

OFFICE OF THE
UNITED STATES TRADE REPRESENTATIVE

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2019 SPECIAL 301 PUBLIC HEARING

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WEDNESDAY
FEBRUARY 27, 2019

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The Hearing was convened in
Conference Rooms I and II of the USTR Annex
Building, 1724 F Street, NW, Washington, D.C. at
10:00 a.m., Daniel Lee, Chair, presiding.

COMMITTEE MEMBERS

DANIEL LEE, Chair

EMILY BLEIMUND, U.S. Department of Health and
Human Services

SUNG CHANG, Office of the U.S. Trade
Representative

WON CHANG, U.S. Department of the Treasury

KARIN FERRITER, U.S. Patent and Trademark Office

BRAD GREENBERG, U.S. Copyright Office

DAVID HENRY, U.S. Department of State

OMAR KARAWA, U.S. Department of Agriculture

MATTHEW LAMBERTI, U.S. Department of Justice

STEVAN MITCHELL, U.S. Department of Commerce

MAUREEN M. PETTIS, U.S. Department of Labor

RACHEL SALZMAN, U.S. Department of Commerce

ANNE SNYDER, U.S. Department of Health and Human
Services

GOVERNMENT WITNESSES

ALEJANDRO BILBAO LA VIEJA, Embassy of Bolivia
REZA PAHLEVI CHAIRUL, Embassy of the Republic of
Indonesia

ALEJANDRA GASTELU-SOTOMAYOR, Ministry
of International Trade and Integration,
Government of Bolivia

IVO KONSTANTINOV, Embassy of the Republic of
Bulgaria

BOKYUN NAM, Ministry of Health and Welfare,
Government of the Republic of Korea

SCARLEY MARINA VALERIANO BARROSO, National
Service for Intellectual Property,
Government of Bolivia

VALERII ZHALDAK, Ministry of Economic
Development and Trade, Government of Ukraine

NON-GOVERNMENT WITNESSES

JAIME CASTANEDA, Consortium for Common Food
Names (CCFN)

GUAN JIAN, China Chamber of International
Commerce (CCOIC)

TAN JIAN, China Chamber of International
Commerce (CCOIC)

MARIANA JORGE, MFJ International, LLC

PAUL KILMER, Trademark Working Group

MARK LAUROESCH, Intellectual Property Owners
Association (IPO)

JAMES LOVE, Knowledge Ecology International
(KEI)

PETER MAYBARDUK, Public Citizen

CHRISTINA MITROPOULOS, American Apparel and
Footwear Association (AAFA)

CHRIS MOORE, Pharmaceutical Research and
Manufacturers of America (PhRMA)

ROGER MURRY, Alliance for Fair Trade with India
(AFTI)

RYAN ONG, National Association of Manufacturers

JUSTIN PINE, Biotechnology Innovation
Organization (BIO)

MATT PRIEST, Footwear Distributors and Retailers
of America (FDRA)

KEVIN ROSENBAUM, International Intellectual
Property Alliance (IIPA)

BRIAN SCARPELLI, ACT/The App Association

NON-GOVERNMENT WITNESSES (cont'd)

MATTHEW SCHRUERS, Computer and Communications
Industry Association (CCIA)

DAYAAR SINGLA, NALSAR Litigation Project (NLP)

ELLEN SZYMANSKI, U.S. Chamber of Commerce

JOSEPH WHITLOCK, BSA, The Software Alliance

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

2 10:04 a.m.

3 CHAIR LEE: Good morning folks. Well,
4 we're going to get started. I know some people
5 are still filing in from security.

6 But, good morning. My name is Daniel
7 Lee, and I am the Acting Assistant U.S. Trade
8 Representative for Innovation and Intellectual
9 Property.

10 I would like to welcome everyone to
11 the public hearing for the annual Special 301
12 Review. The Special 301 Review is a statutorily
13 mandated exercise we undertake every year to
14 develop an overall strategy to ensure adequate
15 and effective intellectual property rights
16 protection and equitable market access in foreign
17 countries for United States persons that rely on
18 protection of intellectual property right such as
19 copyright and related rights, trademarks,
20 patents, and trade secrets.

21 Ensuring that U.S. owners of
22 intellectual property or IP have a full and fair

1 opportunity to use and profit from their IP is
2 one of the top trade priorities outlined in the
3 President's annual Trade Policy Agenda.

4 This is the 31st annual Special 301
5 Review, and the 10th public hearing that USTR has
6 hosted in connection with the Review.

7 I would like to note for the record
8 that today is Wednesday, February 27th, 2019.
9 And that this hearing is taking place at the
10 Office of the U.S. Trade Representative or USTR.

11 We will make a transcript of today's
12 hearing available to the public on USTR's
13 website. Today's hearing is scheduled to go
14 until approximately 3:30.

15 And we will break for one hour between
16 12:20 and 1:20. I would like to ask for
17 everyone's cooperation with keeping the hearing
18 on track.

19 At this point I would like to ask
20 colleagues on the hearing panel, all of whom
21 represent U.S. government agencies that serve on
22 the Special 301 Subcommittee to introduce

1 themselves. Maybe we can start at the end.

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

5 MS. BLEIMUND: Good morning. Emily
6 Bleimund, Department of Health and Human
7 Services.

8 MS. PETTIS: Good morning, Maureen
9 Pettis, Department of Labor.

10 MR. LAMBERTI: Good morning everyone.
11 My name is Matt Lamberti. I'm with the U.S.
12 Department of Justice.

13 MR. CHANG: Good morning. My name is
14 Sung Chang. I am with the Office of the U.S.
15 Trade Representative.

16 MR. MITCHELL: I'm Stevan Mitchell
17 with the International Trade Administration,
18 Department of Commerce.

19 MR. HENRY: I'm David Henry with the
20 Department of State.

21 MR. CHANG: I'm Won Chang, Department
22 of Treasury.

1 MR. GREENBERG: Brad Greenberg, U.S.
2 Copyright Office.

3 MS. FERRITER: Good morning, Karin
4 Ferriter, U.S. Patent and Trademark Office.

5 CHAIR LEE: Thank you. The Special
6 301 Subcommittee of the Trade Policy Staff
7 Committee is comprised of the agencies you've
8 just heard from, and chaired by USTR. It
9 conducts the annual Special 301 Review each year.

10 The Review is driven by stakeholder
11 contributions and by contributions of Washington-
12 based agencies and our embassy-based personnel
13 around the world. The Subcommittee is currently
14 in the information gathering phase.

15 On behalf of the agencies here, we
16 thank you for the views, insights, opinions, and
17 factual information that you will share with us
18 today.

19 The schedule of today's hearing is
20 comprised of interested parties from foreign
21 government officials, private sector interest,
22 and civil society, who responded to USTR's notice

1 in the Federal Register, published on December
2 28th, and voluntarily requested the opportunity
3 to appear at this public hearing.

4 As a reminder, the purpose of today's
5 hearing is to provide the Special 301
6 Subcommittee with additional information that we
7 can use in deliberations that will lead to the
8 publication of the 2019 Special 301 Report to
9 Congress on or about April 26, 2019.

10 This year we have received public
11 filings that address over 75 countries and many
12 country-specific IP protection and enforcement
13 issues that may negatively affect our bilateral
14 trading relationships.

15 Those filings are available to the
16 public at www.regulations.gov. The Docket Number
17 is USTR-2018-0037.

18 The Special 301 Report is the result
19 of a Congressionally-mandated annual review of
20 the state of intellectual property rights,
21 protection, enforcement in trading partners
22 around the world, which the United States -- or

1 which the Office of the United States Trade
2 Representative conducts pursuant to Section 182
3 of the Trade Act of 1974 as amended by the
4 Omnibus Trade and Competitive Act of 1988, and
5 the Uruguay Round Agreements Act.

6 The provisions of Section 182 are
7 commonly referred to as the Special 301
8 Provisions of the Trade Act. Hence, the Special
9 301 Report.

10 Specifically, Section 182 of the Trade
11 Act requires that the United States Trade
12 Representative identify countries that deny
13 adequate and effective protection of intellectual
14 property rights, or that deny fair and equitable
15 market access to U.S. persons who rely on
16 intellectual property protection.

17 The statute requires USTR to determine
18 which, if any, countries should be identified as
19 priority foreign countries. Acts, policies, or
20 practices that are the basis of a country's
21 identification as a priority foreign country, can
22 be subject to the procedures set out in Sections

1 301 through 308 of the Trade Act.

2 In addition to the statutorily defined
3 priority foreign country designation, USTR
4 created the priority watch list and watch list
5 categories to assist the Administration in
6 pursuing the goals of the Special 301 Provisions.

7 USTR is also charged with developing
8 priority watch list action plans where a country
9 has been on the priority watch list without
10 change for at least one year.

11 The format of today's hearing is as
12 follows: each party will be allotted ten minutes.
13 Each person will start with five minutes of
14 prepared statements, leaving five minutes for
15 panel questions.

16 However, we will remain flexible
17 within the ten minute period, making adjustments
18 as needed. We will be watching the clock and
19 will interrupt with a time queue when one minute
20 remains from the allotted five minutes of
21 prepared statements.

22 The panel will hold its questions

1 until the presenter concludes his or her
2 statement.

3 In some cases we have prepared
4 questions based on the written finding --
5 filings. In others, we will respond to your
6 testimony today.

7 In general, please keep in mind the
8 purpose of this hearing, to provide information
9 that the Committee can use in satisfying the
10 charge of the Special 301 statute when conveying
11 your testimony and responding to any questions
12 that we may ask.

13 Again, we will break for one hour from
14 12:20 to 1:20. And at this time I would like to
15 invite the Government of Bolivia to start us off.

16 Welcome. Please introduce yourself
17 and your organization, for the record. And begin
18 your testimony.

19 DR. BILBAO LA VIEJA: Thank you very
20 much. Thank you all of you to -- to receive us
21 today.

22 We are here on behalf of the Bolivian

1 government, the Bolivian State, the International
2 State of Bolivia. My name is Alejandro Bilbao la
3 Vieja. I'm the DCM with the Bolivian Embassy
4 here to the U.S.

5 I'm joined today by the Ambassador
6 Pablo Canedo from the Embassy of Bolivia, the
7 head of the Bolivian Authority of Intellectual
8 Property, Ms. Scarley Valeriano, and the head of
9 the Department of the Economics and Law at the
10 Ministry of Foreign Affairs of Bolivia.

11 So, and we are here to answer about
12 your concerns on the 301 Subcommittee. So, we
13 are due to say our -- I will let the floor to Ms.
14 -- to Alejandra to respond to that.

15 MS. GASTELU-SOTOMAYOR: Hi. My name
16 is Alejandra Gastelu. We will explain the effort
17 that our government has made to combat the
18 infringement of intellectual property rights in
19 its commitment to enforce the law.

20 First of all, I would like to commend
21 activities that the government implemented to
22 simplify the process of registration and

1 enforcing intellectual property for this year.

2 First point, the administrative
3 concentration. In September 2018 the National
4 Service of Intellectual Property expanded the
5 attribution of its regional office in the City of
6 Santa Cruz where it presents and carries out
7 commercial transactions.

8 The aforementioned office has powers
9 related to the registration and the defense of
10 intellectual property. The second point is the
11 ratification and entry into force of the Hague
12 Apostille Treaty.

13 Bolivia signed the Convention of 5
14 October 1961 abolishing the requirement of
15 legalization for foreign public documents at the
16 Convention of the Apostille in November 2017.
17 And it entered into force in May of 2018.

18 That brought the procedures out by the
19 right holders are faster, easier, and are
20 cheaper. It should also be noted that SENAPI
21 plays an active role in terms of issuing
22 documents and their opposite parameters when

1 granting intellectual property rights.

2 Therefore, the direct beneficiaries are the
3 holders of these rights.

4 The third point is turning to another
5 -- it's necessary to mention a specific norm, the
6 Administrative Resolution No. 019/2016, because
7 it regulates the internal procedure for action in
8 case of infringement of industrial property
9 rights.

10 The aforementioned regulation provides
11 effective and simplified procedures to the
12 holders of rights who much actively participate
13 in the infringement proceedings, either on their
14 own, or through their representative.

15 As a result of the implementation of
16 the aforementioned regulation, there's an
17 increase in the requests for infringement actions
18 and precautionary measures. As a result of these
19 actions in the last year 34,330 products were
20 destroyed.

21 The fourth point, the Customs
22 Administration path has passed a resolution in

1 October 4. And these now regulate the
2 destructions. One decision for the destruction
3 of goods by administrative process and is
4 declared to execute without established
5 deadlines.

6 We have to mention the creation of the
7 Vice Ministry to combat contraband. This Vice
8 Ministry was created last year as a realization
9 of the State's Air Force to strengthen the
10 protection of different areas of commerce.

11 It should also be noted that this Vice
12 Ministry has assumed the task of intelligence and
13 operation against contraband. Which is the main
14 source of income of pirated and counterfeit
15 goods.

16 The permanent working group called
17 Preventive and Educational Measures to Promote
18 Licit Trade and Respect for Intellectual
19 Property.

20 The Vice Ministry's fight against
21 contraband is constituted as the Chair of the
22 working group, it should be noted that in the

1 last year their tasks were focused in the
2 infringement of industrial property and
3 copyright, with emphasis on plagiarism and
4 piracy.

5 We want to mention just one little
6 thing, that is the National Border Control
7 Center. And the location is in Desaguadero with
8 Peru. We launched it. It is an integrated
9 contract facility where all border control
10 agencies from both countries join forces. There
11 is a SENAPI in the copy. And they have the
12 faculty to exchange information.

13 I will further mention Bolivia --
14 committed to protect intellectual property rights
15 in accordance with the international instruments
16 to which it's signed. Thank you.

17 CHAIR LEE: Do you have more
18 testimony? Or can we begin asking questions?

19 MS. GASTELU-SOTOMAYOR: Yes. That's
20 all.

21 CHAIR LEE: Perfect. We'll start
22 questions from USTR.

1 MR. CHANG: Thank you very much for
2 joining us and for your testimony. We would like
3 to learn more about the work of the Vice Ministry
4 to find contraband activities.

5 You just mentioned that the Vice
6 Ministry does address counterfeit and pirated
7 goods. What type of enforcement actions have the
8 Vice Ministry taken thus far?

9 MS. VALERIANO BARROSO: Good morning
10 and thank you for having me. The work of -- or
11 having us. The work of my Ministry is more
12 operative in nature.

13 And it is coordinated with SENAPI,
14 AGEMED and also Customs and Border Control, and
15 with our neighbors. And for example we have been
16 strengthening our work especially with Peru.

17 And then we also do training workshops
18 and awareness workshops along the borders.

19 CHAIR LEE: Thank you very much. The
20 next question comes from the U.S. Patent and
21 Trademark Office.

22 MS. FERRITER: Thank you. Under

1 Bolivia's Law 1134, the 2018 Bolivian Cinema and
2 Audio/Video Visual Arts Law, how will film
3 registration with the Bolivian Film and
4 Audio/Visual Development Agency, ADOCINE, affect
5 enforcement of copyright for films that have not
6 been registered?

7 MS. VALERIANO BARROSO: Besides the
8 law and SENAPI has been working on internal
9 regulations that it will soon be presenting in a
10 written format.

11 CHAIR LEE: Okay. Thank you very
12 much. I believe that's all the time we have for
13 questions.

14 Next, I would like to call the
15 government of Bulgaria. Thank you very much.

16 MR. KONSTANTINOV: Good morning
17 everyone, esteemed committee --

18 CHAIR LEE: Sorry. Let me first ask
19 you to state your name and organization for the
20 record. And then begin your testimony. Thank
21 you.

22 MR. KONSTANTINOV: I was about to do

1 that. My name is Ivo Konstantinov. I represent
2 the government of Bulgaria within the Embassy of
3 the Republic of Bulgaria in the United States in
4 Washington, D.C., and Ministry of the Economy of
5 the country.

6 I am grateful for the Committee
7 accommodating us in our participation today. We
8 are here on a very positive note.

9 As testimony of the positive outcome
10 of a good cooperation with the USTR. As our
11 country last year was excluded -- removed from
12 the Special 301 list, which we were extremely
13 appreciative of.

14 Our government runs -- has been
15 running for many years, more than a decade now a
16 very highly organized interagency -- involving
17 nine government agencies, law enforcement and the
18 Attorney General's office, which is in permanent
19 contact and cooperation with the USTR.

20 Upon our removal from the watch list
21 last year, there was also a list of
22 recommendations issued by the USTR. Which we

1 have followed very closely in implementing in our
2 country.

3 And today I'm here as an example of a
4 good outcome. And also to report on our progress
5 after the removal of our country from the list,
6 following the good recommendations issued to us
7 from the USTR.

8 We -- first of all one of the most
9 important works we have to stress on our efforts
10 -- direct our efforts, was in the area of the
11 Attorney General's office. And appointed contact
12 and the Chief Prosecutor for IP-related cases was
13 appointed.

14 And regional prosecutors were
15 designated. Especially for IP-related cases.
16 The manual for the IP prosecution was mandated by
17 the Attorney General with a normative act, and
18 distributed among the regional prosecutors.

19 The law enforcement unit, especially
20 the cybercrime unit with the IP enforcement part
21 of our equivalent of the DHS in our country, it
22 doubled -- tripled its staff from 18 to 40. But

1 especially tripled the staff prosecuting IP-
2 related cases.

3 The interagency on IP enforcement
4 continues to meet on a regular basis. Even after
5 the exclusion from the list, to continue on
6 following the policy of the government and the
7 USTR recommendations for IP enforcement.

8 Amendments to the Copyright Act were
9 made also that were very necessary. We are
10 working on looking for ways to use samples in
11 court trials. It's a very complicated legal
12 methodology, but we are finding ways to also use
13 that.

14 And a very special change was made
15 where the IP prosecution unit of the main law
16 enforcement body can now investigate individuals.

17 There's very good reporting also on
18 behalf of our country, even from last year. Also
19 of sentences, IP-crime related cases,
20 prosecutorial acts, convictions, penalties, and
21 even imprisonments.

22 There's 13 -- 30 imprisonments, one of

1 which effective and 29 conditionals related to IP
2 breaches.

3 And finally, I'd like to also express
4 our high appreciation and evaluation -- positive
5 evaluation of the training provided by the USTR
6 and the U.S. government to our prosecutors and
7 law enforcement that were extremely helpful.

8 And we would encourage that they
9 continue. And I'm here as an after case, before
10 and after.

11 And we're the after case where we
12 implemented your recommendations, and were taken
13 out of the list, but continue the work. Because
14 this is important for us.

15 And I remain available for your
16 questions.

17 CHAIR LEE: Thank you very much.
18 We'll start questionings with USTR.

19 MR. CHANG: Thank you very much for
20 your time today, and your testimony.

21 The 2018 Special 301 Report did not
22 include Bulgaria on the watch list, as you said.

1 But noted enforcement concerns including high
2 levels of online piracy, inadequate prosecution
3 efforts, judicial delays, and insufficiently
4 determined criminal penalties.

5 Your submission indicates that
6 Bulgaria has appointed specialized IP prosecutors
7 on page two. But also that enforcement activity
8 has sharp -- was sharply down, new pre-trial
9 proceedings, prosecutorial acts, and convictions,
10 by 50 percent or more in certain categories in
11 the first nine months of 2018, compared to the
12 same period in 2017.

13 Can you please explain the seeming
14 discrepancy?

15 MR. KONSTANTINOV: A lot of the --
16 especially internet-related IP breaches of
17 entertainment and software content are now
18 migrating to illicit software service operations,
19 always in service outside of the country.

20 And in the area of entertainment
21 content, there's a sharp decrease of current
22 tracker usage in favor of streaming, also illegal

1 streaming services. Always, always the server is
2 located physically in foreign countries.

3 And there's been a very serious
4 success in IP enforcement in 2017 which has led
5 to also decreased number of cases and of
6 prosecutorial acts last year, that's the second
7 reason.

8 CHAIR LEE: Thank you very much. The
9 next question is from the Department of Justice.

10 MR. LAMBERTI: Thank you very much.
11 On March 29, 2018, Ambassador Stoytchev stated in
12 a letter to Ambassador Lighthizer that the
13 Bulgarian Prosecutor General shall -- quote,
14 shall undertake in 2018 the improvement of
15 procedures for investigating IP cases by among
16 other steps, adopting sampling and IPR cases.

