that's a great question. I have some very specific things that I think I mean you collectively, the administration, you USTR can do if you really want to work with the global public health community on some of these issues.

So the first thing you can do is release the text of ACTA. If you want to talk about counterfeiting with the global health community, you have to release the text of the major multilateral agreement that's discussing counterfeiting as soon as possible.

We would like to comment on it. We would like to be here at forums like this telling you what we think of your exact specific policy proposals.

Second, we should be talking about drug regulatory systems and not intellectual property systems. Intellectual property

systems don't protect public health, drug regulatory systems do.

Third, you should at least immediately return to the waning years of the Clinton Administration policies when there is an active debate between the global health community and a democratic administration.

And under that era, HHS would be sitting here at the table, they were mandated to be part of the subcommittee looking over 301, they were actually given the final word for an administration policy on all TRIPS plus issues, HHS was required to look at those issues and make a final determination on it.

And to quote that specific policy, the policy further stated, should a government determine to avail itself of the flexibility of the TRIPS agreement that provides to address health issues, the United States will weighs no objection.

That was not the policy under the Bush Administration, it was not the policy

under the 2009 Special 1 report.

And finally in the section of the 301 report that discusses TRIPS and public health, at minimum we should go back and read the 2000 301 Special report -- Special 301 report that was written under the Clinton Administration.

That's the fullest statement on that issue that we have had to date. You should endorse in full the Doha declaration, not just as applied to crisis and not just as applied to compulsory licenses or parallel importation.

And especially not as was done in the Bush Administration, only applied to the obvious 30 paragraph 6 solution, which was simply about compulsory licenses for exporting drugs was not about TRIPS flexibilities.

You need to have a sentence in the 301 report that says we affirm, and as we did in 2001, the rights of all developing countries to use all TRIPS flexibilities to

the full to address access to medicines matters.

And then you need to apply that standard throughout the 301 report. You should not be listing developing countries for data exclusivity matters as is discussed exhaustively in my written submission.

The idea that the article 393 requires data exclusivity was amended out of TRIPS. TRIPS 393 does not require data exclusivity, it can't. That proposal of the U.S. was rejected.

Up unto 2003, the 301 report continued to say that article 393 required data exclusivity. Please abandon that legal interpretation of TRIPS in the context of this unilateral adjudication.

And all other TRIPS plus issues should be eliminated on access to medicines and patent issues from the 301 report. That would be a great starting point to working with the NGO community on these issues.

MR. McCOY: Thanks very much Professor Flynn, Sean. Could I Universities Allied for Essential Medicines to come forward.

MR. STERN: Good afternoon. My name is Benjamin Stern and I represent the Universities Allied for Essential Medicines. What you have there is two declarations made by universities that I'll discuss and just a preliminary version of what I'm going to say.

Personally, and on behalf of UAEM I'd like to express my gratitude for the opportunity to be here today. This is a new procedure and for whatever procedural issues you might have, it's not everyday that students get to testify before a committee.

I am a second year law student at Yale and I studied engineering, biomedical engineering at Columbia and I'm going into a professional career in patent law.

UAEM is an incorporated non-profit made up of over 60 campus chapters but it's

comprised of students. Our membership is as diverse as the student bodies of the institutions we call home.

UAEM brings together law students, medical students, public health, business and undergraduates and that's what makes it great, it's one of the few organizations on campus that actually does that.

We come from across the political spectrum, all the diversity views, but what we have in common is that we all care about access to medicines and we all care that our respective universities ensure that access.

We all believe that, and the universities agree with us that university held patents should not be a barrier to access.

University life science research is at a nexus of academia and industry. I'm currently taking a class in pharmacology, the Yale Law School lets us do that, take classes in whatever field we want and I happen to be

interested in pharmacology.

And just yesterday we had a lecture from a professor who's started three companies, one for each new cancer drug that he's invented.

And one of those companies was purchased by Pfizer, it became very profitable and very successful and the next two look like they're just as promising, if not more.

Another lecture in the same class was given by a professor who wrote a computer program that simulates interactions between molecules and can predict how effective drugs will be, what their side effects will be, how to change the molecular structure of drugs so that they work better, all on computer, no, you know, no chemicals involved.

And that software is used by over 30 biotech and pharma companies and it's been very successful, it's been uses for 20 years and he and a partner has refined that and it's produced some very impressive results.

These university developed technologies have saved millions of lives and will save millions more, but they're publically funded largely and those publically funded innovations must be made affordable to be truly accessible.

Universities have committed themselves to global health and repeatedly ensured that their intellectual property not become a barrier.

We believe that the USTR should demonstrate a similar commitment in line with its international obligations as discussed with compiling the Special 301 report.

So I'll talk about some of the lovely commitments that we've made. In 2007, working with UAEM several universities adopted the Stanford nine points to consider in licensing university technology. That's the cream -- in order, the cream colored sideways printed page.

The ninth point is what I want to

focus on that universities should strive to construct licensing arrangements in ways that underprivileged populations have low or no cost access to adequate -- quantities of medical innovations.

The list of organizations on the first page is only the initial sponsoring organization. Since then, 70 have signed on.

Most recently, our efforts have led to the adoption of a more concrete global access policy, the statement of principles and strategies for the equitable dissemination of medical technologies, which is the white handout there.

Several major research universities, including Yale and Harvard and the AUTM, Association of University Technology Managers, the NIH and the CDC have signed on to that.

MR. McCOY: Could I ask you to pause and allow for a question?

MR. STERN: Yes, sir.

MR. McCOY: Let me give the floor to my colleague from the U.S. Patent and Trademark Office for a question.

MR. STERN: Absolutely. The rest of what I had to say was basically repeating points that have been made before, so that's what was new.

MS. MOEZIE: Thank you for your comments. We understand the debate regarding widely available drugs in the western world and their direct impact upon diseases such as HIV/AIDS in particular.

