

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

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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.

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

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

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

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

22                  Earlier this week, the President

1 delivered his 2010 trade policy agenda to the  
2 Congress.

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 my colleagues on the panel to pose questions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 As a clear commitment to  
22 protection of IPR national and

1 internationally, since October 23, '07, Mexico  
2 was part of these multilateral engagements  
3 with several countries with a negotiation of  
4 ACTA.

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

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

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

19 The government of Mexico is also  
20 committed to transparency and therefore in  
21 2010, the Minister of Economy the Mexican  
22 Institute of Intellectual Property and the



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

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

9                   On the 15 in Guadalajara, and the  
10 19 in Vera Cruz, both of October `09, Mexico  
11 hosted two sub-regional conferences on IP and  
12 Competitiveness of Small and Medium  
13 Enterprises in the Agro-Foods Sector in Latin  
14 America, respectively. Regarding  
15 international corporation of the specialized  
16 agencies protecting your rights, we would like  
17 to share with you that Mexico incorporation  
18 with INTERPOL hosted the fifth congress in  
19 counterfeiting and piracy in Cancun during  
20 December 1st to the 3rd 2009.

21                   More than 800 delegates  
22 representing more than 80 countries met to

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

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

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

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

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

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

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

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

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

1 important among the agencies in Mexico.

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

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

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

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

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

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

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

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

16 MS. PETTIS: Good morning. Could  
17 you explain in your view how intellectual  
18 property protection and enforcement has  
19 changed in Mexico since the release of the  
20 2009 Special 301 report?

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

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

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

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

13 Nevertheless, we have deployed, in  
14 '09 for example, one camcording campaign,  
15 which basically means it was the first time  
16 ever we did it.

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

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

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

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

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

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

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

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

1 which is a huge development for Mexico as  
2 well.

3 MR. McCOY: Thank you.

4 MR. BEHAR: Thank you very much.

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

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

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

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



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

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

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

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

22 In addition to these legislation,

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

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

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

22 Also it's important to mention

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

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

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

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

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

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

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

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

1 body between both government agencies and with  
2 the private sector.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 of operating a specialized office.

2 MR. McCOY: Thank you very much.

3 Could I also ask you, we received a couple of  
4 submissions indicating concern that the  
5 Attorney General's office had instructed  
6 enforcement officials to refrain from  
7 intellectual property raids. Is that  
8 something that you could clarify for us?

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

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

22 And I believe this is why there is



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

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

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

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

1 have available.

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

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

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

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

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

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

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

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

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

1 MS. VASQUEZ: Sure it is, yes.

2 MS. WILSON: Okay.

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

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

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

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

1 Embassy to come to the table.

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

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

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

21 Given that, Thailand should be  
22 removed from the Special 301 priority watch

1 list for the following reasons. First, there  
2 has been an unyielding political will to  
3 elevate intellectual property protection as a  
4 national agenda.

5 The National Committee on IP  
6 Policy was established and chaired by the  
7 Prime Minister himself, we also create the  
8 National IP Strategy and proactive plan on  
9 prevention and suppression of IPR violations.

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

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

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

1 enforcement and amendment to copyright optical  
2 disk law.

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

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

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

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

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

4 Sixth, due to proactive action to  
5 combat piracy, there's been a decline in the  
6 case of software piracy from 80 percent in  
7 2006 to 76 percent in 2008 as reported by this  
8 software alliance.

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

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

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

22 Ninth, the government actively is



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

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

13 Ten, the government realize that -  
14 - the government realize importance of  
15 expedited patent examination and allocated  
16 significant budget of \$7,000 to upgrade the  
17 patent system to increase the number of patent  
18 examiners.

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

1 which has been in effect since December 2009.

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

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

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

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

1 matter.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 MS. AMBUNARIS: Thank you.

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

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

1 forward.

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

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

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

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

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

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

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

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

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



1 DR. KOMOLSIRI: Thank you.

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

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

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

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

14 MS. FEISEE: That's okay.

15 MR. McCOY: I apologize.

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

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

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

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

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

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

22 The ability of the biotechnology

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

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

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

17 Biotechnology companies are also  
18 leading the way in creating alternative fuels  
19 from renewable sources without compromising  
20 the environment. The U.S. biotechnology  
21 industry currently employs or supports 7.5  
22 million jobs in the U.S. alone.

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

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

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

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

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

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

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

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

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

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

1 and converted into valuable products and  
2 services for people.

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

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

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

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

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

3 MS. FEISEE: Sure. Yes.

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

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

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

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

22 Some countries don't even allow

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

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

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

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

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

22 So those types -- those two



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

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

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

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

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

22                    When they go to these countries

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

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

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

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

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

1 on that statement?

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

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

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

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

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

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

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

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

1 at the outset.

2 MS. FEISEE: That's okay.

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

6 MS. FEISEE: Great. Thank you  
7 very much.

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

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

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

22 I want to emphasize one key point

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

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

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

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

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

1 is much more that needs to be done.

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

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

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

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

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

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

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

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



1 manufacturers.

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

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

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

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

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

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

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

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

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

20 AMBASSADOR DONNELLY: Okay.

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

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

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

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

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

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

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

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

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

22                  MR. McCOY: Let me give the floor

1 to my colleague from the Department of  
2 Commerce.

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

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

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

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

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

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

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

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

22 I honestly believe personally that

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

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

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

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

1 who would like to participate with you.

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

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

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

20 AMBASSADOR DONNELLY: Good.  
21 Thanks Mr. Chairman.

22 MR. McCOY: Could I invite Rashmi



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

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

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

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

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

1 or a priority watch list.

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

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

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

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

1 to bring their products into a system market.

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

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

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

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

1 convention and TRIPS.

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

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

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

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

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

1 a possible ACTA in future.

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

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

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

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

1 limitations and exceptions or increase  
2 penalties.

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

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

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

18 Second, provide a clear written  
19 explanation stating the basis for  
20 identification of a country in the Special 301  
21 report and placement on watch list or priority  
22 watch list offer an out of cycle review.

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

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

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

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

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

22                  But I'd like to know if you have

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

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

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

19 MS. WILSON: Thank you.

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



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

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

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

22 MR. McCOY: Yes. You indicated

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

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

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

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

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

1       them is also useful.

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

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

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

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

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

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

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

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

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

22 MR. SMITH: Thank you Madame

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

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

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

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

1 world.

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

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

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

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

22 Today, as a result of your efforts

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

6 These improvements over the last  
7 25 years have made our copyright-based  
8 industries among the most productive and  
9 fastest growing sectors of our economy. They  
10 have also resulted in significant growth of  
11 the creative sectors among our trading  
12 partners.

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

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

22 Exports and foreign sales of the

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

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

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

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

21 In its 2010 submission, IAPA has  
22 highlighted progress and remaining



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

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

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

1 and circumvention devices.

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

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

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

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

1 any copyrighted content.

2 Enact and enforce laws against  
3 camcording motion pictures --

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

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

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

20 We follow, our association members  
21 and IIPA follow -- have followed for the last  
22 25 years in almost all of these countries the

1 development of IP legal reform and  
2 enforcement.

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

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

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

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

22 In IIPAs view, which market do you

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

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

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

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

1 economy.

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

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

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

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

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

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

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

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

1 many countries.

2 China is one of them, there are  
3 750 million mobile device users in China.  
4 Broadband has been introduced, as of January,  
5 3G. That, unless something is done soon to  
6 establish the legal enforcement infrastructure  
7 in a country like China.

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

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



1 MR. SMITH: Thank you, Stan.

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

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

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

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

22 People in developing countries are

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

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

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

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

22 The sustainability and

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

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

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

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

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

1 over \$10,000 to under \$80 today.

2 MSF could not provide treatment to  
3 140,000 people in more than 30 countries  
4 without generic competition. The U.S.  
5 Government acknowledges the significance of  
6 generic competition in its own global AIDS  
7 contributions.

8 PEPFAR has reported savings up to  
9 90 percent through the purchase of Indian  
10 generic medicines.

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

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

22 A recent study found that the

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

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

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

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

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

1 through generic competition.

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

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

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

1 to issue compulsory licenses.

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

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

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

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

22 Just because Australia grants a

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

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

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

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

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

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



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

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

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

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

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

20 MS. MACLEAN: Last paragraph.

21 MR. McCOY: Go ahead.

22 MS. MACLEAN: The Special 301

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

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

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

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

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

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

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

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

1 with regard to intellectual property.

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

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

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

22 MR. McCOY: Could I give the floor

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

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

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

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

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

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

6 MS. PETTIS: Thank you very much.

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

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

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

1 by the Clinton Foundation.

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

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

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

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

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

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

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

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

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

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



1 Manufacturers of America to come forward.

2 Thank you. Brian, the floor is yours.

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

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

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

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

1 lives.

2 Our membership ranges from small  
3 research firms to large corporations that  
4 employ tens of thousands of Americans and  
5 encompass both research-based pharmaceutical  
6 and biotechnology companies.

7 Our sector is one of the most  
8 knowledge-intensive in the U.S. economy  
9 responsible for 80 percent world's global  
10 health care biotechnology research and  
11 development, totaling more than \$65 billion in  
12 2008, of that roughly 70 percent was invested  
13 right here in the United States.

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

18 In 2006, our industry supported  
19 more than 3 million U.S. jobs and contributed  
20 88.5 billion to gross domestic product, more  
21 than triple the average contributions of other  
22 sectors.

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

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

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

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

21                   Without the enforcement of  
22 intellectual property laws around the globe,

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

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

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

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

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

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

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

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

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

1 neglected topical diseases.

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

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

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

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

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

1 Thank you very much for your time.

2 I'm happy to answer any questions.

3 MR. McCOY: Thank you very much.

4 Let me give the floor to my colleague from the

5 U.S. Patent and Trademark Office, Susan?

6 Sorry, Minna.

7 MS. MOEZIE: Thank you for your

8 comments. With respect to Thailand and

9 several other countries, your submission

10 mentioned industry efforts to engage

11 constructively with foreign governments.

12 Could you please elaborate on why you consider

13 this important?

14 MR. TOOHEY: Well, we think a

15 constructive engagement on the part of our

16 industry -- we consider ourselves part of the

17 health infrastructure in the country and it's

18 critical that we have an open engagement to be

19 part of that infrastructure, have the ability

20 to both have access to foreign government

21 officials to have our fair field in no favor,

22 but also to have a continuing dialog.

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

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

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

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

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

22                 In many countries around the world



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

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

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

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

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

3 MS. AMBUNARIS: Mr. Chairman,  
4 thank you for this opportunity. Thank you for  
5 your testimony Mr. Toohy.

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

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

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

1 the Special 301 report?

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

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

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

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

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

1 medicines are counterfeit or substandard.

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

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

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

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

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

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

14                   But thanks very much for your  
15 participation today.

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

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

22                   MR. MELLIS: Chairman McCoy,

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

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

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

13 On television our game telecasts  
14 are distributed nationally through DirectTV,  
15 ESPN, Fox in Demand, the MLB Network, TBS and  
16 Verizon, locally through broadcast television  
17 stations and regional sports networks and  
18 internationally to over 200 counties and  
19 territories and the U.S. Armed Forces  
20 overseas.

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

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

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

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

20 This can be accomplished through  
21 the use of this \$70 device and some software.  
22 The threat this poses to the U.S. televised

1 media sector must be taken seriously.

2           Although there is much that  
3 remains unknown about this problem,  
4 particularly with respect to its offshore  
5 aspects, it is clear that on an annual bases,  
6 tens of thousands of hours of live television  
7 programming from networks around the world are  
8 being pirated.

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

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

18           Approximately 75 percent of the  
19 pirated retransmissions of our games --  
20 telecast, excuse me, have occurred through  
21 offshore sites and services and approximately  
22 50 percent of the total through Chinese sites



1 and services.

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

8 This is because the piracy is a  
9 global phenomenon often involving sites and  
10 services that operate entirely offshore and  
11 outside the effective reach of our courts. We  
12 therefore believe that international  
13 cooperation must be improved.

14 Most nations are both exporters  
15 and importers of television programming so we  
16 see common ground both in terms of shared  
17 economic interests and legal obligations for  
18 the United States and its trading partners to  
19 work cooperatively to curtail this problem.

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

1 dialog we had with USTR about this matter.

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

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

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

15 The House Judiciary Committee  
16 hearing record and the OECD case study are  
17 significant new sources of information about  
18 the problem from which USTR and the Special  
19 301 committee can draw.

20 We have provided relevant  
21 documents in our submissions to you. As we  
22 develop more experience in this area, we look

1 forward to the opportunity to make additional  
2 recommendations to you.

3 Once again, thank you very much  
4 for your interest in this matter and for the  
5 privilege of addressing you this morning.

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

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

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

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

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

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

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

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

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

1 significant expenditure being applied across  
2 the board.

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

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

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

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

22 Do you have or does any of the

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

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

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

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

1 much more in a proactive way toward this  
2 problem.

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

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

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

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

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

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

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

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

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

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



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

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

12 MR. MELLIS: Thank you.

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

16 MR. MALPANI: You got the  
17 pronunciation right.

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

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

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

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

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

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

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

1 affordable medicines.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1       these priorities must be set independently by  
2       public health officials.

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

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

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

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

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

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

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

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

22                   By narrowing the scope of



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

7 If India were -- I'm almost done.

8 MR. McCOY: Okay.

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

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

22 MR. McCOY: Thanks very much.

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

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

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

22                   When you look at a country like

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

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

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

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

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

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

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

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

22 MR. MALPANI: I think to add on to

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

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

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

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

22 And in order to deal with

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

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

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

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

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

4 How do you feel that the Special  
5 301 review process can balance incentives for  
6 development of new medicines with the need of  
7 countries to be able to provide that  
8 affordable health care?

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

1 something that should put a country in the 301  
2 list.

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

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

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

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

1 in some country.

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

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

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

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

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

1 so unpack those things.

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

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

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

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

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

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

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

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

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

1 from that.

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

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

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

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

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

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

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

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

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



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

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

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

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

21 MR. McCOY: Thank you very much.

22 Let me give the floor to my colleague from the

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

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

6 I wonder could you comment on the  
7 relevance of the obligation in TRIPS article  
8 39 to protect tested against unfair commercial  
9 use as well as other international obligations  
10 that you view as relevant.