17 As you know, European countries and
18 the United States typically use sampling in
19 international property cases. For example, if
20 the police seize multiple servers loaded with
21 terabytes of infringing material, police experts,
22 prosecutors, and judges do not examine each work

1 seized to determine if it is infringing.

2 Rather, they rely upon a sample of
3 what is seized for both the charging and the
4 sentencing.

5 So you just testified that Bulgaria is
6 looking to use sampling in court trials. And in
7 your written testimony, it looks like the
8 Bulgarian government drafted a report last year
9 regarding steps that could be taken to improve
10 procedures for investigating IP cases, including
11 sampling.

12 It's not clear that whether or not
13 Bulgaria actually did take concrete, specific
14 action to implement that report. And actually
15 adopt sampling and other improvements in
16 intellectual property enforcement procedures.

17 Can you tell us if and when Bulgaria
18 has taken specific concrete actions to improve
19 the procedures for investigating IP cases,
20 including sampling?

21 MR. KONSTANTINOV: Well, thank you.
22 We're not ready with a written report. But doing

1 a very complex legal analysis of how this can be
2 utilized in prosecutorial activity.

3 And that would include blitz raids and
4 sting operations. Which is mostly the cases
5 where we need to employ these things very much.
6 And surprise searches.

7 It's a complex procedure of obtain
8 court warrants. And the main challenge continues
9 to be the expenses in time storage and personnel
10 for what are extremely diverse types of materials
11 during -- taken during searches.

12 So both authorities, the FBI/DHS
13 equivalent, the cybercrime prevention unit, and
14 the Prosecutor General's office, are in active
15 processes of improving these methods, in spite of
16 heavy challenges. And the challenges are related
17 to cost, time, and qualified law enforcement
18 personnel.

19 They are finding ways to do that. But
20 not ready with the recon report. It's a matter
21 of a legal analysis of how this can be done.

22 CHAIR LEE: All right. We have time

1 for one last question. And it comes from the
2 State Department.

3 MR. HENRY: Good morning. One of the
4 concerns we described in last year's Special 301
5 Report was inadequate prosecution efforts. You
6 mentioned in your submission that the
7 effectiveness of the judicial system when hearing
8 cases in the field of IPR, was improved.

9 Could you elaborate a bit more on
10 this? And is Bulgaria also considering
11 instituting intellectual property courts?

12 MR. KONSTANTINOV: I will have to come
13 back on that on the question of intellectual
14 property courts.

15 But, directly answering your question,
16 the manual for prosecution -- a prosecutor's
17 manual, and Attorney General's issue and mandated
18 manual for prosecuting IP related cases has been
19 a breakthrough in the improvement of efficiency
20 in prosecuting IP-related crimes. That was the
21 major step in the area that you are referring to.

22 And as the Attorney General's office

1 by our country's constitution represents actually
2 the country's judiciary, a completely independent
3 branch of government.

4 There are also constitutionally
5 mandated time frames where improvements in
6 prosecutorial technology have to be implemented.
7 Which we're working on.

8 CHAIR LEE: Thank you very much for
9 your testimony.

10 MR. KONSTANTINOV: Appreciate it.

11 CHAIR LEE: Thank you. May I call up
12 the government of Indonesia? Is the
13 representative of the government of Indonesia
14 here yet?

15 Thank you. Please state your name and
16 organization for the record. And begin your
17 testimony.

18 MR. CHAIRUL: Good morning, Mr.
19 Chairman, sir, David Lee and U.S. colleagues. My
20 name is Reza Pahlevi Chairul, Commercial Attache
21 of the Indonesian Embassy in Washington, D.C.

22 I would like to thank USTR for

1 allowing us to be present here today. As stated
2 on the Special 301 Report 2018, the government of
3 Indonesia acknowledges United States concerns on
4 intellectual property rights.

5 And at this hearing, I would like to
6 raise Indonesia progress on intellectual property
7 right protections and enforcement for your
8 consideration on the ongoing Special 301 review
9 in 2019.

10 Intellectual property rights, again,
11 has been one of the top priorities for the
12 Indonesian government for the past year. Even we
13 know there are some difficulties for us.

14 The government of Indonesia has always
15 taken and will continue to take concrete steps
16 and actions to enhance protections and
17 enforcement of IPR. Including among other,
18 amendment of IPRO, improvement of interagency,
19 which is really difficult task, and internal
20 cooperation.

21 One positive milestone that is worth
22 noting is the agreement between the government of

1 Indonesia and the United States on the work plan
2 on IPR concluded at the '17 Trade and Investment
3 Framework Agreement meeting in Jakarta last year.

4 Closing this five-year negotiation
5 signifies a concrete foundation of IPR
6 protections and enforcement joint effort between
7 the two governments.

8 As a follow up, the government of
9 Indonesia is now optimizing the interagency IP
10 task force under the leadership of the
11 coordinating ministry for political, legal, and
12 security.

13 To accelerate the role of the task
14 force, related ministries, institutions such as
15 the Indonesian National Police, the Ministry of
16 Communication and Informatics, the Supreme Court,
17 and the Ministry of Law and Human Rights have
18 established an MOU.

19 We also currently establish a
20 technical team to combat piracy for creative
21 economy products under the coordination of
22 Indonesian creative economy body, whose role

1 includes provisions of public patrol to report on
2 pirated products.

3 Within the period of 2015 to 2018, the
4 craft have received substantial number of
5 consultations and efficacy concerning the IP
6 infringement, in collaboration with the Motion
7 Picture Association of America.

8 The National IP Task Force itself has
9 met several times during the last quarter of
10 2018. And came up with a set of activities for
11 the implementations of Indonesia/U.S. IPR work
12 plan in the coming years.

13 Including public education awareness,
14 legal framework strengthening, IPR enforcement
15 and cooperation as well as budgeting for those
16 activities.

17 With regard to patent law, in
18 principal the low number in 2016 aimed to provide
19 robust intellectual property regulatory
20 protections that demonstrate patent is a valuable
21 property of its inventor, and therefore must be
22 protected.

1 While amendment of the law will take
2 a long time, we are addressing this with short-
3 term actions.

4 With the implementation of Ministry of
5 Regulation No. 15 on July 2018, in which a patent
6 holder who has not used or applied its patent in
7 Indonesia could formally request a postponement
8 in product manufacturing or utilization of the
9 patent process for up to five years.

10 We're also building an online system
11 to ease the process of application for patent
12 holders. The government of Indonesia is also
13 focused on the improvement of other areas in IP
14 protection.

15 Moreover the ongoing protections of
16 existing industrial design law, proficient of
17 online complaining and reporting mechanism for IP
18 piracy like websites, movie applications, and
19 counterfeit products, of which there has been 93
20 cases of IPR handled by investigators during the
21 period of 2016 to 2018.

22 And then initiating review of existing

1 film law. Though the government of Indonesia
2 strongly believes that Indonesia market is
3 currently open to imported movie, that is shown
4 with 94 percent of market share held by North
5 American film.

6 To sum up, I think it is Indonesia
7 interest to create a conducive environment for
8 trade and investment including IPR. And we look
9 forward to closely work with you.

10 CHAIR LEE: Thank you very much.
11 We'll begin questions with the International
12 Trade Administration of the Department of
13 Commerce.

14 MR. MITCHELL: Thank you. This is a
15 multi-part question, a three-part question.

16 You mentioned a number of initiatives.
17 Which specific IP reforms will Indonesia
18 prioritize over the next 12 months?

19 Will these involve changes to statutes
20 or the development of implementing regulations?
21 Or perhaps both?

22 And finally, is Indonesia committed to

1 adhering to a transparent process for developing
2 these policies that will allow for interested
3 parties to submit comments on draft proposals
4 prior to their implementation?

5 Thank you.

6 MR. CHAIRUL: Thank you so much. I
7 believe that we have a working plan already. And
8 Mr. David Lee was involved in that negotiation.

9 And I think this is good momentum for
10 us to closely work with the IPR protection and
11 enforcement. And we, like I said, that we have
12 optimizing the IP Task Force of Indonesia.

13 Of course there are some activities
14 including welcome and engaging with the U.S.
15 government or U.S. business community who rely on
16 IPR right.

17 And we welcome any discussion. And
18 also, we'll take any concern from U.S. business
19 community.

20 And again, the National IP Task Force
21 right now is setting up budget and activities to
22 be implemented soon in this 2019.

1 MR. MITCHELL: And as a follow up, what
2 about the transparency piece? Will stakeholders
3 have an opportunity to comment on these
4 developments before they're implemented?

5 MR. CHAIRUL: I do believe, yeah.
6 Because like I said, we have a work plan in which
7 both sides remain committed.

8 And agreed to intensify efforts
9 specifically in protecting IPR issues including
10 market process issues.

11 MR. CHAIR LEE: Thank you. The next
12 question comes from the U.S. Department of
13 Justice.

14 MR. LAMBERTI: Good morning. The
15 Creative Economy Agency, or BEKRAF, announced
16 several months ago that it would form a task
17 force with the Communications and Information
18 Ministry, the Intellectual Property Directorate
19 General, the Prosecutor's Office, and the
20 National Police to make it easier for people to
21 report intellectual property violations in
22 Indonesia to the right government institutions.

1 A related issue is that people who do
2 report intellectual property violations in
3 Indonesia cannot easily see what happens with
4 those reports.

5 In fact, other than the listing of
6 proceedings and the publication of decisions by
7 the Indonesian Supreme Court, it is very, very
8 difficult for the public in Indonesia and also
9 those of us here in other countries, to determine
10 what, if any, intellectual property rights
11 enforcement is occurring through Indonesia's
12 court system.

13 Could the BEKRAF Task Force create a
14 website to list intellectual property cases in
15 the lower courts, below the Supreme Court,
16 including identifying the parties, the legal
17 basis for the cases, and any penalties assessed?

18 MR. CHAIRUL: Again, we have optimized
19 the National Task Force, including BEKRAF. And
20 BEKRAF has worked with Motion Picture of America.

21 And we also started a technical team
22 like I mentioned before, to conduct the IPR

1 violations. So we will impose any penalties or
2 detain goods who violate the IPR.

3 But again, this is work -- more work
4 remains to be done. And we take note of your
5 questions and probably we will answer in more
6 detail in a post-hearing brief.

7 But again, --

8 MR. LAMBERTI: On the website, yeah.

9 MR. CHAIRUL: Yes. Including the
10 website. Including the statistic and any
11 information.

12 CHAIR LEE: Great. Thank you for your
13 testimony.

14 MR. CHAIRUL: Thank you, Mr. Lee.

15 CHAIR LEE: Thank you. Next, could we
16 have the government of Korea, please?

17 Thank you. Please state your name and
18 organization for the record and begin your
19 testimony.

20 MR. NAM: Good morning everyone. I am
21 Bokyun Nam, Director for Trade Affairs for
22 Ministry of Health and Welfare of the Republic of

1 Korea.

2 Concerning the recent Special 301
3 Review where PAMA requested the USTR to taking
4 Korea as a priority foreign country. And BIO
5 requested the USTR to place Korea on the priority
6 watch list.

7 I wish to explain the Korean
8 government's position focusing on drug pricing
9 and reimbursement policy. Also, I would like to
10 take this opportunity to help multinational
11 pharmaceutical companies and the U.S. government
12 to better understand the Korean pricing and
13 reimbursement policies.

14 Above all, the Korean government is
15 aware that global innovative drug makers have
16 made a significant contribution to fighting
17 disease, such as rare and incurable diseases, and
18 cancer.

19 We also understand that protecting
20 intellectual property rights is one of the most
21 critical factors to encouraging pharmaceutical
22 manufacturers to develop new drugs.

1 Comments submitted by the U.S.
2 industry to the USTR on the 2019 Special 301
3 issues concerning intellectual property rights
4 include the following issues. First, Korea's
5 pricing and reimbursement system.

6 Second, Korea's premium pricing policy
7 for global innovative new drugs. Third, other
8 issues on Korea's health insurance system such as
9 an independent review process and the risk
10 sharing development system.

11 Let me explain the Korean government's
12 position on those matters. First, unlike the
13 healthcare system of the U.S., Korea has a public
14 insurance system from which all citizens can
15 benefit.

16 Korea's public health insurance system
17 has been making a substantial contribution to
18 expanding patient access to medicine. The Korean
19 government also sympathizes with the need to
20 recognize the value of innovative drugs.

21 In this regard, the Korean government
22 is operating to properly recognize the value of

1 innovative drugs. Accordingly, the Korean
2 government ensures the value of innovative drugs
3 to the maximum extent possible within the public
4 health insurance system, through the objective
5 criteria of clinical usefulness and
6 pharmaceutical economy violations.

7 Lastly, that the intellectual property
8 rights of innovative new drugs are not impeded.

9 Second, Korea's premier pricing policy for global
10 innovative new drugs, Korea amended on December
11 31, 2018, implemented the premier pricing policy
12 consistent with those of FTA which is fair,
13 reasonable, and nondiscriminatory.

14 In terms of operation of the amended
15 premium pricing policy, there is a concern that
16 qualification criteria are so strict that U.S.
17 companies cannot qualify for premium pricing and
18 thus obtain practical benefits.

19 However, only two months have passed
20 since the implementation of this new pricing
21 system. And it is too early to determine what
22 outcomes will occur.

1 If necessary, the Korean government
2 looks forward to another opportunity in the
3 future to seek mutually satisfactory outcomes in
4 the operation of the system.

5 Lastly, other issues on Korea's health
6 insurance system. Korea is attempting to strike
7 a balance between patient access to medicine and
8 reimbursement for new drugs, include introducing
9 the RSA, the provider pathway for reimbursement
10 listing that would end cancer and rare disease
11 products without authority.

12 All our total existing companies
13 receiving benefits from the RSA are 14. Fourteen
14 companies. Seven of the 14 are from the U.S. So
15 the Korean government plans to seek an
16 opportunity in the future to discern opinions
17 from the U.S. industry concerning new tests that
18 the scope of RSA applications should be extended.

19 In addition, the Korean government has
20 an institutional mechanism to properly seek the
21 review of some pharmaceutical companies through
22 an independent review process. The U.S. industry

1 has requested that the IRP should be applied even
2 to the negotiation process full appraisal though
3 the National Health Insurance Office.

4 The Korean government has continued to
5 make it clear that the price negotiations with
6 those NHIS are not subject to the IRP, as drug
7 price negotiations are made by mutual agreement.

8 Between negotiating parties on equal
9 footing, we recommend that what the U.S. industry
10 has stated is not directly related to those
11 infringement of intellectual property rights.
12 And they will have a chance to be mostly
13 reflected through the first FTA.

14 Therefore, we respectfully ask the
15 USTR to take into account compliance factors,
16 including Korea's contribution to fair,
17 reasonable, and nondiscriminatory quotas FTA when
18 finally drawing a reasonable conclusion in the
19 Special 301 Report.

20 The Korean government will endeavor to
21 value innovative new drugs. And to create
22 mutually beneficially trading conditions.

1 I would like to conclude by adding
2 that the Korean government plans to actively
3 recognize the opinions of the industry in the
4 future. Thank you.

5 CHAIR LEE: Thank you. We will begin
6 with questions from USTR.

7 MR. CHANG: Thank you for your
8 testimony. Are there any companies, whether
9 domestic or foreign, that have qualified for
10 premium pricing under the new criteria of the
11 Premium Pricing Policy, recognizing that it has
12 only been two months?

13 And -- but, if you know of any foreign
14 or domestic companies that have since qualified,
15 we'd like to know. Thank you.

16 MR. NAM: As I mentioned, it's just
17 only two months have passed since the
18 implementation of this new system.

19 Basically, the Korean government's
20 position on this new system is to wait and see
21 how things will go. If necessary, Korea is
22 looking forward to another opportunity into the

1 future to seek mutually satisfactory outcomes, or
2 mutually beneficially trading conditions under
3 operation of the system.

4 CHAIR LEE: All right. Thank you for
5 your testimony. Next we have the government of
6 Ukraine.

7 Thank you. Please state your name and
8 your organization for the record. And begin your
9 testimony.

10 MR. ZHALDAK: Good morning everyone.
11 My name is Valerii Zhaldak. I am representing
12 here the government of Ukraine, the Ministry of
13 Economic Development and Trade, and the
14 Department for Intellectual Property.

15 Actually, I would like to share with
16 you the progress with which the government of
17 Ukraine has been done through the last year,
18 actually together with the intent to create
19 cooperation with USTR office, with American
20 Embassy in Ukraine.

21 And I think they did quite a good
22 progress. Especially when it comes to actually

1 reload in the system of collective management in
2 Ukraine.

3 Last year in the middle of the year we
4 actually got a new law on collective management.
5 Affecting management of our organizations. And
6 now we are in the process of implementation of
7 this law.

8 We have started already the process of
9 registration of those collective management
10 organizations. A couple of them already have
11 been registered.

12 And we are planning to put in again to
13 the provision of the law to accredit those
14 organizations which will be doing collective
15 management in the sphere of extended and mandated
16 spheres of collective management.

17 But now, according to this law, those
18 which we have registered already can actually
19 manage their activity on the voluntary --
20 voluntary sphere of collective management.

21 So again, we are planning to actually
22 accomplish the process of reloading of this

1 collective management organization until the end
2 of this year. First stage accreditation in some
3 spheres of collective management of mandated and
4 extended.

5 And at the end of the year, it will be
6 happening in October, the rest of the spheres in
7 mandated and extended collective management.

8 So, this is what we have done, again,
9 together in the close cooperation with our U.S.
10 partners and in cooperation with our European
11 partners.

12 So, we have also focused on the
13 process of legalization of so-called unlicensed
14 software. And together again, with a private
15 company, Microsoft Ukraine, we have elaborated
16 the methodology of so-called identification or
17 verification of the unlicensed software.

18 And we started the process of --
19 inventory process, so-called, together again with
20 Microsoft Ukraine. And we also find the sources
21 which can actually provide the possibility that
22 in case there are some unlicensed software, we

1 found the sources how we can buy or found or bind
2 licenses for the software if those software is
3 needed in this or that governmental agency.

4 As you know also, in Ukraine we've got
5 so-called anti-piracy law. We've got cyber
6 police together with the U.S. government we have
7 trained. We have established the boot, we build
8 the capacity. And we believe they are doing very
9 well, our law enforcement bodies when it comes to
10 cyber police.

11 What we also have done, we established
12 the highest court on intellectual property. It
13 is already established.

14 And there is a competition procedure
15 for appointment on a position of judges of that
16 high intellectual property court. And again, we
17 expect according, again judicial body is a
18 separate body.

19 According to judicial body what they
20 say, they are going to accomplish the process
21 until the end of the second quarter of this year.
22 We expect to do it too about -- to get those

1 judges appointed.

2 And also, we believe which we've got
3 also, a very productive mechanism is the IP
4 Council. This is an intergovernmental advisory
5 board which aims to coordinate between all
6 agencies, including law enforcement agency.

7 And in the end I will also tell our
8 plan to reestablish the institution of the State
9 Inspectors. Because we have political level of
10 let's say, communication between agency,
11 interagency.

12 And now we need to establish, let's
13 say, working level. And we -- I actually expect
14 from those inspectors they will be very efficient
15 and effective. And they hope to launch this
16 institution this year. Thank you.

17 CHAIR LEE: Thank you very much. The
18 first question comes from USTR.

19 MR. CHANG: Thank you. We understand
20 that the accreditation process and composition of
21 the Accreditation Commission for Collective
22 Management Organizations or CMOs is being

1 finalized.

2 Would you comment on the composition
3 of the commission and confirm that the timelines
4 in your submission for the accreditation process
5 have not changed?

6 MR. ZHALDAK: Yes. We decided to
7 extend. First of all, I will tell you about the
8 Accreditation Commission.

9 The recommendation from USTR office,
10 from U.S. Embassy, from European Commission, the
11 recommendation was not to establish a so-called
12 this Accreditation Commission.

13 But, our legislation and the
14 government, we decided, let's establish this
15 Accreditation Commission. And we form this from
16 different representatives including NGOs.

17 But, we now need to establish those --
18 collect those representatives. And we decided to
19 make this process transparent and more let's say,
20 I would say, it needs to -- it needs some time.