Your submission states that past 301 reports have often failed to live up to the letter or spirit of international commitments in this area. Could you identify examples of how you consider that has occurred?

MR. STERN: Considered as a, I'm sorry, a what?

MS. MOEZIE: How it's occurred.

MR. STERN: Oh, how the failures

have occurred?

MS. MOEZIE: How -- yes.

MR. STERN: Well in terms of the honesty of the reports, I think have not been -- the reasoning behind the reports have not been as straightforward or as accurately representing.

A specific one would be, I guess, perhaps the reasoning statement behind why Israel was put on the -- or one of the reasons Israel was put on the priority watch list about access to generics.

The last 301 report speaks that the -- that Israeli patent law gives an unfair -- or gives an unfair disadvantage to American or innovative companies, meaning American companies.

And we think, and based on my research, it seems that it not be disadvantaged to American innovators, it's actually an advantage to Israeli over -- Israeli, sorry, Israeli generics over American

generic companies.

So, medicines that are available generically for things like HIV, as soon as the patent expires, generics can enter the market if the proper research has been done.

Certain countries, such as Israel, don't have the same data exclusivity of protections and those allow them to enter the market very quickly.

When you do have data exclusivity and you do have patents from extensions, you've got a de facto patent extension.

So, and most of the drugs in the -- or most of the first AIDS drugs, the first effective AIDS drugs have gone off patent in the past five to seven years. And that's one area I feel is -- that the USTR has not lived up to its commitment.

MR. McCOY: Anything else you'd like to share with us in the time available that can help us to assess the adequacy and effectiveness of IP protection and

reinforcement by our trading partners?

MR. STERN: Sure. What we do want to repeat that we really hope that the USTR and State Department will not use diplomatic pressure to discourage compulsory licenses. We feel that tactical opposition to compulsory licenses undermines the Doha declaration and the TRIPS flexibilities.

And we think that -- I think PEPFAR has been mentioned today that it would benefit the U.S. to have increased access to generics. GM, for example, spends more money on prescription drugs than it does on steel.

I don't know if that's been mentioned today. And gram for gram, drugs can be the most expensive substances on the planet. And since the government owns the majority stake in GM now, I think that's something you might want to consider as a government organization.

And PEPFAR being an executive branch initiative also is an important thing

to consider, because if resources are not spent on expensive drugs are spent on widely available, very simple to manufacture drugs, they can be spent on patient care and clinical and more valuable initiatives and approaches.

MR. McCOY: Let me just say on these documents that you've passed out, happy to have them. If they're not already part of your submissions, you may want to submit them as part of the official record as post hearing statement.

So you can do that on regulations.gov. But thank you very much for joining us today and for sharing your views.

MR. STERN: Well, thank you very much for having me. And we will be submitting several post hearing statements.

MR. McCOY: Thank you. And we're trying to figure out what that noise is. I don't know if it's as annoying for everyone in the room.

MR. STERN: It stops when your

microphone goes off.

MR. McCOY: That's the solution, I'll keep running my mouth. So on that theme, I think next we have Asia Russell from Health GAP. Welcome.

MS. RUSSELL: Good afternoon.

MR. McCOY: Have a -- make yourself comfortable and the floor is yours.

MS. RUSSELL: Thank you very much. Good afternoon. My name is Asia Russell, I direct international policy for Health GAP. Health GAP is a policy and advocacy organization working for the urgent scale to provide access to affordable HIV treatment in developing countries.

We've worked over the last decade to improve the response of the U.S. Government to the global AIDS crisis through increasing the U.S. Government investment in AIDS treatment and improving U.S. Government policies.

Because of the critical role in

our experience that generic competition among manufacturers have played in reducing the cost of live saving AIDS drugs in developing countries.

We've also focused over the last decade on ensuring that U.S. trade policy is guided by and accountable to the needs of people suffering unnecessarily without medicines access.

Our efforts have helped contribute to significant shifts in the U.S. response to the AIDS crisis in Sub-Saharan Africa and other countries in need.

This has included dramatic scale up and appropriations for HIV treatment and prevention, the creation of the U.S. President's Emergency Plan for AIDS Relief, PEPFAR, in 2003 as well as in 2001 the creation of the Global Fund to Fight AIDS Tuberculosis and Malaria.

We also note that there have been some changes over the last decade in trade

policy relating to intellectual property rights and access to medicines over the course of the previous two administrations.

Unfortunately, I -- it's referenced by the Special 301 report from 2009. It appears that this administration, like the previous one, is committed to use of the Special 301 report as a tool to bully countries that are attempting to assure access to affordable medicines through intellectual property provisions that make use of the flexibilities enshrined in the TRIPS agreement and reaffirms by the Doha declaration on the TRIPS agreement in public health.

This persistent deployment of a flawed policy under this administration and previous ones is a matter of serious concern to the AIDS and global health communities. The assessment by USTR of quote, "Adequate and effective protection of intellectual property rights," unquote, fair and equitable market access in our view can and must be determined

in the context of the U.S. obligation to uphold the provisions of the Doha declaration on the TRIPS agreement in public health.

We expect to see a 2010 Special 301 report that does more than pay lip service to the idea of the diplomacy of public health and access to medicines.

We expect to see countries removed from the watch list in each and every case where their actions are consistent with TRIPS compliant efforts to promote access to medicines for all.

Our comments today build on arguments provided in the submission that you have available and are combined to these brief points.

One, that the administration's public commitments to responding to global health priorities including, but not limited to the epidemic of untreated HIV or undermined by USTRs use of Special 301 and other measures to punish and pressure countries using TRIPS

compliant measures to increase the availability of medicines.

Two, that USTRs current use of the Special 301 report contradicts U.S. obligations as well according to the Doha declaration on TRIPS agreement in public health.

