

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

+ + + + +

WEDNESDAY, MARCH 2, 2011

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

PANEL MEMBERS PRESENT:

OFFICE OF THE U.S. TRADE REPRESENTATIVE:

PAULA PINHA, Chair
STANFORD McCOY

U.S. DEPARTMENT OF COMMERCE:
SUSAN WILSON

U.S. CUSTOMS AND BORDER PROTECTION:

THERESA RANDAZZO

U.S. DEPARTMENT OF HOMELAND SECURITY:
LAURIE WEEKS

U.S. DEPARTMENT OF LABOR:
MAUREEN PETTIS

U.S. DEPARTMENT OF STATE:
DAVID DRINKARD

PANEL MEMBERS PRESENT: (Continued)

U.S. DEPARTMENT OF THE TREASURY:
WON CHANG

U.S. COPYRIGHT OFFICE:
MICHELLE WOODS

U.S. PATENT AND TRADEMARK OFFICE:
MINNA MOEZIE

WITNESSES:

JITTIMA SRITHAPORN, Government of Thailand,
Office of Commercial Affairs, Royal Thai
Embassy

KAJIT SUKHUM, Government of Thailand,
Department of Intellectual Property,
Minister of Commerce

DANIEL KOSTOVAL, Government of Czech Republic,
Embassy of the Czech Republic

JOSEPH DVORACEK, Government of Czech Republic,
Embassy of the Czech Republic

FABRIZIO MAZZA, Government of Italy, Ministry
of Foreign Affairs

SALVADOR BEHAR, Legal Counsel for
International Trade, Government of

Mexico

SEAN FLYNN, Global Health Organization

JON GELFAND, BeachBody LLC

JAY TAYLOR, Pharmaceutical Research and
Manufacturers of America (PhRMA)

RASHMI RANGNATH, Public Knowledge

JAMES LOVE, Knowledge Ecology International

JUDY DREOS (phonetic), Doctors Without Borders

JOE KARAGANIS, Social Science Research Council

ROHIT MALPANI, Oxfam America

BRENDAN HUDSON, Balanced IPR Organization

MICHAEL SCHLESINGER, International

Intellectual Property Alliance (IIPA)

PETER MAYBARDUK, Public Citizen

MICHAEL MELLIS, MLB Advanced Media, L.P.

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P R O C E E D I N G S

(10:02 a.m.)

1
2
3 MR. McCOY: Well, thanks,
4 everyone, for coming. I want to welcome you
5 today to the 2011 Special 301 Review Public
6 Hearing. And, thanks, everyone, for coming.

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

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

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

22 Let me just say, for those of you

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

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

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

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

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

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

3 I want to say a word about one
4 change -- or, two changes, in fact, in this
5 year's Special 301 Report, compared to the
6 2010 Report.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 The 11:50 slot for Social Science

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

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

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

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

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

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

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

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

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

22 We are grateful, again, for the

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

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

11 PARTICIPANT: I think they are in
12 security.

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

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

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

22 Let me say, as you are taking your

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

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

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

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

1 are developing.

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

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

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

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

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

22 My name is Kajit Sukhum, and an

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

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

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

11 MR. McCOY: Yes.

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

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

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

1 MR. SUKHUM: Right.

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

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

8 Well, I wish to thank the Special
9 301 Committee for the opportunity to appear
10 before it to present the comment of the Royal
11 Thai Government.

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

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

1 Special 301 Priority Watch List for the
2 following reasons:

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

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

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

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

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

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

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

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

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

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

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

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

1 Embassies were also invited to participate
2 openly.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 Thank you.

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

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

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

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

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

22 MR. McCOY: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 So, to the extent you can

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

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

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

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

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

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

6 Czech institutions includes Czech
7 Customs Administration, Czech trade
8 inspection, the police of the Czech Republic
9 and regional departments of the Business
10 Licensing Office.

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

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

21 This confirms the trend of
22 decreasing availability of goods infringing

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

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

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

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

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

1 came into effect January 1st, 2010.

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

9 In general, there has been a
10 significant increase in the number of persons
11 convicted for IPR-related crimes in 2009 and
12 2010. The details are in the report we have
13 submitted.

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

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

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

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

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

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

1 dimension to it.

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

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

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

22 Fourth point, infringement -- IPR

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

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

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

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

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

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

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

1 them. The source of the whole problem is here
2 in the United States because, for example,
3 members of the Academy of -- of Movie Academy
4 --

5 MR. McCOY: You have about a
6 minute left.

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

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

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

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

5 MR. KOSTOVAL: Thank you.

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

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

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

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

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

5 And then, we were also interested
6 by the fact that on page nine of your
7 submission, it mentioned that there were more
8 that 2,500 people reported to the authorities
9 for audiovisual internet and book piracy and
10 136 arrests.

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

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

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

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

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

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

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

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

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

1 Italian economy.

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

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

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

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

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

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

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

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

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

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

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

22 The hearings started like one

1 month ago and they are going on very,
2 intensely.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 internet joint packages.

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

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

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

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

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

12 We may say that --

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

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

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

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

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

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

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

7 MR. MAZZA: We will.

8 MR. McCOY: -- or otherwise.

9 MR. MAZZA: We will.

10 MR. McCOY: Thank you very much.

11 MR. MAZZA: Thanks to you.

12 MR. McCOY: Appreciate it.

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

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

8 The floor is yours.

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

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

18 Well, we, of course, appreciate
19 the opportunity to appear before you at this
20 hearing and express our views on the Special
21 301 process.

22 For the record, I am Salvador

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

3 Let me say firstly, that these
4 comments will be cumulative of what I said in
5 2010. Some -- most of the actions we have
6 done in the past continue. It is a continuous
7 effort. We don't change. We move forward and
8 we accumulate, so I would like you to go back
9 to the files and see my testimony before.

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

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

18 As our president stated in May
19 2010, innovation and investment in technology
20 and human capital are keys to sustain economic
21 growth and competitiveness involving Mexico
22 and the U.S., and the protection of

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

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

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

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

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

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

5 With regards to enforcement taken
6 by the Attorney General's Office, responsible
7 for IPR crimes, we have more than 1899
8 premises, search warrants, 3,000 -- more than
9 3,000 operations in flea markets and streets,
10 97 laboratories dismantled just in this year,
11 16 people in jail time and one -- more than
12 1,000 people detained.

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

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

22 Moreover, the National Institute

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

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

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

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

22 Now, to address your question

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

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

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

21 Collaboration, training and
22 increasing intelligence-sharing among law

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

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

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

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

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

1 several hundred millions of dollars, and in
2 Mexico it resulted in the seizure of more than
3 300 tons of counterfeited goods.