21 Again, just to establish this
22 commission, to make this process more, let's say

1 transparent and open. So, we extend it until the
2 end of this month. And we again, there is an
3 announcement on our web portal. And anyone from
4 users and from right holders can apply to be a
5 member of this Accreditation Commission.

6 Thank you.

7 CHAIR LEE: Thank you. The next
8 question is from the U.S. Copyright Office.

9 MR. GREENBERG: Good morning. The New
10 CMO law mandates that registration of existing
11 CMOs be done by April 23, 2019.

12 And we understand that as of February
13 19, two new CMOs have been registered. Do you
14 have any updates regarding the registration
15 process? And has there been outreach to
16 development stakeholders to ensure that they are
17 able to participate in the process?

18 MR. ZHALDAK: Yes. Actually due too
19 again -- again, according to the law, this would
20 have started the process in the end of October.

21 But again, due to -- again, there were
22 bureaucratization and bureaucratic procedure, and

1 making this process more again, open and
2 transparent, we decided to postpone and to extend
3 the process of registration.

4 And everyone who wants it actually to
5 be registered as a mem -- as a CMO, had enough
6 time to get registration.

7 And again, as far as I know, yesterday
8 there were only two registered companies, the CMO
9 companies registered -- organizations registered.

10 But, again, it's enough time for
11 everyone. There is a methodology for
12 recommendation and explanation how to do that.

13 And everyone from the market knows how
14 to do it. And that all of them had enough time
15 to do that, to prepare all the documentation to
16 submit to our ministry to get registration.

17 CHAIR LEE: Thank you. One last
18 question. It comes from the Department of
19 Agriculture.

20 MR. KARAWA: Good morning. With
21 respect to the draft bills on geographical
22 indications, semiconductor products, patents and

1 trademarks, can you tell us what the next steps
2 are for these draft bills in the parliament?

3 MR. ZHALDAK: I would say so. Two
4 draft laws, one of them which is on
5 semiconductors as well as on GI, geographical
6 indicators, they are -- actually they're more
7 technical.

8 And the aim of those is to approximate
9 our legislation to the legislation of the
10 European Union. And they both -- they both ran
11 through all procedure and ready to be wrote in a
12 second reading and, you know, as a whole.

13 And they've been a couple of times
14 already included in the voting agenda within our
15 parliament. But again, in our parliament we have
16 more burning issues.

17 Because, you know, we are in fighting
18 with aggression of a neighboring state. And our
19 parliament is focused more on military issues
20 rather than on, unfortunately, unfortunately on
21 intellectual property issues.

22 But again, maybe -- well, our

1 expectation to be vote until the -- well, until
2 the end of this session of the parliament, which
3 ends in June.

4 When it comes to the patent law, so-
5 called patent law, it went again, all the
6 discussion was in the stakeholders. But, shall
7 be considered within again, parliamentarian
8 profile for meeting.

9 Again, this should be done until the
10 -- I would say until the end of October before
11 all the, let's say, our parliament will be
12 reelected.

13 This is my -- my will, so to say. And
14 our expectations. Thank you.

15 CHAIR LEE: Thank you very much.

16 MR. ZHALDAK: Thank you.

17 CHAIR LEE: Next we have the App
18 Association. Thank you. Please state your name
19 and organization for the record and begin your
20 testimony.

21 MR. SCARPELLI: Thank you. My name is
22 Brian Scarpelli and my organization is ACT/The

1 App Association. All right, I'll get going.

2 Thank you for the opportunity to
3 appear today at this important hearing. The App
4 Association represents thousands of small
5 business software application development
6 companies and high-tech firms located across the
7 United States.

8 Alongside the rapid adoption of mobile
9 technologies our members develop innovative
10 applications and products that improve workplace
11 productivity, accelerate academic achievement,
12 monitor health and support the global digital
13 economy.

14 Today the App Association, the app
15 ecosystem, sorry, we estimate is worth
16 approximately \$950 billion and is responsible for
17 4.7 million American jobs, serving as a key
18 driver of the \$8 trillion Internet of Things
19 revolution.

20 The global digital economy holds great
21 promise for app development companies and small
22 business innovators, but our members face a

1 diversity of trade barriers when entering new
2 markets, including failures to provide adequate
3 and effective protection of IPR.

4 The infringement and theft of IPR
5 jeopardizes the success of App Association
6 members and really hurts the billions of
7 customers who rely on their app-based products
8 and services.

9 For us each kind of intellectual
10 property right -- copyright, trademark, patent
11 and trade secret -- represent distinct utilities
12 upon which our members depend.

13 App developers and publishers as well
14 lose an estimated \$3 billion to \$4 billion
15 annually due to pirated apps it's estimated, and
16 IPR violations lead to, for us, customer loss,
17 interruption of service, revenue loss,
18 reputational damage.

19 For smaller companies that my
20 association represents each of these alone can
21 potentially represent an end-of-life occurrence.
22 For our members IPR violation scenarios range

1 widely. They can be basic and well known.

2 There are some basic, well known
3 approaches. There is also some very complex and
4 novel approaches that are emerging and we
5 experience all of them.

6 With regard to copyrights we find
7 pirates that just simply disregard copyrights and
8 completely replicate a software app but remove
9 the digital rights management component enabling
10 them to publish a copy of an app on illegitimate
11 websites or even in legitimate app stores, which
12 deceives customers.

13 These same pirates may change
14 advertising keys to redirect ad revenue from a
15 legitimate business to theirs. In some other
16 instances they have removed locked functions,
17 such as in-app purchases.

18 In some cases pirates have injected
19 malicious code into an app that collects users'
20 private information and re-publishes a copy of
21 the app.

22 That re-published app will look and

1 function like the original app often using the
2 same name and logo and graphics, but ultimately
3 is intended to lure customers who trust the brand
4 into downloading the counterfeit app and
5 providing their sensitive information and putting
6 it at risk.

7 With copyrights, disregarding those
8 rights, we found pirates will use an apps name or
9 trademark brand and just trick users into
10 providing their information for exploitation.

11 Further, with regard to patents we
12 find issues there as well. You know, our name,
13 the branded App Association, sometimes leads to
14 an assumption that it's all software applications
15 but many of our members, increasingly, in fact,
16 if you look at a breakdown in the membership, are
17 developing both software and hardware innovations
18 in combination.

19 So patents really do play in both of
20 those contexts and our members experience
21 infringement from both utility and design
22 patents.

1 We also face issues with trade
2 secrets. It will probably be raised many times
3 today, but an issue for us, and, again, a very
4 serious issue.

5 And, finally, but far from the least
6 important, our members do face issues where
7 market regulators impose joint venture
8 requirements, foreign equity limitations,
9 ambiguous regulations or regulatory approval
10 processes or other creative means, such as source
11 code escrowing, for example, that would force our
12 members to transfer IP to others in order to
13 access the market, and for our members this is
14 pretty much a non-starter.

15 The risks of infringement from this
16 forced disclosure and in return for market access
17 are usually too great to absorb and they just
18 simply leave the market.

19 I appreciate the opportunity to appear
20 here today before you all and we support U.S.
21 government efforts to protect American small
22 businesses that rely on IPR to innovate.

1 We commit to partnership with USTR and
2 other stakeholders sitting here to create
3 responsible IPR protections across the globe for
4 our members seeking to enter new markets and
5 create more U.S. jobs. Thank you.

6 CHAIR LEE: Thank you. We will begin
7 questions with USTR.

8 MR. S. CHANG: Thank you for your
9 testimony. Specific to China and standard
10 essential patents, or SEPs, your submission
11 notes, certain entities, like the Standardization
12 Administration of China, have attempted to
13 publish policies that would have instructed
14 Chinese-backed standardization bodies to lower or
15 undermine royalty payments for patents without
16 differentiating between a fair, reasonable and
17 non-discriminatory FRAND-encumbered SEPs and
18 other patents, close quotes.

19 Could you please elaborate on these
20 policies and their effects?

21 MR. SCARPELLI: Sure. It's a very
22 serious issue for our members. Generally

1 standard essential patents have really risen up
2 as they are critical to any technology that will
3 utilize any kind of baseline standardized
4 technology in order to innovate.

5 You know, I think that there is -- at
6 this point, I think it's pretty safe to call it
7 an unfair assumption that standard essential
8 patent disputes only affect, you know, a handful
9 of large cell phone manufacturers or something
10 like that.

11 And we are finding that is not the
12 case as new verticals, most recently the auto
13 industry, for example, are incorporating sensors
14 and internet connectivity, wireless connectivity,
15 into their products to introduce new
16 efficiencies.

17 They are facing the same, in some
18 cases demands for supra-FRAND rates despite the
19 owner of the, the holder of the standard
20 essential patent making a voluntary FRAND
21 commitment far before that to license on FRAND
22 rates.

1 It is a global issue for us generally
2 and China specifically, it is an issue. You
3 know, generally with standardization we face
4 essentially a situation where the government may
5 mandate the use of a standardized technology that
6 is then developed through an anointed
7 standard-setting organization.

8 Participation in that organization is
9 typically restricted and not accessible to our
10 members and the net effect of -- and the
11 intellectual property rights policy of that
12 standard-setting organization we have found have
13 had reflected what you quoted from our comment.

14 The net effect being that in order to
15 comply with the law one has to use the standard,
16 therefore, hey, supra-FRAND royalties. So it's a
17 big issue for us definitely.

18 CHAIR LEE: Thank you. The next
19 question is from the U.S. Copyright Office.

20 MR. GREENBERG: Good morning. Your
21 submission details various kinds of IP theft,
22 including copyright infringement and

1 circumvention of technological protection
2 measures.

3 With respect to India, Kuwait and
4 Argentina could you provide further details on
5 the specific kinds of copyright-related
6 challenges you are seeing in those markets?

7 MR. SCARPELLI: Sure. Thank you very
8 much for that question. I guess I would say
9 first a common thread I think across the concerns
10 we are expressing with the markets you mentioned,
11 India, Kuwait, Argentina, is sometimes, and I
12 believe it is the case probably more so with
13 Argentina, is that laws may even be on the books
14 but they are simply not being enforced.

15 Nonetheless, I don't want to, you now,
16 I don't want to fail to give credit to attempts
17 across all three markets to adopt laws and put
18 into place enforcement regimes that will provide
19 reasonable protection for copyrights and I hope
20 that we give enough of a hat-tip in our comment,
21 in our written comments to those efforts, but
22 there is much progress to be made so I think that

1 we make the recommendations that they remain on,
2 for example, the priority watch list.

3 CHAIR LEE: All right. Thank you very
4 much. Next up is the Alliance for Fair Trade
5 with India.

6 MR. MURRY: Good morning.

7 CHAIR LEE: Good morning. Please
8 state your name and organization for the record
9 and please begin your testimony.

10 MR. MURRY: Yes. I am Roger Murry
11 with the Alliance for Fair Trade with India.
12 Thank you all for your time today and for your
13 hard work advancing stronger intellectual
14 property rights around the globe, and
15 particularly in India.

16 As I mentioned I represent AFTI. It's
17 a diverse group of trade associations that
18 support increased action to address the many
19 trade and investment barriers that U.S. companies
20 face in India, including those adversely impacted
21 by India's intellectual property practices and
22 policies.

1 AFTI joins the many organizations
2 testifying today calling for USTR to once again
3 place India on the priority watch list. This
4 reflects the range of IP concerns that have yet
5 to be addressed and are emerging.

6 These longstanding concerns, and some
7 new, directly limit market access and place U.S.
8 innovative industries at a disadvantage. They
9 also hold back Indian innovators, creators and
10 entrepreneurs and rob India of critical
11 investment and trade that could move India's
12 economy forward.

13 We recognize that India has made some
14 progress in discrete areas, and those are
15 important. Last year India acceded to the WIPO
16 Internet Treaties.

17 Earlier this month it finally
18 criminalized video piracy. In January India's
19 Supreme Court ruled in favor of Monsanto's patent
20 rights, which if followed may set a thoughtful
21 precedent.

22 Now we commend these actions and ask

1 India to finalize these and other encouraging
2 steps. For example, while India adopted revised
3 rules for software patents in 2017 it has yet to
4 define what it considers patentable under the new
5 rules.

6 To implement the WIPO Internet
7 Treaties India needs to adopt multiple amendments
8 to the Copyright Act. However, despite these
9 important but measured steps, the Government of
10 India has yet to meaningfully address numerous
11 onerous and longstanding shortcomings to its IPR
12 regime identified in the 2018 and prior Special
13 301 reports.

14 These include major hurdles to patent
15 protections for innovative medicines, pressure to
16 localize manufacturing and price controls on
17 medical devices and seed technology.

18 Our written comments detail these
19 priority challenges. In the interest of time,
20 AFTI would like to highlight one re-emerging
21 challenge that has gathered steam even in the
22 past few months: royalty caps.

1 The Indian Government is actively
2 considering proposals to severely restrict
3 royalty payments related to technology transfer
4 and brand licensing on a sliding scale.

5 The proposals go to the heart of
6 effective commercialization of IP. India
7 liberalized its royalty caps in 2009 because in
8 the words of the then-Economic Minister, quote,
9 India needs to access the best technologies
10 available abroad. The caps were coming in this
11 way, unquote.

12 Since then U.S. exports of IP
13 royalties quadrupled from \$850 million to over \$3
14 billion while U.S. portfolio investment income
15 more than doubled to about \$4 billion.

16 This also helped grow India's own
17 economy and job creation, yet the Indian
18 Government has taken an increasingly narrow
19 domestically-focused view of these issues.

20 When the new proposals were first
21 leaked last year one press report quoted an
22 unnamed, quote, senior government official

1 concerned not about how to boost the investment
2 inflows that create so many jobs, but that,
3 quote, increased royalty payments, and his quote
4 was, his or her quote was increase royalty
5 payments deplete 4X reserves.

6 India's preoccupation with capital
7 flight is holding back India's global
8 competitiveness and ability to grow its middle
9 class.

10 Indian trade negotiators in their
11 Model Bit, in RCEP negotiations and elsewhere,
12 insist that investment provisions exclude
13 portfolio investments.

14 As is no surprise, India is having
15 trouble convincing its negotiating partners of
16 the merits here. We certainly don't see any and
17 we would ask that the United States make clear
18 how important it is for India to maintain its
19 liberal royalty policies.

20 In general, AFTI continues to believe
21 that together our governments can advance strong
22 intellectual property rights that promote

1 innovation, trade and investment, but the United
2 States must respond when India takes shortsighted
3 populist actions.

4 We encourage USTR to engage with India
5 throughout 2019, including in a re-launch trade
6 policy forum, including in a commercial dialogue,
7 and wherever else possible.

8 In conclusion, I would like to thank
9 you all again for your tireless work to promote
10 intellectual property rights for Americans and I
11 am happy to answer any questions that you might
12 have.

13 CHAIR LEE: Thank you. Well, we will
14 begin the questions with one from USTR.

15 MR. S. CHANG: Thank you for your
16 testimony. Over the past two years since the
17 issuance of India's national IP policy, how does
18 AFTI evaluate India's implementation of that
19 policy?

20 What recommendations do you have to
21 the Government of India for implementation of the
22 policy going forward?

1 MR. MURRY: Good question. And, in
2 fact, AFTI decided to remove mention of the IP
3 policy from its summary, in its written comments,
4 because other intellectual property issues were
5 really dominating our bandwidth.

6 And so we have kind of shifted our
7 focus to topics like royalty caps, you know,
8 encouraging continued progress on copyright
9 enforcement specific to, you know, passage of the
10 cinematograph amendments earlier this month.

11 So we have decided to kind of break
12 away from the set policy document and really
13 focus in on discrete policies themselves.

14 CHAIR LEE: Thank you. The next
15 question is from the U.S. Department of State.

16 MR. HENRY: India's compulsory
17 licensing policies remain a top concern for AFTI
18 yet AFTI's submission notes that the number of
19 compulsory licenses issued over the past year has
20 again dropped.

21 Could you please describe what
22 challenges exist for your members in India due to

1 India's compulsory licensing policies?

2 MR. MURRY: Thanks for the question.

3 Kind of high-level, compulsory licensing policy
4 is a bit like discussion of royalty caps
5 proposals where the mention, the existence of the
6 willingness to proceed down that path can chill
7 the investment environment, can chill the
8 intellectual property environment.

9 Specifically we find that India's
10 compulsory licensing practices are troubling
11 because they are, we regularly hear of an intent
12 to benefit Indian industries, domestic
13 industries, to the detriment of U.S. exporters.

14 And kind of some specific things that
15 we are tracking currently the Ministry of Health
16 continues to entertain potential recommendations
17 to impose CLs on certain anti-cancer medicines
18 under Section 92 of India's Patents Act as well
19 as Indian pharmaceutical companies continue to
20 make requests for voluntary licenses under
21 Section 84.

22 So those are some concerns where we

1 have seen encouragement and we mention this in
2 our written comments.

3 The Indian Government does seem to
4 have taken a more we think thoughtful approach on
5 compulsory licenses where it has kind of managed
6 domestic stakeholder pressure in ways that we
7 think are more productive and we would certainly
8 encourage continuing that.

9 CHAIR LEE: Thank you very much. The
10 next question is from the U.S. Patent and
11 Trademark Office.

12 MS. FERRITER: Thank you. AFTI
13 recognized and welcomed India's recent accession
14 to the WIPO Internet Treaties and calls for India
15 to move forward with implementation in order to
16 comply with its obligations.

17 Can you please describe where AFTI
18 believes India falls short of WIPO Internet
19 Treaty standards and what specific steps India
20 needs to take to fully comply?

21 MR. MURRY: Thank you for that
22 question. Yes, we have taken a look at that

1 pretty closely and we think that a handful of
2 amendments are necessary to the Copyrights Act.

3 These include defining technological
4 protection measures, including civil and criminal
5 penalties, and within that we believe that
6 sanctions should apply to both acts of
7 circumvention and trafficking in devices,
8 components and services that circumvent.

9 Kind of Part 2 would be adopting
10 definitions and sanctions for the unauthorized
11 removal of rights management information. And so
12 implementation of these two pieces we think would
13 allow Indian innovators the opportunity to
14 benefit from the commercial opportunities
15 enabled.

16 So we think that WIPO Internet Treaty
17 is a significant improvement and something we
18 note strongly in our comments both today and in
19 our submitted comments.

20 I guess one other thing that we would
21 recommend that India amend Section 52C of the
22 Copyright Act to bring it in line with existing

1 safe harbor provisions in the Information
2 Technology Act, which also would be aligned with
3 international standards pertaining to temporary
4 copies. So a little bit more work to do.

5 CHAIR LEE: All right. Thank you for
6 your testimony.

7 MR. MURRY: Thank you, all.

8 CHAIR LEE: Next up we have American
9 Apparel and Footwear Association. Thank you very
10 much. Please state your name and organization
11 for the record and begin your testimony.

12 MS. MITROPOULOS: My name is Christina
13 Mitropoulos and I am a Government Relations
14 Representative at the American Apparel and
15 Footwear Association.

16 AAFA appreciates the opportunity to
17 testify before the Special 301 Committee. AAFA
18 is the national trade association representing
19 apparel, footwear, travel goods and other sewn
20 products companies and their suppliers which
21 compete in the global market.

22 We represent more than a thousand

1 world famous name brands, their management and
2 shareholders. Our industry is nearly four
3 million U.S. workers and its contribution of \$400
4 billion annually in U.S. retail sales.

5 Intellectual property remains a top
6 concern for our members. Our members'
7 competitiveness is highly dependent on the
8 protection of the intellectual property embedded
9 in their designs, their brands and their images.

10 Stolen IPR costs our members billions
11 in lost sales, damages to reputation and
12 substantial legal expenses.

13 In Fiscal Year 2017 Customs and Border
14 Protection reported that the merchandise category
15 with the highest number of IPR seizures continued
16 to be wearing apparel and accessories, resulting
17 in approximately 15 percent of all IPR seizures,
18 footwear accounted for 12 percent and handbags
19 and wallets accounted for 10 percent.

20 But it is more than lost sales for our
21 member companies. This is about child safety and
22 knowing that the pajamas a consumer has bought

1 for her newborn will not result in a rash. This
2 is about worker safety and knowing that a t-shirt
3 a consumer bought was sewn in an ethical factory.
4 This is about the environment and knowing that
5 the water used to dye the jeans a consumer is
6 wearing was properly treated.