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

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

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

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

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

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

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

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

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

22           MR. McCOY: Thank you James. Let

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

3 CHAIR PINHA: Thank you Stan.

4 Mr. Love, thank you for your testimony. As  
5 Ambassador Sapiro said earlier, we are here to  
6 seek to fulfill our mandate from Congress to  
7 identify countries that deny adequate and  
8 effective intellectual property protection or  
9 deny fair and equitable market access to U.S.  
10 persons who rely on that protection.

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

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

22 I don't think anyone has been as

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

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

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

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

1 well.

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

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

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

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

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

3                   MR. LOVE: Thank you very much.

4                   MR. McCOY: Thank you.

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

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

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

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

22                   CCIA has been a long supporter of



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

4 That being said, just as adequate  
5 protection of rights is important to certain  
6 creative industries, clear and enforceable  
7 substantive limitations on rights are a  
8 necessary to information and technology  
9 companies that depend on those limitations to  
10 the copyright laws to export information,  
11 goods and services and create jobs here at  
12 home.

13 A study commissioned by CCIA in  
14 2007 following a WIPO methodology found that  
15 industries which rely on one form or another  
16 on limitations to copyright contribute to \$.2  
17 trillion in value-added to the U.S. economy,  
18 employ 17 million Americans and so on.

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

1 benefits as using Special 301 to improve  
2 enforcement overseas.

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

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

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

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

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

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

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

1 trade act.

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

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

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

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

1       opposed to actual enforcement.

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

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

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

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

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

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

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

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

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

22                  Do you have any specific examples

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

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

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

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

22 And a violation of that long

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

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

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

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

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



1           That's not what we do here in the  
2 U.S. We do notice and takedown under section  
3 512, which was part of the Digital Millennium  
4 Copyright Act.

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

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

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

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

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

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

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

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

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

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

1 now, but return here promptly at 1:40, not  
2 1:30 as scheduled.

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

9 (Whereupon, the foregoing matter  
10 went off the record at 12:42 p.m.  
11 and resumed at 1:45 p.m.)  
12  
13  
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1 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

2 1:45 p.m.

3 MS. TREAT: Okay. Good afternoon.

4 Thank you very much for this opportunity to  
5 testify. I am Sharon Treat, I'm a Maine state  
6 representative and a member of the Maine  
7 Citizen Trade Policy Commission.

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

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

22 As I mentioned, we're bipartisan,

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

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

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

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

1 report as well.

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

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

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

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

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

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

16 Reference pricing is something  
17 that is basically what we're doing in the  
18 state of Maine and many others states around  
19 this country. So to see that language in the  
20 report raises a grave concern in our mind that  
21 states may be the next country targeted in the  
22 301 report for not complying with the kinds of



1 policies that you would like to see.

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

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

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

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

1 State Department. Go ahead.

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

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

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

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

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

1       how we run those programs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 And we saw in our state that that  
10 came back to our state in a proposed solution  
11 to that which would have offered up regulation  
12 of liquefied natural gas off our cost of  
13 Maine, which was of high interest to our  
14 fisherman.

15 So, you know, these kinds of  
16 issues, the complexity of them, are the reason  
17 that we have a trade commission in the state  
18 of Maine to try to educate members of our  
19 legislature and our administrative offices as  
20 well, the executive and try to get ourselves  
21 involved with what you're doing to make sure  
22 that you're fully aware of the implications

1 for us at the state level.

2 MR. McCOY: Thank you for being  
3 involved in what we're doing and making your  
4 presentation today. I did see that you're on  
5 the schedule to come back shortly on behalf of  
6 another group.

7 MS. TREAT: Yes. Our budget was  
8 cut, we're trying to downsize our --

9 MR. McCOY: So, we have next Sean  
10 Flynn on behalf of Forum on Democracy and  
11 Trade. Sean, you're welcome to take a seat  
12 there and the floor is yours.

13 MR. FLYNN: Great. Thank you very  
14 much. I'll be speaking here on behalf of the  
15 Forum on Democracy and Trade but we submitted  
16 a joint submission with Sharon's group as well  
17 which is the National Legislative Association  
18 Prescription Drug Prices.

19 And our program at American  
20 University, which is a clinical type research  
21 and advocacy program serves as council to both  
22 groups. And so you will have me to sandwich

1 in between Sharon's two comments and I'm sure  
2 we can trade back and forth.

3 I'm going to try to leave most of  
4 the technical questions to Sharon, since she's  
5 the actual state legislator and focus on some  
6 of the legal questions that were raised in our  
7 submissions and perhaps reflect back on some  
8 of the policy information as well.

9 So first just to set the  
10 background, so you know, the reason these  
11 pricing issues popup into 301 is the link  
12 between patents on pharmaceuticals and high  
13 drug prices around the world, but including  
14 the U.S. is I think that Sharon very  
15 forcefully documented.

16 So when you have patents on  
17 essential good and service, it crates an  
18 extremely strong forum of market power unlike  
19 a substitutable good no one will choose to not  
20 purchase a medicine that's needed for their  
21 health.

22 And so we see the very extreme



1 pricing in developing countries that  
2 submissions like MSF today have very  
3 forcefully advocated.

4 It's commonly recounted, for  
5 instance, that drug prices for first line AIDS  
6 drugs were priced about \$12,000 a year in  
7 every country around the world in 1999  
8 regardless of income level of that country.  
9 And we also see extreme drug prices in this  
10 country as well.

11 Now one of the most effective  
12 tools to counter monopoly pricing of an  
13 essential good and service is to pool  
14 purchasing, is to pool a consumer side of the  
15 equation and then to negotiate drug prices  
16 between a large buyer and a single seller.  
17 It's countering a monopoly with a monopsony.

18 And that's what states do through  
19 Medicaid, it's what the VA does through their  
20 purchasing list and it's what foreign  
21 countries do with their preferred drug lists  
22 as well.

1                   It's what Australia does through  
2                   the program that's regulated by the  
3                   Australia/U.S. Free Trade Agreement. It's  
4                   what Korea does by the program that's  
5                   regulated by the U.S./Korea Free Trade  
6                   Agreement.

7                   Now the one big difference, of  
8                   course, between the U.S. and other countries  
9                   is that we have -- other developed countries,  
10                  is we have an extremely large population of  
11                  uninsured people who actually face unpooled  
12                  prices at the retail markets.

13                  And it's those people who pay  
14                  prices that are between 100 and 500 percent  
15                  higher than the prices in other countries.  
16                  But government programs in this country pay  
17                  the same and often lower prices than countries  
18                  like Canada, Germany, Japan and many of the  
19                  other countries that are singled out in the  
20                  last 2009 301 report for having unreasonable  
21                  pricing policies.

22                  And that's why you see states like

1 Maine and Vermont before you here today, the  
2 Forum on Democracy and Trade, which represents  
3 states across the country and trade officials  
4 that are worried about trade agreement effects  
5 on state programs around the country, and the  
6 National Legislative Association Prescription  
7 Drug Prices, which Sharon will just talk about  
8 which represents 12 or 13 states across the  
9 country.

10 So the message is this, the kind  
11 of programs that 301 has been targeting in  
12 foreign countries as being unreasonable are  
13 the same programs that are being used  
14 effectively in the United States. That is an  
15 unreasonable use of Section 301.

16 And now let me put the cap on it.  
17 I think it's also illegal. You are  
18 implementing a Congressional statute. That  
19 statute demands that you look at other  
20 countries intellectual property practices,  
21 adequate and effective protection of  
22 intellectual property and then market access

1 issues.

2 But the phrase market access has a  
3 definition. It says that unreasonable market  
4 access issues are either market access  
5 problems that violate an international trade  
6 agreement, and the pharmaceutical chapters of  
7 301 never mention any international trade  
8 agreement that's been violated, or that  
9 constitute a non-tariff barrier.

10 Now, a non-tariff barrier is a  
11 term of art in trade law and I've never seen  
12 it applied to a non-discriminatory price  
13 regulation.

14 So when you use 301 to target a  
15 price regulation without demonstrating how it  
16 is discriminatory, how it treats different  
17 countries products differently, you are  
18 breaking new legal ground in international  
19 trade law, you're doing so without  
20 Congressional authority and you're doing so in  
21 a way that harms interests in this own  
22 country.

1                   So we are asking you to remove  
2                   that section from 301, to stop using Special  
3                   301 to target non-discriminatory price control  
4                   mechanisms on pharmaceuticals that do not  
5                   violate any other trade agreement. To do  
6                   otherwise, is to violate your statutory  
7                   mandate.

8                   MR. McCOY: Thanks very much for  
9                   your comments. We'd like to revert back to  
10                  the discussion that we just had with the  
11                  previous speaker on transparency.

12                  Is transparency in how these  
13                  pricing schemes are operated, is that not a  
14                  great thing, should not maybe opportunities  
15                  for the affected industries to understand how  
16                  the schemes function (Inaudible due to faulty  
17                  in-house sound).

18                  MR. FLYNN: Yes. So let me answer  
19                  that in two parts. First of all, the statute  
20                  that you're implementing does not mention  
21                  transparency.

22                  It does not mandate that USTR go

1 around the world and define transparency  
2 provisions within other country's regulatory  
3 schemes, just as they do not do so here.

4 The statutory phrase is market  
5 access. Transparency doesn't give you market  
6 access, it's not a market access term, it's  
7 not a statutory term that empowers you to do  
8 so.

9 Now I believe to paraphrase what  
10 Sharon just said, and I think you can ask her  
11 this question again, do U.S. programs provide  
12 the type of transparency that you're requiring  
13 either through 301 or through Free Trade  
14 Agreements abroad?

15 And the answer is, no. When  
16 states create pricing boards to help them  
17 create preferred drug price lists, and that's  
18 the mechanism that's used in the states,  
19 states create a list of drugs that are  
20 preferred within their reimbursement programs,  
21 one of the factors that's included is price  
22 and that creates an incentive for

1 pharmaceutical companies to lower their price  
2 in order to gain access to that purchase list.

3 They don't include pharmaceutical  
4 companies on the board, which has been  
5 requested in past 301 decisions and was  
6 actually brought today by the Thailand example  
7 as a reason they should be taken off because  
8 they actually have two government pricing  
9 committees with pharmaceutical representatives  
10 on the committee.

11 That's one of the definitions that  
12 USTR has used for heightening transparency.  
13 That's not done in any state in the United  
14 States. There's at least 40 states that have  
15 preferred drug price lists and none of them  
16 include pharmaceutical representatives on the  
17 bodies that make those decisions.

18 You can challenge court --  
19 pharmaceutical companies can challenge those  
20 decisions under normal administrative process  
21 rules, but there are not special rules for any  
22 of those lists that give pharmaceutical

1 companies the right to appeal specific listing  
2 decisions, other than under due process norms,  
3 or that include them in the determination of  
4 pricing or that give them seats at the table  
5 or that even have a notice and comment process  
6 beforehand.

7 So you are requiring procedures  
8 abroad that we don't follow at home.

9 MR. McCOY: We received several  
10 submissions talking about whether or not we  
11 should consider issues of so-called TRIPS plus  
12 standards protection.

13 And since you've been talking a  
14 bit about the Special 301 statute, I wonder if  
15 you have a view on the fact that the Special  
16 301 statute states that countries may be  
17 determined to deny adequate and effective IP  
18 protection even if they're in compliance with  
19 the TRIPS agreement.

20 In that light, do you think it's  
21 appropriate for us to limit this review to  
22 such compliance?



1                   MR. FLYNN: So I'm going to, like  
2 Sharon, you're going to have me twice and I'm  
3 actually going to have a whole other  
4 submission on behalf of Global Health  
5 Organization. So I'll answer that briefly,  
6 but I'm going to have a lot more to say on it.

7                   So the short answer is, you're  
8 very right, the statute itself says that  
9 compliance with TRIPS itself does not mandate  
10 a finding that that country has adequate and  
11 effective intellectual property.

12                   However, the counter is also true.  
13 It is left in your discretion. It does not  
14 say that compliance with TRIPS is not adequate  
15 and effective intellectual property.

16                   If this administration and this  
17 panel decides, to take a not random example,  
18 that developing countries on access to  
19 medicine issues compliance with TRIPS is  
20 adequate and effective, there's nothing in the  
21 statute that would say that's a wrong  
22 determination.

1           That is a policy choice that this  
2           administration is making. And I'll put a cap  
3           on it.

4           This is really, in our opinion,  
5           the first 301 report that's being drafted  
6           under this new administration and that is  
7           frankly why you've had 700 or so submissions  
8           in this process when last year there were 55.  
9           You've had over 30 NGOs submit into this  
10          process when in the past four years there's  
11          been one.

12          So people are interested in seeing  
13          policy change and they're interested in seeing  
14          policy change on particular areas that the  
15          Obama Administration campaigned on, that the  
16          Obama Administration has made public  
17          statements on.

18          And one of the key ones is on the  
19          access to medicines issue. And I'll follow  
20          that up in my next comment which will be  
21          focused on global health care.

22          MR. McCOY: Thanks very much.

1 MS. TREAT: Thank you.

2 MR. McCOY: So we'll hear from you  
3 again on behalf of someone else. Let me just  
4 address the fact that the AIDS Access  
5 Foundation, look around the room and see if  
6 there is anybody here who's authorized to  
7 speak on their behalf.

8 I don't see that that's the case,  
9 so I'll just say that this is covered by the  
10 people who mentioned a phone connection as  
11 possibly appropriate for another hearing.

12 So I think Sharon Treat, you can  
13 go back again now on behalf of National  
14 Legislative Association on Prescription Drug  
15 Prices.

16 MS. TREAT: Thank you very much.  
17 I am Sharon treat and as I said, I'm a state  
18 representative. In Maine we have a part time  
19 legislature and so we almost all hold other  
20 jobs and my other job is as Executive Director  
21 of the National Legislative Association on  
22 Prescription Drug Prices.

1                   This is an organization that was  
2                   founded back 2000 by a group of state  
3                   legislators that were focused on drug pricing  
4                   in the United States and ensuring access to  
5                   prescription drugs.