And finally, we'd like to express concern that the continued use of Special 301 in this manner is in fact a prohibited form of unilateral action by the U.S. in violation of its commitments to a multilateral system of dispute resolution within the WTO.

On the first point, I'd just like to remind you that this administration has pledged repeatedly to reach the global goal of universal access to HIV treatment in developing countries as well as complementary international commitments to tackle diseases that are the leading preventable killers of people in developing countries worldwide.

And I should add contribute to a

great deal of lack of economic productivity around the world.

Moreover, as presidential candidates, not only President Obama, but also President -- Vice President Biden and Secretary of State Clinton, as well as Senator McCain, made repeated promises to scale up the U.S. response to global AIDS, including through adoption of trade policies that ensure access to affordable generic medicines.

These public commitments were preceded by President Bush in 2003 of PEPFAR, seeking appropriations over five years of $15 billion and pledging to extend treatment to at least two million people with HIV.

As I'm sure other witnesses have mentioned, the U.S. is now the largest funder of antiretroviral therapy in the world and PEPFAR has been reauthorized to a level of $48 billion in its second five years.

PEPFAR reports directly supporting treatment of more than 2.4 million people

worldwide and indirectly supporting many more through investments multilaterally such as through the Global Fund to Fight AIDS Tuberculosis and Malaria.

Why does this matter? PEPFAR has steadily increased its procurement of generic medicines and is now the world's largest procurer of HIV, of generic HIV treatment according to PEPFARs own estimates in 2007, proportion of generics by volume procured by PEPFAR reached 73 percent in 2008.

In the fiscal year 2008 PEPFAR spent approximately $202 million on antiretrovirals and of that, the investment in generic HIV -- in generic, excuse me, antiretrovirals increased from 11 percent upwards to 27 percent and finally by 2008 to 57 percent with corresponding savings as estimated by PEPFAR to be more than $115 million over three years.

In addition to its own ARV procurement, the U.S. is the biggest donor to

the Global Fund to Fight AIDS Tuberculosis and Malaria which by the end of 2008 had spent more than $4.4 billion on AIDS programs of which roughly a third was spent on ARV treatment and monitoring.

ARV treatment has reached, at this stage, over four million people in urgent need by the end of 2009.

An additional 10 million patients who need treatment according to new peer reviewed assessments by the World Health Organization or their experts, are still without access to medicines and many millions more will require treatment over the next decade.

These patients need treatment in their own right, but there's also a growing body of evidence that treating HIV might be one of the best ways to prevent HIV transmission.

I actually just have one more paragraph, if that's okay I'll just finish and

then be happy to take your questions.

In addition, new treatment guidelines recommend discontinuation of older, more toxic, less effective therapies including d4T-based therapies and replacement with more effective durable regimes based on newer medicines such as Tenofovir and Zidovudine with concomitant current increases in price points.

Therefore, first line medicines are becoming more expensive as people initiate therapy on newer second generation medicines. At the same time, second and third line combinations of treatment for people who are HIV positive and become resistant to their current therapies are by some estimates as much as 8 to 40 times more expensive than first line products.

The administration's pledged commitment to reach universal access to AIDS treatment cannot be met unless the price of HIV treatment is affordable.

Other generic companies in India and elsewhere, other countries have production capacity have been able to manufacturer older generic, quality generic versions of older antiretroviral medicines at a fraction of the cost of brand name products, a benefit that PEPFAR has reaped heartedly over the last several years.

These same opportunities have dwindled with respect to newer medicines. Accordingly and as a result of having become TRIPS compliant in 2005, a number of newer antiretroviral treatments remain much more costly because patent holders face more generic competition from India or elsewhere.

This is a public health concern that our trade policy has to address. Moreover, the production and export capacity -- the production and export of generic antiretrovirals in India and other countries with production capacity, has been a driving force scaling of access to medicines in Sub-

Saharan Africa.

Therefore, USTRs pressure on India and other countries with manufacturing capacity whether they'll be middle income countries or otherwise, through Special 301 report listing and other means, harms not only Indians in need of affordable treatment, but also people living with HIV and other health priorities in Sub-Saharan African countries that are now primarily importing countries because they lack domestic manufacturing capacity.

That's a very important point to make. It is in this context that the USTR in our views pursuit of heightened intellectual property protection for pharmaceutical products and its punishment of countries that use TRIPS compliant flexibilities by means of USTRs Special 301 reports directly undermines this administration's public commitment to reaching universal access.

Beneficiaries of U.S. global AIDS

programs, as well as U.S. taxpayers, urgently require the U.S. to pursue trade policies that support generic production of first and second generation HIV treatment, their interests must be promoted and protected by the administration and by USTR, not only the interests of multinational pharmaceutical companies.

My final point, as I'm sure previous witnesses have mentioned, this administration, this country, the U.S. is a signatory, like every other WTO member country, to the Doha declaration on the TRIPS agreement in public health.

And that declaration emphasized the gravity and primacy in developing countries public health needs and clarified member's rights to promote access to medicines for all.

As you've noted by our submission and the submission of the joint submission of Global Health Organizations, we've highlighted

the multiple ways we feel that USTR has consistently pursued TRIPS plus intellectual property protections in contravention of our obligations under the Doha declaration.

Special 301 reports have listed countries for use of compulsory licenses such as in the case of Thailand.

MR. McCOY: This is a long paragraph.

MS. RUSSELL: Oh, almost done. Such as in the case of Thailand and Brazil. And it's the question you just asked the previous witness, in the case of Thailand and Brazil for refusing -- for countries refusal to expand its global patentability despite the fact that countries have a right to define on their own terms scope of patentability, that's in the case of Brazil.

There are many, many very disturbing examples. So I think in conclusion, we call on USTR to conduct a complete review of its use of Special 301

listings soliciting analysis and review from health and other experts through a multi agency process.