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

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

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

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

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

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

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

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

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

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

5 In 2009, the government of Mexico
6 conducted more than 460 operations in which 48
7 -- 38 million pieces of counterfeited goods
8 were confiscated. The program will have
9 generated approximately \$220 million in the
10 black market.

11 MR. McCOY: You have about a
12 minute left.

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

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

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

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

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

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

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

1 infringing goods at the border.

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

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

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

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

17 Thank you very much.

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

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

5 So, thank you very much for being
6 here today.

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

11 MR. McCOY: Thank you. Thank you.

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

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

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

22 So, quickly, in terms of the -- in

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

7 And we also noted on pages 23 and
8 24 of your submission that you had talked
9 about the Special 301 report in 2010,
10 encouraging countries to adopt ex officio
11 border enforcement of patents and we would be
12 interested in, if you can explain where you
13 perceive that encouragement as existing in the
14 -- in the 2010 Special 301 Report.

15 With that, the floor is yours for
16 ten minutes.

17 MR. FLYNN: Sure. Thank you very
18 much.

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

22 MR. McCOY: We will have to wait.

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

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

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

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

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

22 And that is the comment from the

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

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

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

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

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

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

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

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

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

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

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

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

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

1 and provide for the remaining 10 or 20
2 percent.

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

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

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

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

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

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

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

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

22 So you need on the back end, if

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

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

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

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

22 You have to have policy tools on

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

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

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

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

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

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

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

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

22 I'll stop there for a minute. I

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

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

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

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

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

1 of time.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 MR. FLYNN: I'm particularly
5 talking about within Special 301. There is a
6 section last year. There was a section in
7 2009 that identifies programs for having
8 unfair reimbursement programs.

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

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

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

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

21 MR. FLYNN: Do they mean something
22 else?

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

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

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

22 So, what do you mean when you

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

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

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

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

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

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

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

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

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

22 What's the discriminatory aspect?

1 What's the aspect that violates a trade
2 principle?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 And that's within Medicaid.
19 That's within State reimbursement policies.
20 That's within Veterans Administration
21 purchasing. That's within GSA purchasing.

22 MR. McCOY: Okay. Thanks, Sean.

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

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

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

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

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

21 But, in your submission you
22 provided some interesting statistics about

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

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

11 MR. GELFAND: I will, for sure.

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

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

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

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

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

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

14 In addition to our core in-home
15 products, we also now have a network of peer-
16 to-peer person distributors. On the
17 multilevel marketing network we have over
18 55,000 Americans that distribute our products.

19 The company's growing due to the
20 success of our fitness products. Last year,
21 alone, in a challenging economy, we employed
22 138 new Americans, bringing our total up to

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 We do have a lot of people that

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

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

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

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

1 great enough deterrence, especially
2 internationally, to prevent piracy.

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

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

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

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

22 And, even when you spend all that

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

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

11 MR. McCOY: You have about a
12 minute left.

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

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

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

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

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

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

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

15 MR. GELFAND: Thank you.

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

19 MR. GELFAND: Yes.

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

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

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

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

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

1 together to tackle this humongous problem.

2 So, the more data we can provide, we are more
3 than willing to do that.

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

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

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

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

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

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

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

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

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

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

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

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

1 of American, known in short as PhRMA.

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

6 To accomplish these goals,
7 biopharmaceutical companies invested over \$64
8 billion in new research and development in
9 2009, with almost \$45 billion invested
10 directly by PhRMA's member companies.

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

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

1 strong intellectual property protection.

2 The result has been significant
3 research and development investment by our
4 members in the United States over the last 30
5 years.

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

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

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

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

3 This highlights why the Special
4 301 process is so critically important to the
5 biopharmaceutical sector, patients globally
6 and America's economy and health care sector.

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

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

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

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

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

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

21 Second, assist countries to fully
22 implement and enforce international IP

1 obligations.

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

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

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

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

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

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

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

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

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

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

1 intellectual property that our companies have
2 invested in these products.

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

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

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

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

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

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

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

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

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

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

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

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

1 the case going forward with the TPP.

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

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

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

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

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

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

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

11 Thanks, Jay.

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

14 (No response.)

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

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

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

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

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

10 MR. McCOY: Thank you for coming.

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

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

22 So, although we don't identify

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

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

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

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

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

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

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

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

22 Second, not use the Special 301

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

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

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

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

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

22 Therefore, we urge you not to be

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

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

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

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

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

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

1 obligations too onerous on their limited
2 resources.

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

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

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

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

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

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

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

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

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

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

9 Thank you, and I look forward to
10 your questions.

11 MR. McCOY: Thank you, Rashmi.

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

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

1 301 Report, on page two, a section on country
2 placement that elaborates a bit on the Special
3 301 decisionmaking process.

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

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

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

22 For example, I think this year's

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

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

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

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

1 MR. McCOY: In that same spirit,
2 Rashmi, we would be interested in any examples
3 that you would care to provide, either now or
4 in a follow-up submission of where the Special
5 301 Report has treated the existence of a
6 limitation and exception in foreign copyright
7 law as a trade barrier.

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

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

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

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

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

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

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

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

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

1 International after lunch.

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

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

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

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

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

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

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

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

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

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

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

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

7 Now, I will shift to the other
8 gear.

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

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

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

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

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

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

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

1 with public health problems in developing
2 countries.

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

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

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

14 MR. LOVE: Yes. Yes, sir.

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

1 stabilization.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 So, I just think, as your work

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

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

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

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

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

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

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

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

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

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

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

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

1 drive into the process.

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

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

13 That concludes my oral testimony.

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

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

1 last couple of years.

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

4 MR. LOVE: Appreciate that.

5 MR. McCOY: Yes, go ahead, David.

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

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

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

22 MR. LOVE: As you know, there's

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

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

5 MR. LOVE: Thank you.

6 MR. McCOY: Thanks, James.

7 MR. LOVE: Thank you very much.

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

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

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

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

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

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

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

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

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

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

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

20 Through the release of the Special
21 301 Watch List every year, the U.S. Government
22 is trying to drive countries to implement

1 intellectual property standards above
2 requirement for international law.

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

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

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

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

1 their governments or they cannot afford them.

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

10 MSF could not provide treatment to
11 160,000 people in more than 30 countries
12 without generic competition. The U.S.
13 Government has also acknowledged the
14 significance of generic competition in its
15 global AIDS contributions.

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

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

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

3 MSF data shows how this will
4 impact the cost of treatment programs. The
5 WHO recommended second-line treatment is
6 around 4.4 times more expensive than the most
7 affordable front-line regimes, and extended
8 third-line regimes are estimated to cost about
9 2,200 U.S. Dollars for one-year treatment.

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

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

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

1 all for generic competition to continue.

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

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

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

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

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

6 I have a point on -- also on
7 patentability criteria. We are especially
8 concerned also as Knowledge Ecology
9 International, with a reference including the
10 2010 Special Report to produce stable forms of
11 drugs or new means of drug delivery in
12 reference to Section 3-D.