7 While I am prepared to talk about any
8 of the issues raised in our written submission,
9 out of the interest of time today I would like to
10 focus on two countries: China and Spain.

11 Despite members noting some
12 improvements in China the country remains a
13 source of pervasive counterfeiting. Members
14 emphasize that bad-faith registrants take
15 advantage of the first to file system.

16 The administration imposed tariffs
17 under Section 301 on U.S. imports from China
18 totaling \$250 billion worth of goods as part of
19 the United States' response to Chinese theft of
20 American intellectual property.

21 While there are significant IP
22 concerns in China, we stress, as we have in the

1 past, that China remains an invaluable trading
2 partner for our members and for our industry.

3 Steps to address Chinese IP practices
4 must be taken in a manner that ensures that
5 supply chains and the U.S. jobs that support them
6 are not interrupted by U.S. actions or Chinese
7 retaliation.

8 As we noted in our submission, the
9 imposition of tariffs may actually stimulate the
10 trade of counterfeit goods. The tariffs
11 announced by the administration will impose a tax
12 on legitimately traded goods from China and these
13 taxes will be paid by U.S. branded companies who
14 also take steps to ensure that their products
15 comply with applicable laws and taxes.

16 Counterfeiters, on the other hand,
17 will likely avoid these duties, driving up the
18 delta between legitimately traded items and their
19 illegal knock-offs.

20 This could have the unintended adverse
21 impact of driving certain consumers to purchase
22 counterfeit goods as a cheaper alternative.

1 Turning now to Spain. Street vendors
2 from Africa without legal status have now covered
3 major cities like Barcelona and Madrid and their
4 counterfeit goods from dozens of brands.

5 Many members have been vocal about the
6 illegal street vendors operating in Barcelona and
7 offering for sale counterfeit goods of their
8 products.

9 Members report that the problem is
10 growing and authorities are backing away from
11 acting because the issue is social rather than
12 criminal.

13 City officials in Barcelona have told
14 the police to do nothing. This situation is
15 relevant to keep in mind as the U.S. and E.U.
16 continue negotiations on the U.S.-E.U. trade
17 agreement.

18 The U.S. and E.U. have a shared
19 commitment on the protection of intellectual
20 property rights which are critically important
21 for our industry.

22 We support provisions in the U.S.-E.U.

1 trade agreement that reflect a shared commitment
2 in the form of clearly articulated requirements
3 to easily record and register marks, commitments
4 to enforce against counterfeiting, including
5 third party marketplaces and efforts to cooperate
6 on international efforts to thwart intellectual
7 property rights theft.

8 Aafa appreciates this opportunity to
9 raise these concerns and we look forward to
10 working with USTR to address these IP issues. We
11 consider this to be an ongoing process and will
12 provide USTR with updated information as our
13 members bring them to our attention.

14 I will now take any questions you may
15 have. Thank you.

16 CHAIR LEE: Thank you. We will begin
17 with USTR.

18 MR. S. CHANG: Thank you for your
19 testimony. You identified several concerns about
20 policies related to intellectual property in
21 various markets.

22 However, you do not make any

1 recommendations about the listing of these
2 countries. How do you think this input should be
3 reflected in the Special 301 report? Are you
4 equally concerned about all trading partners you
5 mentioned?

6 MS. MITROPOULOS: Thank you for that
7 question. So we have provided input from our
8 members based on the updates they have seen since
9 the last year and since the last report has been
10 issued and we leave the ultimate determination as
11 to which country should make the priority watch
12 list to USTR.

13 With that being said, we will continue
14 to provide these updates to USTR to make that
15 ultimate determination.

16 CHAIR LEE: Thank you very much. The
17 next question is from the U.S. Patent and
18 Trademark Office.

19 MS. FERRITER: Thank you. The Gulf
20 region, especially free trade zones, or FTZs,
21 continue to be a major hub for transshipment.
22 These FTZs have come under greater scrutiny

1 recently for lack of enforcement of intellectual
2 property rights, especially FTZs in the UAE,
3 namely Jebel Ali.

4 Have AAFA members expressed any IPR
5 enforcement challenges in this region and what
6 steps, if any, has the AAFA taken to articulate
7 these concerns?

8 Can you provide more background on the
9 factors you considered in evaluating the Middle
10 East and North Africa, or the MENA region, this
11 year for this year's Special 301 recommendations?

12 Thank you.

13 MS. MITROPOULOS: Thank you for that
14 question. So foreign trade zones are hubs of
15 counterfeiting activity and we have definitely
16 heard that from members.

17 I can get back to you with specifics
18 as to which countries members have been flagging
19 for our attention, but I can say that generally
20 this issue has been brought to our attention.

21 CHAIR LEE: Okay. Thank you very
22 much. Next we have a question from the State

1 Department.

2 MR. HENRY: My question deals with
3 Canada. AAFA reports that there is minimal
4 support from Canadian law enforcement and customs
5 to handle IP work.

6 Could you please explain in more
7 detail the issues your members face with regard
8 to Canadian law enforcement and customs?

9 MS. MITROPOULOS: Sure. Thank you for
10 that question. So as far as the Royal Canadian
11 Mounted Police, members have expressed to us the
12 difficulties when it comes to dealing with
13 trademark and counterfeiting matters in Canada.

14 If you are looking for specific
15 information I can certainly get that to you from
16 our members, but generally speaking, Canada has
17 been a very difficult country to enforce in in
18 terms of IPR.

19 CHAIR LEE: Thank you. The next
20 question is from the Department of the Treasury.

21 MR. W. CHANG: Thanks. On the
22 Philippines, your members raised concerns that

1 the Department of Justice prosecutors are giving
2 lower priority to criminal actions in cases
3 involving seized counterfeit goods.

4 On what do you base this assertion and
5 do you have evidence that the public prosecutors
6 are not making use of the rules of procedures for
7 intellectual property rights cases?

8 MS. MITROPOULOS: Thank you for your
9 question. Yes, so one of our members flagged the
10 difficulties that they are encountering in the
11 Philippines so that came directly from that
12 particular member and I know having spoken to a
13 number of our members as we were collecting
14 information for this process that the Philippines
15 continues to be a difficult region to enforce in,
16 but as far as specifics I can get back to you on
17 that.

18 CHAIR LEE: Thank you. And one last
19 question from the Department of Labor.

20 MS. PETTIS: Your submission states
21 that the Turkish customs require lawyers to do
22 in-person inspections of suspected counterfeit

1 goods.

2 Even if the goods are counterfeit,
3 customs will not seize them unless brands file a
4 motion before the courts order the seizures. Can
5 you provide further information on this process?

6 For example, do the courts routinely
7 issue such seizure orders once requested by the
8 right holder or is it considered an extraordinary
9 remedy and if the court does issue the order does
10 the customs proceed to seize the merchandise?

11 MS. MITROPOULOS: Thank you for your
12 question. So we have heard from members that
13 working with the Patent and Trademark Office in
14 Turkey has been quite difficult.

15 As far as the particular member that
16 we flagged saying that Turkey is the country
17 where they have the largest number of oppositions
18 in the world, I am happy to provide more
19 information as far as that member's particular
20 issues when it comes to Turkey, but this is what
21 we have been hearing generally.

22 MS. PETTIS: Okay, great. Thank you.

1 CHAIR LEE: Thank you for your
2 testimony. Next up is the Biotechnology
3 Innovation Organization.

4 Thank you. Please state your name and
5 organization for the record, and begin your
6 testimony.

7 MR. PINE: Sure, thank you. Good
8 morning. My name is Justin Pine and I'm here on
9 behalf of the Biotechnology Innovation
10 Organization.

11 We appreciate the opportunity to
12 provide the statements. Part of our
13 participation at 2019 Special 301 review process.

14 BIO is a non-profit organization with
15 a membership of more than 1,000 biotechnology
16 companies, academic institutions, state
17 biotechnology centers, investors and related
18 organizations from all 50 states and
19 approximately 30 foreign countries.

20 Our members are involved in the
21 research and development of biotechnology
22 products and the human health, animal health,

1 agriculture and industrial and environmental
2 sectors.

3 These innovations improve health
4 outcomes, increase agricultural productivity,
5 produce cleaner energy and provide for a more
6 sustainable economic future around the world.

7 A vast majority of BIO's members are
8 small and medium sized enterprises that currently
9 do not have products on the market. Their major
10 assets are their ideas protected by their
11 intellectual property.

12 Biotech is a capital-intensive,
13 long-term and high-risk research and development
14 endeavor. And venture capitalists really only
15 invest in the sector if they believe that there
16 will be an attractive return on their investment.

17 Without strong predictable patent,
18 regulatory data protection investors may shy away
19 from investing in biotech and will simply put
20 their money to projects or products that are less
21 financially risky without regard to the great
22 value that biotechnology offers to society.

1 While the IP environment of the U.S.
2 has contributed to the emergence of many
3 biotechnology businesses and provided their first
4 market opportunities, these businesses need to
5 participate in the global economy. And their
6 search for global collaborations, partnerships
7 and for a marketplace for those products that
8 have been developed.

9 Unfortunately, some U.S. trading
10 partners are implementing policies or practices
11 that frustrate the commercialization development
12 of biotech innovations.

13 Principally, global challenges
14 impacting our sector of global compulsory
15 licensing trends, lack of adequate or any
16 regulatory data protection and restrictive
17 patentability frameworks.

18 In addition to these IP challenges, we
19 would also like to reiterate market assets
20 concerns, particularly with respect to draconian
21 pricing policies for patented biotechnology
22 products, which undervalue American innovations

1 abroad.

2 With respect to compulsory licensing,
3 Malaysia was a focus of concerns last year and
4 nothing has diminished that concern. Its
5 issuance of a compulsory license on an innovative
6 patented treatment for Hepatitis C, in the
7 absence of any justified access problem and
8 without fair or transparent processes involving
9 the patent holder, is deeply troubling to BIO and
10 our members.

11 Using compulsory licensing to promote
12 the importation of, or local production of
13 medicines that the expensive innovators and
14 manufacturers in the U.S. and elsewhere, is a
15 threat to U.S. intellectual property rights and a
16 direct attack on the innovators' ability to
17 compete fairly in the global market.

18 Given that the Malaysian Government
19 has identified biotech as a strategic economic
20 sector, it's concerning that the compulsory
21 licensing scheme may become a supporting factor
22 to Malaysia's industrial policy strategy. Given

1 the situation, BIO recommended Malaysia be
2 designated as a priority foreign country.

3 We'd also like to highlight, Chile and
4 Colombia have also taken irresponsible compulsory
5 licensing actions issuing declarations of public
6 interests, citing public health reasons without
7 any fair or transparent process to support a
8 compulsory license, again, on a drug for the
9 treatment of Hepatitis C.

10 Although to date, no compulsory
11 license has been issued in Chile or Colombia, the
12 threat of pursuing compulsory licensing in these
13 key U.S. trading partners presents real concerns
14 for the innovative biotech community. Not just
15 the biopharmaceutical sector but across all
16 biotech sectors.

17 There are many U.S. trading partners
18 that do not provide adequate, if any, regulatory
19 data protection as well. Chief among these
20 countries are Argentina, Brazil, Chile, China,
21 India and Malaysia, for example.

22 In some cases, there is no legislation

1 for regulatory data protection, and in other
2 cases, as highlighted in more detail in our
3 submission, there is legislation or international
4 trade commitments that are inadequately
5 implemented.

6 China, for example, has a regulatory
7 data protection policy in place providing market
8 exclusivity for drugs first launched in China.
9 However, in practices, this has effectively not
10 provided any protection to U.S. innovators
11 because medicines are typically first launched
12 first outside of China.

13 This is particularly discriminating
14 towards our small and medium sized biotech
15 enterprises that may not have the resources or
16 expertise in global commercialization of their
17 products.

18 Generally speaking, BIO recognizes an
19 increasingly challenging global environment for
20 obtaining patents for biotechnology innovations,
21 international markets. In some jurisdictions,
22 patent-eligible subject matter and patentability

1 criteria are so narrow that obtaining some degree
2 of protection is a monumental undertaking.

3 Finally, in many foreign countries
4 where the government is responsible for health
5 care costs, prices on patented innovations are
6 being lowered through policies that appear
7 arbitrary and without transparent justification.

8 Unfortunately, longer term savings and
9 population health and productivity gains are
10 often overlooked for short-term budgetary gains.

11 This results in the value of
12 biopharmaceutical innovations and their IP being
13 unreasonably restricted. Particular, BIO's
14 concern with the practices of Canada, Japan and
15 South Korea.

16 In Japan and Korea, for example,
17 conditioning preferential pricing on localized
18 manufacturing and R&D were joint partnerships
19 with domestic firms effectively discriminates
20 against our small and medium sized enterprises
21 that account for about 75 percent of the global
22 drug pipeline and development.

1 With that, I conclude. I'll take any
2 questions.

3 CHAIR LEE: Thank you very much. We
4 will begin questions with USTR.

5 MR. S. CHANG: Thank you. BIO's
6 recommendation that Malaysia be designated as a
7 priority foreign country appears to stem largely
8 from actions, and I quote, actions of the
9 Malaysian Government which constitute a blatant
10 disregard of patent rights protection, close
11 quote, and describes specific concerns related to
12 compulsory licensing and lack of effective
13 regulatory data protection.

14 Could you please explain how
15 Malaysia's actions set them apart from other
16 markets and what steps BIO would like Malaysia to
17 take to address these issues?

18 MR. PINE: Sure. Effectively in
19 Malaysia what we've seen is an actual compulsory
20 license being granted, rather than in other
21 countries there's more of a threat of a
22 compulsory license.

1 And Malaysia action has actually been
2 taken by the government. And one of the most
3 concerning issues in Malaysia is the lack of
4 transparency, the lack of dialogue with patent
5 holders and with our organization, for example.

6 CHAIR LEE: Thank you. The next
7 question comes from the Department of Health and
8 Human Services.

9 MS. BLEIMUND: BIO is focused on
10 Chile's proposal to clarify and its national law
11 that access to medicines is not adequate, quote,
12 when there are economic, financial and geographic
13 or opportunity barriers that prevent access to a
14 medication, end quote.

15 How might that change in law effect
16 Chile's protection if IP or your access to the
17 Chilean market?

18 MR. PINE: Sure. There are efforts,
19 not just in the executive branch in Chile to
20 explore compulsory licensing, but there have been
21 a number of developments in the legislative
22 branch to codify compulsory licensing as a tool

1 to undermine intellectual property rights.

2 There is a current bill in the Chilean
3 legislature that codifies a term of economic
4 inaccessibility to justify compulsory licensing.
5 And that's something that's unprecedented to our
6 knowledge globally and of serious concern.

7 CHAIR LEE: Thank you very much. The
8 next question comes from the International Trade
9 Administration of the Department of Commerce.

10 MR. MITCHELL: Yes. This question
11 concerns Colombia. And the record reflects your
12 concerns about the Ministry of Health review of
13 patents, as defined by Article 70 of Colombia's
14 2015 national development plan.

15 Colombia had stated that Article 70
16 does not give the Ministry of Health any special
17 institutional role to oppose or interfere with
18 patent applications or take any other steps that
19 would improperly delay the patent process for
20 inventions in a particular field of technology.

21 That's contained in a Memorandum of
22 the Legal Department of the Presidency of the

1 Republic, published in Colombian patent
2 authority's intellectual property bulletin in
3 February of 2018.

4 The question is, in your view, does
5 this memorandum provide enough certainty, as to
6 the Ministry of Health's role in this patent
7 review process, and if it does not, what
8 additional clarity would you be seeking from
9 Colombia on this issue?

10 MR. PINE: Thank you. The primary
11 concern with this issue, you may be familiar with
12 the issue of prior consent that the, really was
13 born out of Brazil where the local Brazilian
14 regulatory authority had a role in examining
15 patents under the, essentially based on public
16 health concerns.

17 And this was separate, or in addition
18 to, really the examination of patents from the,
19 by the Intellectual Property Office in Brazil.

20 In Colombia there were initiatives to
21 essentially mimic the policy that had existed in
22 Brazil for many years, and it has provided proof

1 to be very challenging for our members and
2 contributed to the significant lack of security
3 of our, of IP rights in Brazil.

4 So there is a major concern in
5 Colombia that they were following that precedent.

6 I will note that with a new
7 administration in Colombia, there will be a new
8 national development plan, so we'd like to see
9 further clarification that there will not be any
10 involvement by the regulatory authority or the
11 Ministry of Health in Colombia and the review of
12 patentability criteria, that that should remain a
13 function of the Patent Office.

14 CHAIR LEE: Thank you. Thank you for
15 your testimony. And next is BSA, the Software
16 Alliance.

17 Thank you. Please state your name and
18 organization for the record and begin your
19 testimony.

20 MR. WHITLOCK: My name is Joe Whitlock
21 and I'm here on behalf of BSA, the Software
22 Alliance.

1 BSA thanks the Special 301
2 Subcommittee for this opportunity to testify
3 today. Your work under the Special 301 statute
4 is invaluable.

5 Today I will discuss BSA member
6 contributions to U.S. innovation, leadership and
7 growth and opportunities and challenges in
8 foreign markets. And those are, on the one hand,
9 trade and IP policies that serve as models for
10 other countries, and on the other hand, digitally
11 protectionist and discriminatory policies that
12 are harming U.S. IPR holders and innovation.

13 BSA members provide, primarily,
14 enterprise software solutions. We include Adobe,
15 Box, Cadence, DocuSign, IBM, Microsoft and
16 Salesforce, among others.

17 We are at the forefront of the global
18 development of cutting-edge enterprise software
19 innovations. From artificial intelligence to
20 machine learning and data analytics, to smart
21 devices and cloud computing.

22 And we are among the most innovative

1 IPR holders in the world. Based on U.S. PTO
2 data, BSA members accounted for nearly 50 percent
3 of all patents issued in 2018 to the top ten U.S.
4 patent holders.

5 Software also accounts for \$63 billion
6 in annual R&D expenditures, which is nearly 20
7 percent of all U.S. private sector R&D. And it
8 is widely recognized that BSA members are
9 responsible for developing the world's most
10 valuable and transformative enterprise software
11 solutions.

12 Software industry accounts for over \$1
13 trillion in U.S. GDP and 11 million jobs each
14 year. In short, BSA members rely heavily on your
15 work to ensure open access to U.S. trading
16 partners markets, and IP frameworks that promote
17 the progress of science and the useful arts.

18 So, I'd first like to discuss model
19 trade and IP policies. BSA conducts a biannual
20 review of dozens of countries reflected in our
21 cloud computing scorecard.

22 The scorecard measures each countries

1 legal frameworks relating to IP, trade, privacy
2 and cybersecurity, among other areas. Countries
3 that historically score well include Germany,
4 Japan, Singapore, the United Kingdom and the
5 United States.

6 This is due to these countries forward
7 looking innovation policies. Those are policies
8 that promote cross-border data transfers,
9 protection and enforcement of IP with appropriate
10 exceptions and safeguards, clear copyright rules
11 permitting commercial data gathering and rules
12 providing protections from liability for unlawful
13 content posted by third-parties.

14 The use of innovation, innovative
15 technology in the public sector, recognition of
16 electronic signatures and commercial
17 transactions, interoperability and adherence to
18 internationally recognized standards and
19 non-discriminatory cybersecurity and supply chain
20 security rules.

21 Those types of rules are also policies
22 that deterred digital protectionism by

1 prohibiting source code or algorithm disclosure
2 requirements and other force technology transfer
3 mechanisms and data localization requirements.

4 And I will next discuss the digitally
5 protectionist and discriminatory policies that
6 are harming U.S. IPR holders and innovation.

7 So, U.S. software innovation is under
8 a rising threat from digital protectionism,
9 coercive technology transfer and discrimination
10 against foreign software. And we outline a few
11 of the key issues below.

12 First, on cross-border data flows and
13 data localization. BSA members, and then U.S.
14 companies in all sectors that deploy our software
15 tools, depend upon cross-border data transfers to
16 realize a return on investments in R&D and to
17 commercialize, their IPR.

18 Data related market access barriers
19 take many forms and are accelerating and
20 increasing around the globe. And the situation
21 is urgent, and I would refer you to our
22 submission.