We're actually concerned that we don't see Health and Human Services or other health experts represented on this subcommittee today and that's an easy fix that we think you would be eager to pursue.

As a condition of respecting U.S. endorsement of the Doha declaration of TRIPS and public health and for the purpose of achieving the goals of President Obama's global health initiatives the USTR should act affirmatively to promote access to medicines by promoting implementation on the part of countries in need of TRIPS affirmed by the Doha declaration instead of pursuing the course that it appears to be pursuing now.

That is the one of erecting intellectual property protections that serve only to increase pharmaceutical industry profits.

These monopoly-based profits come at two high a cost in terms of health outcomes for people living with HIV and other people seeking secure, healthy and productive lives in these developing countries, in middle income countries and around the world.

MR. McCOY: Thanks very much for your statement. I think we've used up the time for questions, but as you said, you covered some of the questions that were addressed before about TRIPS plus and so on.

If there's anything else you feel you need to elaborate on, you're certainly welcome to do that in a post hearing submission.

But let me say we're very grateful for your participation and for your statement today and thank you very much for being a part of the process.

MS. RUSSELL: Thanks Stan.

MR. McCOY: Take care. I think our next speaker is Michael Palmedo from the

Program on Information Justice and Intellectual Property.

MR. PALMEDO: Hello.

MR. McCOY: The floor is yours.

MR. PALMEDO: All right. Is the mic on? Here we go. All right. Hi. Once again, my name is Mike Palmedo, I'm with American Universities Program on Information Justice and Intellectual Property, though the comments I've prepared are my own.

Since 2000, I've worked in the non-profit or academic sectors on issues of access to medicines, intellectual property and trade policy. And I appreciate the opportunity to testify before you today. I think it's great that you are starting to open the process up.

I want to go kind of quickly over some stuff that I think has been brought up by previous speakers and then just highlight a few things from the PhRMA submission.

But to open up I'd like to

reemphasize the U.S. is the largest purchaser of antiretroviral medicines in the world funding purchases through PEPFAR and through contributions to international programs like the Global Fund and that even in existing programs that are buying generics cost is definitely an issue.

Most people receiving medicines through these programs get sub-optimal first line antiretroviral therapies because the older drugs came to the market before TRIPS was fully in effect are vastly more affordable.

And in many cases, people in these programs remain on treatment, though inevitably require second like, which are seven times more expensive on average than first line regimens and then third line treatments that are more than that.

PEPFARs fifth annual report to congress notes that the prices of both second line treatments and pediatric treatments

remain, quote, "a significant challenge."

So in short, current and near future treatment needs require that these U.S. funded programs get the best price possible when purchasing, so more and not less generic competition is necessary.

If our trade policy is designed to favor brand name producers over generic producers, this will conflict with the U.S. taxpayers interest to purchase the most treatment possible through PEPFAR and through our funding of international programs like the Global Fund.

Generic producers need flexible intellectual property regimes to continue producing competitively priced treatments. And I urge you to keep this in mind when assessing comments submitted by IP owners urging USTR to use the Special 301 report to push countries towards ever higher levels of IP protection.

And so now to bring up a couple of

points brought up by PhRMA and their comments submitted on February 18th, their written ones. PhRMA asserts that India must take steps to ensure that compulsory licenses issued for export are quote, "granted for humanitarian non-commercial use only," unquote.

As has been brought up currently, most people in developing countries that are on therapy are taking medicines provided by generic suppliers and these suppliers at these businesses supplying low quantities at low marginal profit.

If these companies are -- if they're unable to obtain voluntary or compulsory license for second or third line treatments, prices for these medicines will remain prohibitively high.

Limiting exports of generic drugs from India to those for humanitarian enterprises could prevent the producers from selling to the largest possible markets. They

need to achieve economies of scale if costs are going to fall.

If PEPFAR does not have access to competitively priced generic second line treatments in the near future, it's hard to see how it will continue to provide life saving medicines.

On China, PhRMA criticizes a lot of things, but PhRMA criticizes the government's enforcement of health regulations for active pharmaceutical ingredients noting that chemical manufacturers may sell and ship API products to locations within China and abroad with either no regard for the intended use of the API or choosing not to comply with existing regulations.

The enforcement of Chinese regulation of APIs is outside the scope of the Special 301 report.

It doesn't address the adequacy or effectiveness of intellectual property rights and PhRMA doesn't suggest that these Chinese

health regulations deny fair and equitable market access to United States persons that rely upon intellectual property protection.

So if this complaint is included in the Special 301 report, it will be nothing more than an attempt to intimidate Chinese companies which many developing country producers rely on to produce affordable generics.

I see my time is running short. A note on data protection. Data exclusivity, which is clearly favored by the industry has been brought up, not necessary for TRIPS compliance.

There's no need for all countries to adopt U.S. or EU style data exclusivity. And paragraph 4 clearly states that TRIPS can and should be interpreted and implemented in the manner supportive of all WTO members rights to protect health and to promote access to medicines for all.

So it should therefore be

acknowledged in the 2010 Special 301 report that TRIPS does not require data exclusivity, but that it requires countries to protect against unfair commercial use as interpreted by each WTO member.

And so I'd like to thank you for this opportunity to testify. And just as a very quick last point, I'd ask you to reconsider the wisdom of using the Special 301 report to advance TRIPS plus policies that will lead to higher medicine prices, which would conflict with the Obama Administration stated policy to support the rights of sovereign nations to access quality assured medicines.

It would contradict the statement that -- or the President's trade policy that they just released that Ambassador Kirk is presenting to The Hill today that supports the Doha declaration.

It makes no sense since we're buying the medicines and it contrasts

awkwardly with the TRIPS article 1 which states that WTO members shall not be obliged to adopt TRIPS plus intellectual property provisions. Thank you.