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

21 Public health implications and
22 access cost, monopoly protection in developing

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

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

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

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

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

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

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

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

1 bringing prices down as robust generic
2 competition does.

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

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

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

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

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

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

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

22 Thank you.

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

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

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

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

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

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

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

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

1 very challenging because we find the Special
2 301 list to be full of generalities, and to be
3 very lacking of specificity.

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

8 On the patentability criterias,
9 the language is completely unclear and very
10 general, but even in compulsory license, when
11 you are criticizing Thailand and without
12 saying it, for using compulsory license, and
13 you are asking Thailand -- the Thailand
14 government to incorporate pharmaceutical
15 companies, you seem to be asking Thailand
16 government to incorporate pharmaceutical
17 companies and their deliberation process in
18 compulsory license.

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

1 for us to respond if not.

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

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

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

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

1 MS. DREOS (phonetic): Okay.

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

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

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

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

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

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

5 Social Science Research Council.
6 Okay.

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

1 think have implications for how the Special
2 301 Report handles questions of software
3 enforcement.

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

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

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

22 So, if these comments interest you

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

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

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

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

1 301 Reports.

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

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

17 The advisory groups to the Special
18 301 process still compose largely of the dozen
19 or so industries that helped found Special 301
20 20 years ago. Why aren't there consumer
21 groups as part of those advisory committees?
22 Why aren't there other kinds of organizations

1 with a structural voice in the process?

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

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

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

17 And just to speak a little -- say
18 a couple of words about software piracy and
19 the organization of software markets, Special
20 301 Reports talk repeatedly about software
21 piracy. In fact, it's probably fair to say
22 that over the last ten years debates about

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

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

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

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

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

22 The IDC dropped this one-to-one

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

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

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

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

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

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

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

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

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

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

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

11 MR. KARAGANIS: Sure.

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

17 MR. KARAGANIS: Sure.

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

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

1 through civil means.

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

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

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

1 language.

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

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

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

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

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

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

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

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

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

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

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

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

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

22 Before I start, sort of following

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

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

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

19 Any thoughts around that or --

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

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

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

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

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

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

12 MR. McCOY: Well --

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

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

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

22 MR. McCOY: Concerns of what --

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

4 MR. McCOY: Go ahead.

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

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

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

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

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

22 With the remainder of my testimony

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

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

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

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

1 property laws.

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

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

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

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

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

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

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

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

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

1 in total approximately 15 percent of global
2 pharmaceutical demand.

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

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

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

1 efficacy.

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

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

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

1 We are concerned that the Special
2 301 Report, in assessing appropriate levels of
3 IP protection, ignores the high rate of
4 poverty in middle-income countries.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 MR. MALPANI: For the record,

1 Rohit Malpani from Oxfam America.

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

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

10 I have had about 12 years of
11 experience in IPR enforcement efforts, and
12 that's the issue that I want to talk with you
13 about today, the USTR's role in that.

14 I formerly worked with the U.S.
15 movie industry. I'm no longer associated with
16 them, to be clear, and have had experience in
17 running or supervising IPR enforcement
18 programs in at least 20 countries and two
19 different continents.

20 I have also had about 12 years of
21 experience with the 301 process and I would
22 like to say thank you for all of the work that

1 you've done over the last 12 years. It has
2 been a very effective leverage for us in
3 improving IPR enforcement for U.S. companies
4 and U.S. products.

5 I would also like to mention,
6 completely off-topic, that a 95-year or more
7 extension of copyright is not a little fish to
8 fry. It's rather a very cute little mouse to
9 protect, so I hope you would continue to do
10 that.

11 It is my hands-on experience in
12 those countries that brings me to talk with
13 you today about an issue that I also consider
14 to be a very big fish for you to consider and
15 fry, and that's corruption.

16 Corruption, piracy and
17 counterfeiting all go hand-in-hand. It's been
18 my experience that the underlying problem in
19 IPR enforcement really has much more to do
20 with corruption than any other issue that I
21 have come across.

22 Corruption and ineffective IPR

1 enforcement goes hand-in-hand, and corruption
2 in the inability for American companies to
3 properly sell their product in foreign markets
4 goes hand-in-hand.

5 Corruption is a fundamental
6 impediment to effective achievement of U.S.
7 trade policy and trade law objectives.
8 Anticorruption, on the other hand is a
9 fundamental policy, a fundamental principle of
10 U.S. foreign policy.

11 It is an issue that, at the very
12 highest levels from the President to the
13 Secretary of State, to the Attorney General,
14 has been stated as a commitment and priority
15 of this Administration.

16 So, it's really our purpose today
17 just to take a few minutes to encourage you to
18 make sure that anticorruption and trade
19 policy, particularly as it affects IPR
20 enforcement, go hand-in-hand.

21 We believe that USTR can have an
22 immediate impact on improving IPR enforcement

1 in a number of markets where we have problems,
2 simply by addressing this issue.

3 Now, it's kind of unusual, I
4 think, that you -- for to bring the issue up
5 saying that IPR can address it and
6 specifically can address it by bringing up the
7 issue with U.S. companies.

8 But that not only is consistent
9 with comments that the U.S. Attorney General
10 and the Secretary of State have made, it's
11 also very much consistent with reality.

12 If we take a look at how IPR
13 enforcement works in foreign countries, it
14 really is the private sector. It is U.S.
15 companies that run it. It is -- in nearly
16 every country where there are IPR enforcement
17 efforts, 75, 80 percent of all enforcement is
18 done in coordination with the U.S. private
19 sector or their foreign agents.

20 I managed millions of dollars in
21 various countries that we used to contract
22 agents, foreign agents to do our work. You

1 rarely see a U.S. Government official actually
2 doing the hands-on antipiracy or IPR
3 enforcement, it's the U.S. private sector,
4 either directly or through associations.

5 Now, the problem really is this,
6 is that there are millions of dollars that are
7 used to hire foreign agents. They have
8 incredible financial incentives to get results
9 for U.S. companies.

10 They work in an environment that's
11 corrupt. It's just basically corrupt on
12 almost every level in a lot of countries, and
13 they often have very little control, and
14 certainly no awareness of U.S. position on
15 anticorruption.

16 So, concerning USTR's role and the
17 role of 301, I had mentioned previously that
18 301 actually does have an important aspect, an
19 important impact in leveraging IPR enforcement
20 in a lot of countries and I have used that,
21 myself, and have had other people use it.

22 Seen from the U.S. point of view,

1 you know, sometimes people just kind of raise
2 their eyebrows at the 301 list, but the truth
3 of the matter is, we have used that, that
4 listing and admittedly has been our PR effort.