6                   Even then, prices were considered  
7                   extremely high and these legislators got  
8                   together to figure out what mechanisms they  
9                   could employ at their state level to try to  
10                  reduce drug prices.

11                  Part of what our organization has  
12                  done is try to focus on the trade issue and we  
13                  have a working group of legislators and we've  
14                  also had some attorney general representatives  
15                  and others from around the country to  
16                  participate in our meetings.

17                  That working group is co-chaired  
18                  by Arizona Senator Meg Burton Cahill and  
19                  Connecticut Representative Kevin Ryan. I'm  
20                  here today to speak on their behalf.

21                  I just want to say specifically  
22                  that we oppose any expansion of the 301 report

1 into the realm of disciplining countries for  
2 implementing effective and non-discriminatory  
3 pharmaceutical pricing policies.

4 We also oppose the recent trend of  
5 the U.S. Trade Representative to use trade  
6 agreements in negotiations to develop new  
7 international standards restricting the use of  
8 the most effective programs to restrain drug  
9 prices.

10 As I already have testified, we  
11 believe these programs will directly and  
12 negatively effect the capacity of states to  
13 provide health care and pharmaceuticals to  
14 their residents through existing Medicaid and  
15 state funded programs and will cripple the  
16 ability of states to expand access to health  
17 care in the future.

18 I'm going to go off message just a  
19 little bit to talk about that transparency  
20 issue. We actually consider a best practice  
21 to have conflict of interest policies applied  
22 to any preferred drug list committee that's

1 making up those decisions to ensure that there  
2 is zero pharmaceutical industry representation  
3 on those preferred drug list or DUR  
4 committees.

5 And in fact, the District of  
6 Columbia has passed a law restricting any  
7 funding or gifts to those people and indeed  
8 Vermont and Massachusetts and others have  
9 gift, more broad gift ban provisions anyway.  
10 So those would clearly violate the Korea  
11 agreement and other proposals.

12 I want to also mention that we --  
13 this is an issue, if you go to the written  
14 submission that we worked with Professor Flynn  
15 to put together, you might want to take a look  
16 at the footnote on page 6 through 7, footnote  
17 14.

18 It details at least eight letters  
19 that have gone from legislators as well as  
20 chief executives.

21 The Governor of Washington State,  
22 for example, Governor Granholm focusing on --

1 I mean Gregoire, Christine Gregoire, writing  
2 to either USTR, to members of Congress  
3 expressing concern about the free trade  
4 agreements language as well as other  
5 initiatives of the U.S. Trade Representative  
6 over the last several years. So you can take  
7 a look at those that are mostly posted online.

8 Medicaid costs topped \$350 billion  
9 in 2008. It's the single largest state  
10 government expenditure after education and I  
11 really wish there was the HHS representative  
12 sitting on the panel right now because it is  
13 really our signature program at the state  
14 level for health care.

15 I just want to point out some of  
16 -- I mentioned Maine's success in using the  
17 preferred drug list and other mechanism to  
18 reduce prices. Here's some other statistics.

19 Iowa has saved \$100 million  
20 between 2005 and 2009 savings equal to 34.7  
21 percent of its total drug budget. Oregon  
22 saved 40 percent per prescription due to

1 generic uptake because of its preferred drug  
2 list.

3           You know, discounts negotiated by  
4 private companies for Part D, which did not  
5 use the same mechanisms, were substantially  
6 higher, 30 percent higher than what states  
7 have previously been spending for the Medicaid  
8 population that then was moved to Part D under  
9 the Medicare Part D.

10           So that's an indication, that 30  
11 percent figure is an indication of sort of a  
12 minimum amount nationally that is being saved  
13 right now using these pricing mechanisms.

14           Again, I want to end with the  
15 concern that this approach and these policies  
16 are really on a head-on collision with other  
17 policies of this administration; policies that  
18 I, as a state legislator and that many  
19 legislators around the country, are very much  
20 in support of, which are about expanding  
21 access to health care across this country,  
22 affordable health care.



1                   And we hope that you will take  
2                   into consideration those policies as well as  
3                   you try to navigate your direct requirements  
4                   here.

5                   MR. McCOY: Thanks very much. And  
6                   we will not be surprised to learn the  
7                   questions we have based on the National  
8                   Legislative Association on Prescription Drug  
9                   Price submission, were again, very similar on  
10                  this question on the transparency and merits  
11                  of encouragement of transparency in systems  
12                  overseas (Inaudible due to faulty in-house  
13                  sound).

14                  Is there anything else that you  
15                  would like to say on behalf of this group, on  
16                  that?

17                  MS. TREAT: Well I'm not going to  
18                  go into those legal argument, but I'll just  
19                  tell you that someone I work with who works on  
20                  these prescription drug issues went to the  
21                  meeting on setting up a preferred drug list in  
22                  Maine and she said she was amazed to find that

1 it was a room sort of the size of this that  
2 was completely filled with representatives of  
3 the pharmaceutical industry.

4 Clearly, it's being done in a  
5 transparent manner, but it does not meet the  
6 definition of transparency that has been used  
7 in, for example, the Korea Free Trade  
8 Agreement.

9 And we actually were very  
10 concerned about that language. I'll leave it  
11 to Professor Flynn to say whether or not  
12 you're allowed to define, you know, those  
13 things are part of what your responsibility  
14 is.

15 But clearly the kinds of  
16 requirements that have been put into these  
17 agreements are very much inconsistent with  
18 what states are doing.

19 And we, I've been told directly by  
20 state Medicaid directors that they could not  
21 do their job, they could not do these  
22 preferred drug lists the way they do and

1       comply with those requirements, which would  
2       delay for in many cases for several years, the  
3       actual putting something on to a list, for  
4       example.

5                They need to be nimble so they can  
6       take advantage of, as I mentioned before, if  
7       a drug suddenly goes on to a generic list, you  
8       know, becomes generic after it's been an  
9       incredibly expensive drug, something that is  
10      taken by, you know, thousands or millions of  
11      people.

12               State Medicaid directors need to  
13      be able to move quickly to change their drug  
14      lists to, you know, get those reduced prices.

15               And so, you know, we are very  
16      concerned and we don't see the trend -- I  
17      guess what's disturbing is that these are  
18      issues that we have been raising for, you  
19      know, many years, four or five years.

20               And it doesn't -- it just seems  
21      like instead of going -- really considering  
22      them, I mean this footnote was put in the

1 Korea agreement, but instead of really  
2 understanding it, there seems to be an even  
3 greater effort to focus on this whole area in  
4 a way that clearly would have repercussions  
5 for us at the state level.

6 MR. McCOY: I'm interested in what  
7 you mentioned about the open meeting. Would  
8 I be correct in understanding that to mean  
9 that the state policies are transparently run  
10 in the sense that folks who are affected can  
11 know when decisions would be made and provide  
12 information to decision makers, the process is  
13 transparent in that sense.

14 And would you agree that foreign  
15 government processes should be similarly  
16 transparent?

17 MS. TREAT: I'm not here to  
18 pontificate about what foreign government  
19 should do. My concern is what the effect is  
20 on our state.

21 I do care about access to health  
22 care for people all over the world as an

1 individual, but as state legislators what  
2 we're focused on is policies being played out  
3 at the federal and international level that  
4 have an impact on access to health care in our  
5 states and so that is our concern.

6 MR. McCOY: That's understandable.  
7 Thank you very much for making the trip here  
8 and sharing your views.

9 MS. TREAT: Thank you. I  
10 appreciate it.

11 MR. McCOY: So I think Robin Lunge  
12 from Vermont Commission on International Trade  
13 and State Sovereignty. Robin did I pronounce  
14 your name correctly?

15 MS. LUNGE: You did.

16 MR. McCOY: Thank you.

17 MS. LUNGE: Good job. It's a  
18 rarity actually.

19 MR. McCOY: The floor is yours,  
20 please.

21 MS. LUNGE: Thank you. My name is  
22 Robin Lunge I work for the Vermont Legislative

1 Council's Office which is the non-partisan  
2 legal and policy staff for the Vermont  
3 Legislature.

4 I'm here today on behalf of the  
5 Vermont Commission on International Trade,  
6 which was created in 2005 by state law. Our  
7 commission has eight members, it's a  
8 bipartisan commission.

9 We have two legislative members, a  
10 representative of the Attorney General's  
11 office, our Secretary of Commerce and four  
12 members appointed by our Governor including a  
13 representative of labor, environmental  
14 interests and two representatives from  
15 business one of whom is from IBM, which is one  
16 of our largest employers in Vermont, the other  
17 of whom represents the interests of small  
18 exporters in the state.

19 So just a little bit about us.  
20 Our statutory charge is to look at the balance  
21 between promoting trade as a vital economic  
22 interest for Vermont and a way to increase our

1 economic development potential with  
2 maintaining the state's ability to determine  
3 its own policies recognizing that there are  
4 certain areas that are specific to state  
5 sovereignty under the 10th Amendment of the  
6 United States Constitution.

7 So why should you be interested in  
8 state pharmaceutical policy? I think that's  
9 an obvious question for you to be asking  
10 yourselves.

11 And the short answer to that, I  
12 think you've already heard, which is when you  
13 apply international standards to other  
14 countries, which could then become  
15 memorialized in a reciprocal trade agreement,  
16 it's vital for you to understand if that  
17 policy is in conflict with something that a  
18 state or other locality or domestic policy  
19 issue here.

20 So I want to talk to you a little  
21 bit about Vermont. Vermont has been a leader  
22 in health care reform. And one of our state

1 senators talks about the health care reform in  
2 Vermont as a three-legged stool.

3 We like three-legged stools, you  
4 use them in milking, probably a lot of you  
5 don't milk a lot of cows, but we do that in  
6 Vermont.

7 So and our three legs are access,  
8 quality and cost containment. And cost  
9 containment has been a vital piece of our  
10 health care reform because without cost  
11 containment, there's no way that we would be  
12 expanding our coverage to the numbers of folks  
13 that we do cover in Vermont.

14 We have 93 percent of our  
15 population covered, the majority of that is  
16 through some state funded program either  
17 through a Medicaid expansion program, state  
18 employees or teachers.

19 Ninety-seven percent children in  
20 Vermont have health insurance. So we've  
21 achieved nearly universal access without a  
22 mandate as Massachusetts did.



1                   This started a long time ago with  
2                   Former Governor Dean creating a children's  
3                   health insurance policy called Dr. Dinosaur.  
4                   The other thing that we've been doing for a  
5                   long time is providing affordable access to  
6                   pharmaceuticals for low and middle income  
7                   elderly and individuals with disabilities.

8                   Our state programs go up to 400  
9                   percent of poverty, which is higher than what  
10                  the Federal Government is currently  
11                  considering its subsidies in the national  
12                  health care reform.

13                  We provided access to  
14                  pharmaceuticals through state only pharmacy  
15                  programs and then after the Medicare Part D,  
16                  because Part D was worse than the coverage  
17                  that the state offered through a wrap-around  
18                  program for those individuals.

19                  So, we recognize the importance of  
20                  pharmaceuticals as being vital to people's  
21                  health and a necessary part of our health care  
22                  system.

1           In fact, we're focusing now on a  
2 program called the Blueprint for Health, which  
3 focuses on the prevention and management of  
4 chronic disease largely through pharmaceutical  
5 management. So drugs are important to us and  
6 having access to drugs is important to us.

7           But we would not have been able to  
8 achieve that level of coverage or to put it in  
9 a different way, the pharmaceutical company  
10 wouldn't have the market penetration in  
11 Vermont if we had not also pursued cost  
12 containment.

13           In terms of our prescription drug  
14 cost containment, it's important to note that  
15 Vermont has achieved a negative spending trend  
16 in pharmaceuticals in our Medicaid program.

17           In addition, through the  
18 implementation of our preferred drug list, we  
19 saved \$3.8 million within the first eight  
20 months, which for many people is not a lot of  
21 money, but in Vermont \$1 million is a lot of  
22 money.

1                   In addition, we've saved over 10  
2 percent of our prescription drug benefit for  
3 state employees by restructuring our benefit  
4 to include a preferred drug list. So this has  
5 been a vital tool.

6                   Our preferred drug list in  
7 Medicaid includes an evidence-based process  
8 focused on clinical efficacy and cost.  
9 There's also a focus on generics. We include  
10 generics on our preferred drug list.

11                   And we use the preferred drug list  
12 as a mechanism to negotiate additional rebates  
13 from drug manufacturers. We also do both  
14 purchasing with other state Medicaid programs  
15 to increase our buying power.

16                   This is not all that different  
17 from what other countries do in terms of  
18 managing their drug costs.

19                   So I would just close by saying  
20 that the Vermont Commission is very interested  
21 in having you focus on whether it's necessary  
22 to look at pricing and reimbursement

1 strategies and reeling it in light of the  
2 importance it has to states.

3 MR. McCOY: Would you help us with  
4 this question of transparency that we  
5 discussed with the last couple of speakers.  
6 I'm particularly interested in whether that  
7 you could consider that Vermont runs its  
8 program in a transparent way with open  
9 meetings?

10 I don't know what the state  
11 statutes are in Vermont on that score, but  
12 would you consider that you have transparency  
13 in the process there and would you consider  
14 that it's appropriate to seek that kind of  
15 transparencies from foreign entities?

16 MS. LUNGE: Sure. I'll address  
17 that issue. I should just provide a caveat,  
18 which is that the Vermont Commission on  
19 International Trade has not specifically  
20 discussed transparency issues.

21 So in speaking now, I'm speaking  
22 really more as a general health policy person

1 for the state of Vermont and not specifically  
2 for the commission, because they haven't  
3 considered that question.

4 Our state statute establishes  
5 what's called the drug utilization review  
6 board, which is a board made up of state  
7 Medicaid officials, pharmacists, doctors and  
8 other clinicians.

9 There are no consumers on that  
10 board, there are no industry representatives  
11 on that board.

12 In fact, I feel confident in  
13 saying that my health committees would  
14 probably see it is a conflict of interest to  
15 put industry on that board because we are  
16 purchasing from -- we don't usually put people  
17 that we're buying things from on the board  
18 setting up how we're going to procure the  
19 items.