1 Standards. Technology standards play
2 a vital role in facilitating innovation and
3 trade. But unfortunately, some countries use
4 mandatory country specific standards to favor
5 local companies. Which not only excludes U.S.
6 IPR holders but impacts the cost and quality of
7 available technologies.

8 Third, copyright and artificial
9 intelligence. Innovation in the digital
10 environment also requires legal frameworks that
11 offer effective enforcement tools but are also
12 geared to innovation and rapidly evolving 21st
13 century technologies.

14 So, these frameworks must not
15 unreasonably prejudice the legitimate interests
16 of copyright holders and must be limited to
17 special cases that do not conflict with the
18 normal exploitation of the work.

19 At the same time, with the
20 establishment of such frameworks is critical to
21 future U.S. leadership in artificial
22 intelligence. Which the White House identify is

1 a top strategic priority in its February 11
2 executive order on maintaining American
3 leadership in artificial intelligence.

4 In this regard, we note that a few
5 countries have followed the U.S. lead in
6 developing IP frameworks to promote artificial
7 intelligence. They include Japan, Singapore and
8 the EU.

9 This is, in our view, an important
10 policy objective for U.S. advocacy, which should
11 promote national policies to permit data
12 analytics of lawfully accessed data in the AI
13 context.

14 There are a number of other issues,
15 which I could cover, and are discussed more in
16 our submission, including ISP liability and safe
17 harbors, software license compliance and SOE
18 legalization, non-discriminatory availability of
19 patent protection and other issues, but let me
20 thank you, again, for the opportunity to testify
21 and I look forward to your questions.

22 CHAIR LEE: Okay, thank you. We'll

1 begin questions with USTR.

2 MR. S. CHANG: Thank you for your
3 testimony. What is your most serious concern in
4 China?

5 How would you compare the environment
6 today in China to five years ago?

7 Your submission mentioned that
8 positive, some positive experiences in China's
9 specialized IP courts. How significant is that
10 advance relative to the concerns you've
11 identified?

12 MR. WHITLOCK: Thank you very much.
13 Our most serious concern in China, and in any
14 every country referenced in our submission,
15 relates to restrictions on the ability to engage
16 in cross-border data transfer and in data
17 localization requirements.

18 In short, this is not simply an issue
19 for enterprise software providers. It is an
20 issue for every single one of our customers
21 that's operating internationally.

22 And let me just preface with an

1 explanation of the issue a little bit before we
2 get into China. Just to provide a few examples
3 of that.

4 For example, if one considers the
5 entire manufacturing, design manufacturing and
6 marketing process of a product, multinational
7 companies today are operating around the globe in
8 multiple jurisdictions for design, blueprints,
9 scoping, for developing manufacturing plant
10 operations, then for the products once they're
11 sold in the marketplace. If they have any kind
12 of software functionality, data needs to be able
13 to transfer across borders at every single phase.

14 In China in particular, there are a
15 number of measures that would restrict
16 cross-border data transfer or require data to be
17 localized. They include implementing measures
18 under the cybersecurity law.

19 They also include cybersecurity
20 measures that require secure and controllable
21 products. They include certain restrictions.

22 The cybersecurity classified

1 protection regulations, new measures that are
2 under development today regarding personal data
3 protection. And services measures, services
4 related measures that effectively block all U.S.
5 cloud computing providers from being licensed or
6 participating in the market place.

7 CHAIR LEE: All right, thank you. The
8 next question is from the U.S. Copyright Office.

9 MR. GREENBERG: Good morning. BSA
10 highlighted the challenge of unlicensed software
11 by governments for years. Indeed, some countries
12 often, in central government or key ministries,
13 have adopted legislation, regulations or a high
14 level of decrees to require some aspects of
15 acquisition and/or maintenance of legitimate
16 software.

17 Does BSA have a current list or survey
18 of countries that have such measures?

19 MR. WHITLOCK: We, the short answer is
20 we do not, but we'll do what we can to supplement
21 within the time frame to provide what we can.

22 We would refer you more broadly to our

1 2018 global software survey, which does provide
2 the rates of unlicensed use of software. But
3 we'll see if we can supplement that information.

4 CHAIR LEE: And thank you. We have
5 one last question from the U.S. Patent and
6 Trademark Office.

7 MS. FERRITER: Thank you. We note
8 that several software companies have experienced
9 significant IPR challenges in the Middle East and
10 that this region continues to be an area of
11 growing concern. Especially with respect to
12 Saudi Arabia.

13 U.S. government officials have
14 consistently met with representatives of software
15 companies in the region to understand these
16 challenges. However, we note that BSA omitted
17 the Middle East region from its recommendations.

18 Can BSA provide a little more
19 background on the factors they considered as to
20 incorporating any Middle East and North Africa
21 countries into their recommendations, despite
22 ongoing software piracy in the region?

1 MR. WHITLOCK: Thank you very much for
2 the question. Yes. In the 2018 submission you
3 will have noted, 2019 submission, you will have
4 noted a smaller listing of recommended countries
5 than in prior years.

6 We sought to streamline the submission
7 by focusing on those countries in which we have
8 active policy compliance operations. We have
9 offices around the world.

10 With that said, our submission does
11 include data on unlicensed software use in a
12 number of countries, and links to more detailed
13 BSA reports that provide further analyses that
14 would include Saudi Arabia and other countries.
15 But for this submission we did streamline.

16 CHAIR LEE: Thank you very much for
17 your testimony.

18 MR. WHITLOCK: Thank you.

19 CHAIR LEE: Next is the China Chamber
20 of International Commerce. Okay, welcome, and
21 please state your name and organization for the
22 record, and please begin your testimony.

1 MR. T. JIAN: Thank you. Good
2 morning. My name is Tan Jian on behalf of the
3 China Chamber of International Commerce, CCOIC.
4 This is my assistant, Mr. Guan Jian.

5 CCOIC is a national Chamber of
6 Commerce in China with more than 180 sovereign
7 enterprise members across various sectors. CCOIC
8 and our members have witnessed substantial
9 progress China has made in IP rights protection.

10 We wish to assist the USTR to gain a
11 more accurate understanding of China's IPR
12 protection related to market access so as to
13 carry out constructive cooperation in IPR
14 protection, which will, in turn, benefit the
15 people of both countries.

16 And we have elaborated in our written
17 comments. Since 2018 China has made even greater
18 achievements in IPR protection for domestic and
19 foreign IP rights-holders. It's our view that
20 China be removed from the priority watch list in
21 2019.

22 In 2018, in order to establish a

1 better regulatory framework. China revised, or
2 is revising, major IP legislations.

3 For instance, the Patent Law Amendment
4 draft substantially revised more than 33 articles
5 and is significantly stringent patent protection.
6 A new anti-unfair competition law substantially
7 increased the level, the legal liabilities for
8 all kind of unfair condition activities.

9 The Foreign Investment Law draft,
10 which explicitly prohibits forced transfer,
11 technology transfer, was revealed by the Standing
12 Committee of the National People's Congress and
13 is expected to pass on.

14 In 2018, China overhauled the
15 intellectual property administration system at
16 both the national and the provincial level in
17 order to improve IP reviews, quality and
18 operational efficiency.

19 For example, the registration review
20 cycle for trademark was shortened from eight
21 months to six months, surpassing the average
22 level of prior rights review parties in the OECD

1 countries.

2 In 2018, China continued to intensify
3 IP law enforcement. For instance, the number of
4 patent law enforcement cases was 77 saw increased
5 15.9 percent from last year.

6 Thirty-one thousand illegal trademark
7 cases were investigated. The National
8 Intellectual Property Administration published
9 the Internet-plus Intellectual Property
10 Protection Work Plan to promote the efficiency of
11 combating IP infringement.

12 Most remarkably, 38 administrative
13 departments jointly issued a memorandum of
14 collaboration on joint punishment for serious
15 dishonest subjects in the field of intellectual
16 property patent to enhance the effectiveness of
17 IP law enforcement.

18 In 2018, China advanced the judicial
19 reform of IP protection. The quality, efficiency
20 and consistency of IP authentication was
21 significantly improved.

22 For instance, the Supreme People's

1 Court, as we see, established a unified appellate
2 division exclusively for intellectual property
3 appeals to new internet caught or created in
4 Beijing and Guangzhou.

5 SPC issued prohibitions on several
6 issues concerning verification of law in review
7 of cases involving behavior preservation in
8 intellectual property rights disputes so that
9 right-holders can get timely, adequate and
10 effective relief in the event of IP violations.

11 In 2018, China markedly relaxed market
12 access. On June 28th, China published special
13 administrative measures for foreign investment
14 access navigating list, reducing restrictions
15 from 63 to 48.

16 And introducing new opening up
17 measures in 22 sectors. As WTO has noted, China
18 remains one of the top foreign investment
19 recipients. And China involved FDI, has kept
20 rising for many years.

21 In conclusion, China has made
22 remarkable achievements in IPR protection. We

1 believe China should be removed from the priority
2 watch list in 2019. Thanks.

3 CHAIR LEE: Thank you. We will begin
4 questions with USTR.

5 MR. S. CHANG: Thank you for your
6 testimony. We continue to receive reports that
7 patent infringement damage awards in China are
8 very low relative to U.S. damages, and that in
9 some cases the damages are not deterrent.

10 Do you have a position on that, and
11 what has been the experience of your members?

12 MR. G. JIAN: Thank you for the
13 question. According to the draft revised patent
14 law, the damages awarded by the court has been
15 substantially increased.

16 And if I have the number on hand, it
17 was increased from \$10,000 to \$30,000, out of a
18 maximum award could be \$5 million. According to
19 the draft patent law.

20 MR. S. CHANG: Thank you. As a
21 follow-up question, I understand that the draft
22 law contains those provisions, however, in

1 practice, since that time, have your members
2 experienced any increased damages awarded?

3 MR. G. JIAN: Based on my personal
4 experience, there was certain kind of awards that
5 was substantially increased the damage awarding
6 to the IPR holders. And I would like to give
7 them more detailed cases after this hearing. And
8 I'll submit it in a post-hearing submission.

9 CHAIR LEE: Thank you. The next
10 question is from the State Department.

11 MR. HENRY: Your submission mentioned
12 the 2018 patent law amendment draft contains a
13 change to the rules of evidence in order to
14 resolve the hard to prove problem. Could you
15 elaborate on this please?

16 MR. G. JIAN: Thank you very much for
17 the question. And the draft patent law kind of
18 streamlines the procedures for the IPR holders to
19 submit evidence in the court.

20 And they also state in certain
21 standards and the criteria for what kind of
22 standards should be made for a court to accept

1 this kind of evidence. So, there is a lot of
2 details in the draft patent law. And if I may, I
3 would like to write it in detail in a
4 post-hearing submission.

5 CHAIR LEE: Thank you. We have one
6 final question from the U.S. Copyright Office.

7 MR. GREENBERG: Can you provide any
8 update on the status of efforts to amend the
9 copyright law?

10 MR. G. JIAN: There's, based on my
11 understanding, there was, amendment to the
12 copyright law was on agenda. We expect there
13 would be a substantial movement for that
14 amendment to the copyright are in this year.

15 CHAIR LEE: Okay, thank you very much
16 for your testimony.

17 MR. G. JIAN: Thank you.

18 CHAIR LEE: Next on the agenda is the
19 Computer and Communications Industry Association.
20 Thank you. Please state your name and
21 organization for the record and begin your
22 testimony.

1 MR. SCHRUEERS: Sure. Matt Schruers
2 for the Computer and Communications Industry
3 Association.

4 Thank you for the chance to convey
5 CCIA's views on the Special 301 process this
6 year. And thank you to the Committee for the
7 effort, the time and resources that you invest in
8 this important process.

9 As an association of internet and
10 technology firms, CCIA members' exports are
11 considerably affected by the domestic
12 intellectual property laws of the countries into
13 which we export in our trading partners. These
14 exports benefit, obviously, from intellectual
15 property protection.

16 They are also significantly impeded
17 when the markets in which they're operating lack
18 the copyright exceptions that enable innovation,
19 which have been set down in bilateral or
20 multilateral instruments. I will focus my oral
21 remarks on two examples of that, that are
22 described at greater length in our written

1 submission.

2 First, the need for implementation of
3 intermediary protections abroad, particularly
4 where those have already been required by our
5 free trade agreements.

6 And secondly, I want to emphasize
7 CCIAs growing concern about the rise of link or
8 snippet taxes in foreign markets.

9 So, first, the issue of online
10 intermediary protections. U.S. firms operating
11 abroad face an increasingly hostile environment
12 in a variety of markets, which are impeding the
13 ability to export services.

14 These conditions manifest through a
15 variety of new copyright laws and regulations, as
16 well as court interpretations. Which, in a
17 number of cases, are explicitly targeting U.S.
18 firms. And if not explicitly than certain
19 implicitly.

20 The Special 301 process should be used
21 to identify areas where our trading partners
22 protections fall short of agreed upon U.S.

1 implemented norms. In particular, U.S. trading
2 partners who have entered into free trade
3 agreements have neglected for, in some cases many
4 years, to honor longstanding commitments in the
5 intellectual property chapters.

6 And as our written submission
7 describes at greater length, our trading
8 partners, including particularly Australia and
9 Colombia, have yet to bring copyright law into
10 alignment with their commitments, despite having
11 many years to do so. And, have directly amended
12 legislation, amended the provisions of their law
13 where these implementation obligations exist.

14 So, it's not like the issue is a
15 subject that cannot be opened, right. These laws
16 have been amended and these particular
17 obligations have been neglected.

18 To some extent, leaves our trading
19 partners with the impression that our U.S. FTAs
20 are comprised of air quote commitments and real
21 commitments. And we would not want to find
22 trading partners testing the waters as to which

1 are which.

2 So, the second issue I mentioned is
3 the spread of link or quotation taxes, sometimes
4 referred to as ancillary or neighboring rights.
5 These have grown in foreign markets, which we
6 have been raising in this process for several
7 years.

8 We appreciate the Special 301
9 committee and the NTE process for evaluating this
10 and taking note of this issue. Unfortunately,
11 the problem continues to develop.

12 We've witnessed detrimental laws
13 throughout Europe. Including member states,
14 Spain, Germany and France. The EU copyright
15 directive now being explored in Brussels would
16 create a pan-European problem on this front.

17 And the directive is only a floor.
18 Even as we speak, the Swiss legislature is
19 considering introducing a ten year snippet tax in
20 their ongoing copyright reform. Which will
21 considerably exceed the EU directive.

22 There is no limit to the rents that

1 could be extracted from U.S. services through
2 these kinds of processes. And as CCIA has
3 previously noted, these clearly contradict our
4 trading partners Berne convention and thereby
5 their TRIPS obligations.

6 So, in conclusion, the Special 301
7 process should identify discriminatory practices
8 directed, in particular, at U.S. internet
9 services through the creation of these new
10 rights. Or through failure to meet longstanding
11 obligations involving intermediaries.

12 Thank you for your time, I'm happy to
13 take any questions.

14 CHAIR LEE: Thank you. We'll begin
15 questions with USTR.

16 MR. S. CHANG: Thank you for your
17 testimony. You identify several concerns about
18 policies related to intellectual property in
19 various markets, however, you do not make any
20 recommendations about the listing of these
21 countries.

22 For example, you identify concerns

1 with the European Union and Australia and other
2 countries, without making recommendations about
3 listings. How do you think this input should be
4 reflected in the Special 301 report?

5 Are you equally concerned about all
6 trading partners you mentioned?

7 MR. SCHRUERS: So, my proposal would
8 be that watch listing should be reserved for
9 countries that have failed to meet explicit
10 obligations.

11 I am aware that a number of
12 constituencies will come before the Committee
13 saying, we would like to see our trading partners
14 implement the following laws. And indeed, as
15 CCIA and many other constituents have long told
16 this Committee, we regard U.S. copyright law as a
17 gold standard, which our trade policy should be
18 to export.

19 This particular process seems most
20 appropriately focused on identifying failure to
21 meet existing commitments. And so, where we are
22 talking about FTAs, such as we have with

1 Australia, Colombia, Peru, where commitments have
2 gone unmet for many years, in some jurisdictions
3 even acknowledged that the commitment has gone
4 unmet and then taking no action, that that would
5 be an appropriate context for watch listing.

6 And similarly, with respect to the
7 snippet and link taxes. The clear inconsistency
8 with Berne Article 10(1), which of course we
9 regard as having trade implications by virtue of
10 TRIPS, is also a basis.

11 That's not to say that other
12 jurisdictions aren't pursuing policies that may
13 prove problematic, but that we should reserve
14 watch listing for countries that are clearly out
15 of step with explicit commitments already made.

16 CHAIR LEE: Thank you very much. The
17 next question is from the U.S. Copyright Office.

18 MR. GREENBERG: Regarding Colombia's
19 recent copyright legislation, you noted the
20 absence of what you deem "widely recognized
21 exceptions to just text and data mining display
22 of snippets or quotations and other

1 non-expressive or non-consumptive uses."

2 Could you provide further details
3 about how other nations provide such exceptions
4 in their loss?

5 MR. SCHRUERS: So, as scholars of U.S.
6 copyrights, of course we'll know that the U.S.
7 has no such explicit exception and relies on the,
8 a flexible and equitable doctrine for use to
9 handle many of those use cases.

10 There are trading partners, U.S.
11 trading partners, particularly Commonwealth
12 nations, achieve the same through a fair dealing
13 doctrine. Obviously, many countries have also
14 looked to the U.S. and implemented their own
15 application of fair use.

16 So, I would not suggest that an
17 explicit one-for-one implementation of these, of
18 such exceptions is required, but we should look
19 at flexibilities understood broadly. And in some
20 cases, flexible rules of reason, like for use in
21 for dealing, may be inappropriate context to do
22 that.

1 This is a case where we obviously want
2 to promote U.S. norms, but the obligations that
3 these countries will have are somewhat limited to
4 what's in Berne, Article 10(1) and Article 2's
5 news of the day exception, which are more
6 confined.

7 So, obviously we should expect people
8 to meet those commitments and encourage them to
9 adopt the approach that the U.S. has adopted.

10 CHAIR LEE: Thank you. We have one
11 last question from the U.S. Patent and Trademark
12 Office.

13 MS. FERRITER: Thank you. Are there
14 markets that, in your view, do a good job of
15 balancing the respective rights and obligations
16 of content providers and internet service
17 providers, or ISPs? What would those markets be
18 and why?

19 MR. SCHRUERS: Well, I think as I
20 mentioned previously, we regard the U.S. approach
21 to copyright as the gold standard in something
22 that we should encourage our trading partners to

1 adopt, in large part because of the success
2 stories we have here. A very strong and robust
3 creative sector and a very strong and robust
4 market for exporting digital services.

5 When we struck that balance, there are
6 many examples of other jurisdictions following
7 our lead. And we should encourage them to do so.

8 And there are emerging consensus on
9 these issues, including intermediary protection.
10 And I'd say emerging consensus on technology
11 friendly flexibilities.

12 And we should foster that consensus
13 and try and bring our trading partners in
14 compliance with our approach.

15 CHAIR LEE: Okay, thank you for your
16 testimony. The last organization before the
17 lunch break is the Consortium for Common Food
18 Names. Please state your name and organization
19 for the record and please begin your testimony.

20 MR. CASTANEDA: Thank you, Mr.
21 Chairman. My name is Jaime Castaneda and I
22 represent the Consortium for Common Food Names.

1 The Consortium of Common Food Names,
2 or CCFN, is a non-profit alliance that represents
3 the interest of farmers, food producers and
4 consumers.

5 Our mission is to preserve the
6 legitimate right of producers worldwide to use
7 generic names. Mr. Chairman and Members of the
8 Interagency Committee, we appreciate the
9 opportunity to address the continued problems
10 that a legitimate practice involving geographical
11 indications, or GIs, have caused for the U.S. and
12 international food industry.

13 Let me start by making one thing very
14 clear. CCFN is not opposed to genuine
15 geographical indication or certification marks.
16 We have no issue with Napa Valley wine or Idaho
17 potatoes.

18 Or for that matter, a wide variety of
19 other compound name GIs describing products that
20 are genuinely unique and whose qualities are
21 inherently defined by the specific region in
22 which they were produced.

1 Intellectual property is very
2 important, and we should defend the rights of
3 trademark holders. But we should, and I
4 emphasize, we should equally protect and support
5 the rights of people who use generic food names.