5 It significantly impacts public
6 opinion and the opinion of governments in
7 those areas. And, you know, the problem with
8 that is that -- what that does is it, then,
9 gives a certain amount of credibility to the
10 local effort.

11 It is almost -- it is very
12 difficult sometimes determining where U.S.
13 influence stops and where foreign agents that
14 work for U.S. companies begin.

15 And for enforcement officials it
16 is -- it can lead to some difficult
17 situations, particularly when there is not
18 sufficient controls.

19 Given that, what we have done --
20 and I hope you will take a few minutes to read
21 the submission that we had. We would like
22 USTR to take at least three specific actions

1 that we do believe would have an immediate
2 impact.

3 The first is discussing any new
4 301 Report, and discussing it as a serious
5 position consistent with the seriousness that
6 it's been given by the President, by the
7 Secretary of State and by the Attorney
8 General, at least.

9 Second is working with the U.S.
10 Intellectual Property Enforcement Coordinator,
11 who -- I am not sure his -- I believe he is
12 not here today, but as I understand, USTR will
13 be working with the IPEC to come up with
14 action plans, and we would encourage that
15 those action plans include anticorruption
16 efforts. It could be education, awareness and
17 especially for reporting.

18 And third, and to include that in
19 your -- on going forward annual reports to the
20 Ways and Means Committee and to the Senate
21 Finance Committee as a way of showing how we
22 have -- how you are addressing that issue.

1 And, given that, if you have any
2 questions.

3 MR. McCOY: We appreciate your
4 input on this. A couple of questions,
5 thoughts. One is, are there particular
6 countries where you feel this needs to be
7 addressed?

8 I recall, in past reports, we have
9 talked about local protectionism and
10 corruption as an IP enforcement issue in
11 China. So, it has come into the picture from
12 time to time before.

13 I think it is an interesting
14 suggestion that we do this more -- more
15 comprehensively, but one thing that would be
16 helpful to us is your thoughts on where there
17 are particular countries you would like us to
18 look at or if you are more asking us to look
19 at other efforts that are already undertaken
20 to assess corruption overseas and sort of
21 incorporate those into our thinking?

22 MR. HUDSON: Well, specifically

1 for those countries that you are going to list
2 and for those countries for which you will
3 have an action plan done with IPEC, that it
4 should be included in every single one of
5 those.

6 Now, it is difficult to say that
7 only third-world countries have corruption.
8 The truth of the matter is, you can go from
9 northern Europe to Southern American, to Asia,
10 and you are going to have those problems for
11 the reasons that I have given you.

12 There are extreme financial
13 advantages and incentives and a lack of
14 control. So, I would say included in every
15 country that you list.

16 MR. McCOY: Okay. Thanks very
17 much. If you would like, as a matter of, you
18 know, posthearing submission, to provide us
19 any more details on particular countries and
20 how the -- how the anticorruption issue has
21 concretely impacted IP enforcement in those
22 countries, that's always welcome.

1 I know we have received
2 considerable input from our folks in China on
3 that, but should you want to expand that out
4 a bit, by all means, please do so.

5 MR. HUDSON: Thank you. Thank you
6 for your time.

7 MR. McCOY: Thanks for joining us
8 today. We appreciate it.

9 The next speaker on our list is
10 International Intellectual Property Alliance.

11 Michael, welcome. I wanted to --
12 I wanted to ask you the -- first, thanks for
13 your highly country-specific recommendations.

14 We -- most of our questions, as we
15 read through your submission, related to
16 particular countries where your perspective
17 has changed in one way or another from last
18 year, so I might just ask you a blanket
19 question.

20 If you can take advantage of your
21 remarks today to mention a couple of the most
22 prominent countries where you feel the

1 circumstances have changed, and make sure we
2 are apprised of the change in circumstances
3 that you feel is relevant, I think that would
4 be of greatest interest based on the feedback
5 I have received from the members of the
6 Subcommittee.

7 MR. SCHLESINGER: Certainly, Stan.
8 Thank you very much. I will try to do so. To
9 the extent that I fail, you can remind me
10 again at the end.

11 Well, good afternoon. I'm Michael
12 Schlesinger. I'm counsel to the IIPA. I'm
13 appearing before you on behalf of IIPA, a
14 coalition of seven associations, 1900
15 companies which make up the major sectors of
16 the U.S. copyright industries.

17 We appreciate the opportunity to
18 weigh in on the 2011 Special 301 process, and
19 we thank you for your time and want to thank
20 you for your efforts here in Washington and
21 around the world.

22 In this year's Special 301

1 submission, IIPA has identified 40 countries
2 that deny adequate and effective protection of
3 intellectual property rights and/or deny fair
4 and equitable market access.

5 By denying such basic protections
6 and access to their markets, these countries'
7 practices harm our creative content businesses
8 that bring movies, music, software, video
9 games and books to the world.

10 These businesses remain critical
11 to the future growth of the U.S. economy,
12 provide millions of jobs and help expand
13 exports in line with the Administration's
14 goals.

15 It should, therefore, be a
16 critical part of the Special 301 process to
17 define concrete plans of action for the year
18 ahead and longer term, to improve copyright
19 protection, reduce global piracy levels and
20 open markets to U.S. copyright content around
21 the world.

22 There are massive costs

1 attributable to piracy, market access
2 barriers, investment barriers and
3 discriminatory treatment to U.S. firms.

4 Unfortunately, today, not only
5 physical piracy, but more than ever, internet
6 and mobile piracy threaten businesses built on
7 copyright protection.

8 Legitimate online business models,
9 while growing in number and size, are still
10 dwarfed by and have significant difficulty
11 competing with the massive proliferation of
12 illegal services.

13 IIPA's filing seeks to help the
14 U.S. Government define and seek implementation
15 of concrete solutions. We do this through
16 identifying key copyright industry's
17 initiative and challenges for 2011.

18 We first address the overarching
19 need for deterrent enforcement responses to
20 copyright piracy through passage and
21 implementation of good TRIPS-compatible and
22 WIPO internet treaties, WCT and WPPT-

1 compatible laws and enforcement procedures to
2 deal with specific problems.

3 We discussed the enormous
4 challenge posed by internet and mobile piracy,
5 including the need for a multifaceted
6 approach, a strong legal framework,
7 appropriate levels of responsibility for
8 online infringements that foster cooperation
9 among all stakeholders involved in the online
10 supply change for creative content and strict
11 enforcement by governments against online
12 theft of copyright.

13 As one example of this problem,
14 the entertainment software association study
15 found that in 2010, ESA vendors detected more
16 than 144 million connections by peers
17 downloading illegally only some of ESA members
18 titles.

19 The top five countries in that
20 study were Italy, China, Spain, Brazil and
21 France.

22 We also point out the independent

1 and Envisional study which concluded that
2 almost 24 percent of all worldwide internet
3 traffic is copyright infringing.