20 The meetings are subject to our  
21 open meeting law, there are minutes. However,  
22 a couple years ago we actually changed the

1 state law to provide the ability of that board  
2 to go into executive session.

3 We did that in part in response to  
4 the pharmaceutical industry indicating that  
5 they did not want information about the price  
6 negotiations to be held in an open meeting.

7 So, they certainly, the  
8 pharmaceutical company is able to attend the  
9 open meeting, but the meetings do go into  
10 closed session when they discuss price  
11 negotiations and when they're actually  
12 choosing which drugs to put on the list  
13 because they were trying to be sensitive to  
14 the assertion that the prices they negotiated  
15 were subject to trade secret.

16 So, I think in terms of  
17 transparency you can't have it both ways.  
18 Either it's open information or it's a trade  
19 secret and you need to kind of sort through do  
20 you want to have the ability to keep some of  
21 that information confidential for the  
22 protection of the industry as well as have an

1 open process.

2 Now similarly, consumers can't go  
3 to the closed meetings either. Consumers and  
4 industry have the same rights of appeal either  
5 way, neither of which is specifically  
6 specified in the DUR board statute, it would  
7 be through our other state rules and statute.

8 I did compare our process to the  
9 transparency provisions in the Australia  
10 agreement a number of years ago and we did not  
11 -- we weren't 100 percent in alignment with  
12 those requirements.

13 I don't remember the details off  
14 the top of my head, but I'd be happy to see if  
15 I can dig that up and provide you with that  
16 specific comparison of whether or not our  
17 statute met the transparency requirements in  
18 that agreement. So I hope that's helpful.

19 MR. McCOY: That is helpful,  
20 thanks very much. I think that was the main  
21 area of questions that we had on this course.  
22 So unless there's anything else that you want

1 to elaborate on, I'll just say thank you very  
2 much for your participation.

3 MS. LUNGE: Thank you.

4 MR. McCOY: Can we squeeze in one  
5 more before the break and invite you back  
6 again? Are we having problems with both mics  
7 now? Right, I don't know if these are doing  
8 any good. We're going to go to the break and  
9 see if we can get microphones. Thank you.

10 (Whereupon, the foregoing matter  
11 went off the record at 2:28 p.m.  
12 and resumed at 2:36 p.m.)

13 MR. McCOY: You are now speaking  
14 on behalf of American University Program on  
15 Information Justice and Intellectual Property  
16 on behalf of AdHoc Civil Society Coalition on  
17 IP and Access to Medicine. So the floor is  
18 yours, please go ahead.

19 MR. FLYNN: Okay. Thank you. So  
20 as I mentioned previously and as you just did,  
21 this submission is on behalf of the joint  
22 submission of the global public health groups,



1 some of whom are testifying in their  
2 individual capacity today, but this was the  
3 joint submission that was signed by a number,  
4 I think it was 12, global health groups.

5 I intend to, you know, follow up  
6 and answer some of the questions that Stan was  
7 asking and hit upon some other points as well.

8 And this is my longer submission,  
9 so I'm going to have to cut through and hit to  
10 a bunch of points and hope you'll give me the  
11 opportunity to expand in question and  
12 comments.

13 So first of all, in considering  
14 your mandate, I think it's important to  
15 consider from an administrative law standpoint  
16 what it is you're doing.

17 So from an administrative law  
18 standpoint, this is an adjudication, it's  
19 backward looking, not forward looking, you're  
20 not making a rule, you are looking, you're  
21 implementing a statute and interpreting that  
22 statute and applying it to facts as they come

1 before you and you're adjudicating those facts  
2 and making factual findings at the end.

3 And I introduce that way to say  
4 that we have procedural concerns with this  
5 process. We want to thank the committee for  
6 opening this process significantly more than  
7 has been the case and I think that was at  
8 least in part to some submissions from many of  
9 the people who signed this joint submission  
10 asking for a more open process to hear from  
11 public interest concerns.

12 But it's still not a very adequate  
13 process for the determinations that you need  
14 to make both on facts and law. Some of the  
15 submissions that we've been making both in our  
16 written submissions and that I'm submitting to  
17 you today are legal disputes.

18 We have disputes with the way that  
19 the 301 statute has been interpreted and  
20 implemented particularly over the last eight  
21 or nine years.

22 The expansion of 301 into

1 pharmaceutical pricing is one such issue and  
2 the expansion of 301 to put pressure on  
3 developing countries to implement TRIPS plus  
4 intellectual property policies on access to  
5 medicines is another.

6 And that's the one that I want to  
7 focus on now. There's a series of procedural  
8 suggestions that we make in the submission.

9 I think you can sum them up by  
10 saying that you should be following the  
11 procedures that would be required by the  
12 administrative Procedure Act in a process  
13 that's required by statute to be done on the  
14 record after a hearing.

15 I'm not arguing that you're  
16 legally required to implement that rule,  
17 because I don't think you are. I'm arguing  
18 that as a matter of policy to adopt best  
19 transparency and participation practices,  
20 those are the standards that you should be  
21 implementing in the future.

22 Let me return to the question that

1 Stan left off with which is that doesn't the  
2 statute, I'm paraphrasing wrongly, does the  
3 statute essentially require us to look into  
4 enforced TRIPS plus standards because of the  
5 provision in the statute that says compliance  
6 with TRIPS does not mandate that something be  
7 considered adequate and effective intellectual  
8 property.

9 You do have to give meaning to  
10 that phrase within the statutes, but you also  
11 have to interpret this statute against the  
12 background of the other United States and  
13 administration commitments that promote access  
14 to medicine specifically and that have turned  
15 against past policies of using TRIPS plus  
16 intellectual property requirements on access  
17 to medicines, and they just list those.

18 You should be interpreting the  
19 mandates against the background of the TRIPS  
20 provisions that address and emphasize the  
21 importance of balance and national discretion,  
22 which include Articles 1, 6, 7 8 and 40.

1                   You should be interpreting all of  
2 your statutory mandates against the background  
3 of the WTO accords, which mandate  
4 multilateral, unilateral adjudication of trade  
5 disputes.

6                   This is a pre-WTO statute and  
7 actually my legal opinion is that this process  
8 violates the WTO.

9                   You should be interpreting all of  
10 your access to medicines intellectual property  
11 standards against the background of the 2001  
12 WTO Doha declaration, which has been extremely  
13 narrowly misinterpreted by the past  
14 administration to include only public health  
15 crisis and that's not what the declaration  
16 says.

17                   And specifically, the declaration  
18 affirms the rights of every country to use all  
19 TRIPS flexibilities in full, quote, unquote,  
20 "in full."

21                   And that specific phrase within  
22 the WTO Doha declaration has been attacked

1 essentially by the U.S. over and over again in  
2 the Special 301 process in the past, including  
3 in the 2009 report, as exhaustively  
4 demonstrated in our written submission.

5           You should also be adhering to  
6 U.S. commitments in the WIPO development  
7 agenda. You should be adhering to the ethical  
8 guidelines of the declaration of Helsinki,  
9 which James Love mentioned.

10           You should be adhering to the  
11 Obama Administration's expressed policy to  
12 quote, "increase access to affordable drugs in  
13 developing countries," including through  
14 support for, quote, "the rights of sovereign  
15 nations to access quality assured low cost  
16 generic medication to meet their pressing  
17 health needs under the WTOs declaration on  
18 trade related aspects of intellectual property  
19 rights."

20           And you should also, I submit, be  
21 interpreting your mandates against the  
22 background of international human rights

1 obligations including documents the U.S. has  
2 not signed and including common international  
3 law that promote the rights of all countries  
4 to access to health care and have been  
5 specifically interpreted by the Special  
6 Rapporteur on the Right to Health, who  
7 requested to submit comments by telephone  
8 today and was not made available.

9 That in position of TRIPS pressure  
10 on developing countries violates other  
11 country's citizens rights to health. That  
12 should be the normative and legal framework  
13 guiding your determinations on all access to  
14 medicines to principals.

15 MR. McCOY: Can I give the floor  
16 to my colleague from the State Department for  
17 a question, please.

18 MR. FLYNN: I'd be happy to answer  
19 a couple questions that I have for myself if  
20 you don't have --

21 MR. McCOY: Excuse me, my  
22 colleague from the Copyright office. Let me

1 just give the floor to Susan then, go ahead  
2 would you.

3 MS. WILSON: Thank you very much  
4 for your presentation. I believe there's more  
5 to come. We've tried to get at this  
6 particular question a couple of times today  
7 and heard, I think very clearly the opinions  
8 of some of your colleagues on this issue of  
9 counterfeit medicines versus substandard  
10 medicines, so I won't ask the question in the  
11 same way.

12 But I think one of the things that  
13 we're trying to get at in the medicine space  
14 from an enforcement perspective since there's  
15 clearly disagreements about some of the policy  
16 issues surrounding medicines.

17 But in the enforcement space, one  
18 thing that I think is very important to all of  
19 us in this room, regardless of where we are on  
20 some of the other issues, is the fact that  
21 there is a tremendous amount of counterfeit  
22 medicine and truly counterfeits, packaged,



1 trademark bearing, false, dangerous ingredient  
2 counterfeit medicines circulating in the  
3 market place globally.

4 How, and one of the things that  
5 we've done as the U.S. Government is used  
6 Special 301 to highlight that issue and to  
7 draw attention to the issue and to get  
8 enforcement resources focused on the issue in  
9 the United States and also use that -- used it  
10 to focus foreign government's on the issue.

11 And one of the things that we've  
12 tried to do, and I think under some  
13 circumstances less successfully than under  
14 others is enlist the NGO community or try to,  
15 to help us.

16 And maybe we haven't used the  
17 right words and we haven't approached in the  
18 right way or maybe years of being on opposite  
19 sides and other circumstances have led to less  
20 than the kind of relationship you need to work  
21 together under these circumstances.

22 But one of the things I think that

1 we're looking for is how can we work together  
2 in this area in which we all agree there is an  
3 enormous problem, we may not have the contacts  
4 that you have, I know we don't, with the  
5 people who are in the first line, in the  
6 trenches distributing medicine, you see it all  
7 the time where as close as you are.

8           How can we work together, what  
9 suggestions can you give us on tackling this  
10 problem on getting a hold of the true  
11 counterfeit problem?

12           Not using IP to get at, you know,  
13 substandard drugs, not using IP as a shield  
14 for trying to disrupt what are otherwise  
15 valuable humanitarian efforts, but really  
16 tackling this menace, this scourge. We all  
17 know where it's coming from, we all want to do  
18 something about it and we haven't been able to  
19 and it's growing by leaps and bounds and it's  
20 killing people.

21           And what suggestions do you have,  
22 and I'm posing that question not only to you,

1 but for everyone else who takes the microphone  
2 for the rest of the day, what can you tell us,  
3 how can we help each other on this issue.

4 MR. FLYNN: I mean I think that's  
5 a great question. I have some very specific  
6 things that I think I mean you collectively,  
7 the administration, you USTR can do if you  
8 really want to work with the global public  
9 health community on some of these issues.

10 So the first thing you can do is  
11 release the text of ACTA. If you want to talk  
12 about counterfeiting with the global health  
13 community, you have to release the text of the  
14 major multilateral agreement that's discussing  
15 counterfeiting as soon as possible.

16 We would like to comment on it.  
17 We would like to be here at forums like this  
18 telling you what we think of your exact  
19 specific policy proposals.

20 Second, we should be talking about  
21 drug regulatory systems and not intellectual  
22 property systems. Intellectual property

1 systems don't protect public health, drug  
2 regulatory systems do.

3 Third, you should at least  
4 immediately return to the waning years of the  
5 Clinton Administration policies when there is  
6 an active debate between the global health  
7 community and a democratic administration.

8 And under that era, HHS would be  
9 sitting here at the table, they were mandated  
10 to be part of the subcommittee looking over  
11 301, they were actually given the final word  
12 for an administration policy on all TRIPS plus  
13 issues, HHS was required to look at those  
14 issues and make a final determination on it.

15 And to quote that specific policy,  
16 the policy further stated, should a government  
17 determine to avail itself of the flexibility  
18 of the TRIPS agreement that provides to  
19 address health issues, the United States will  
20 weighs no objection.

21 That was not the policy under the  
22 Bush Administration, it was not the policy

1 under the 2009 Special 1 report.

2 And finally in the section of the  
3 301 report that discusses TRIPS and public  
4 health, at minimum we should go back and read  
5 the 2000 301 Special report -- Special 301  
6 report that was written under the Clinton  
7 Administration.

8 That's the fullest statement on  
9 that issue that we have had to date. You  
10 should endorse in full the Doha declaration,  
11 not just as applied to crisis and not just as  
12 applied to compulsory licenses or parallel  
13 importation.

14 And especially not as was done in  
15 the Bush Administration, only applied to the  
16 obvious 30 paragraph 6 solution, which was  
17 simply about compulsory licenses for exporting  
18 drugs was not about TRIPS flexibilities.

19 You need to have a sentence in the  
20 301 report that says we affirm, and as we did  
21 in 2001, the rights of all developing  
22 countries to use all TRIPS flexibilities to

1 the full to address access to medicines  
2 matters.

3 And then you need to apply that  
4 standard throughout the 301 report. You  
5 should not be listing developing countries for  
6 data exclusivity matters as is discussed  
7 exhaustively in my written submission.

8 The idea that the article 393  
9 requires data exclusivity was amended out of  
10 TRIPS. TRIPS 393 does not require data  
11 exclusivity, it can't. That proposal of the  
12 U.S. was rejected.

13 Up unto 2003, the 301 report  
14 continued to say that article 393 required  
15 data exclusivity. Please abandon that legal  
16 interpretation of TRIPS in the context of this  
17 unilateral adjudication.

18 And all other TRIPS plus issues  
19 should be eliminated on access to medicines  
20 and patent issues from the 301 report. That  
21 would be a great starting point to working  
22 with the NGO community on these issues.

1                   MR. McCOY: Thanks very much  
2           Professor Flynn, Sean. Could I Universities  
3           Allied for Essential Medicines to come  
4           forward.