6 Over hundreds of years, various types
7 of cheeses, meats, wines and many other foods and
8 beverage have been produced outside the areas
9 where they originated. Including those from
10 Europe.

11 Despite this, the EU has, of late,
12 chosen to respond to legitimate growing global
13 competition, not by upping its own game, but
14 instead by seeking to erect roadblocks to other
15 suppliers to artificially favor its own
16 producers.

17 The misuse, this misuse of GI is to
18 create barriers to trade isn't just and most not
19 be tolerated. The EU is very clear in its
20 intentions.

21 Already, right here in the U.S.
22 market, we have seen European groups attempt to

1 seize usage of specific names. Including
2 Parmesan, Asiago, Romano and Gruyere, among many
3 others.

4 Their goal is to increase their market
5 share by blocking U.S. competition and forcing
6 U.S. companies to re-brand, which confuses
7 consumers and results in U.S. companies losing
8 markets.

9 Considered that in some areas where
10 the EU is trying to confiscate a generic name,
11 they don't even have a market there yet. But we
12 do.

13 For instance, there is little to no
14 Italian-made Asiago in some developing markets in
15 Latin American. How can we stand by and allow
16 the EU to still generic names of our products and
17 push us out? The answer is we cannot.

18 What is the value of the U.S. gaining
19 no or low tariff into a country's market in an
20 FTA if U.S. producers are then banned from
21 selling products in the country due to new GI
22 concessions to the EU.

1 Last year we were extremely
2 disappointed to see the previous Mexican
3 Government of President Pena Nieto, caving to EU
4 demands that relinquish many valuable names
5 giving the EU a virtual monopoly on these
6 products upon implementation of this agreement.

7 We have a number of different products
8 already in the market. We were the only ones in
9 this market.

10 Over the past few years, the U.S.
11 Government has been supportive on the common
12 names issue, but our opponents are gaining ground
13 because we have not done enough to shore-up our
14 existing market access rights.

15 To meet this challenge, the U.S.
16 Government must step up its game too much or
17 exceed the force that Europe has thrown behind
18 its GI agenda. It's not enough to warrant our
19 trading partners to not give up generic names to
20 the EU, the U.S. must insist upon it by securing
21 binding commitments from our trading partners
22 that preserve our market access rights.

1 A new economic study supports previous
2 studies and helps lay out the consequences for
3 one of the EU's primary target. The whole issue
4 of GIs.

5 To counter this risk of keep having
6 the EU, European Union crawl into different
7 markets, we urge the Administration to secure
8 commitments from our trading partners to build
9 upon the positive precedent established in USMCA
10 site letter agreement with Mexico, which even
11 though it excludes some generic names, it sets a
12 clear precedent that we have these products
13 trading freely between markets.

14 In addition, we encourage the
15 Administration to evaluate the full range of
16 tools at its disposal to address the deeply
17 asymmetrical nature of the U.S. EU food trade
18 relationship. The U.S. is a large and lucrative
19 market for many European food makers.

20 Even as the EU bans the import of
21 accurately labeled common names U.S. foods into
22 their own market. It is time to enhance U.S.

1 efforts and to hold our trading partners to their
2 commitments.

3 We look forward to continue to work
4 closely with your government agencies in the
5 future. Thank you.

6 CHAIR LEE: Thank you very much. We
7 will start questions off with USTR.

8 MR. S. CHANG: Thank you for your
9 testimony. In your submission you highlight the
10 United Kingdom as an example of a country that
11 has taken a reasonable approach to GIs and
12 highlight the example of the U.K.'s multiple GIs
13 for types of cheddar, which make clear that use
14 of the generic term cheddar is preserved.

15 Could you elaborate on why you
16 consider this to be an appropriate approach for
17 the protection of GIs and could this approach be
18 used in other countries?

19 MR. CASTANEDA: Absolutely. Thank you
20 for the question.

21 So, we have been promoting for many,
22 many years, the whole issue of compound names.

1 There is no problem understanding that there is a
2 product that may be coming specifically from, in
3 a specific region.

4 So, in the case of Provolone Valpadana
5 in Italy or the case of Brie de Meaux, Camembert
6 de Normandie. So, we are not being confused.
7 Consumers will not be confused.

8 It is completely understandable that
9 if we go through that approach, people know what
10 they're buying. But the European Union, that's
11 not their intent.

12 The European Union wants to actually
13 have complete monopoly of these names and
14 completely, more importantly, complete monopoly
15 of markets that have been developed by the U.S.
16 Specifically, examples are, for instance, Mexico.

17 CHAIR LEE: Thank you. The next
18 question comes from the U.S. Patent and Trademark
19 Office.

20 MS. FERRITER: Thank you. On
21 Singapore you've raised a concern in your
22 submission regarding implementation of the

1 obligations concerning GIs in the 2012 EU
2 Singapore FTA.

3 What is the status, if you know, of
4 any regulations and guidance being issued
5 addressing the issue of their implementation?

6 MR. CASTANEDA: I think that, let me,
7 and I can come back with you with more specifics
8 to the Interagency Committee, but what I can
9 assure you is that, even though in many cases,
10 like in the case of Singapore, we thought
11 positive, as well as in Japan and other places,
12 the way that actually Singapore handled the
13 overall negotiations with Europe.

14 We're constantly concerned of how
15 Europe has continued to push and uses different
16 angles and different avenues to try to undermine
17 their own negotiations. So what we have to be
18 absolutely clear is that we need to be vigilant
19 of what the EU continues to do in a number of
20 different countries. But I'll get back to you on
21 the specifics.

22 CHAIR LEE: Okay. Thank you. Next,

1 we have a question from the Department of
2 Agriculture.

3 MR. KARAWA: Thank you, Mr. Castaneda.
4 My question is related to Japan. In your
5 submission, you commended Japan for having the
6 transparent process while also expressing concern
7 that Japan restricted some terms, such as various
8 wine terms and other single wed GIs, but not
9 others.

10 Could you please elaborate on this?

11 MR. CASTANEDA: Yes, thank you. This
12 goes a little bit to the point that we were just
13 making before.

14 I think Japan, as well as Singapore
15 and others, made a concerted effort, and a view I
16 can't expand too much because we have a limited
17 amount of time, but if you follow the path that
18 Japan went about in trying to secure a generous
19 GI system that would continue to protect generic
20 names, I think that that was very commendable.

21 Having said that, the EU, and we know
22 this for a fact, they pressure on the

1 negotiations. I mean, we have the example of
2 Canada that at the last minute, I mean, they were
3 offering the Canadians a few more pounds of pork
4 and other products for an exchange of protecting
5 Asiago.

6 So, in many of these cases, the issue
7 has been that at the end of the day, even though
8 Japan has followed a legal system as opposed to
9 other countries, they were pushed to accept by
10 the European Union on some of these names that we
11 consider generic.

12 CHAIR LEE: Thank you very much for
13 your testimony.

14 MR. CASTANEDA: Certainly.

15 CHAIR LEE: So we are heading into the
16 lunch break. We will come back and start at
17 1:20. Promptly at 1:20 p.m. And this hearing is
18 in recess until then. Thank you.

19 (Whereupon, the above-entitled matter
20 went off the record at 12:28 p.m. and resumed at
21 1:20 p.m.)

22 CHAIR LEE: All right, everyone. Thank

1 you. The hearing is back in session. Let's try
2 this again. Thank you, everyone, for coming back
3 from lunch on time. I would like to get started
4 with the afternoon session. First up is the
5 Footwear Distributors and Retailers of America.
6 Thank you. If you don't mind, please state your
7 name and organization for the record and then
8 please begin your testimony.

9 MR. PRIEST: Thank you. My name's Matt
10 Priest, I'm the president and CEO for Footwear
11 Distributors and Retailers of America.

12 On behalf of FDRA, thank you for the
13 opportunity to participate again in this 2019
14 Special 301 review. We serve as the footwear
15 industry's trade and business association, and we
16 represent nearly 500 footwear companies and
17 brands across the U.S., including the majority of
18 U.S. footwear manufacturers. Our member companies
19 work hard to design, produce, and deliver shoes
20 to global footwear consumers.

21 Here in the U.S., 2.3 billion pairs of
22 shoes cross U.S. borders every year. That's 7.2

1 pairs of shoes for every man, woman, child, every
2 single year.

3 Today we want to highlight several
4 recent global IP trends. Our written testimony
5 includes greater detail on these issues as they
6 relate to specific countries, but our concerns
7 about global IP protection and enforcement trends
8 fall into what we see as three different
9 categories.

10 Number one, significant challenges on
11 ecommerce platforms. With the ecommerce boom that
12 we're experiencing, footwear companies have seen
13 a substantial and troubling rise in both
14 unauthorized sales and counterfeiting as bad
15 actors use popular ecommerce sites to target
16 unsuspecting consumers here in the U.S.

17 Brands usually have little information
18 on these offenders, because platforms do not
19 share the information they have on these sellers
20 with the rights-holders. It is impossible for
21 brands to get in touch with each and every online
22 seller suspected of selling counterfeits to ask

1 for additional information and pictures. In fact,
2 many individuals and entities selling counterfeit
3 goods on these platforms do so using false
4 identities, making it impossible for brands to
5 take action.

6 The GAO highlighted in its 2018 report
7 that 20 of the 47 products it purchased from
8 third-party sellers on popular ecommerce sites
9 turned out to be counterfeit. Every platform
10 selected by the GAO for the study yielded at
11 least one counterfeit good, and it was a very
12 small sample size, to say the least.

13 For this year's report, we encourage
14 you to closely examine the ways in which these
15 ecommerce channels directly attack IPR protection
16 and enforcement globally.

17 Our second area we focus on are
18 enforcement gaps. In recent years, bad actors
19 from around the world have discovered new ways to
20 evade customs and deliver counterfeit goods to
21 the U.S. market. Many counterfeiters ship labels
22 and tags separately from infringing products, and

1 then they attach those labels to the infringing
2 products here in the domestic market in order to
3 avoid seizure.

4 Infringers often use express mail and
5 postal services to deliver counterfeit goods in
6 small packages, making it more challenging for an
7 enforcement official to confiscate these goods.
8 The sheer volume of small shipments makes it
9 impossible for customs to adequately screen or
10 X-ray all incoming mail to detect such shipments.

11 When customs seized counterfeit
12 products and alerts the rights-holders, many
13 cases never go further than the seizure of the
14 product because of the lack of information.
15 Additional information and processes for better
16 information sharing could help track the real
17 importer, increase enforcement and reduce repeat
18 counterfeit sellers and shippers. Customs
19 officials may lack sufficient training or
20 knowledge to consider trade dress or design
21 patent infringement as a basis for seizure.

22 In today's 21st century retail

1 environment, the way that a brand presents a
2 shoe, from its appearance to packaging, is a
3 critical part of the customer's experience.
4 Companies devote significant resources to
5 innovation in these areas in particular, which
6 directly impact the brand's reputation and the
7 relationship it has built with the customer.

8 The last bucket we focus on is
9 inadequate protections for U.S. companies in
10 foreign markets, which is obviously important to
11 this group. In numerous companies, legal
12 procedural obstacles exist to secure and enforce
13 trademark rights. Penalties are often inadequate
14 to deter criminal enterprises from engaging in
15 trademark counterfeiting operations.

16 In many countries the penalties
17 imposed on these enterprises are so low that they
18 only add to the cost of doing business. Many
19 countries need to establish or improve
20 transparency and consistency in their
21 administrative trademark registration procedures.

22 Also, at times the judicial systems in

1 developing nations lack transparency and
2 independence, making it difficult for
3 rights-holders to pursue claims. Counterfeiters
4 now commonly register domains that advertise and
5 sell counterfeit goods. Many of these
6 counterfeiters use a country code top-level
7 domain to avoid detection and to avoid the reach
8 of the U.S. judicial system.

9 FDRA member companies face significant
10 trademark infringement and lose valuable internet
11 traffic because of misleading and fraudulent
12 domain names, and it can be hard for companies to
13 find relief.

14 The theft of trade secrets has become
15 an increasingly important issue for global
16 brands. For U.S. companies to grow and compete
17 globally, they must have confidence in the legal
18 protections provided to trade seekers
19 domestically and around the world. At times,
20 foreign governments are complicit in and even
21 participate in, the theft of trade secrets.

22 So as the U.S. works to strengthen IP

1 protection and enforcement for American workers
2 and American businesses, we encourage the
3 administration to enter into new bilateral and
4 multilateral trade agreements that will benefit
5 U.S. companies and consumers and include strong
6 IP protections for the 21st century economy. We
7 stand ready to work with the USTR and to bolster
8 respect for and enforcement of IP by our trade
9 partners because doing so protects American jobs
10 and benefits consumers. Thank you.

11 CHAIR LEE: Thank you very much. For
12 questions, we'll start with USTR.

13 MR. SUNG CHANG: Thank you for your
14 testimony. You identified several concerns about
15 policies related to intellectual property in
16 various markets. However, you do not make any
17 recommendations about the listing of these
18 countries. How do you think this input should be
19 reflected in this Special 301 Report? Are you
20 equally concerned about all trading partners that
21 you mentioned?

22 MR. PRIEST: Yes, in our written

1 submission we highlight several countries. China
2 is obviously the number one creator of
3 counterfeit goods. It's also our number one
4 supplier of legitimate goods created, and so we
5 obviously have a concern with China. We have
6 concerns with Russia, Brazil, India, Indonesia,
7 these are all countries for which counterfeit
8 goods are produced and exported into the United
9 States market.

10 And so ensuring that we have
11 engagement with these countries in a bilateral
12 sense, continuing to list them within the Special
13 301 Report gives us a lot of leverage as we talk
14 with our trading partners, both at the
15 governmental levels as well as the industry
16 levels, because this has to be a collective
17 response.

18 One of the things that we see
19 particularly with ecommerce is that there is no
20 domestic market anymore. Ecommerce creates a
21 global market for everyone, everywhere, and so we
22 have to be engaging with these countries both for

1 their internal procedures and laws and
2 enforcement, as well as how do we collectively
3 respond to the prevalence of counterfeit goods on
4 online platforms.

5 CHAIR LEE: Thank you. The next
6 question is from the U.S. Patent and Trademark
7 Office.

8 MS. FERRITER: Thank you. Your
9 submission indicates that China has made a number
10 of significant improvements in the protection and
11 enforcement of intellectual property in the past
12 year, particularly work that the central
13 government has done to raise the importance of
14 IP. Can you provide specific examples that you
15 are referring to and does it provide a road map
16 for the future?

17 MR. PRIEST: I think there is a road
18 map for the future. I think that China has seen
19 the need to develop more robust laws as it
20 relates to patent and trademark protection.
21 Establishing courts, establishing legal
22 procedures to kind of maneuver through the system

1 to ensure that rights-holders views are upheld,
2 both domestic and foreign rights-holders.

3 So there is a road map there, but I
4 think as I've stated before in front of this
5 group, it's a maturation process. I think the
6 important thing that China needs to realize, and
7 I think they understand this to some extent, is
8 that development of, you know they have their own
9 program, Famous Brands, and we as a government,
10 we've kind of pushed back on that WTO.

11 But they have a strong desire to
12 develop brands that global consumers want and
13 they have a strong desire to come in with those
14 brands and sell those worldwide. So if you cannot
15 create an infrastructure, legal infrastructure,
16 and you're not enforcing that equally amongst the
17 provinces and localities and cities, then you're
18 not going to be protecting the rights of your own
19 domestic brands that you look to kind of put on
20 the global stage.

21 That's what we constantly encourage
22 the Chinese to do, to look it from where do you

1 want to be, how do you want to emulate the United
2 States and certain countries within the EU to
3 develop these global brands. And so I think
4 there's a roadmap there but there's a lot of ways
5 to go.

6 CHAIR LEE: I guess we have time for
7 one more question, and it comes from the
8 International Trade Administration of the
9 Department of Commerce.

10 MS. SALZMAN: Thank you for your
11 testimony. With regard to India and Indonesia,
12 your submission states that, quote, given the
13 importance of these two countries to a growing
14 number of U.S. companies that make and sell
15 shoes, much more has to be done to strengthen IP
16 protection and enforcement, end quote.

17 Could you further elaborate your
18 concerns in these countries, and also describe
19 what improvements you would like to see? How do
20 these countries' IP protection and enforcement
21 regimes compare to other international markets
22 where your members may do business?

1 MR. PRIEST: It's a great question. If
2 you look at the sourcing profile for the footwear
3 industry and the import profile, 95 percent of
4 our imports come from China, Viet Nam and
5 Indonesia, in that order. Most of that is China
6 and Viet Nam, by far.

7 So you have these countries,
8 particularly Indonesia and India, who have robust
9 domestic manufacturing footwear. They're trying
10 to figure out best ways to promote themselves to
11 export, and we are particularly with Indonesia,
12 seeing a growth in exports to the U.S.
13 marketplace, in a variety of different product
14 categories.

15 When you have those two countries
16 looking to export, what we find is that there's
17 also the prevalence of counterfeit good creation,
18 not just for local market but for export. Right
19 now we kind of have the leverage at this point,
20 because both countries are hungry for investment.

21 We work with them directly with their
22 trade associations, our sister associations, and

1 we talk about the need for broader enforcement,
2 for if you want to attract foreign direct
3 investment and orders for footwear, global
4 footwear companies, you have to ensure that their
5 rights are protected as they engage with those
6 factories in those countries.

7 For both countries I think there's a
8 strong desire to do that but it does come down to
9 the e-word, it always comes down to enforcement
10 and the political will to enforce.

11 So, I think we're at an opportune time
12 to deliver that message, because both countries
13 are hungry to capture market share that China's
14 currently shedding.

15 CHAIR LEE: Thank you very much for
16 your testimony.

17 MR. PRIEST: Thank you.

18 CHAIR LEE: Next up we have the
19 Intellectual Property Owners Association. Thank
20 you, and please state your name and organization
21 for the record, and begin your testimony.

22 MR. LAUROESCH: Good afternoon. My name

1 is Mark Lauroesch, I'm the executive director for
2 the Intellectual Property Owners Association,
3 also known as IPO.

4 On behalf of IPO, I'd like to thank
5 you for the opportunity to testify today and for
6 your continued work in ensuring U.S. trading
7 partners provide adequate and effective
8 protection of intellectual property rights and
9 fair and equitable market access to companies who
10 rely on IP protection.

11 IPO is an international trade
12 association, representing companies and
13 individuals from all industries and fields of
14 technology. IPO's membership includes about 200
15 companies and around 12,000 individuals who
16 participate with the Association through their
17 company or as inventors, authors, or law firm
18 members.

19 IPO members make vital contributions
20 to America's economic success by developing
21 advances that drive exports and create jobs.
22 Innovators assume considerable risk and rely on

1 IP to protect investments in new technology.

2 In our comments to the subcommittee,
3 we outline existing and emerging threats to the
4 intellectual property rights of our members.
5 Today I'd like to highlight two issues that are
6 particularly concerning.

7 The first, a number of foreign
8 initiatives and policies are undermining
9 incentives for innovation historically created by
10 IP protection.

11 Second, technology has made global
12 trade secret theft all the easier and trade
13 secret protection remains woefully lacking
14 abroad, to the detriment of innovators.

15 These issues must be addressed to
16 protect our innovation economy and the American
17 jobs that result from it.

18 Around the world, IP owners face
19 initiatives and policies that undermine the
20 incentive to innovate. Some of the initiatives
21 might not appear at first glance to relate to IP.
22 Nonetheless, upon closer examination they all

1 undermine the innovative incentive provided by IP
2 protection.

3 Examples include countries with
4 regulatory laws seeking more information than
5 reasonably necessary, or where regulatory
6 agencies share submitted information to others.
7 Several countries, including Brazil and India,
8 provide compulsory licensing schemes, and China's
9 discriminatory technology transfer regulations
10 are just some examples.

11 Such issues and policies contribute to
12 the lessening of the value of IP. They discourage
13 rather than encourage innovation. They are
14 detrimental to the many companies that drive our
15 innovation-based economy. Encouraging trading
16 partners to eliminate these types of initiatives
17 and policies should be an important priority.

18 Turning to the second issue I wanted
19 to discuss, trade secret protection, technology
20 continues to develop at a rapid pace.
21 Unfortunately, that technology makes it easier to
22 obtain trade secrets illicitly. Companies face

1 threats to their hard-earned trade secrets
2 through both illicit means and forced regulatory
3 disclosure, as I mentioned earlier.