4 The IIPA submission also addresses
5 the unauthorized use of software within
6 businesses, enterprise and user software
7 piracy, the principal and most damaging form
8 of infringement to the business software
9 industry today.

10 More than \$55 billion worth of
11 unlicensed software was used globally in 2010,
12 including more than \$32 billion of U.S. vendor
13 software.

14 This problem requires a specific
15 enforcement response, including deterrent
16 level civil and criminal actions, inspections,
17 audits, and ensuring legal software licensing
18 practices ensue among corporate entities and
19 governments, thereby setting a good example
20 for the populace-at-large.

21 And, if I have time at the end I
22 would love to respond to the statements of my

1 colleague at SSRC.

2 We talk about the critical nature
3 of technological protection measures, TPM's,
4 which are used to foster new business models
5 for distributing creative content and also use
6 to ensure that works made available in the
7 digital and online environments are not easily
8 stolen.

9 We highlight the need to address
10 the ever-increasing threat from those who
11 build their business models around providing
12 devices, tools or technologies to gain
13 unlawful access to our content, including our
14 video games and defeat these TPM's.

15 Examples include mod chips, game-
16 copiers, softmodding. These are just some of
17 the sophisticated techniques used to ravage
18 the console-based video game market, as an
19 example.

20 Redress illegal camcording by
21 which 90 percent of newly-released movies that
22 are pirated can be traced to those who use a

1 digital recording device in a movie theater to
2 literally steal the image and sound right off
3 the screen.

4 One thousand major motion pictures
5 were stolen this way in 2010, causing dramatic
6 harm to the markets for those motion pictures.

7 This harms U.S. films, but it also
8 harms the local film market. For example, we
9 had 52 detections of Thai films that were
10 stolen right off the screen in 2010, illegally
11 camcordered. We also show a 48 percent increase
12 in 2010 in illegal camcords in Thailand.

13 The motion picture industry
14 urgently needs help to address this problem
15 through adequate laws, training of cinema
16 personnel and strict enforcement.

17 Submission addresses both piracy,
18 large-scale photocopying of entire books,
19 commercial print piracy and increasing
20 unlawful digitizations or online copying of
21 published materials.

22 This form of piracy also needs

1 governments to recognize the extreme harm, and
2 we need help to set a good example in the
3 education sector.

4 Redress game cartridge
5 counterfeiting which is essentially a Chinese
6 export, damaging the world's markets for those
7 games. We also discussed physical optical
8 disk piracy and signal theft of pay TV
9 content.

10 India accounts for more than \$1
11 billion in value in unauthorized pay TV
12 content through individual tapping into
13 systems illegally, illegal distributions and
14 underdeclaration.

15 The IIPA submission also draws out
16 the direct relationship between piracy and
17 market access barriers and calls upon
18 policymakers to recognize and draw on this
19 relationship to help make the reduction of
20 market access impediments a key component of
21 ongoing efforts to combat piracy.

22 Simply put, if we can't bring in,

1 publish, show, sell, promote creative products
2 in countries due to artificial barriers, we
3 cannot do business there.

4 Such barrier is an additional
5 burdensome, discriminatory requirements such
6 as censorship on foreign titles, such as we
7 experience in China or undue costs, such as
8 unusually high customs valuations, as is being
9 introduced in Indonesia, act to subsidize
10 pirates who do not have to deal with such
11 barriers.

12 Such barriers also stifle the
13 growth of local creative communities since
14 they discourage creative collaborations.

15 Recognizing all these challenges
16 in each country report, in our submission,
17 IIPA has sought to identify specific priority
18 actions, short-term goals with expected real
19 commercial returns as well as medium and
20 longer term systemic changes.

21 There are commonalities in the
22 report that are highlighted there, and you can

1 take a look at them, but I think I'll stop
2 here to leave a couple of minutes for any
3 additional questions.

4 MR. McCOY: You've got exactly a
5 couple of minutes, and I think what would be
6 of greatest interest to the subcommittee is if
7 you could mention a couple of countries that
8 you think are particularly notable where
9 something has changed, causing you to change
10 your perspective.

11 I think the one that stood out to
12 the Subcommittee was Saudi Arabia where a year
13 ago I think IIPA had recommended favorably on
14 their removal from the list and this year your
15 view has changed, but we would be open to
16 hearing about others as well.

17 MR. SCHLESINGER: Well, sure.
18 Very, very briefly on Saudi Arabia, obviously
19 we are talking about the largest potential
20 market in the Middle East, in the Gulf.

21 The other countries in the Gulf
22 have effectively addressed their -- most

1 intellectual property concerns, not all, but
2 Saudi Arabia is the one market where we still
3 face difficulties.

4 We note in the report that
5 legitimate revenues in the UAE are actually
6 greater than the legitimate revenues that we
7 received in Saudi Arabia, notwithstanding the
8 exponentially larger size of the potential
9 Saudi market populace.

10 We also note that gains that we
11 expected to see in the criminal enforcement
12 process were not achieved in 2010, and thus,
13 we are asking for USTR, once again, to note
14 Saudi Arabia and to watch the developments
15 there.

16 A couple other markets, just to
17 mention, ones where we have recommended an
18 elevation from previous years. In the
19 Philippines we have not seen sufficient
20 progress on implementing the new anti-
21 camcording law.

22 We also have a situation where,

1 frankly, the court system is so unreliable
2 with respect to the issuance of search
3 warrants and quashal of the search warrants,
4 that it's very hard for us to devote
5 significant resources into a system where we
6 don't know whether we will get any justice at
7 the end of the day or actual protection.

8 So, those are just two reasons.
9 In Costa Rica we saw a roll-back in copyright
10 protection, in particular, with respect to
11 phonograms and performers.

12 In Viet Nam and in Spain we see
13 the rapid increase in the internet piracy
14 problem, proliferation of online access. Viet
15 Nam doesn't like to hear it, but they are
16 going down a very similar road to China in
17 terms of relying mainly on administrative
18 enforcement mechanisms and not having any
19 effective criminal enforcement mechanism place
20 or one that is arguably in violation of their
21 BTA obligations. You could --

22 MR. McCOY: Let me say, just thank

1 you very much.

2 MR. HUDSON: Sure.

3 MR. McCOY: A quick highlighting,
4 and I also want to thank you for what I'm sure
5 must have been a considerable effort to
6 streamline your two-phone-book-sized
7 submission into a one-phone-book-sized
8 submission. Those of us who have to read them
9 all appreciate it greatly.

10 But, thanks for your remarks
11 today. If there's anything that you needed to
12 say that you weren't able to say, we welcome
13 a posthearing submission, but we have got your
14 submissions and we are pouring over them.