5                   MR. STERN: Good afternoon. My  
6           name is Benjamin Stern and I represent the  
7           Universities Allied for Essential Medicines.  
8           What you have there is two declarations made  
9           by universities that I'll discuss and just a  
10          preliminary version of what I'm going to say.

11                  Personally, and on behalf of UAEM  
12          I'd like to express my gratitude for the  
13          opportunity to be here today. This is a new  
14          procedure and for whatever procedural issues  
15          you might have, it's not everyday that  
16          students get to testify before a committee.

17                  I am a second year law student at  
18          Yale and I studied engineering, biomedical  
19          engineering at Columbia and I'm going into a  
20          professional career in patent law.

21                  UAEM is an incorporated non-profit  
22          made up of over 60 campus chapters but it's

1       comprised of students. Our membership is as  
2       diverse as the student bodies of the  
3       institutions we call home.

4               UAEM brings together law students,  
5       medical students, public health, business and  
6       undergraduates and that's what makes it great,  
7       it's one of the few organizations on campus  
8       that actually does that.

9               We come from across the political  
10       spectrum, all the diversity views, but what we  
11       have in common is that we all care about  
12       access to medicines and we all care that our  
13       respective universities ensure that access.

14              We all believe that, and the  
15       universities agree with us that university  
16       held patents should not be a barrier to  
17       access.

18              University life science research  
19       is at a nexus of academia and industry. I'm  
20       currently taking a class in pharmacology, the  
21       Yale Law School lets us do that, take classes  
22       in whatever field we want and I happen to be



1 interested in pharmacology.

2 And just yesterday we had a  
3 lecture from a professor who's started three  
4 companies, one for each new cancer drug that  
5 he's invented.

6 And one of those companies was  
7 purchased by Pfizer, it became very profitable  
8 and very successful and the next two look like  
9 they're just as promising, if not more.

10 Another lecture in the same class  
11 was given by a professor who wrote a computer  
12 program that simulates interactions between  
13 molecules and can predict how effective drugs  
14 will be, what their side effects will be, how  
15 to change the molecular structure of drugs so  
16 that they work better, all on computer, no,  
17 you know, no chemicals involved.

18 And that software is used by over  
19 30 biotech and pharma companies and it's been  
20 very successful, it's been used for 20 years  
21 and he and a partner has refined that and it's  
22 produced some very impressive results.

1                   These university developed  
2                   technologies have saved millions of lives and  
3                   will save millions more, but they're  
4                   publically funded largely and those publically  
5                   funded innovations must be made affordable to  
6                   be truly accessible.

7                   Universities have committed  
8                   themselves to global health and repeatedly  
9                   ensured that their intellectual property not  
10                  become a barrier.

11                  We believe that the USTR should  
12                  demonstrate a similar commitment in line with  
13                  its international obligations as discussed  
14                  with compiling the Special 301 report.

15                  So I'll talk about some of the  
16                  lovely commitments that we've made. In 2007,  
17                  working with UAEM several universities adopted  
18                  the Stanford nine points to consider in  
19                  licensing university technology. That's the  
20                  cream -- in order, the cream colored sideways  
21                  printed page.

22                  The ninth point is what I want to

1 focus on that universities should strive to  
2 construct licensing arrangements in ways that  
3 underprivileged populations have low or no  
4 cost access to adequate -- quantities of  
5 medical innovations.

6 The list of organizations on the  
7 first page is only the initial sponsoring  
8 organization. Since then, 70 have signed on.

9 Most recently, our efforts have  
10 led to the adoption of a more concrete global  
11 access policy, the statement of principles and  
12 strategies for the equitable dissemination of  
13 medical technologies, which is the white  
14 handout there.

15 Several major research  
16 universities, including Yale and Harvard and  
17 the AUTM, Association of University Technology  
18 Managers, the NIH and the CDC have signed on  
19 to that.

20 MR. McCOY: Could I ask you to  
21 pause and allow for a question?

22 MR. STERN: Yes, sir.

1 MR. McCOY: Let me give the floor  
2 to my colleague from the U.S. Patent and  
3 Trademark Office for a question.

4 MR. STERN: Absolutely. The rest  
5 of what I had to say was basically repeating  
6 points that have been made before, so that's  
7 what was new.

8 MS. MOEZIE: Thank you for your  
9 comments. We understand the debate regarding  
10 widely available drugs in the western world  
11 and their direct impact upon diseases such as  
12 HIV/AIDS in particular.

13 Your submission states that past  
14 301 reports have often failed to live up to  
15 the letter or spirit of international  
16 commitments in this area. Could you identify  
17 examples of how you consider that has  
18 occurred?

19 MR. STERN: Considered as a, I'm  
20 sorry, a what?

21 MS. MOEZIE: How it's occurred.

22 MR. STERN: Oh, how the failures

1 have occurred?

2 MS. MOEZIE: How -- yes.

3 MR. STERN: Well in terms of the  
4 honesty of the reports, I think have not been  
5 -- the reasoning behind the reports have not  
6 been as straightforward or as accurately  
7 representing.

8 A specific one would be, I guess,  
9 perhaps the reasoning statement behind why  
10 Israel was put on the -- or one of the reasons  
11 Israel was put on the priority watch list  
12 about access to generics.

13 The last 301 report speaks that  
14 the -- that Israeli patent law gives an unfair  
15 -- or gives an unfair disadvantage to American  
16 or innovative companies, meaning American  
17 companies.

18 And we think, and based on my  
19 research, it seems that it not be  
20 disadvantaged to American innovators, it's  
21 actually an advantage to Israeli over --  
22 Israeli, sorry, Israeli generics over American

1 generic companies.

2           So, medicines that are available  
3 generically for things like HIV, as soon as  
4 the patent expires, generics can enter the  
5 market if the proper research has been done.

6           Certain countries, such as Israel,  
7 don't have the same data exclusivity of  
8 protections and those allow them to enter the  
9 market very quickly.

10           When you do have data exclusivity  
11 and you do have patents from extensions,  
12 you've got a de facto patent extension.

13           So, and most of the drugs in the -  
14 - or most of the first AIDS drugs, the first  
15 effective AIDS drugs have gone off patent in  
16 the past five to seven years. And that's one  
17 area I feel is -- that the USTR has not lived  
18 up to its commitment.

19           MR. McCOY: Anything else you'd  
20 like to share with us in the time available  
21 that can help us to assess the adequacy and  
22 effectiveness of IP protection and

1 reinforcement by our trading partners?

2 MR. STERN: Sure. What we do want  
3 to repeat that we really hope that the USTR  
4 and State Department will not use diplomatic  
5 pressure to discourage compulsory licenses.  
6 We feel that tactical opposition to compulsory  
7 licenses undermines the Doha declaration and  
8 the TRIPS flexibilities.

9 And we think that -- I think  
10 PEPFAR has been mentioned today that it would  
11 benefit the U.S. to have increased access to  
12 generics. GM, for example, spends more money  
13 on prescription drugs than it does on steel.

14 I don't know if that's been  
15 mentioned today. And gram for gram, drugs can  
16 be the most expensive substances on the  
17 planet. And since the government owns the  
18 majority stake in GM now, I think that's  
19 something you might want to consider as a  
20 government organization.

21 And PEPFAR being an executive  
22 branch initiative also is an important thing

1 to consider, because if resources are not  
2 spent on expensive drugs are spent on widely  
3 available, very simple to manufacture drugs,  
4 they can be spent on patient care and clinical  
5 and more valuable initiatives and approaches.

6 MR. McCOY: Let me just say on  
7 these documents that you've passed out, happy  
8 to have them. If they're not already part of  
9 your submissions, you may want to submit them  
10 as part of the official record as post hearing  
11 statement.

12 So you can do that on  
13 regulations.gov. But thank you very much for  
14 joining us today and for sharing your views.

15 MR. STERN: Well, thank you very  
16 much for having me. And we will be submitting  
17 several post hearing statements.

18 MR. McCOY: Thank you. And we're  
19 trying to figure out what that noise is. I  
20 don't know if it's as annoying for everyone in  
21 the room.

22 MR. STERN: It stops when your



1 microphone goes off.

2 MR. McCOY: That's the solution,  
3 I'll keep running my mouth. So on that theme,  
4 I think next we have Asia Russell from Health  
5 GAP. Welcome.

6 MS. RUSSELL: Good afternoon.

7 MR. McCOY: Have a -- make  
8 yourself comfortable and the floor is yours.

9 MS. RUSSELL: Thank you very much.  
10 Good afternoon. My name is Asia Russell, I  
11 direct international policy for Health GAP.  
12 Health GAP is a policy and advocacy  
13 organization working for the urgent scale to  
14 provide access to affordable HIV treatment in  
15 developing countries.

16 We've worked over the last decade  
17 to improve the response of the U.S. Government  
18 to the global AIDS crisis through increasing  
19 the U.S. Government investment in AIDS  
20 treatment and improving U.S. Government  
21 policies.

22 Because of the critical role in

1 our experience that generic competition among  
2 manufacturers have played in reducing the cost  
3 of live saving AIDS drugs in developing  
4 countries.

5 We've also focused over the last  
6 decade on ensuring that U.S. trade policy is  
7 guided by and accountable to the needs of  
8 people suffering unnecessarily without  
9 medicines access.

10 Our efforts have helped contribute  
11 to significant shifts in the U.S. response to  
12 the AIDS crisis in Sub-Saharan Africa and  
13 other countries in need.

14 This has included dramatic scale  
15 up and appropriations for HIV treatment and  
16 prevention, the creation of the U.S.  
17 President's Emergency Plan for AIDS Relief,  
18 PEPFAR, in 2003 as well as in 2001 the  
19 creation of the Global Fund to Fight AIDS  
20 Tuberculosis and Malaria.

21 We also note that there have been  
22 some changes over the last decade in trade

1 policy relating to intellectual property  
2 rights and access to medicines over the course  
3 of the previous two administrations.

4           Unfortunately, I -- it's  
5 referenced by the Special 301 report from  
6 2009. It appears that this administration,  
7 like the previous one, is committed to use of  
8 the Special 301 report as a tool to bully  
9 countries that are attempting to assure access  
10 to affordable medicines through intellectual  
11 property provisions that make use of the  
12 flexibilities enshrined in the TRIPS agreement  
13 and reaffirms by the Doha declaration on the  
14 TRIPS agreement in public health.

15           This persistent deployment of a  
16 flawed policy under this administration and  
17 previous ones is a matter of serious concern  
18 to the AIDS and global health communities.  
19 The assessment by USTR of quote, "Adequate and  
20 effective protection of intellectual property  
21 rights," unquote, fair and equitable market  
22 access in our view can and must be determined

1 in the context of the U.S. obligation to  
2 uphold the provisions of the Doha declaration  
3 on the TRIPS agreement in public health.

4 We expect to see a 2010 Special  
5 301 report that does more than pay lip service  
6 to the idea of the diplomacy of public health  
7 and access to medicines.

8 We expect to see countries removed  
9 from the watch list in each and every case  
10 where their actions are consistent with TRIPS  
11 compliant efforts to promote access to  
12 medicines for all.

13 Our comments today build on  
14 arguments provided in the submission that you  
15 have available and are combined to these brief  
16 points.

17 One, that the administration's  
18 public commitments to responding to global  
19 health priorities including, but not limited  
20 to the epidemic of untreated HIV or undermined  
21 by USTRs use of Special 301 and other measures  
22 to punish and pressure countries using TRIPS

1 compliant measures to increase the  
2 availability of medicines.

3 Two, that USTRs current use of the  
4 Special 301 report contradicts U.S.  
5 obligations as well according to the Doha  
6 declaration on TRIPS agreement in public  
7 health.

8 And finally, we'd like to express  
9 concern that the continued use of Special 301  
10 in this manner is in fact a prohibited form of  
11 unilateral action by the U.S. in violation of  
12 its commitments to a multilateral system of  
13 dispute resolution within the WTO.

14 On the first point, I'd just like  
15 to remind you that this administration has  
16 pledged repeatedly to reach the global goal of  
17 universal access to HIV treatment in  
18 developing countries as well as complementary  
19 international commitments to tackle diseases  
20 that are the leading preventable killers of  
21 people in developing countries worldwide.

22 And I should add contribute to a

1 great deal of lack of economic productivity  
2 around the world.

3 Moreover, as presidential  
4 candidates, not only President Obama, but also  
5 President -- Vice President Biden and  
6 Secretary of State Clinton, as well as Senator  
7 McCain, made repeated promises to scale up the  
8 U.S. response to global AIDS, including  
9 through adoption of trade policies that ensure  
10 access to affordable generic medicines.

11 These public commitments were  
12 preceded by President Bush in 2003 of PEPFAR,  
13 seeking appropriations over five years of \$15  
14 billion and pledging to extend treatment to at  
15 least two million people with HIV.

16 As I'm sure other witnesses have  
17 mentioned, the U.S. is now the largest funder  
18 of antiretroviral therapy in the world and  
19 PEPFAR has been reauthorized to a level of \$48  
20 billion in its second five years.

21 PEPFAR reports directly supporting  
22 treatment of more than 2.4 million people

1 worldwide and indirectly supporting many more  
2 through investments multilaterally such as  
3 through the Global Fund to Fight AIDS  
4 Tuberculosis and Malaria.

5           Why does this matter? PEPFAR has  
6 steadily increased its procurement of generic  
7 medicines and is now the world's largest  
8 procurer of HIV, of generic HIV treatment  
9 according to PEPFARs own estimates in 2007,  
10 proportion of generics by volume procured by  
11 PEPFAR reached 73 percent in 2008.

12           In the fiscal year 2008 PEPFAR  
13 spent approximately \$202 million on  
14 antiretrovirals and of that, the investment in  
15 generic HIV -- in generic, excuse me,  
16 antiretrovirals increased from 11 percent  
17 upwards to 27 percent and finally by 2008 to  
18 57 percent with corresponding savings as  
19 estimated by PEPFAR to be more than \$115  
20 million over three years.

21           In addition to its own ARV  
22 procurement, the U.S. is the biggest donor to

1 the Global Fund to Fight AIDS Tuberculosis and  
2 Malaria which by the end of 2008 had spent  
3 more than \$4.4 billion on AIDS programs of  
4 which roughly a third was spent on ARV  
5 treatment and monitoring.