MR. McCOY: Thanks very much. Let me give the floor to my colleague from Customs and Border Protection for a question. Go ahead, please.

MR. WRIGHT: Thank you for coming here to tell us about your issues. My question would be I think one that my colleague from the Department of Commerce had inquired about.

And it's a little bit off the subject, I think, of your testimony, but perhaps you could give us some information about what your familiarity, your organizations familiarity with counterfeit medicines and other products that might threaten health and consumer safety and what the Special 301 process or how that should be used in connection with dealing with

counterfeit medicines.

MR. PALMEDO: Okay. I think the real counterfeit substandard drugs -- I think the real problem is substandard drugs, as other people have said before, and that it's a health problem that's best dealt with health officials.

The 301 report obviously, you know, focuses on intellectual property so you have trademark issues. But we definitely respect the fact that people that sell dangerous products need to be stopped.

I think the counterfeiting solution as it's currently being pushed by the U.S. Government through various agencies is meaning resistance because it's being wrapped up in a larger effort to enforcing -- to up the enforcement of intellectual property that worries people.

Because it includes things like ACTA, which so many people have been asking for the text and it's still not available.

It includes recent African legislation that's highly, highly restrictive that has wildly opened definitions of what a counterfeit that's much broader than the U.S. definition, much broader than the WTOs definition, much broader than the WHOs definition.

And it basically boils down to anything not approved by the IP owner. It's wrapped up with this -- the enforcement drive that's led to a number of seizures in Europe of drugs that were in transit and, you know, one was a shipment of drugs from England through Europe to Nigeria purchased by the Clinton Administration that seized.

One was going from India to Brazil and it's a case where there is no intellectual property being violates, but it was just -- it was the fact that someone could pick the phone and call a border's agent who then seized a legitimate shipment of drugs.

And that's the sort of thing

that's being pushed for through ACTA, through other parts of this broader anti-counterfeiting push. And I think that if we have open --

MR. McCOY: Could I ask you a follow up specifically on that relating something you said earlier that I understood you to say that the unregulated production of active pharmaceutical ingredient in China should not be a concern of this subcommittee.

Is that not at all relevant to the problem of either counterfeit medicines or substandard medicines or both?

MR. PALMEDO: It's not relevant to the enforcement of intellectual property. It's outside the scope of the 301, it does not -- what I specifically referred to, which is on page 39 of PhRMA written testimony, has to deal with the enforcement of health regulations within China of the input going into a product.

It doesn't have to deal with

approval of a finished drug. It's, more narrowly, it's just not part of enforcement of intellectual property standards as through the 301 report.

As far as fighting counterfeits generally, I do think that there should be an open conversation between health people and government officials in the north and government officials in the south.

That instead of looking for a way to punish people who might be violating patents or trademarks, that really gets to the issue of the health side.

Like for instance, I believe the best data on the health -- posed is held by the pharmaceutical companies, but it's not shared widely, which would be very helpful in honest efforts to combat substandard drugs.

MR. McCOY: Thanks very much for coming and talking with us today, we really appreciate it.

MR. PALMEDO: All right. Thank

you.

MR. McCOY: All right. Next on our program today is Peter Maybarduk from Public Citizen. Peter, I probably mispronounced your name too, I apologize.

MR. MAYBARDUK: I think you actually got it right.

MR. McCOY: All right.

MR. MAYBARDUK: Testing, testing.

MR. McCOY: The floor is yours.

MR. McCOY: Okay. Excellent. Thank you very much for this opportunity to come in today and comment.

And at the conclusion of my remarks, I wish to signal that I'd be quite happy to discuss the issue of fake and substandard medicines in appropriate frameworks, to deal with that today or in any later time at your offices as you please.

I'm here today with Public Citizen, I'm Public Citizen's Access to Medicines Coordinator. I provide technical

assistance to government's and NGOs around the world on issues related to access to medicines and intellectual property.

Public Citizen is a consumer advocacy organization with 150,000 members and supporters founded in 1971 working largely on health and safety issues among others.

You'll note in your folders, I have folders that I've distributed to the panel and there are folders in the back for anyone that's interested. There should be enough for anyone who cares to see them.

So, Public Citizen believes with our colleagues here today that USTR Special 301 report should reflect U.S. commitment under the Doha declaration to promote access to medicines for all.

And in particular I wish to address Ecuador and its TRIPS compliant compulsory licensing protocol. I've been providing technical assistant to Ecuador for some time and there's some interest in the

issue at USTR and other agencies.

We wish to emphasize that USTR should not cite Ecuador for any matter related to that country's protocol on the compulsory licensing of pharmaceutical patents in the public interest.

USTR should also not sanction Ecuador's protocol indirectly, for example, through in precise references to alleged IPR protection failings in Ecuador or through otherwise unwanted elevation in Ecuador's watch list status.

We skip ahead a page in the comments. On October 23rd, Ecuador's President Rafael Correa issued decree 118 declaring access to priority medicines effecting the health Ecuadorian population to be a matter of public interest.

Although not required by TRIPS, the decree satisfies an Indian community proviso enabling Ecuador's patent office in cooperation with the Ministry of Health to

receive compulsory license request and issue licenses case-by-case on public interest grounds.

Ecuador has yet to issue a compulsory license, but Ecuador's patent office, IEPI, has published formal guidance to license applicants, their Instructivo.

Both these documents, decree 188 and the Instructivo are in your folders on the right-hand side, along with an unofficial English translation of the decree.

IEPI has met at least twice with the American embassy in Quito as well as the patent-based pharmaceutical companies Trade association in Ecuador, IFI, which issued a public statement, quote, "democratically accepting," unquote, decree 118.

I can run through a brief analysis. The punchline for us is that there's no substantive basis for citing Ecuador's policy on compulsory licensing in the 301 report because the protocol envisioned

is entirely TRIPS compliant.