15 MR. HUDSON: Thank you very much.
16 I would certainly like to clarify some of the
17 SSRC's statements that have been made today
18 and we may do that in writing. Thank you.

19 MR. McCOY: Thank you very much.

20 The next speaker we have is Public
21 Citizen. Welcome. Thanks very much for
22 coming. Thanks very much for coming, Peter,

1 and we are looking forward to your
2 presentation. The floor is yours for ten
3 minute.

4 MR. MAYBARDUK: Thank you, Stan.

5 Thanks, everyone, very much for
6 holding this hearing. My name is Peter
7 Maybarduk. I'm the Access to Medicines
8 program director at Public Citizen, a
9 nonprofit consumer advocacy organization based
10 here in Washington, D.C. We have 80,000
11 members, 200,000 members and supporters.

12 In my hearing statement I offered
13 to yield my statement time for questions
14 regarding Ecuador's compulsory license issued
15 in April of this year and their Access to
16 Medicines policy.

17 As some of you know, Public
18 Citizen has provided technical assistance to
19 Ecuador in the Access to Medicines area,
20 assisted in the development of the policy and
21 ensuring its TRIPS compliance.

22 So, I'm more than happy to answer

1 any questions that you have. In the absence
2 of the questions at the outset, I can walk you
3 through some of the documents I have just
4 handed you, if that would be for the best.

5 MR. McCOY: I think we would
6 welcome that.

7 MR. MAYBARDUK: Okay. Okay.
8 Well, as a threshold matter, I think it merits
9 saying that Public Citizen does support many
10 of the criticisms articulated today regarding
11 the 301 process.

12 But we would like to focus in on
13 one country that is making use of its public
14 health rights under WTO rules and the Doha
15 Declaration.

16 We have been working with the
17 government of Ecuador for several years, not
18 in any paid capacity, but consistent with our
19 mission to improve access to medicine
20 worldwide.

21 And we have maintained a dialogue
22 during that process with U.S. Government

1 agencies and with the U.S. Government, the
2 U.S. embassy in Quito regarding any updates as
3 a part of the compulsory licensing Access to
4 Medicines policies out of Ecuador.

5 I'd like to have a look real quick
6 at the 2010 Special 301 Report and note some
7 language on page 13 which we appreciate.

8 Consistent with these views, the United States
9 respects our trading partners' rights to grant
10 compulsory licenses in a manner consistent
11 with the provisions of the TRIPS Agreement and
12 encourages our trading partners to consider
13 ways to address their public health challenges
14 while maintaining intellectual property
15 systems that promote investment, research and
16 innovation.

17 I would contend that Ecuador's
18 process, certainly consistent with the
19 provisions of the TRIPS Agreement and it will
20 be important in terms of demonstrating the
21 veracity of this statement in the 2010 report
22 to not list, to make any reference to Ecuador

1 for compulsory licensing policy in the 2011
2 report.

3 In your packets here, the comments
4 that we submitted to the 301 process,
5 narrative brief review because these hold
6 true, and the compulsory license, itself, is
7 included both as a -- both in the official
8 Spanish and an unofficial translation. For
9 any legal questions, please refer back to the
10 original Spanish.

11 But on October 23rd, 2009,
12 Ecuador's president, Rafael Correa, issued
13 Decree 118 declaring access to priority
14 medicines affecting the health of the
15 Ecuadorian population to be a matter of public
16 interest.

17 Although not required by TRIPS,
18 the decree satisfies an Andean Community
19 Proviso enabling Ecuador's Patent Office, in
20 cooperation with the Ministry of Health, to
21 receive compulsory license requests and issue
22 licenses case-by-case on public interest

1 grounds.

2 Since that time, in April of 2010,
3 Ecuador issued its first compulsory license
4 for the HIV-AIDS medicine Ritonavir, which is
5 an essential component of the Kaletra second-
6 line AIDS treatment, say the terms of the
7 license, as I said, are included there.

8 It's a license for public use
9 satisfying -- and now we have biddings between
10 Abbott and Cipla, which is represented in
11 Latin America by ESKEGROUP to help reduce
12 costs in that treatment.

13 So, I guess, just to highlight
14 some of the ways in which it's a TRIPS -- you
15 know, in which it's a TRIPS-compliant policy
16 and a transparent policy, the patent office in
17 Ecuador has met at least twice with the
18 American embassy in Quito. Probably several
19 more times by now, as well as with the patent-
20 based pharmaceutical companies' trade
21 association, IFI in Ecuador, which issued a
22 public statement accepting the decree.

1 The compulsory license policy
2 adopts many TRIPS terms verbatim,
3 nonexclusivity, predominant supply of the
4 domestic market, adequate compensation patent
5 holders, license review and termination.

6 Interagency agreement is required
7 for the issuance of public interest licenses,
8 so there is a process and there is a case-by-
9 case evaluation.

10 The royalty payment system --
11 well, actually, at this juncture probably
12 merits turning to earlier this year when
13 Ecuador's trade preferences were being
14 reviewed there was a submission by the
15 Emergency Committee for American Trade to
16 USTR, which put forward several what we would
17 characterize as -- well, certainly unsupported
18 claims regarding that policy.

19 And in there you have our
20 submission clarifying the truth behind some of
21 these questions. ECAT stated that TRIPS
22 provides countries with the right to use

1 compulsory licensing when there's a national
2 health emergency but, of course, under WTO
3 rules, countries have the freedom to determine
4 the grounds upon which such licenses are
5 granted.

6 ECAT stated that Ecuador appears
7 to be basing licensing findings on the
8 presidential "degree" rather than making
9 individualized decision, but it does require
10 -- but, in fact, the decree requires licensed
11 applicants -- that license applicants, each
12 require that a license request be evaluated
13 according to the supported circumstances of
14 each case, must be reviewed case-by-case by
15 the patent office and the Ministry of Public
16 Health.

17 ECAT accuses Ecuador of failing to
18 promptly notify rightholders and asserts that
19 patent holders are denied the ability to
20 participate in a meaningful way but, in fact,
21 Abbott was notified of ESKEGROUP's license
22 request within days of admitting the completed

1 license application for consideration, and
2 five weeks before the compulsory license was
3 granted on April 14th and so on.

4 So, we considered some of the
5 criticisms that have been put forward of
6 Ecuador's policy. While they are unsupported,
7 it's very hard to find any evidence for the
8 claims.

9 In last year's 301 Report, on page
10 31, Ecuador is cited in the realm of
11 compulsory licensing as follows: "The United
12 States will continue to monitor recent
13 developments concerning compulsory licensing
14 of pharmaceutical and agricultural chemical
15 products in Ecuador, bearing in mind the
16 discussion of the Doha Declaration on TRIPS
17 and public health in Section One of this
18 report."