6 ARV treatment has reached, at this  
7 stage, over four million people in urgent need  
8 by the end of 2009.

9 An additional 10 million patients  
10 who need treatment according to new peer  
11 reviewed assessments by the World Health  
12 Organization or their experts, are still  
13 without access to medicines and many millions  
14 more will require treatment over the next  
15 decade.

16 These patients need treatment in  
17 their own right, but there's also a growing  
18 body of evidence that treating HIV might be  
19 one of the best ways to prevent HIV  
20 transmission.

21 I actually just have one more  
22 paragraph, if that's okay I'll just finish and



1 then be happy to take your questions.

2 In addition, new treatment  
3 guidelines recommend discontinuation of older,  
4 more toxic, less effective therapies including  
5 d4T-based therapies and replacement with more  
6 effective durable regimes based on newer  
7 medicines such as Tenofovir and Zidovudine  
8 with concomitant current increases in price  
9 points.

10 Therefore, first line medicines  
11 are becoming more expensive as people initiate  
12 therapy on newer second generation medicines.  
13 At the same time, second and third line  
14 combinations of treatment for people who are  
15 HIV positive and become resistant to their  
16 current therapies are by some estimates as  
17 much as 8 to 40 times more expensive than  
18 first line products.

19 The administration's pledged  
20 commitment to reach universal access to AIDS  
21 treatment cannot be met unless the price of  
22 HIV treatment is affordable.

1                   Other generic companies in India  
2                   and elsewhere, other countries have production  
3                   capacity have been able to manufacturer older  
4                   generic, quality generic versions of older  
5                   antiretroviral medicines at a fraction of the  
6                   cost of brand name products, a benefit that  
7                   PEPFAR has reaped heartedly over the last  
8                   several years.

9                   These same opportunities have  
10                  dwindled with respect to newer medicines.  
11                  Accordingly and as a result of having become  
12                  TRIPS compliant in 2005, a number of newer  
13                  antiretroviral treatments remain much more  
14                  costly because patent holders face more  
15                  generic competition from India or elsewhere.

16                  This is a public health concern  
17                  that our trade policy has to address.  
18                  Moreover, the production and export capacity -  
19                  - the production and export of generic  
20                  antiretrovirals in India and other countries  
21                  with production capacity, has been a driving  
22                  force scaling of access to medicines in Sub-

1 Saharan Africa.

2           Therefore, USTRs pressure on India  
3 and other countries with manufacturing  
4 capacity whether they'll be middle income  
5 countries or otherwise, through Special 301  
6 report listing and other means, harms not only  
7 Indians in need of affordable treatment, but  
8 also people living with HIV and other health  
9 priorities in Sub-Saharan African countries  
10 that are now primarily importing countries  
11 because they lack domestic manufacturing  
12 capacity.

13           That's a very important point to  
14 make. It is in this context that the USTR in  
15 our views pursuit of heightened intellectual  
16 property protection for pharmaceutical  
17 products and its punishment of countries that  
18 use TRIPS compliant flexibilities by means of  
19 USTRs Special 301 reports directly undermines  
20 this administration's public commitment to  
21 reaching universal access.

22           Beneficiaries of U.S. global AIDS

1 programs, as well as U.S. taxpayers, urgently  
2 require the U.S. to pursue trade policies that  
3 support generic production of first and second  
4 generation HIV treatment, their interests must  
5 be promoted and protected by the  
6 administration and by USTR, not only the  
7 interests of multinational pharmaceutical  
8 companies.

9 My final point, as I'm sure  
10 previous witnesses have mentioned, this  
11 administration, this country, the U.S. is a  
12 signatory, like every other WTO member  
13 country, to the Doha declaration on the TRIPS  
14 agreement in public health.

15 And that declaration emphasized  
16 the gravity and primacy in developing  
17 countries public health needs and clarified  
18 member's rights to promote access to medicines  
19 for all.

20 As you've noted by our submission  
21 and the submission of the joint submission of  
22 Global Health Organizations, we've highlighted

1 the multiple ways we feel that USTR has  
2 consistently pursued TRIPS plus intellectual  
3 property protections in contravention of our  
4 obligations under the Doha declaration.

5 Special 301 reports have listed  
6 countries for use of compulsory licenses such  
7 as in the case of Thailand.

8 MR. McCOY: This is a long  
9 paragraph.

10 MS. RUSSELL: Oh, almost done.  
11 Such as in the case of Thailand and Brazil.  
12 And it's the question you just asked the  
13 previous witness, in the case of Thailand and  
14 Brazil for refusing -- for countries refusal  
15 to expand its global patentability despite the  
16 fact that countries have a right to define on  
17 their own terms scope of patentability, that's  
18 in the case of Brazil.

19 There are many, many very  
20 disturbing examples. So I think in  
21 conclusion, we call on USTR to conduct a  
22 complete review of its use of Special 301

1 listings soliciting analysis and review from  
2 health and other experts through a multi  
3 agency process.

4 We're actually concerned that we  
5 don't see Health and Human Services or other  
6 health experts represented on this  
7 subcommittee today and that's an easy fix that  
8 we think you would be eager to pursue.

9 As a condition of respecting U.S.  
10 endorsement of the Doha declaration of TRIPS  
11 and public health and for the purpose of  
12 achieving the goals of President Obama's  
13 global health initiatives the USTR should act  
14 affirmatively to promote access to medicines  
15 by promoting implementation on the part of  
16 countries in need of TRIPS affirmed by the  
17 Doha declaration instead of pursuing the  
18 course that it appears to be pursuing now.

19 That is the one of erecting  
20 intellectual property protections that serve  
21 only to increase pharmaceutical industry  
22 profits.

1                   These monopoly-based profits come  
2                   at two high a cost in terms of health outcomes  
3                   for people living with HIV and other people  
4                   seeking secure, healthy and productive lives  
5                   in these developing countries, in middle  
6                   income countries and around the world.

7                   MR. McCOY: Thanks very much for  
8                   your statement. I think we've used up the  
9                   time for questions, but as you said, you  
10                  covered some of the questions that were  
11                  addressed before about TRIPS plus and so on.

12                  If there's anything else you feel  
13                  you need to elaborate on, you're certainly  
14                  welcome to do that in a post hearing  
15                  submission.

16                  But let me say we're very grateful  
17                  for your participation and for your statement  
18                  today and thank you very much for being a part  
19                  of the process.

20                  MS. RUSSELL: Thanks Stan.

21                  MR. McCOY: Take care. I think  
22                  our next speaker is Michael Palmedo from the

1 Program on Information Justice and  
2 Intellectual Property.

3 MR. PALMEDO: Hello.

4 MR. McCOY: The floor is yours.

5 MR. PALMEDO: All right. Is the  
6 mic on? Here we go. All right. Hi. Once  
7 again, my name is Mike Palmedo, I'm with  
8 American Universities Program on Information  
9 Justice and Intellectual Property, though the  
10 comments I've prepared are my own.

11 Since 2000, I've worked in the  
12 non-profit or academic sectors on issues of  
13 access to medicines, intellectual property and  
14 trade policy. And I appreciate the  
15 opportunity to testify before you today. I  
16 think it's great that you are starting to  
17 open the process up.

18 I want to go kind of quickly over  
19 some stuff that I think has been brought up by  
20 previous speakers and then just highlight a  
21 few things from the PhRMA submission.

22 But to open up I'd like to



1 reemphasize the U.S. is the largest purchaser  
2 of antiretroviral medicines in the world  
3 funding purchases through PEPFAR and through  
4 contributions to international programs like  
5 the Global Fund and that even in existing  
6 programs that are buying generics cost is  
7 definitely an issue.

8           Most people receiving medicines  
9 through these programs get sub-optimal first  
10 line antiretroviral therapies because the  
11 older drugs came to the market before TRIPS  
12 was fully in effect are vastly more  
13 affordable.

14           And in many cases, people in these  
15 programs remain on treatment, though  
16 inevitably require second line, which are  
17 seven times more expensive on average than  
18 first line regimens and then third line  
19 treatments that are more than that.

20           PEPFARs fifth annual report to  
21 congress notes that the prices of both second  
22 line treatments and pediatric treatments

1 remain, quote, "a significant challenge."

2           So in short, current and near  
3 future treatment needs require that these U.S.  
4 funded programs get the best price possible  
5 when purchasing, so more and not less generic  
6 competition is necessary.

7           If our trade policy is designed to  
8 favor brand name producers over generic  
9 producers, this will conflict with the U.S.  
10 taxpayers interest to purchase the most  
11 treatment possible through PEPFAR and through  
12 our funding of international programs like the  
13 Global Fund.

14           Generic producers need flexible  
15 intellectual property regimes to continue  
16 producing competitively priced treatments.

17           And I urge you to keep this in mind when  
18 assessing comments submitted by IP owners  
19 urging USTR to use the Special 301 report to  
20 push countries towards ever higher levels of  
21 IP protection.

22           And so now to bring up a couple of

1 points brought up by PhRMA and their comments  
2 submitted on February 18th, their written  
3 ones. PhRMA asserts that India must take  
4 steps to ensure that compulsory licenses  
5 issued for export are quote, "granted for  
6 humanitarian non-commercial use only,"  
7 unquote.

8 As has been brought up currently,  
9 most people in developing countries that are  
10 on therapy are taking medicines provided by  
11 generic suppliers and these suppliers at these  
12 businesses supplying low quantities at low  
13 marginal profit.

14 If these companies are -- if  
15 they're unable to obtain voluntary or  
16 compulsory license for second or third line  
17 treatments, prices for these medicines will  
18 remain prohibitively high.

19 Limiting exports of generic drugs  
20 from India to those for humanitarian  
21 enterprises could prevent the producers from  
22 selling to the largest possible markets. They

1 need to achieve economies of scale if costs  
2 are going to fall.

3 If PEPFAR does not have access to  
4 competitively priced generic second line  
5 treatments in the near future, it's hard to  
6 see how it will continue to provide life  
7 saving medicines.

8 On China, PhRMA criticizes a lot  
9 of things, but PhRMA criticizes the  
10 government's enforcement of health regulations  
11 for active pharmaceutical ingredients noting  
12 that chemical manufacturers may sell and ship  
13 API products to locations within China and  
14 abroad with either no regard for the intended  
15 use of the API or choosing not to comply with  
16 existing regulations.

17 The enforcement of Chinese  
18 regulation of APIs is outside the scope of the  
19 Special 301 report.

20 It doesn't address the adequacy or  
21 effectiveness of intellectual property rights  
22 and PhRMA doesn't suggest that these Chinese

1 health regulations deny fair and equitable  
2 market access to United States persons that  
3 rely upon intellectual property protection.

4 So if this complaint is included  
5 in the Special 301 report, it will be nothing  
6 more than an attempt to intimidate Chinese  
7 companies which many developing country  
8 producers rely on to produce affordable  
9 generics.

10 I see my time is running short. A  
11 note on data protection. Data exclusivity,  
12 which is clearly favored by the industry has  
13 been brought up, not necessary for TRIPS  
14 compliance.

15 There's no need for all countries  
16 to adopt U.S. or EU style data exclusivity.  
17 And paragraph 4 clearly states that TRIPS can  
18 and should be interpreted and implemented in  
19 the manner supportive of all WTO members  
20 rights to protect health and to promote access  
21 to medicines for all.

22 So it should therefore be

1       acknowledged in the 2010 Special 301 report  
2       that TRIPS does not require data exclusivity,  
3       but that it requires countries to protect  
4       against unfair commercial use as interpreted  
5       by each WTO member.

6               And so I'd like to thank you for  
7       this opportunity to testify. And just as a  
8       very quick last point, I'd ask you to  
9       reconsider the wisdom of using the Special 301  
10      report to advance TRIPS plus policies that  
11      will lead to higher medicine prices, which  
12      would conflict with the Obama Administration  
13      stated policy to support the rights of  
14      sovereign nations to access quality assured  
15      medicines.

16              It would contradict the statement  
17      that -- or the President's trade policy that  
18      they just released that Ambassador Kirk is  
19      presenting to The Hill today that supports the  
20      Doha declaration.

21              It makes no sense since we're  
22      buying the medicines and it contrasts

1       awkwardly with the TRIPS article 1 which  
2       states that WTO members shall not be obliged  
3       to adopt TRIPS plus intellectual property  
4       provisions. Thank you.

5                   MR. McCOY: Thanks very much. Let  
6       me give the floor to my colleague from Customs  
7       and Border Protection for a question. Go  
8       ahead, please.

9                   MR. WRIGHT: Thank you for coming  
10      here to tell us about your issues. My  
11      question would be I think one that my  
12      colleague from the Department of Commerce had  
13      inquired about.

14                   And it's a little bit off the  
15      subject, I think, of your testimony, but  
16      perhaps you could give us some information  
17      about what your familiarity, your  
18      organizations familiarity with counterfeit  
19      medicines and other products that might  
20      threaten health and consumer safety and what  
21      the Special 301 process or how that should be  
22      used in connection with dealing with

1 counterfeit medicines.

2 MR. PALMEDO: Okay. I think the  
3 real counterfeit substandard drugs -- I think  
4 the real problem is substandard drugs, as  
5 other people have said before, and that it's  
6 a health problem that's best dealt with health  
7 officials.

8 The 301 report obviously, you  
9 know, focuses on intellectual property so you  
10 have trademark issues. But we definitely  
11 respect the fact that people that sell  
12 dangerous products need to be stopped.

13 I think the counterfeiting  
14 solution as it's currently being pushed by the  
15 U.S. Government through various agencies is  
16 meaning resistance because it's being wrapped  
17 up in a larger effort to enforcing -- to up  
18 the enforcement of intellectual property that  
19 worries people.

20 Because it includes things like  
21 ACTA, which so many people have been asking  
22 for the text and it's still not available.



1           It includes recent African  
2           legislation that's highly, highly restrictive  
3           that has wildly opened definitions of what a  
4           counterfeit that's much broader than the U.S.  
5           definition, much broader than the WTOs  
6           definition, much broader than the WHOs  
7           definition.