And indeed the decree borrows heavily from the TRIPS agreement in some cases regarding non-exclusivity, supplying the domestic market, adequate compensation of patent holders, license review determination, word-for-word from the TRIPS agreement.

And so we believe that citing Ecuador's compulsory licensings policy would represent an inappropriate effort by the United States to influence another WTO member's use of rights preserved by the TRIPS agreement with potentially serious consequences for public health.

I don't want to spend much time on the specifics, but we have analyzed them and I'm happy to talk about them on the side. Decree 118 establishes a public interest in medicines used to treat, quote, "public health priority illness," unquote.

That determination is to be certified by the Ministry of Public Health,

interagency agreement is the norm. They require that licensed applicants -- license requests be evaluated according to supporting circumstances of each case.

Decree 118 requires payment of royalties, borrowing again a language from the TRIPS agreement and licensing applicants are required to certify these in other universally applicable license terms.

Both documents reiterate that all licenses must comply with all applicable legislation. IEPI has published guides and explanatory materials online going to the point of transparency.

They've held multiple meetings for the press and public and they've indicated they remain open to meetings with the American embassy in Quito.

I've met with the American embassy in Quito as well and with IfI. If under the policy, if and when a compulsory license is issued, patent holder would have recourse to

seek review of the terms and grant of the license both through IEPI and through independent judicial process.

Patent holders, of course, American companies remain free to compete with any products introduced under compulsory license.

So the policy is in compliance with TRIPS and neither denies -- it does not deny adequate and effective protection of IPR or fair and marketable -- fair and equitable market access so it does not mention -- merit mention in the 301 report.

I'm available now and in the future for questions. I'm happy to come down and speak to USTR or other agencies at any time on this point and also interested to discuss the matter of fake and substandard medicines.

MR. McCOY: Thanks Peter. And let me just say thanks for speaking to a country specific issue on IP protection and

enforcement.

I think that's particularly relevant to the work that we're asked by Congress to do in this review. So I appreciate your attention to helping us fulfill our mandate in that respect.

Let me give the floor then back to DHS to ask the question that you've invited.

MR. WRIGHT: Thank you Stan. Thank you very much for your testimony again, we appreciate you coming down and talking to us.

I'm going to ask the counterfeit medicines questions. What -- how should we be using the Special 301 process to deal with counterfeit medicines and maybe you could talk about your organization's experience with counterfeit medicines in the various countries where you're active. Thank you.

MR. MAYBARDUK: Sure. Well, I mean it's not entirely clear to me, though I'm open to being told why I'm wrong. But, you

know, Special 301 is an appropriate -- is the appropriate venue for getting at issues of substandards, which we all agree are quite important, including fake medicines.

Counterfeit, of course, is problematic because there are two definitions and widespread technical use. One is the WTO definition relating to trademark violations, the other is the WHO definition relating to misrepresentation of active ingredients.

And while there can be some overlap, they're actually separate standards. And it's very important to apply the correct framework.

Now there is a place for Special 301 of course if you have a clear case, if you have, you know, evidence-based reasons to suspect that there's, you know, widespread misappropriation of a mark going down in pharmaceuticals somewhere in the world, that's appropriate.

But, you know, that's both under

and over inclusive as regards to the issue of medicines quality and fake medicines. You can have a case where, you know, someone is producing medicine that doesn't have an active ingredient, but doesn't misappropriate a mark.

You can have a case where someone does arguable misappropriate a mark, but is producing a quality medicine. But then you have questions of, you know, misappropriation of a mark.

You know, our customs agents and others necessarily set up to make the appropriate legal analysis.

So, you know, our perspective is basically that we have to adequately separate out the issues and we're talking with a lot of different international organizations right now for how we can best do that.

Our priority is on consumer protection, public health and safety. And the appropriate framework for that is a consumer protection and public health and safety

framework.

It's not clear why an IPR framework is needed at all to deal with that issue. The problem is when we start importing the IPR framework, then we get into all kinds of problems and we start importing anti-competitive effects.

Because a lot of the agreements, a lot of the standards that have been put in place in different organizations around the world, don't have adequate anti-abuse provisions.

They don't necessarily provide adequately for a generic firms right, you know, to due process and different cases, you know, whatsoever.

And they can, you know, impose chilling effects, financial chilling effects on the generics industry as well. So these are all quite concerning.

And one thing that we're interested in doing, and I'd be happy come

down to any of your offices and speak about it in person, is establishing a set of best practices for dealing with drug quality at large, you know, of which fake medicines are essentially a subset and with, you know, and specifically with fake medicines as well.

And, you know, a number of these practices are already in place, we can do more to sort of give them more power in different levels. But there are some different things we can do.

We can improve statutory disclose requirements for pharmaceutical firms. Pharmaceutical firms actually have the best information on the prevalence of fake medicines in the market, but they don't always share what they know.

Pharmaceutical security institute records more instances of so-called counterfeiting than does the FDA and they're not mandated to disclose that information anyway.

So we can work on that. We can work on strengthen regulatory agencies, which should be developing better empirical data on the problem of fake and substandard medicines because most of it is extrapolated from anecdotes at this point.

And we don't really understand the scope of the problem and how large a problem is compared to, again, the broader problem with drug quality, which would include licensed medicines that are not -- don't have appropriate quality oversight as well.

So these issues are very important to us. I was speaking earlier today with the Chirac Foundation about their initiative that they have in Francophone Africa on this issue.

I was speaking with a representative, US Pharmacopeia last week, which has a joint venture with USAID on medicines quality in malaria medicines in particular and so on.

So we want to work together to set

up an appropriate quality framework, but the bottom line for us is that if we don't want to compromise access to medicines, then we can't be imposing an IPR framework over it because the cost is too great.

MR. McCOY: Do you have any thoughts on the issue we discussed with some of the speakers earlier about distinguishing between high, middle and low income countries in the Special 301 review and whether and on what issues its appropriate to make such distinctions?