19 With the license issued since,
20 what we would like to see this year, as
21 articulated also in last year's comments,
22 "USTR should not cite Ecuador for any matter

1 related to that country's TRIPS-compliant
2 protocol for the compulsory licensing of
3 pharmaceutical patents in the public interest.

4 "USTR should also not sanction
5 Ecuador's compulsory licensing protocol
6 indirectly, for example, through imprecise
7 references to alleged IPR protection failings
8 in Ecuador through otherwise unwarranted
9 elevation in Ecuador's Watch List status."

10 So, to return to the point, if,
11 indeed this language from the 2010 report on
12 page 13 holds true, that the United States
13 respects partners' rights to grant compulsory
14 license consistent with the TRIPS Agreement,
15 there's a perfect opportunity here to
16 demonstrate the truth of that claim by
17 omitting any reference within the 301 context
18 to Ecuador's compulsory licensing policy.

19 And given that great pains have
20 been taken -- and I'm happy to elaborate on
21 that -- to ensure TRIPS compliance of that
22 policy, I think it would be very difficult to

1 support any -- to support any other treatment
2 in the report, any mention whatsoever of
3 Ecuador's licensing policy in the report
4 without coming into a contradiction with the
5 language on page 13 with the assurance about
6 respecting partners' rights to protect public
7 health under WTO rules.

8 I suppose that's my submission.

9 I'm very happy to answer questions about this
10 policy. Last year there were -- you know, I
11 also offered to answer questions about the
12 interagency process on counterfeit drugs.
13 There were a number of questions for public
14 health groups last year on that set of issues.

15 MR. McCOY: I think it has been a
16 really helpful drill-down for us on the
17 situation in Ecuador if we have -- you know,
18 if we have questions on this going forward.
19 As folks on the Subcommittee study the
20 materials, we will know where to find your
21 but, for the time being, we appreciate the
22 input and your time today to educate us

1 further on the work Public Citizen has been
2 doing in Ecuador.

3 MR. MAYBARDUK: Yes. Let me add
4 one addendum, actually. That occurs to me --
5 we gathered that some of the concern around
6 Ecuador's policy was related to a perceived
7 issue that this could be -- that no one knew
8 where the boundaries were, this could be an
9 entirely open-ended policy.

10 No one knew sort of what would
11 happen next. And, given that there has been
12 one compulsory license granted, and given that
13 -- because I was in Quito three weeks ago, and
14 I can say that there's actually -- you know,
15 there have been license requests, at last one
16 license request staid, basically denied, and
17 multiple times, you know, in this license that
18 was issued as well as the new public request
19 that's been put forward, those requests have
20 been sent back to the license applicants for
21 amendments, basically for failure to dot their
22 I's and cross their T's.

1 I mean, they actually have pretty
2 exacting requirements on this in Quito and be
3 happy to dialogue separately about that.

4 MR. McCOY: Okay.

5 MR. MAYBARDUK: Thank you.

6 MR. McCOY: And I think next we
7 have Mike Mellis from MLB Advanced Media.

8 Hi, Mike. Welcome.

9 MR. MELLIS: Hi.

10 MR. McCOY: We are -- I don't know
11 if you were here at the beginning, but rather
12 than, you know, rather than interrupt you at
13 the five-minute stage, we are just going to
14 let you take your full ten minutes here and
15 I'll let you know, at the outset, some of the
16 questions or thoughts we had in looking at
17 your submission.

18 One was that just wanting to
19 better understand the types of efforts that
20 you are undertaking on sports broadcast piracy
21 around the world and any examples you've
22 encountered of sort of best practices on

1 public/private cooperation on this issue.

2 One of the things we have been
3 asked to do by the Intellectual Property
4 Enforcement Coordinator in the Joint Strategic
5 Plan is to use this year's Special 301 Report
6 to spotlight best practices.

7 So, that's one thing that you
8 could do today that would be helpful to us.
9 Another thing would be to go in a little more
10 detail to a couple of things that you
11 mentioned in your submission.

12 One was the situation in China,
13 the example of TVants is one that was
14 mentioned in your report. Another is the
15 example of Israel and some of the concerns
16 there. Those are both situations of
17 continuing interest to the Subcommittee.

18 But, you have the floor for ten
19 minutes. You can address those questions to
20 the extent you would like, or you can give
21 your prepared statement or you can follow up
22 with a posthearing submission if you would

1 like to do that.

2 MR. MELLIS: Okay. If I might,
3 could I just read my statement and then -- I
4 have taken some note and I think I could try
5 to answer your questions as best I can.

6 MR. McCOY: By all means.

7 MR. MELLIS: Mr. Chairman and
8 members of the Committee, I would like to
9 thank you for the privilege of addressing you
10 this afternoon.

11 My name is Mike Mellis and I'm
12 senior vice president and general counsel of
13 MLB Advanced Media, which is MLB's internet
14 and interactive media company.

15 Under the leadership of
16 Commissioner Selig, MLB has developed highly-
17 successful, diverse and innovative sports
18 media businesses.

19 On television our game telecasts
20 are distributed nationally through direct TV,
21 the ESPN, FOX, IN DEMAND, the MLB Network, TBS
22 and Verizon locally through broadcast

1 television stations and regional sports
2 networks and internationally to over 200
3 countries and territories and the U.S. Armed
4 Forces overseas.

5 On the internet we have been a
6 pioneer. Our first live game webcast was in
7 2002. Since then our mlb.com TV Subscription
8 Service which distributes thousands of games
9 each season to fans on personal computers and
10 wireless devices has served more than one
11 billion live video streams.

12 Clearly, rightsowners like MLB can
13 be adversely impacted by telecast piracy and,
14 as we explained in our past letters and
15 testimony to the Committee, there is an
16 emerging form of telecast piracy now, the
17 unauthorized internet streaming of live
18 television programming of all types, including
19 live sports.

20 The number of rogue sites and
21 services involved is significant. Many are
22 open-doors, permitting any type of television

1 programming to be streamed live, persistently
2 and globally, without authorization from
3 copyright owners.

4 In our recent letters to the
5 Committee we have identified rogue sites and
6 the nations where they are located.

7 The threat this poses to the U.S.
8 televised media sector must be taken
9 seriously. Although there is much that
10 remains unknown about this problem,
11 particularly with respect to its offshore
12 aspects, it is clear that on an annual basis
13 thousands of hours of live television
14 programming from U.S. networks are being
15 pirated, including, a significant piracy of
16 live sports.

17 In our rights enforcement efforts,
18 the dominant pattern we have continued to see
19 is piracy occurring through offshore sites and
20 services and, in particular, streaming over
21 peer-to-peer services based in China.

22 In the recent out-of-cycle review

1 of notorious markets in the 2010 Special 301
2 Report, USTR identified one of the latter
3 services, a streaming over peer-to-peer
4 network called TVants, based in Shijiazhang,
5 China as a notorious internet market. Another
6 is called Stream Torrent, also located in
7 Shijiazhang, China.