4 Many countries fail to provide
5 adequate enforcement mechanisms and punishments
6 to prevent, deter, and remedy trade secret theft.
7 Examples include in China, where our members face
8 high burdens of proof, limited discovery and
9 damages when seeking to enforce their trade
10 secrets.

11 Russia offers nominal, weak, and
12 unpredictable protection for trade secrets, and
13 India lacks civil or criminal statutory
14 protection for trade secrets.

15 In our innovation economy, knowledge
16 is often the most valuable currency. Yet trade
17 secret laws around the country continue to fail
18 to offer a level playing field for innovators.
19 This enables competitors to use an innovator's
20 hard-earned knowledge without the cost of
21 developing it. We urge you to work with and
22 encourage trading partners to adopt much needed

1 trade secret upgrades to safeguard American
2 know-how.

3 In conclusion, innovation-driven jobs
4 depend on high quality intellectual property
5 regimes. Effective intellectual property
6 protection in foreign markets is vital to
7 American innovators. It enables investment in
8 research and development and technology that
9 results in important offerings in the global
10 marketplace.

11 Our members need your continued
12 engagement to ensure the ability to protect their
13 intellectual property. We look forward to working
14 with you to build a global IP environment that
15 encourages innovation and safeguards quality,
16 high-paying jobs in innovation industries.

17 We again thank the subcommittee for
18 its efforts to promote protection of IP rights
19 globally, which will sustain and grow America's
20 economy. Thank you.

21 CHAIR LEE: Thank you. We'll begin
22 questions with USTR.

1 MR. SUNG CHANG: Thank you for your
2 testimony. Regarding Mexico, what additional
3 enforcement measures would you recommend Mexico
4 take to combat inconsistent enforcement of patent
5 and trademark rights at its border?

6 MR. LAUROESCH: We didn't particularly
7 have any comments on enforcement in our written
8 submission. The things we pointed out were some
9 discriminatory conduct with respect to,
10 protection for certain subject matter.

11 CHAIR LEE: Thank you. The next
12 question comes from the U.S. Patent and Trademark
13 Office.

14 MS. FERRITER: Thank you. Your
15 submission notes concern over a lack of
16 regulatory data protection in Australia. Would
17 you please elaborate why the therapeutic goods
18 act or other related laws do not provide adequate
19 data protection relating to the registration of
20 new formulations, combinations, indications,
21 calculations or dosage forms of currently
22 registered therapeutic goods. Are there any new

1 cases that might provide clarity on the
2 application of these laws? Thank you.

3 MR. LAUROESCH: The concern is that
4 area is with the use of the data they've
5 submitted by innovators, and the control of that
6 data as well as whether unnecessary information
7 has to be submitted and subjected to public
8 dissemination.

9 With respect to a case, I do recall
10 there being a case but we can supplement, if I
11 can find that I can supplement it to you.

12 CHAIR LEE: Thank you. Now back to USTR
13 for another question.

14 MR. SUNG CHANG: Could you elaborate on
15 why you chose not to offer specific linkings for
16 the countries you discussed in your written
17 testimony?

18 MR. LAUROESCH: As I mentioned in my
19 opening statement, IPO is an international trade
20 association. It represents many companies and
21 industries, so our members have varying interests
22 in varying countries. We don't particularly

1 highlight any particular ranking.

2 The one thing I would draw your
3 attention that is probably what would be obvious,
4 is the more comments we made with respect to a
5 country means more opportunities for improvement.
6 But again, our members have different interests
7 in different markets.

8 CHAIR LEE: Thank you. Next we have a
9 question from the Treasury Department.

10 MR. WON CHANG: Thank you for your
11 submission. Where do you face the biggest trade
12 secret threats? Could you elaborate?

13 MR. LAUROESCH: Clearly anecdotally, I
14 have members ask me and express concerns
15 primarily with China, but it's not just China.
16 Now with the dissemination of trade secrets
17 usually in electronic form, trade secrets can get
18 disseminated through several countries.

19 In our written submission there's
20 quite a lot of detail on trying to improve the
21 trade secret regime in China, but there are
22 certainly significant issues in India, and then

1 there's a lot of countries in Asia that barely
2 have any trade secret laws that aren't
3 necessarily the larger markets for our members.

4 CHAIR LEE: Thank you very much for
5 your testimony. Next we have the International
6 Intellectual Property Alliance. Thank you. Please
7 state your name and organization for the record
8 and begin your testimony.

9 MR. ROSENBLUM: Thank you. My name is
10 Kevin Rosenblum, I am counsel for the
11 International Intellectual Property Alliance.
12 Thank you for the opportunity to present the
13 views of the IIPA in this year's Special 301
14 process. We applaud the U.S. Government for
15 making this Special 301 review a catalyst for
16 positive change to address the challenges faced
17 by the U.S. creative copyright industries in key
18 markets abroad. We welcome the chance to
19 participate, again, in this crucial annual
20 dialog.

21 IIPA is a private sector coalition
22 formed in 1984 of five trade associations

1 representing U.S. copyright-based industries. The
2 core copyright industries combined, according to
3 a December, 2018, study, contribute over 1.3
4 trillion dollars to the U.S. economy, providing
5 almost 6,000,000 jobs and almost seven percent of
6 the gross domestic product.

7 Our members are the Association of
8 American Publishers, the Entertainment Software
9 Association, the Independent Film & Television
10 Alliance, the Motion Picture Association of
11 America, and the Recording Industry Association
12 of America.

13 These associations comprise over 3200
14 companies producing and distributing materials
15 protected by copyright laws throughout the world.
16 To reach foreign markets through legitimate state
17 of the art distribution channels, these companies
18 rely on four main elements: Consistent modern
19 standards of copyright protection, efficient
20 copyright enforcement, sound legal structures for
21 licensing, and the elimination of market access
22 barriers.

1 Progress in these areas advances U.S.
2 trade goals while enabling our trading partners
3 to develop and expand their own creative and
4 cultural output. The ultimate objective is to
5 promote markets where the creative industries can
6 bring even more products and services than they
7 currently offer, in an increasing variety of
8 ways, from a greater diversity of players, before
9 an ever-growing mobile audience.

10 Advancing that objective is a proven
11 means to grow U.S. exports, create good American
12 jobs and enhance U.S. global competitiveness.
13 With this broad vision in mind, IIPA has
14 participated in every Special 301 review since
15 the 1988 trade act created this process.

16 Given some of the other comments
17 provided, it is worth reviewing the specific
18 statutory language and purpose of this Special
19 301 review, namely to identify, quote, foreign
20 countries that deny adequate and effective
21 protection of intellectual property rights or
22 deny fair and equitable market access to U.S.

1 persons who rely on intellectual property
2 protection, unquote.

3 It is critical for the Special 301
4 process to maintain this focus on intellectual
5 property protection, in our case, copyright
6 protection and enforcement. There are those who
7 ask you to dilute this focus, to weaken
8 protections in order to accommodate the perceived
9 interests of business sectors that by their own
10 words depend on expanding the zone where
11 copyright protections do not apply.

12 This is not what Congress intended
13 when it created the Special 301 process, and it
14 is not consistent with the clear and statutory
15 language of Special 301. This is not the approach
16 that has made Special 301 so successful and the
17 Special 301 process is not the place to advocate
18 that our trading partners weaken their copyright
19 regimes, especially in countries where legitimate
20 copyright rights-holders cannot get a toehold due
21 to grossly inadequate copyright protection or
22 enforcement.

1 In this year's submission, IIPA
2 recommends that 19 countries be identified in the
3 2019 Special 301 Report. All these are listed in
4 our hearing statement, with capsule summaries,
5 under are 10 companies we recommend for inclusion
6 on the priority watch list. Argentina, Chile,
7 China, India, Mexico, Russia, South Africa,
8 Taiwan, Ukraine, and Vietnam.

9 Our submission highlights five legal
10 reforms that our trading partners should focus on
11 to adequately and effectively address all forms
12 or piracy in a fast-changing technological
13 environment. Most fundamentally, U.S. trading
14 partners must both exceed to and fully implement
15 the WIPS Internet Treaties, which set global
16 minimum standards for copyright protection in the
17 digital environment.

18 Furthermore, in many countries around
19 the world, copyright reform efforts have become a
20 vehicle for proposals that threaten
21 well-established global norms, including but by
22 no means limited to the requirements to confine

1 all exceptions and limitations to copyright
2 protections within the well-established
3 three-step test.

4 The U.S. Government should urge U.S.
5 trading partners to adhere to current and
6 evolving global norms, including duration of
7 copyright protection and measures governing
8 collective management organizations.

9 The U.S. Government should also ensure
10 that the numerous and bilateral trade agreements,
11 including the WTO TRIPS agreement, a score of
12 free trade agreements and a wide range of other
13 bilateral agreements into which the U.S. has
14 entered, realize the goal of opening foreign
15 markets to U.S. goods and services dependent on
16 copyright protection.

17 Our submission also lists six
18 enforcement challenges confronting U.S. copyright
19 industries seeking to compete in overseas
20 markets, starting of course with internet and
21 mobile network piracy, an overarching challenge
22 for all businesses that depend on copyright.

1 The growth of new, fully licensed and
2 legitimate channels for consumers around the
3 world to access creative content in a variety of
4 new and innovative ways has been one of the most
5 encouraging trends in global markets for
6 copyright material.

7 CHAIR LEE: I'm sorry, we're, in terms
8 of allotted time we're getting past five minutes,
9 so if you could just wrap it up in a sentence or
10 two that would be great. Thank you.

11 MR. SUNG CHANG: Thank you. The health
12 and competitiveness of the U.S. economy depends
13 on a thriving copyright sector that creates
14 revenues, jobs and exports, for promoting and
15 respecting intellectual property rights in
16 opening markets to products and services that
17 depend on copyright also helps our trading
18 partners. Thank you very much for the opportunity
19 to testify here, and I look forward to your
20 questions.

21 CHAIR LEE: Thank you very much. We'll
22 start with a question from USTR,

1 MR. SUNG CHANG: Thank you. Your
2 submission urges Chinese enforcement authorities
3 to take action against so-called cloned pyramid
4 piracy websites. Can you explain this issue
5 further and describe your efforts to date to
6 alert Chinese enforcement authorities to the
7 problem, and their response? Could you also
8 explain which entities would be the target of
9 such enforcement actions, such as the,
10 quote/unquote, mother site?

11 MR. ROSENBAUM: Thank you very much.
12 Yeah, this is a, I guess a relatively new
13 problem, one that's expanding. It involves sites
14 that essentially entice a user to become their
15 own sort of creator of piracy.

16 A user will download a plugin player.
17 I think the most prominent example is the Xunlei
18 player, and the user will -- and this player is
19 essentially like malware that then allows the
20 user, then there's a back-end infrastructure that
21 permits the user to select content that they can
22 then provide to additional users.

1 Then it's monetized upstream, so it's
2 created this pyramid effect that proliferates,
3 and it's become a growing problem in ways where
4 pirated content is accessed in China.

5 We have brought this to the attention
6 of Chinese enforcement officials, but we have not
7 seen a sustained approach to addressing this
8 problem, and it's one that we remain focused on
9 and hope that China's enforcement authorities
10 will work with us to correct.

11 CHAIR LEE: Thank you. The next
12 question comes from the U.S. Copyright Office.

13 MR. GREENBERG: Regarding South Africa,
14 you know the stakeholder in your submission, you
15 know the stakeholder engagement led to further
16 discussion on the Copyright Amendment Bill of
17 2015. However, it also appears from your
18 submission that subsequent bills, particularly
19 Copyright Bill of 2018 and the Performers
20 Protection Amendment Bill is designed to address
21 concerns in the 2015 bill lacked opportunities
22 for stakeholder engagement.

1 Can you comment on the public
2 consultation process in place for the Copyright
3 Bill of 2018 and the PPAB? Also can IIPA please
4 provide a sense of the priorities among the
5 concerns listed in a submission regarding the
6 Copyright Bill of 2018 and the PPAB?

7 MR. ROSENBAUM: Thank you. I appreciate
8 your bringing this up. This bill is a huge
9 concern for us. It includes all kinds of
10 problematic provisions. The two most prominent
11 ones involve infringement of the freedom to
12 contract for rights-holders in terms of licensing
13 their rights.

14 Then the other issue is exceptions and
15 limitations that are totally out of step with
16 South Africa's international obligations, and
17 really are kind of, in some respects, unique to
18 anywhere in the world.

19 So those are why we have raised this
20 in our submission and in various other forums and
21 why, you know, it's unfortunate that the South
22 African government has not adequately consulted

1 with the broad range of stakeholders, and I guess
2 I will leave it at that since it looks like time
3 has expired.

4 CHAIR LEE: Thank you very much for
5 your testimony. Next we have Knowledge Ecology
6 International.

7 MR. LOVE: Would you like me to limit
8 the initial comments to so you can ask questions?

9 CHAIR LEE: Yes. Generally the format
10 is five minutes for your testimony and then five
11 minutes for questions, if you don't mind, but
12 let's first start off with if you could just
13 state your name and organization for the record
14 and begin your testimony, we'll be flashing your
15 one-minute mark and then when times expired we'll
16 be flashing that as well. Thank you.

17 MR. LOVE: Sure. My name is James Love.
18 You can call me Jamie, that's also okay. I work
19 for a group called Knowledge Ecology
20 International, which doesn't mean we work on
21 climate change or anything like that, it's just a
22 bad branding exercise we had about 12 years ago,

1 and it didn't work. We work a lot on issues about
2 intellectual property rights but also innovation
3 in policy, including things that have to do with
4 copyright and patents, but not limited to.

5 I submitted a written statement. I'm
6 not going to just read the whole statement. I
7 think as you know that we're consistently trying
8 to protect the flexibility of countries to issue
9 compulsory licenses on medicine. There's now over
10 a hundred members of U.S. Congress and the House
11 of Representatives sponsoring new compulsory,
12 mandatory compulsory license and legislation in
13 the United States.

14 There's a big debate about whether
15 Medicare should negotiate prices. We've been
16 telling people if Medicare negotiates prices,
17 then the only option that companies have is to
18 walk away if there's a high price, something that
19 was raised in the Senate hearing yesterday by the
20 companies, that really puts the patients at risk.

21 We see compulsory licensing as an
22 authority the government needs to ensure that

1 there is negotiation that takes place over what a
2 reasonable price should be. It doesn't result in
3 the patient not getting the coverage.

4 I think everybody here has stories
5 about patients, my wife is starting a new regime
6 of chemotherapy today, we're waiting to find out
7 what the copayment on this expensive medicine is.
8 I know that other people face these same
9 problems. She's lucky she's getting this, because
10 other patients have not gotten it right away
11 because it's so expensive, and I think that
12 compulsory licensing is what you have to do to be
13 able to protect health budgets and patients.

14 I recognize there's concerns about
15 innovation, and we consistently argue that we
16 don't like to see the competition between
17 affordability and innovation. We think that
18 however you end up in that competition, it sucks.
19 What we'd like to see is the emphasis on
20 innovation shift from how much monopoly power you
21 have to incentives which are not based on the
22 price of the drug, particularly market entry

1 awards, which are referred to briefly in our
2 testimony. I'm going to stop right there.

3 CHAIR LEE: Great. Thank you. The first
4 question is from USTR.

5 MR. SUNG CHANG: Thank you for your
6 testimony. What trade-related IP developments
7 that have occurred since April of 2018 should
8 this committee consider as it conducts this
9 Special 301 review this year?

10 MR. LOVE: Well, I think what's
11 happening in Europe right now in terms of the
12 copyright reform is something, again as I mention
13 in our written submission, is really problematic
14 from our point of view.

15 We publish things around the world. I
16 think other people do too, and it's hard to think
17 of the copyright law of one country as being only
18 a national thing right now, and certainly
19 American companies are involved and the big
20 platforms in social media. But I think that
21 that's one area.

22 You should take note of the fact that

1 the European Union is about ready to issue
2 compulsory licenses on their patent extensions
3 for export to third-party countries, something
4 the U.S. might consider looking at as well.

5 The SCP reform, which I think are the
6 first part of the EU is the idea that if a
7 monopoly exists in the European Union because of
8 patent extension, it doesn't exist outside the
9 European Union. They want the European companies
10 to be able to supply those markets with products,
11 even if they can't supply them within the EU.
12 That's something that might -- maybe some
13 American companies might want to take advantage
14 of if you had a similar approach.

15 CHAIR LEE: Thank you very much. The
16 next question is from the Treasury Department.

17 MR. WON CHANG: Thank you for your
18 submission. Your public submission comments on
19 the Special 301 process and notes that USYR
20 should, quote, refrain its focus and use the
21 process to develop and outline and policies and
22 norms that it wants to promote. Do you have any

1 specific suggestions for any individual countries
2 nominated for or previously included in the
3 Special 301 Report?

4 MR. LOVE: Well, I will mention, as I
5 think I have mentioned several times in the past,
6 I think it doesn't do you a service if you keep
7 putting Canada on the anti-piracy list, because
8 they have probably one of the lowest rates of
9 piracy on the planet. So it's sort of weird to me
10 that you would go after Canada consistently.

11 But from our point, in terms of
12 reshaping the norms, I think that the real
13 interest that the Americans have in the
14 pharmaceutical area in medical and technology in
15 general is innovation. And I think you should
16 focus on whether or not the policies of countries
17 are engaged in it, are enhancing the rate of
18 innovation and whether there's, but redefine the
19 free rider issue.

20 The free rider issue should not be,
21 you have patent extensions, you have, you know,
22 you grant evergreening patents and stuff. It

1 should be what collections of things do you do to
2 support innovation? We have the NIH, we have
3 BARDA, we have research and development programs
4 in the Navy, in the Army, Veterans
5 Administration, all kinds of different places in
6 the U.S. Government, and those things are a huge
7 engine for innovation in the United States.

8 There's a lot of countries, for
9 example Switzerland, a lot of countries that do
10 very little in terms of funding the basic science
11 that the rest of the world basically takes
12 advantage of. We have open access publishing, for
13 example, on articles funded by the NIH, which
14 other countries, some do but some don't.

15 I think there are policies that would
16 be good for innovation and good for science, to
17 respond to your question, that are trade related.
18 And I think that if the shift is more about
19 innovation, not just IPR, I know this is an IPR
20 list, but the companies themselves are bringing
21 up direct pricing, for example, which is not an
22 IPR issue, so I think it's fair for me to bring

1 up these other issues.

2 CHAIR LEE: Thank you. The next
3 question is from the Department of Health and
4 Human Services.

5 MS. SNYDER: Thank you. Keeping in mind
6 the legislative mandate for the Special 301
7 Report, how do you suggest that the United States
8 use the report to advance the administration's
9 domestic and foreign policy goals related to
10 pharmaceutical pricing and reimbursement?

11 MR. LOVE: One feature of the proposal
12 by Secretary Azar domestically is to engage in
13 international reference pricing for certain drugs
14 on Part B of Medicare. For that to take place,
15 you actually have to know what foreign prices
16 are.

17 As has been noted in hearings this
18 week, there's a real lack of transparency, not
19 just in the United States but in other countries
20 about what pricing is. You can't really implement
21 Secretary Azar's proposal with any confidence if
22 you don't know what U.S. prices are, if you don't

1 know the German price, the secret price in the
2 U.K., etc.

3 So to that end, Italy has tabled a
4 resolution in the WHO during the executive board
5 that will be discussed in May. It was proposed as
6 a draft resolution. I've shared it, of course,
7 with your office and also with Karen and with
8 everyone I thought would like it or not like it.

9 It's one of those rare areas where the
10 things that I put forward, this actually seems to
11 be consistent with the administration's position
12 of pushing for more transparency on prices.
13 That's one thing that I think would really be
14 helpful.

15 I think also in the past, under the
16 Obama administration, there was a lot of
17 hostility to the idea that the WHO pushed
18 countries to have soft norms on how much they
19 fund medical research to the public sector, for
20 example. I never really understood that, because
21 I thought we were kind of carrying the load for
22 the whole world in some sectors, and I thought

1 other countries would be encouraged to do more,
2 and that would be an area I'd hope you'd revisit.

3 CHAIR LEE: Thank you. We have time for
4 one more question. This one comes from the
5 International Trade Administration at the
6 Department of Commerce.