MR. MAYBARDUK: I was not present for that conversation, so I don't think I can comment extensively.

MR. McCOY: Let me try to rehash that. I didn't realize you weren't here, let me try to rehash the question a little more -- in a little more detail.

Several submissions that we received talked about the treatment of low and middle income countries in the report and how

they should be treated in particular.

And earlier in the day that had prompted the question of whether it was appropriate for this process to proceed with different expectations of trading partners based on their having low, middle or high income levels and on what issues it would be appropriate to draw those distinctions.

I'm curious if you have any reactions to that.

MR. MAYBARDUK: Well, you know, I can imagine it makes a difference, of course, in the amount of resources a country has to muster to the different areas that are of concern to USTR.

But I can't say that I necessarily have a clear position on that at the moment, with the exception of, you know, TRIPS plus provisions, we believe are not -- don't have a place at all in Special 301.

I mean the TRIPS standard can be applied because all countries are to be -- all

countries that are signatories to the WTO anyway, are to be held to it. But if it's TRIPS plus, I don't know why we would distinguish between low and middle income.

MR. McCOY: Well thanks very much for your comments today. We appreciate it and let me just say with respect to your folder, if this is not already contained in your submission and you want it to be part of the public record, you should submit it on regulations.gov as part of the post hearing statement.

MR. MAYBARDUK: Okay. I think -- well the primary function there is there are a couple of -- they're supplementary documents, the source documents, for those of you who are interested in the Ecuador policy are there.

So I don't know if it's necessary for the submission. But our contact information is there, my contact information is there as well if anyone from the panel has

any follow up questions, I'd be most happy to answer them. Thanks for your time.

MR. McCOY: Okay. Thank you very much. Now my understanding is that we have Mr. Glover next on the schedule, my understanding is that again falls in the category of folks who we have been encouraged in the future to provide telephonic links for this.

Unless there's anyone here who wants to tell me they've been authorized to speak on behalf of Mr. Grover.

Let's move right on then to the Social Science Research Council, Joe Karaganis. So the floor is yours.

MR. KARAGANIS: Thank you. And thank you for the opportunity to testify. I'm a Program Director at the Social Science Research Council in New York. SSRC is an 85-year old non-profit research organization.

In this capacity, I'm also the director of a three-year study of software,

film and music piracy in developing countries. The project involves some 25 researchers and detailed reports on Russia, India, Brazil, Mexico, Bolivia and South Africa, many of the countries that are centrally -- central roles in the Special 301 reports.

In this brief testimony I plan to simply reiterate my statements about evidentiary standards around Special 301, which have been of considerable importance to us as we examine the connections between piracy, piracy research and policy making processes.

I'll do it very briefly, but also been given the final slot, I wanted to say a few words about why these evidentiary standards matter and what falls out of the conversation because of the way evidentiary standards are currently organized.

It often seems to us that Special 301 process sort of misses the forest through the trees in some important ways that effect

the quality of the policies that derive from Special 301.

Because our work is on copyright, the most relevant research is almost always the work of the IIPA, the IIPA annual submissions. So most of our commentary has sort of been in reference to the IIPA reports, which for obvious reasons can dominate the debate about copyright policies in the targeted countries.

And I'll also just make it clear that I'm restricting my remarks to the sort of set of countries that we've studied and one of the things we found is that subject to piracies of such complexity that you can almost always identify exceptions.

And I do want to be careful about that because I think that degree of care is one of the things that drops out of the piracy conversation all too often.

To begin with, I love the IIPA reports. They are invaluable windows onto the

organization of piracy and enforcement in the targeted countries.

They are the richest source of longitudinal data available to research, but they are not full assessments of the problems of piracy or the challenges of enforcement by a long shot.

And they've never met, in my view, a reasonable interpretation of the standards that USTR itself requires for research submissions.

And just to repeat those, one is to provide all necessary information for assessing the effects of the acts, policies and practices that are involved.

And two, that any comments that include quantitative loss claims should be accompanied by the methodology used in calculating such estimated losses.

To rephrase that, there are two issues at stake. One is indicating that the assessment, that the research submitted is

comprehensive and thorough.

And the second is the principle of showing your work of showing how the work was conducted, of its transparency and of its reproducibility.

And transparency and reproducibility have emerged as the gold standard for government evidentiary standards increasingly, especially in the wake of the 2000 Data Quality act, the 2005 OMB interpretation of that act and then various agency interpretations of the OMB guidelines.

In my comment, I've detailed many of the things that we simply don't know about the research methods of the member groups that submit through the IIPA. I'd be happy to discuss those at more -- in more detail.

But let me say a few words about why I don't feel that they present a comprehensive picture of the larger phenomenon that's the subject of the Special 301 process.

Perhaps most strikingly in our

work, having looked in detail at now six countries, we have not seen any evidence that enforcement has affected much less diminished the availability of pirated media.

The reasons for this should be obvious to all of you, technologies of reproduction and distribution have plummeted to an extent that makes the role of industrial scale intermediaries, like big optical disk factories, increasingly irrelevant to this production and circulation of pirated media.

The best measure of this expansion of supply is simply the diminishing price of pirated media. Between 2000 and 2010, roughly the period in which we've been looking, from ballpark $5 for a high quality DVD to well under $1 and sometimes under $0.50.

So there are two -- well one major exception and two minor exceptions to this statement about enforcement.

There are a couple of areas where we have noted a demonstrable impact of

enforcement efforts and these are worth separating out from what we see as a larger failure of the enforcement agenda.

Software clearly has an effective enforcement strategy that is part of a larger approach to how you work in emerging markets.

Because the large software companies maintain uniform international pricing they're largely uninterested in serving wider markets in those countries, they rely on pirate circulation to acquire market share in those countries.