8           And it basically boils down to  
9           anything not approved by the IP owner. It's  
10          wrapped up with this -- the enforcement drive  
11          that's led to a number of seizures in Europe  
12          of drugs that were in transit and, you know,  
13          one was a shipment of drugs from England  
14          through Europe to Nigeria purchased by the  
15          Clinton Administration that seized.

16          One was going from India to Brazil  
17          and it's a case where there is no intellectual  
18          property being violated, but it was just -- it  
19          was the fact that someone could pick the phone  
20          and call a border's agent who then seized a  
21          legitimate shipment of drugs.

22          And that's the sort of thing

1 that's being pushed for through ACTA, through  
2 other parts of this broader anti-  
3 counterfeiting push. And I think that if we  
4 have open --

5 MR. McCOY: Could I ask you a  
6 follow up specifically on that relating  
7 something you said earlier that I understood  
8 you to say that the unregulated production of  
9 active pharmaceutical ingredient in China  
10 should not be a concern of this subcommittee.

11 Is that not at all relevant to the  
12 problem of either counterfeit medicines or  
13 substandard medicines or both?

14 MR. PALMEDO: It's not relevant to  
15 the enforcement of intellectual property.  
16 It's outside the scope of the 301, it does not  
17 -- what I specifically referred to, which is  
18 on page 39 of PhRMA written testimony, has to  
19 deal with the enforcement of health  
20 regulations within China of the input going  
21 into a product.

22 It doesn't have to deal with

1 approval of a finished drug. It's, more  
2 narrowly, it's just not part of enforcement of  
3 intellectual property standards as through the  
4 301 report.

5 As far as fighting counterfeits  
6 generally, I do think that there should be an  
7 open conversation between health people and  
8 government officials in the north and  
9 government officials in the south.

10 That instead of looking for a way  
11 to punish people who might be violating  
12 patents or trademarks, that really gets to the  
13 issue of the health side.

14 Like for instance, I believe the  
15 best data on the health -- posed is held by  
16 the pharmaceutical companies, but it's not  
17 shared widely, which would be very helpful in  
18 honest efforts to combat substandard drugs.

19 MR. McCOY: Thanks very much for  
20 coming and talking with us today, we really  
21 appreciate it.

22 MR. PALMEDO: All right. Thank

1       you.

2                   MR. McCOY: All right. Next on  
3       our program today is Peter Maybarduk from  
4       Public Citizen. Peter, I probably  
5       mispronounced your name too, I apologize.

6                   MR. MAYBARDUK: I think you  
7       actually got it right.

8                   MR. McCOY: All right.

9                   MR. MAYBARDUK: Testing, testing.

10                  MR. McCOY: The floor is yours.

11                  MR. McCOY: Okay. Excellent.

12       Thank you very much for this opportunity to  
13       come in today and comment.

14                  And at the conclusion of my  
15       remarks, I wish to signal that I'd be quite  
16       happy to discuss the issue of fake and  
17       substandard medicines in appropriate  
18       frameworks, to deal with that today or in any  
19       later time at your offices as you please.

20                  I'm here today with Public  
21       Citizen, I'm Public Citizen's Access to  
22       Medicines Coordinator. I provide technical

1 assistance to government's and NGOs around the  
2 world on issues related to access to medicines  
3 and intellectual property.

4 Public Citizen is a consumer  
5 advocacy organization with 150,000 members and  
6 supporters founded in 1971 working largely on  
7 health and safety issues among others.

8 You'll note in your folders, I  
9 have folders that I've distributed to the  
10 panel and there are folders in the back for  
11 anyone that's interested. There should be  
12 enough for anyone who cares to see them.

13 So, Public Citizen believes with  
14 our colleagues here today that USTR Special  
15 301 report should reflect U.S. commitment  
16 under the Doha declaration to promote access  
17 to medicines for all.

18 And in particular I wish to  
19 address Ecuador and its TRIPS compliant  
20 compulsory licensing protocol. I've been  
21 providing technical assistant to Ecuador for  
22 some time and there's some interest in the

1 issue at USTR and other agencies.

2 We wish to emphasize that USTR  
3 should not cite Ecuador for any matter related  
4 to that country's protocol on the compulsory  
5 licensing of pharmaceutical patents in the  
6 public interest.

7 USTR should also not sanction  
8 Ecuador's protocol indirectly, for example,  
9 through in precise references to alleged IPR  
10 protection failings in Ecuador or through  
11 otherwise unwanted elevation in Ecuador's  
12 watch list status.

13 We skip ahead a page in the  
14 comments. On October 23rd, Ecuador's  
15 President Rafael Correa issued decree 118  
16 declaring access to priority medicines  
17 effecting the health Ecuadorian population to  
18 be a matter of public interest.

19 Although not required by TRIPS,  
20 the decree satisfies an Indian community  
21 proviso enabling Ecuador's patent office in  
22 cooperation with the Ministry of Health to

1 receive compulsory license request and issue  
2 licenses case-by-case on public interest  
3 grounds.

4 Ecuador has yet to issue a  
5 compulsory license, but Ecuador's patent  
6 office, IEPI, has published formal guidance to  
7 license applicants, their Instructivo.

8 Both these documents, decree 188  
9 and the Instructivo are in your folders on the  
10 right-hand side, along with an unofficial  
11 English translation of the decree.

12 IEPI has met at least twice with  
13 the American embassy in Quito as well as the  
14 patent-based pharmaceutical companies Trade  
15 association in Ecuador, IFI, which issued a  
16 public statement, quote, "democratically  
17 accepting," unquote, decree 118.

18 I can run through a brief  
19 analysis. The punchline for us is that  
20 there's no substantive basis for citing  
21 Ecuador's policy on compulsory licensing in  
22 the 301 report because the protocol envisioned

1 is entirely TRIPS compliant.

2 And indeed the decree borrows  
3 heavily from the TRIPS agreement in some cases  
4 regarding non-exclusivity, supplying the  
5 domestic market, adequate compensation of  
6 patent holders, license review determination,  
7 word-for-word from the TRIPS agreement.

8 And so we believe that citing  
9 Ecuador's compulsory licensings policy would  
10 represent an inappropriate effort by the  
11 United States to influence another WTO  
12 member's use of rights preserved by the TRIPS  
13 agreement with potentially serious  
14 consequences for public health.

15 I don't want to spend much time on  
16 the specifics, but we have analyzed them and  
17 I'm happy to talk about them on the side.  
18 Decree 118 establishes a public interest in  
19 medicines used to treat, quote, "public health  
20 priority illness," unquote.

21 That determination is to be  
22 certified by the Ministry of Public Health,



1 interagency agreement is the norm. They  
2 require that licensed applicants -- license  
3 requests be evaluated according to supporting  
4 circumstances of each case.

5 Decree 118 requires payment of  
6 royalties, borrowing again a language from the  
7 TRIPS agreement and licensing applicants are  
8 required to certify these in other universally  
9 applicable license terms.

10 Both documents reiterate that all  
11 licenses must comply with all applicable  
12 legislation. IEPI has published guides and  
13 explanatory materials online going to the  
14 point of transparency.

15 They've held multiple meetings for  
16 the press and public and they've indicated  
17 they remain open to meetings with the American  
18 embassy in Quito.

19 I've met with the American embassy  
20 in Quito as well and with IfI. If under the  
21 policy, if and when a compulsory license is  
22 issued, patent holder would have recourse to

1 seek review of the terms and grant of the  
2 license both through IEPI and through  
3 independent judicial process.

4 Patent holders, of course,  
5 American companies remain free to compete with  
6 any products introduced under compulsory  
7 license.

8 So the policy is in compliance  
9 with TRIPS and neither denies -- it does not  
10 deny adequate and effective protection of IPR  
11 or fair and marketable -- fair and equitable  
12 market access so it does not mention -- merit  
13 mention in the 301 report.

14 I'm available now and in the  
15 future for questions. I'm happy to come down  
16 and speak to USTR or other agencies at any  
17 time on this point and also interested to  
18 discuss the matter of fake and substandard  
19 medicines.

20 MR. McCOY: Thanks Peter. And let  
21 me just say thanks for speaking to a country  
22 specific issue on IP protection and

1 enforcement.

2 I think that's particularly  
3 relevant to the work that we're asked by  
4 Congress to do in this review. So I  
5 appreciate your attention to helping us  
6 fulfill our mandate in that respect.

7 Let me give the floor then back to  
8 DHS to ask the question that you've invited.

9 MR. WRIGHT: Thank you Stan.  
10 Thank you very much for your testimony again,  
11 we appreciate you coming down and talking to  
12 us.

13 I'm going to ask the counterfeit  
14 medicines questions. What -- how should we be  
15 using the Special 301 process to deal with  
16 counterfeit medicines and maybe you could talk  
17 about your organization's experience with  
18 counterfeit medicines in the various countries  
19 where you're active. Thank you.

20 MR. MAYBARDUK: Sure. Well, I  
21 mean it's not entirely clear to me, though I'm  
22 open to being told why I'm wrong. But, you

1 know, Special 301 is an appropriate -- is the  
2 appropriate venue for getting at issues of  
3 substandards, which we all agree are quite  
4 important, including fake medicines.

5 Counterfeit, of course, is  
6 problematic because there are two definitions  
7 and widespread technical use. One is the WTO  
8 definition relating to trademark violations,  
9 the other is the WHO definition relating to  
10 misrepresentation of active ingredients.

11 And while there can be some  
12 overlap, they're actually separate standards.  
13 And it's very important to apply the correct  
14 framework.

15 Now there is a place for Special  
16 301 of course if you have a clear case, if you  
17 have, you know, evidence-based reasons to  
18 suspect that there's, you know, widespread  
19 misappropriation of a mark going down in  
20 pharmaceuticals somewhere in the world, that's  
21 appropriate.

22 But, you know, that's both under

1 and over inclusive as regards to the issue of  
2 medicines quality and fake medicines. You can  
3 have a case where, you know, someone is  
4 producing medicine that doesn't have an active  
5 ingredient, but doesn't misappropriate a mark.

6 You can have a case where someone  
7 does arguable misappropriate a mark, but is  
8 producing a quality medicine. But then you  
9 have questions of, you know, misappropriation  
10 of a mark.

11 You know, our customs agents and  
12 others necessarily set up to make the  
13 appropriate legal analysis.

14 So, you know, our perspective is  
15 basically that we have to adequately separate  
16 out the issues and we're talking with a lot of  
17 different international organizations right  
18 now for how we can best do that.

19 Our priority is on consumer  
20 protection, public health and safety. And the  
21 appropriate framework for that is a consumer  
22 protection and public health and safety

1 framework.

2           It's not clear why an IPR  
3 framework is needed at all to deal with that  
4 issue. The problem is when we start importing  
5 the IPR framework, then we get into all kinds  
6 of problems and we start importing anti-  
7 competitive effects.

8           Because a lot of the agreements, a  
9 lot of the standards that have been put in  
10 place in different organizations around the  
11 world, don't have adequate anti-abuse  
12 provisions.

13           They don't necessarily provide  
14 adequately for a generic firms right, you  
15 know, to due process and different cases, you  
16 know, whatsoever.

17           And they can, you know, impose  
18 chilling effects, financial chilling effects  
19 on the generics industry as well. So these  
20 are all quite concerning.

21           And one thing that we're  
22 interested in doing, and I'd be happy come

1 down to any of your offices and speak about it  
2 in person, is establishing a set of best  
3 practices for dealing with drug quality at  
4 large, you know, of which fake medicines are  
5 essentially a subset and with, you know, and  
6 specifically with fake medicines as well.

7 And, you know, a number of these  
8 practices are already in place, we can do more  
9 to sort of give them more power in different  
10 levels. But there are some different things  
11 we can do.

12 We can improve statutory disclose  
13 requirements for pharmaceutical firms.  
14 Pharmaceutical firms actually have the best  
15 information on the prevalence of fake  
16 medicines in the market, but they don't always  
17 share what they know.

18 Pharmaceutical security institute  
19 records more instances of so-called  
20 counterfeiting than does the FDA and they're  
21 not mandated to disclose that information  
22 anyway.

1                   So we can work on that. We can  
2 work on strengthen regulatory agencies, which  
3 should be developing better empirical data on  
4 the problem of fake and substandard medicines  
5 because most of it is extrapolated from  
6 anecdotes at this point.

7                   And we don't really understand the  
8 scope of the problem and how large a problem  
9 is compared to, again, the broader problem  
10 with drug quality, which would include  
11 licensed medicines that are not -- don't have  
12 appropriate quality oversight as well.

13                   So these issues are very important  
14 to us. I was speaking earlier today with the  
15 Chirac Foundation about their initiative that  
16 they have in Francophone Africa on this issue.

17                   I was speaking with a  
18 representative, US Pharmacopeia last week,  
19 which has a joint venture with USAID on  
20 medicines quality in malaria medicines in  
21 particular and so on.

22                   So we want to work together to set



1 up an appropriate quality framework, but the  
2 bottom line for us is that if we don't want to  
3 compromise access to medicines, then we can't  
4 be imposing an IPR framework over it because  
5 the cost is too great.

6 MR. McCOY: Do you have any  
7 thoughts on the issue we discussed with some  
8 of the speakers earlier about distinguishing  
9 between high, middle and low income countries  
10 in the Special 301 review and whether and on  
11 what issues its appropriate to make such  
12 distinctions?

13 MR. MAYBARDUK: I was not present  
14 for that conversation, so I don't think I can  
15 comment extensively.

16 MR. McCOY: Let me try to rehash  
17 that. I didn't realize you weren't here, let  
18 me try to rehash the question a little more --  
19 in a little more detail.

20 Several submissions that we  
21 received talked about the treatment of low and  
22 middle income countries in the report and how

1 they should be treated in particular.

2 And earlier in the day that had  
3 prompted the question of whether it was  
4 appropriate for this process to proceed with  
5 different expectations of trading partners  
6 based on their having low, middle or high  
7 income levels and on what issues it would be  
8 appropriate to draw those distinctions.

9 I'm curious if you have any  
10 reactions to that.

11 MR. MAYBARDUK: Well, you know, I  
12 can imagine it makes a difference, of course,  
13 in the amount of resources a country has to  
14 muster to the different areas that are of  
15 concern to USTR.