8 Our copyright law is clear. This
9 is copyright infringement. As ICE's recent
10 seizures of rogue site domain names show, it
11 can also be a crime, however, domestic
12 copyright enforcement is a remedial tool
13 available only in limited circumstances.

14 This is because the piracy is
15 global, often involving sites and services
16 that operate offshore, outside the effective
17 reach of our courts.

18 We therefore believe that
19 international cooperation must be improved.
20 Most nations are both exporters and importers
21 of television programming, so we see common
22 ground, both in terms of shared economic

1 interest and legal obligations for the U.S.
2 and its trading partners to work cooperatively
3 to curtail this problem.

4 We would like to commend USTR for
5 identifying this matter in its 2008, 2009 and
6 2010 Special 301 reports and in its recent
7 out-of-cycle review of notorious markets.

8 Since the problem is continuing,
9 we recommend that USTR continues to identify
10 it in the 2011 Special 301 Report and gives it
11 priority in trade negotiations.

12 As we develop more experience in
13 this area we look forward to the opportunity
14 to make additional recommendations to you.

15 Once again, thank you very much
16 for your interest in this matter and the
17 opportunity to address you this afternoon.

18 Okay, Stan, to dive into your --
19 to try to answer your questions: Number one,
20 what do we do in terms of rights enforcement?
21 What we at mlb.com have an in-house rights
22 enforcement team.

1 We have had to hire people to deal
2 with this problem. We are now in our -- we
3 will enter our fifth season of comprehensively
4 monitoring the internet for incidence of live
5 game telecast piracy.

6 You know, we have quite a few
7 games, over 2,400 games a year. It's a big
8 task to monitor literally hundreds of
9 different sites and services that we are aware
10 of where this problem has manifested and
11 document what we see.

12 We think it's important to create
13 a data set, you know, where are we seeing
14 problems, how often, and the like, and that's
15 one reason why we do it.

16 Another reason why we do it is,
17 obviously, to try to stop it from happening
18 where we can, and that involves cease and
19 desist correspondence and, in some cases,
20 specifically in the United States where some
21 services have automated take-down tools, we
22 can click and get streams blocked almost in

1 real time.

2 So, it depends on the level of
3 cooperation of the site or service provider.
4 But with respect to the offshore aspect of the
5 problem -- and let's talk about China for a
6 minute, and a site or service like Stream
7 Torrent, which is a peer-to-peer network, they
8 are unresponsive and our efforts to contact
9 them and other rightsholders that I know of
10 are just ignored.

11 We have not litigated this matter
12 yet, but others in the sports community have.
13 The Premier League has filed a number of
14 lawsuits in Scotland, in England, in Israel,
15 UEFA, the Dutch Soccer League. Erevidisie has
16 had several lawsuits in the Netherlands.

17 So, there has been, you know,
18 litigation taken up by sports leagues out of
19 their home bases to try to address this
20 problem, but we -- we have not been engaged in
21 that exercise yet.

22 MR. McCOY: And can you tell us a

1 little bit about the situation in Israel?

2 MR. MELLIS: Yes. The situation
3 in Israel is that the Premier League started
4 a lawsuit several years ago against a service
5 that was persistently and chronically pirating
6 their soccer matches.

7 They did not know the -- they do
8 not know the identity of the people or the
9 entity behind it, so the case is captioned
10 "Premier League versus Anonymous."

11 And in the Tel Aviv District Court
12 there were two opinions issued. The first
13 opinion which was not given any legal effect
14 was that the matches were not subject to
15 copyright.

16 That is obviously an incorrect
17 decision as a matter of U.S. copyright law and
18 under Israeli copyright laws we see it under
19 treaties.

20 The judge, then, kind of retracted
21 that decision and the decision that is now up
22 to appeal at the Israeli supreme court held

1 that it's a fair use to retransmit live the
2 entirety of a Premier League soccer match or,
3 I should say "matches," because it just goes
4 on and on.

5 And, like I said, that's up on
6 appeal in the Israeli supreme court, and I
7 believe the oral argument -- the argument
8 before the court is next month.

9 The Israeli government has taken a
10 public position against this decision at the
11 district court level. The Israeli government
12 advisor, which I understand is their
13 equivalent of attorney general or solicitor
14 general here in the U.S., filed a memorandum
15 of law arguing why sports telecasts deserve
16 copyright protection as much as any other
17 cinemagraphic work and why and how if, if
18 these rights were not enforced in this case,
19 Israel might run afoul of its treaty
20 obligations.

21 MR. McCOY: Well, very good.
22 Thank you very much for making the trip today

1 and for sharing with us your perspectives on
2 this problem.

3 As I -- I don't think you were
4 here when I mentioned this at the outset, but
5 because you mentioned the notorious markets
6 list, I'll just repeat that the notorious
7 markets list that came out yesterday, our
8 intention is not to duplicate that list again
9 in the report that comes out at the end of
10 April, but to continue the process as an out-
11 of-cycle review, so that would mean we would
12 do a new request for comments later in the
13 year with a view to a new out-of-cycle review
14 in the period between Special 301 Reports.

15 But, thank you very much for your
16 input today. It's much appreciated, and your
17 insights. And I believe, Mike, that brings us
18 to the end of the schedule for today.

19 MR. MELLIS: Thank you all very
20 much.

21 MR. McCOY: Thank you.

22 So, we have nothing further by way

1 of announcements here except to thank you all
2 once again for your participation in this
3 process, and to let you know that the chair of
4 this Special 301 process and the organizer of
5 today's hearing, Paula Pinha, is sitting
6 immediately to my left, and she can be your --
7 she can be your target for all praise and
8 complaint.

9 But I want her to be, first, the
10 target of my praise for her considerable
11 efforts in putting together this hearing
12 today. Thank you very much.

13 Thank you to all the members of
14 the Subcommittee for your time and attention
15 today, and taking time out of what I know are
16 very busy schedules, to hear from members of
17 the public about the important process before
18 us.

19 And, thank you to all the members
20 of the public and representatives of industry
21 organizations. I will remind you one more
22 time that posthearing briefs are completely

1 optional.

2 They may be submitted until five
3 p.m. on March 9th, 2011. Your posthearing
4 briefs should be sent electronically via
5 www.regulations.gov, Docket Number USTR-2010-
6 0037.

7 Please put the term "2011 Special
8 301 Review" in the typed comment and upload
9 field on www.regulations.gov.

10 Thank you very much and have a
11 good day.

12 (Whereupon, the meeting was
13 concluded at 2:38 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Special 301 Hearing

Before: U.S. Trade Representative

Date: 03-02-11

Place: Washington, DC

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