And then they begin to work with the large institutions in those countries to legalize them and to bring them into the fold. That's the only viable strategy for major software companies in developing markets, and the software companies are following it to a T.

That, in our view, is not -- that's an effective enforcement mechanism. Am I out of time? Shall I --

MR. McCOY: Can I ask you to pause there so we can start the question time. And I think you'll be able to continue a lot of these themes in that. Let me give the floor to Susan Wilson from the Department of Commerce.

MS. WILSON: Thank you very much. Your presentation is very interesting and I do hope you get to continue with what you were saying and feel free to work that into the answer to what I'm about to ask.

You were in the process of explaining what's wrong or what's not working effectively with the information, the gathering and presentation of the information that we do get.

As you know, this process is all about bringing to light the problems that are faced by the right owners in foreign countries. I think all of us know that this is an -- that there are things we can do better and we would very much like to hear

what you think we could do better.

So if as part of your answer you want to say a little bit more about what you think we could -- we're not doing right and then go into what you think we could do better, we'd very much like to hear that.

MR. KARAGANIS: Absolutely.

MS. WILSON: So basically, continue with what you think we're doing wrong and then tell us how you think we could best gather and analyze the information that's out there.

MR. KARAGANIS: I mean virtually of this industry research is produced for the USTR and if the industry does not provide an adequate description of its research methods or of the key assumptions that inform the research that would allow you to evaluate it, then the USTR could simply require that it meet higher evidentiary standards regarding how it describes its -- the component research that goes into the IPR reports.

That would be a very simple solution and it would go a long way toward addressing concerns about the credibility of industry research. Many of those arguments, I'm sure, are familiar to you.

There's really even no occasion for having that debate in the context of the Special 301 process, which is really the destination for this research. It was all -- this massive industry research effort was geared up for the Special 301 process.

And as long as Special 301 was a relatively close circuit between the USTR and industry, being a stickler on evidentiary process didn't really matter.

But I think as we've seen this year and increasingly as trade policy and IP policy begin to impinge on other areas of health policy, of, you know, basic economic policy.

That kind of closed circuit is no longer going to be an option. There are many

more stakeholders in the conversation and the small steps toward opening this in the last few years of the USTR, which we welcome, we think really are only the first steps necessarily.

And that the only way to conduct legitimate policy making in this are will be to further expand the conversation.

MR. McCOY: If you'd like to use the remainder of the time just to expand on the points you were already making, please go ahead.

MR. KARAGANIS: Oh, well sure. There's much more where this came from, I can assure you.

So software is really a case of -- I'm not sure why Microsoft would want anything else than 95 percent penetration of the Chinese market, for example. Why it would trade that for slightly greater enforcement of its licenses is beyond me.

And in fact, Bill Gates and

several Microsoft executives have said as much. That's a very viable, and like I said, I think the only viable strategy for them.

The other areas where we found relatively measurable effective enforcement are around efforts to suppress the retail optical disc trade so that, you know, with a sufficient police presence you can drive obviously pirated optical discs out of established retailers.

What that does is it deformalizes the market further and it's not clear to us that it has any long term impact on the supply, but it means that distribution is conducted through much more transient forms of street vending, which you can see in all the countries we've studied.

And then the third fairly minor example, we've seen evidence of success on the part of movie studios who have enlisted the police in, you know, major suppressive actions in the context of major release windows --

release windows for major films where they can, you know, put all the police at work making sure that there are no pirated copies of a particular film on the street within a period of a week or two around the release of a major film.

And, you know, in that respect sort of ensure the most profitable portion of the release window for that move.

But beyond that, we're very hard pressed to see any meaningful impact of any -- of these large scale investments in enforcement.

MR. McCOY: Is there anything you found had a meaningful impact in the area of internet piracy?

MR. KARAGANIS: No. And part of that is because the internet is not the only means of distributing digital media at this point. In fact, P2P piracy in particular is a diminishing channel for distribution.

Increasingly, media collections of

thousands of films or songs can be handed on a thumb drive or on a portable hard drive.

The channels for digital distribution are proliferating in ways that just are not controllable, even with some of the more, sort of aggressive proposed measures like three strikes that apply to the ISP level. So we think that cat is long out of the bag in our view.

MR. McCOY: This is a stupendously hopeful note on which conclude our discussion here about the effectiveness and adequacy of intellectual property protection and enforcement around the world.

Thank you very much for what was really a very interesting presentation. I think we appreciated it and it will be -- we'll look forward to studying your work and your written submissions in more detail.

So thanks very much for all of that. And by way of closing remarks, I really have very little to add today except to say

that, you know, we have been today in the immortal world -- in the immortal words of Don Henley, programmed to receive and we are grateful for all the information that you've provided.

It's been very helpful, I think. I think this process of doing the public hearing, even though the time for each individual speaker was short, has allowed for what we had hoped it would allow for, which is pointing out and highlighting particular issues that should be commended to the attention of the committee.

So I thank you for listening to Ambassador Sapiro's charge from the beginning of the day and helping us to do that. We greatly appreciate all the views that have been expressed and will look forward to considering all of this as part of this year's Special 301 process.

So thank you every one for your participation. I also wanted to -- I also

want to mention that at the -- as a housekeeping matter, I believe our plan is to post the audio of this file on the USTR website so that there will be not a video, but an audio account of what's been said here, except for that part when my microphone wasn't working.

But what I'm saying here isn't important. So that should be available on the USTR website. I don't know how soon that will be possible. But any other housekeeping matters, Paula?

CHAIR PINHA: No. Just to remind people about the period for submitting post hearing comments will be open.

I'll open the docket later on today and it will be open for a whole week. So until the 16th, if I'm not mistaken.

MR. McCOY: So we're adjourned. Thank you.

(Whereupon, the hearing was adjourned at 3:55 p.m.)

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