16 But I can't say that I necessarily  
17 have a clear position on that at the moment,  
18 with the exception of, you know, TRIPS plus  
19 provisions, we believe are not -- don't have  
20 a place at all in Special 301.

21 I mean the TRIPS standard can be  
22 applied because all countries are to be -- all

1 countries that are signatories to the WTO  
2 anyway, are to be held to it. But if it's  
3 TRIPS plus, I don't know why we would  
4 distinguish between low and middle income.

5 MR. McCOY: Well thanks very much  
6 for your comments today. We appreciate it and  
7 let me just say with respect to your folder,  
8 if this is not already contained in your  
9 submission and you want it to be part of the  
10 public record, you should submit it on  
11 regulations.gov as part of the post hearing  
12 statement.

13 MR. MAYBARDUK: Okay. I think --  
14 well the primary function there is there are  
15 a couple of -- they're supplementary  
16 documents, the source documents, for those of  
17 you who are interested in the Ecuador policy  
18 are there.

19 So I don't know if it's necessary  
20 for the submission. But our contact  
21 information is there, my contact information  
22 is there as well if anyone from the panel has

1 any follow up questions, I'd be most happy to  
2 answer them. Thanks for your time.

3 MR. McCOY: Okay. Thank you very  
4 much. Now my understanding is that we have  
5 Mr. Glover next on the schedule, my  
6 understanding is that again falls in the  
7 category of folks who we have been encouraged  
8 in the future to provide telephonic links for  
9 this.

10 Unless there's anyone here who  
11 wants to tell me they've been authorized to  
12 speak on behalf of Mr. Grover.

13 Let's move right on then to the  
14 Social Science Research Council, Joe  
15 Karaganis. So the floor is yours.

16 MR. KARAGANIS: Thank you. And  
17 thank you for the opportunity to testify. I'm  
18 a Program Director at the Social Science  
19 Research Council in New York. SSRC is an 85-  
20 year old non-profit research organization.

21 In this capacity, I'm also the  
22 director of a three-year study of software,

1 film and music piracy in developing countries.  
2 The project involves some 25 researchers and  
3 detailed reports on Russia, India, Brazil,  
4 Mexico, Bolivia and South Africa, many of the  
5 countries that are centrally -- central roles  
6 in the Special 301 reports.

7 In this brief testimony I plan to  
8 simply reiterate my statements about  
9 evidentiary standards around Special 301,  
10 which have been of considerable importance to  
11 us as we examine the connections between  
12 piracy, piracy research and policy making  
13 processes.

14 I'll do it very briefly, but also  
15 been given the final slot, I wanted to say a  
16 few words about why these evidentiary  
17 standards matter and what falls out of the  
18 conversation because of the way evidentiary  
19 standards are currently organized.

20 It often seems to us that Special  
21 301 process sort of misses the forest through  
22 the trees in some important ways that effect

1 the quality of the policies that derive from  
2 Special 301.

3 Because our work is on copyright,  
4 the most relevant research is almost always  
5 the work of the IIPA, the IIPA annual  
6 submissions. So most of our commentary has  
7 sort of been in reference to the IIPA reports,  
8 which for obvious reasons can dominate the  
9 debate about copyright policies in the  
10 targeted countries.

11 And I'll also just make it clear  
12 that I'm restricting my remarks to the sort of  
13 set of countries that we've studied and one of  
14 the things we found is that subject to  
15 piracies of such complexity that you can  
16 almost always identify exceptions.

17 And I do want to be careful about  
18 that because I think that degree of care is  
19 one of the things that drops out of the piracy  
20 conversation all too often.

21 To begin with, I love the IIPA  
22 reports. They are invaluable windows onto the

1 organization of piracy and enforcement in the  
2 targeted countries.

3 They are the richest source of  
4 longitudinal data available to research, but  
5 they are not full assessments of the problems  
6 of piracy or the challenges of enforcement by  
7 a long shot.

8 And they've never met, in my view,  
9 a reasonable interpretation of the standards  
10 that USTR itself requires for research  
11 submissions.

12 And just to repeat those, one is  
13 to provide all necessary information for  
14 assessing the effects of the acts, policies  
15 and practices that are involved.

16 And two, that any comments that  
17 include quantitative loss claims should be  
18 accompanied by the methodology used in  
19 calculating such estimated losses.

20 To rephrase that, there are two  
21 issues at stake. One is indicating that the  
22 assessment, that the research submitted is

1 comprehensive and thorough.

2 And the second is the principle of  
3 showing your work of showing how the work was  
4 conducted, of its transparency and of its  
5 reproducibility.

6 And transparency and  
7 reproducibility have emerged as the gold  
8 standard for government evidentiary standards  
9 increasingly, especially in the wake of the  
10 2000 Data Quality act, the 2005 OMB  
11 interpretation of that act and then various  
12 agency interpretations of the OMB guidelines.

13 In my comment, I've detailed many  
14 of the things that we simply don't know about  
15 the research methods of the member groups that  
16 submit through the IIPA. I'd be happy to  
17 discuss those at more -- in more detail.

18 But let me say a few words about  
19 why I don't feel that they present a  
20 comprehensive picture of the larger phenomenon  
21 that's the subject of the Special 301 process.

22 Perhaps most strikingly in our



1 work, having looked in detail at now six  
2 countries, we have not seen any evidence that  
3 enforcement has affected much less diminished  
4 the availability of pirated media.

5 The reasons for this should be  
6 obvious to all of you, technologies of  
7 reproduction and distribution have plummeted  
8 to an extent that makes the role of industrial  
9 scale intermediaries, like big optical disk  
10 factories, increasingly irrelevant to this  
11 production and circulation of pirated media.

12 The best measure of this expansion  
13 of supply is simply the diminishing price of  
14 pirated media. Between 2000 and 2010, roughly  
15 the period in which we've been looking, from  
16 ballpark \$5 for a high quality DVD to well  
17 under \$1 and sometimes under \$0.50.

18 So there are two -- well one major  
19 exception and two minor exceptions to this  
20 statement about enforcement.

21 There are a couple of areas where  
22 we have noted a demonstrable impact of

1 enforcement efforts and these are worth  
2 separating out from what we see as a larger  
3 failure of the enforcement agenda.

4 Software clearly has an effective  
5 enforcement strategy that is part of a larger  
6 approach to how you work in emerging markets.

7 Because the large software  
8 companies maintain uniform international  
9 pricing they're largely uninterested in  
10 serving wider markets in those countries, they  
11 rely on pirate circulation to acquire market  
12 share in those countries.

13 And then they begin to work with  
14 the large institutions in those countries to  
15 legalize them and to bring them into the fold.  
16 That's the only viable strategy for major  
17 software companies in developing markets, and  
18 the software companies are following it to a  
19 T.

20 That, in our view, is not --  
21 that's an effective enforcement mechanism. Am  
22 I out of time? Shall I --

1                   MR. McCOY: Can I ask you to pause  
2                   there so we can start the question time. And  
3                   I think you'll be able to continue a lot of  
4                   these themes in that. Let me give the floor  
5                   to Susan Wilson from the Department of  
6                   Commerce.

7                   MS. WILSON: Thank you very much.  
8                   Your presentation is very interesting and I do  
9                   hope you get to continue with what you were  
10                  saying and feel free to work that into the  
11                  answer to what I'm about to ask.

12                  You were in the process of  
13                  explaining what's wrong or what's not working  
14                  effectively with the information, the  
15                  gathering and presentation of the information  
16                  that we do get.

17                  As you know, this process is all  
18                  about bringing to light the problems that are  
19                  faced by the right owners in foreign  
20                  countries. I think all of us know that this  
21                  is an -- that there are things we can do  
22                  better and we would very much like to hear

1 what you think we could do better.

2 So if as part of your answer you  
3 want to say a little bit more about what you  
4 think we could -- we're not doing right and  
5 then go into what you think we could do  
6 better, we'd very much like to hear that.

7 MR. KARAGANIS: Absolutely.

8 MS. WILSON: So basically,  
9 continue with what you think we're doing wrong  
10 and then tell us how you think we could best  
11 gather and analyze the information that's out  
12 there.

13 MR. KARAGANIS: I mean virtually  
14 of this industry research is produced for the  
15 USTR and if the industry does not provide an  
16 adequate description of its research methods  
17 or of the key assumptions that inform the  
18 research that would allow you to evaluate it,  
19 then the USTR could simply require that it  
20 meet higher evidentiary standards regarding  
21 how it describes its -- the component research  
22 that goes into the IPR reports.

1                   That would be a very simple  
2                   solution and it would go a long way toward  
3                   addressing concerns about the credibility of  
4                   industry research. Many of those arguments,  
5                   I'm sure, are familiar to you.

6                   There's really even no occasion  
7                   for having that debate in the context of the  
8                   Special 301 process, which is really the  
9                   destination for this research. It was all --  
10                  this massive industry research effort was  
11                  geared up for the Special 301 process.

12                  And as long as Special 301 was a  
13                  relatively close circuit between the USTR and  
14                  industry, being a stickler on evidentiary  
15                  process didn't really matter.

16                  But I think as we've seen this  
17                  year and increasingly as trade policy and IP  
18                  policy begin to impinge on other areas of  
19                  health policy, of, you know, basic economic  
20                  policy.

21                  That kind of closed circuit is no  
22                  longer going to be an option. There are many

1 more stakeholders in the conversation and the  
2 small steps toward opening this in the last  
3 few years of the USTR, which we welcome, we  
4 think really are only the first steps  
5 necessarily.

6 And that the only way to conduct  
7 legitimate policy making in this area will be  
8 to further expand the conversation.

9 MR. McCOY: If you'd like to use  
10 the remainder of the time just to expand on  
11 the points you were already making, please go  
12 ahead.

13 MR. KARAGANIS: Oh, well sure.  
14 There's much more where this came from, I can  
15 assure you.

16 So software is really a case of --  
17 I'm not sure why Microsoft would want anything  
18 else than 95 percent penetration of the  
19 Chinese market, for example. Why it would  
20 trade that for slightly greater enforcement of  
21 its licenses is beyond me.

22 And in fact, Bill Gates and

1 several Microsoft executives have said as  
2 much. That's a very viable, and like I said,  
3 I think the only viable strategy for them.

4 The other areas where we found  
5 relatively measurable effective enforcement  
6 are around efforts to suppress the retail  
7 optical disc trade so that, you know, with a  
8 sufficient police presence you can drive  
9 obviously pirated optical discs out of  
10 established retailers.

11 What that does is it deformalizes  
12 the market further and it's not clear to us  
13 that it has any long term impact on the  
14 supply, but it means that distribution is  
15 conducted through much more transient forms of  
16 street vending, which you can see in all the  
17 countries we've studied.

18 And then the third fairly minor  
19 example, we've seen evidence of success on the  
20 part of movie studios who have enlisted the  
21 police in, you know, major suppressive actions  
22 in the context of major release windows --

1 release windows for major films where they  
2 can, you know, put all the police at work  
3 making sure that there are no pirated copies  
4 of a particular film on the street within a  
5 period of a week or two around the release of  
6 a major film.

7 And, you know, in that respect  
8 sort of ensure the most profitable portion of  
9 the release window for that move.

10 But beyond that, we're very hard  
11 pressed to see any meaningful impact of any --  
12 of these large scale investments in  
13 enforcement.

14 MR. McCOY: Is there anything you  
15 found had a meaningful impact in the area of  
16 internet piracy?

17 MR. KARAGANIS: No. And part of  
18 that is because the internet is not the only  
19 means of distributing digital media at this  
20 point. In fact, P2P piracy in particular is  
21 a diminishing channel for distribution.

22 Increasingly, media collections of



1 thousands of films or songs can be handed on  
2 a thumb drive or on a portable hard drive.

3 The channels for digital  
4 distribution are proliferating in ways that  
5 just are not controllable, even with some of  
6 the more, sort of aggressive proposed measures  
7 like three strikes that apply to the ISP  
8 level. So we think that cat is long out of  
9 the bag in our view.

10 MR. McCOY: This is a stupendously  
11 hopeful note on which conclude our discussion  
12 here about the effectiveness and adequacy of  
13 intellectual property protection and  
14 enforcement around the world.

15 Thank you very much for what was  
16 really a very interesting presentation. I  
17 think we appreciated it and it will be --  
18 we'll look forward to studying your work and  
19 your written submissions in more detail.

20 So thanks very much for all of  
21 that. And by way of closing remarks, I really  
22 have very little to add today except to say

1 that, you know, we have been today in the  
2 immortal world -- in the immortal words of Don  
3 Henley, programmed to receive and we are  
4 grateful for all the information that you've  
5 provided.

6           It's been very helpful, I think.  
7 I think this process of doing the public  
8 hearing, even though the time for each  
9 individual speaker was short, has allowed for  
10 what we had hoped it would allow for, which is  
11 pointing out and highlighting particular  
12 issues that should be commended to the  
13 attention of the committee.

14           So I thank you for listening to  
15 Ambassador Sapiro's charge from the beginning  
16 of the day and helping us to do that. We  
17 greatly appreciate all the views that have  
18 been expressed and will look forward to  
19 considering all of this as part of this year's  
20 Special 301 process.

21           So thank you every one for your  
22 participation. I also wanted to -- I also

1 want to mention that at the -- as a  
2 housekeeping matter, I believe our plan is to  
3 post the audio of this file on the USTR  
4 website so that there will be not a video, but  
5 an audio account of what's been said here,  
6 except for that part when my microphone wasn't  
7 working.

8 But what I'm saying here isn't  
9 important. So that should be available on the  
10 USTR website. I don't know how soon that will  
11 be possible. But any other housekeeping  
12 matters, Paula?

13 CHAIR PINHA: No. Just to remind  
14 people about the period for submitting post  
15 hearing comments will be open.

16 I'll open the docket later on  
17 today and it will be open for a whole week.  
18 So until the 16th, if I'm not mistaken.

19 MR. McCOY: So we're adjourned.  
20 Thank you.

21 (Whereupon, the hearing was  
22 adjourned at 3:55 p.m.)

<b>A</b>				
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