7 MS. SALZMAN: Thank you for your
8 testimony. In KEI's view, are there foreign
9 countries that lack adequate and effective
10 protection and enforcement of intellectual
11 property rights?

12 MR. LOVE: Yes.

13 MS. SALZMAN: What foreign countries
14 should USTR identify?

15 MR. LOVE: I think there's, there are
16 many countries where piracy of copyright
17 materials, for example, is fairly common. There's
18 a lot of misunderstanding about some of these
19 issues. For example, I'm not aware of any
20 compulsory licenses on patents ever been issued
21 for drugs in China, for example, even though if
22 you take a poll most people think they're doing

1 it every day.

2 But copyright, I think, is one area
3 where there's been a real lack of enforcement. I
4 think part of it is because some of the copyright
5 or pricing models by the publishers in some of
6 those countries aren't realistic given the income
7 of some countries. So I think that I can't give
8 you specifics, well, I could, probably, but I'd
9 prefer not to without more verification. But I
10 believe that's an issue.

11 And I think on the drug area, I mean,
12 it's tough. I work on compulsory licenses. Almost
13 no compulsory licenses are issued in any given
14 year. It's not like people think it is. It's
15 really unusual and it's really hard to get
16 generic drugs into a country even through a
17 barter club. I tried to get a cancer drug from
18 India to Egypt for a patient who was facing a
19 \$900 a week price, and he made \$300 a month. I
20 was contacted by his family.

21 We couldn't get it shipped with DHL,
22 we couldn't get -- I mean it was just an absolute

1 nightmare. So I think the problems on the
2 pharmaceutical side are probably a bit overrated.
3 I will say, though, that better enforcement of
4 counterfeit products so they're safe and
5 effective, which the U.S. government's been a
6 leader on, is a good mission.

7 CHAIR LEE: Thank you very much for
8 your testimony. Next we have MFJ International,
9 LLC. Thank you. Please state your name and
10 organization for the record and begin your
11 testimony.

12 MS. JORGE: Thank you very much. My
13 name is Mariana Jorge for MFJ International. I
14 appreciate the opportunity to testify today. MFJ
15 International is a consulting firm with a
16 significant focus on increasing access to
17 affordable drugs throughout the world. This
18 testimony is not made on the behalf of any
19 client.

20 IP provisions are important to provide
21 incentives for the development of new drugs, but
22 they cannot and should not be seen in isolation.

1 As is stated by the Federal Trade Commission,
2 competition and patents stand out among the
3 federal policies that influence innovation.

4 Both competition and patent policy can
5 force the innovation but each one requires a
6 proper balance with the other to do so. Error or
7 systematic biases and how one policy's rules are
8 interpreted and applied can harm the other
9 policies' effectiveness.

10 Therefore, patents and intellectual
11 property rights must be seen within the context
12 of competition. The Special 301 review seeks to
13 identify countries that denied adequate and
14 effective protection of intellectual property
15 rights.

16 While for some industries these can be
17 pretty straightforward exercise, in the case of
18 the pharmaceutical industry it is much more
19 complex as the industry has two sides, the
20 originator industry and the genetic biosimilar
21 industry.

22 Therefore in this case it is even more

1 critical to strike the right balance between IP
2 laws and regulations and competition policies so
3 that both sides of the industry can thrive to
4 ensure that patients have access to new drugs as
5 well as to more affordable generic and
6 biosimilars.

7 It is critical to have a careful
8 assessment of what constitutes adequate and
9 effective protection, which should not be
10 interpreted as meaning that more protection is
11 better as it would in fact undermine the
12 necessary balance that must be struck to promote
13 innovation.

14 Hence the identification of countries
15 based on whether they are providing adequate and
16 effective IP protection should be based on
17 objective criteria that reflects the obligations
18 undertaken by the countries in treaties like
19 TRIPS, and bilateral original agreements.

20 However, it is deeply concerning that
21 recent trade negotiations like the USMCA lack the
22 necessary balance on intellectual property

1 provisions related to pharmaceuticals.

2 US trade policy has led to new and
3 increasingly higher barriers to entry for genetic
4 biosimilar products. This is not just about the
5 market, other markets, but also for the U.S.
6 market. The clearest example is the fact that the
7 TRIPS agreement changed U.S. law by expanding the
8 patent terms from 17 years from the day of
9 granting of a patent to 20 years from its filing.

10 This single provision continues to
11 cost billions of dollars to U.S. consumers in the
12 generic biosimilar industry. Neither trade
13 agreements or the Special 301 should delay or
14 block the lines of generic or biosimilar products
15 under the pretense of providing adequate and
16 effective protection.

17 Moreover, if such protection
18 undermines the U.S. generic biosimilar industry,
19 it cannot possibly be considered to be providing
20 adequate and effective protection as trade policy
21 should not take sides to benefit one industry
22 sector at the expense of the other.

1 Trade policy should not undermine, but
2 be consistent with other government policies like
3 health initiative that seek to make drugs more
4 accessible. We know that this is a top priority
5 of this administration. It is deeply concerning
6 that U.S. trade policies are inconsistent, and in
7 fact detrimental to other government policies
8 that seek to increase access to affordable drugs.

9 For example, while the July 2018
10 Biosimilar Action Plan highlights the importance
11 of striking a balance between encouraging and
12 rewarding innovation in drug development and
13 facilitating robust and timely market competition
14 across the spectrum of pharmaceutical products
15 from traditional small molecules to complex
16 products to biologics, the Special 301 seems to
17 focus only on how to broaden and expand the
18 rights of originator pharmaceutical companies.

19 In our own opinion, this needs to
20 change to endorse balanced provisions that allow
21 both sides of the industry to thrive. That way,
22 it will complete President Trump's goal of

1 increasing competition and lowering drug prices.

2 In conclusion, we believe that trade
3 policy implemented through the Special 301 review
4 and trade agreement should be adjusted to strike
5 a balance and promote both innovation and access
6 to affordable drugs. The protection of
7 intellectual property right as it relates to
8 pharmaceuticals must not be seen in isolation,
9 but within the context of competition. Only then
10 will such protection be adequate and effective.

11 CHAIR LEE: Thank you very much. We'll
12 start questions with one from USTR.

13 MR. SUNG CHANG: Thank you. In your
14 opinion and under the mandate that we have under
15 the Special 301 statute, what is the most useful
16 part of the Special 301 review process, anyway?

17 MS. JORGE: I think that one issue that
18 is important is that the Special 301 cannot be
19 looked at in isolation. It has to be connected
20 with trade agreements. So when we say, oh, well,
21 let's identify the countries that are not
22 providing adequate and effective protection and

1 we look at what are the trade agreements, that
2 should be the objective standard.

3 And if those trade agreements are only
4 siding with one side of an industry, the whole
5 process is undermined. It's not consistent with
6 what the FTC says. Intellectual property is not
7 an end in itself. It is hopefully the means for
8 innovation but it has to be in balance with
9 competition.

10 So, in terms of what you are asking,
11 I don't think that we can take only the Special
12 301 and just look only at whether it's providing
13 enough protection. We need to make sure where the
14 balance is, and in my opinion that balance is
15 off, and for a long time. It's also off with
16 regard to the trade agreement.

17 CHAIR LEE: Thank you. The next
18 question is from the Department of Health and
19 Human Services.

20 MS. SNYDER: Hi. Your submission gives
21 a number of examples of policies and practices
22 that you do not see as appropriate grounds for

1 listing a country in the Special 301 Report. Can
2 you provide examples of specific policies and
3 practices that would warrant listing a country in
4 the report? What criteria would strike the
5 appropriate balance that you reference in your
6 submission?

7 MS. JORGE: One of the things we are
8 talking about, this is about trade, right? This
9 is about helping the U.S. industries to grow, to
10 sell more, to export more. When we are focusing
11 only on export more, one side of the industry
12 where we are establishing barriers to entry to
13 the other, that's a problem.

14 So in terms of actual policies, for
15 instance, when it's only if one hand is looking
16 for patent term extensions but none of the
17 limitations or requirements that are to
18 counterbalance. It's no balance.

19 There is, for instance, a focus on
20 exclusivity but there is nothing about incentives
21 to launch a pharmaceutical product. At the end of
22 the day, what we are trying to do or what I think

1 we are supposed to do here, is to maximize U.S.
2 exports. We are not doing that in
3 pharmaceuticals, because it's like communicating.
4 If you give too much protection on one industry
5 you are actually establishing barriers to entry
6 to the other.

7 And at the end of the day we're
8 undermining one side of the industry, and in my
9 opinion for the last 25 years we have been
10 undermining one side of the industry.

11 For instance, on another policy we are
12 talking about best mode. Best mode is in U.S. law
13 and is critical so we are not reinventing the
14 wheel every time. So after patent expiration,
15 people, society can benefit from this.

16 Well, that is never focused on. We are
17 only cherry-picking only the side of regulations
18 that benefit only to the patent holder at the
19 expense of everyone else. And the problem is,
20 sometimes we might fail to just look at these as
21 oh, well, it's all about foreign countries.

22 But this is not about foreign

1 countries. Everything is connected right now. I
2 had a sentence from Gottlieb where it says, we
3 need economies of the scale to be able to give
4 the competition that we need in the domestic
5 market to provide a biosimilar.

6 If we are locking access to U.S.
7 biosimilar companies to other markets because we
8 found a super-high levels of intellectual
9 property and they cannot export it, we'll never
10 reach economies of scale. We will not develop the
11 biosimilar industry and we will hurt U.S.
12 consumers as well as the budget and the deficit.
13 It's all connected.

14 CHAIR LEE: Thank you very much for
15 your testimony. Next we have National Association
16 of Manufacturers. Thank you. Please state your
17 name and organization for the record and begin
18 your testimony.

19 MR. ONG: Sure. My name is Ryan Ong.
20 I'm with the National Association of
21 Manufacturers. Members of the Special 301
22 subcommittee, thank you for the opportunity to

1 testify today on behalf of the NAM and the more
2 than 14,000 manufacturers, large and small, that
3 we represent.

4 Innovation and intellectual property
5 are the backbone for the manufacturing industry,
6 which is the bedrock of the American economy. In
7 2015, value added from IP was nearly 40 percent
8 of total U.S. gross domestic product, and
9 according to the latest data, the United States
10 was responsible for one-quarter of all research
11 and development conducted globally. So yes, this
12 matters.

13 American is a leader when it comes to
14 innovation, but that also puts our businesses and
15 ideas in the crosshairs of bad actors that would
16 rather cheat than compete.

17 IP theft means that businesses on the
18 verge of breakthroughs that can change lives and
19 reshape industries can have their products
20 stolen, their products undercut and their work
21 decimated before they reach their full potential.

22 The NAM's Special 301 submission

1 identifies the need for a strategy and
2 broad-based approach to address multiple
3 cross-cutting challenges to manufacturing
4 innovation. We also recommend seven countries for
5 the priority watch list and an additional six
6 countries for the watch list as a focus for this
7 year's Special 301 Report. These targets include
8 longstanding challenges such as China and India,
9 as well as countries of growing concern such as
10 Chile and Japan.

11 The NAM's written submission provides
12 greater detail in these areas, but I'd like today
13 to highlight three main threats facing
14 manufacturers' intellectual property and
15 innovation around the world, and the global
16 context that makes this a critical opportunity
17 for setting new precedence moving forward.

18 First, our competitors are
19 increasingly using international organizations to
20 weaken critical IP protections. Reports and
21 policy guidance coming out of organizations like
22 the World Health Organization erroneously claim

1 that IP is an inherent barrier to progress,
2 overlooking the importance of innovation in
3 finding powerful new solutions to global problems
4 and ignoring the actual barriers in health,
5 energy, and clean technologies and other areas
6 that prevent innovative products from getting
7 into the hands of those who need them most.

8 Second, foreign countries have
9 expanded their use of unbounded compulsory
10 licensing and other patent limitations, steps
11 that harm innovation. Compulsory licensing has an
12 important role in cases of emergency that comply
13 fully with international rules and agreements,
14 but too often this power is being used by
15 competitors as a protectionist tool to promote or
16 protect local manufacturing in the long-term
17 damage to U.S. interests. This is a growing
18 concern globally, but has been particularly
19 problematic over the last year in Latin America.

20 Finally, rampant counterfeiting and
21 piracy steals the successes of innovators large
22 and small, and undercuts manufacturers across

1 industries. Manufacturers have long battled fake
2 products sold in physical markets, but they face
3 new challenges due to the explosion of fake
4 products being sold online.

5 A 2017 estimate by the Commission of
6 the Theft of Intellectual Property shows that
7 counterfeit and pirated goods cost the U.S.
8 economy between 29 and 41 billion dollars every
9 year, and fake products can pose a direct risk to
10 public health and the safety of consumers.

11 These are only three of the challenges
12 facing innovative manufacturers, but there are
13 plenty more challenges to innovation that put
14 manufacturers and jobs at risk. That's why the
15 United States has spent decades building a strong
16 domestic legal framework to protect and enforce
17 manufacturers' IP and why it has been a champion
18 for stronger global enforcement of IP rights, but
19 we must do more.

20 The Trump administration has shown a
21 commitment to holding other countries accountable
22 when they cheat, and rebalancing trade with our

1 foreign partners. We commend them for that
2 commitment. We must strategically use all
3 appropriate tools, including Special 301-related
4 tools such as country classifications,
5 out-of-cycle reviews and results-oriented action
6 plans but also other tools such as full
7 implementation of legislative authorities to
8 enforce IP.

9 In addition, we must use this critical
10 moment to set new precedence for IP protection.
11 In bilateral and multilateral trade agreements,
12 IP protection and enforcement should be an
13 explicit priority. The U.S.-Mexico-Canada
14 Agreement, for example, includes best-in-class
15 intellectual property rules to protect the full
16 range of U.S. manufacturing, inventions and
17 innovations from foreign theft from its
18 appropriation.

19 As Congress moves to consider USMCA
20 and as the administration seeks new bilateral
21 trade deals with the EU, UK, China, Japan and
22 others, we have an unparalleled opportunity to

1 create fair and more enforceable systems that
2 protect IP and promotes American innovation.

3 The NAM urges the agencies in this
4 committee to seize this opportunity and create a
5 fair and more enforceable trade network that
6 promotes American innovation, that starts with
7 protecting the IP that is so critical to the
8 growth and success of manufacturers large and
9 small. Thank you again for this opportunity. I'd
10 be glad to take questions.

11 CHAIR LEE: Thank you. The first
12 question comes from USTR.

13 MR. SUNG CHANG: Thank you for your
14 testimony. Your submission noted a trend in Latin
15 America towards the issuance of compulsory
16 licenses, or at least initial status in that
17 direction, and these steps appear associated with
18 price negotiations over patented drugs.

19 Have any of your members indicated
20 that they will revisit entering these markets in
21 view of these developments? What steps has the
22 industry taken to communicate its concerns to the

1 countries in this region, and what types of
2 responses have those governments provided?

3 MR. ONG: Sure. Happy to answer this
4 question to provide follow up information after
5 additional conversations.

6 But I will note for our innovative
7 manufacturers, they look very, very carefully and
8 closely at the business environment as they're
9 considering trade, investment and integration
10 into other markets.

11 And so the environment for protection
12 of intellectual property has a direct impact on
13 consideration for what they may do in that
14 market.

15 As a broad, cross-cutting
16 manufacturing association, we watch a variety of
17 IP issues that impact a range of sectors. I will
18 tell you from our broader membership that
19 companies outside of the innovative
20 pharmaceutical sector are also very closely
21 watching events and actions in Latin America.

22 We highlighted a couple of specific

1 instances in our written submission that I won't
2 go into now, in Chile and Colombia and other
3 locations.

4 I do know from our own conversations
5 with members as well as our constituent
6 associations that there have been active and
7 robust efforts to engage locale governments and
8 local stakeholder groups, including business and
9 other groups to communicate the level of concern
10 and try to find appropriate paths and ways
11 forward, and to be able to communicate the long
12 term impact for those markets of taking and
13 moving in a more anti-intellectual property
14 direction. Those conversations are ongoing.

15 CHAIR LEE: Thank you. The next
16 question is from the Department of Health and
17 Human Services.

18 MS. SNYDER: In your submission, you
19 assert that countries like South Africa and
20 Indonesia are contributing to the problem of IP
21 erosion in multilateral fora.

22 Can you provide more specific

1 information? How do you suggest using the
2 special 301 Report to address your concerns
3 related to what you describe as IP erosion in
4 multilateral fora?

5 MR. ONG: Sure. And that's a good
6 question because multi-lateral organizations,
7 themselves, are not directly subject for the
8 special 301 within scope. You know, these
9 instances really pop into a variety of specific
10 initiatives.

11 Sort of the largest area that we've
12 seen some of these particular discussions as I
13 mentioned before is at the World Health
14 Organization where whether we talk about
15 initiatives or language related to the U.N. high
16 level panel and access to medicines, discussions
17 on the WHO roadmap on access to medicines and
18 vaccines, or broader discussions related to
19 compulsory license and balance of IP versus other
20 provisions, countries like India, South Africa,
21 Brazil and others are frequently drivers for
22 moving those conversations in a direction away

1 from traditional IP rules and criteria and sort
2 of in that particular direction.

3 A couple of things that I would note.
4 One, given sort of member state focus and member
5 state driving on these issues that opens up
6 opportunities within the scope of the 301 and
7 bilateral conversations and action plans that
8 take place to be able to raise these concerns and
9 hopefully find more constructive conversations to
10 take place within these organization, for the
11 U.S. to work with other member states on an
12 individual basis.

13 But the other element to this is
14 awareness of the ways in which these
15 conversations that may take place at say the
16 World Health Organization directly impact
17 regulatory regimes and regulatory frameworks in
18 individual markets that may themselves be the
19 subject of 301 investigation.

20 And so understanding how a discussion
21 on IP and access to medicines at the WHO may then
22 directly port into an influence, say, compulsory

1 licensing discussions in Latin America.

2 CHAIR LEE: Thank you for your
3 testimony. Next, we have the National Academy of
4 Legal Studies and Research Litigation Project.
5 Thank you. Could you please state your name and
6 organization and begin your testimony?

7 MR. SINGLA: Dayaar Singla for the
8 NALSR Litigation Project.

9 Good afternoon members of the
10 subcommittee. I'm an Indian exchange student at
11 the Santa Clara University School of Law and I
12 would like to thank Professor Gross and Dean
13 Kloppenberg for this opportunity.

14 I speak here on behalf of the the
15 NALSR Litigation Project. The NLP is an
16 independent student joined group based out
17 National Academy of Legal Studies and Resource
18 University of Law, Hyderabad, one of India's
19 premier national law universities.

20 I would -- before I begin -- and we
21 are extremely grateful for the invite to present
22 our views before the subcommittee. Before I

1 proceed further, I would like to note that the
2 NLP, views of the NLP do not necessarily reflect
3 those of NALSR or of those in NALSR.

4 I shall be submitting before you on
5 two areas of concern. Firstly, I note that the
6 Indian government over the last, over the course
7 of last year has taken various steps as well as
8 policies which are pro-IPR and on the basis of
9 these I recommend the removal of India from the
10 priority watch list.

11 Secondly, we submit the global trends
12 regarding various governments mandating source
13 code disclosure requirements.

14 In regard to India, as per the 2018,
15 301 report, it took note of concerns related to
16 IP enforcement, protection mechanisms, online
17 piracy, lack of camcording legislation and
18 India's IPR stance in the global fora, we have
19 submitted through our written statement, the
20 positive steps that have been taken in regard to
21 these issues.

22 Firstly, I bring to your kind

1 attention that the cover of protection under the
2 IPR regime in India has increased over the last
3 year. The Indian government has approved
4 extension of the WIPO Internet Treaties.

5 It has made progress on amending the
6 Cinematograph Act to curb camcording incidents.
7 It has also made appointments to the intellectual
8 property appellate board, which is now
9 functional.

10 These were some of the issues that
11 were raised in the 2018 301 report and have now
12 been resolved. Secondly, various steps have been
13 taken to increase the ease in securing
14 intellectual property rights.

15 During the last year, the IP offices
16 have been radically transformed through numerous
17 initiatives. Thirdly, the government has taken
18 various steps to encourage IP awareness amongst
19 the youth, which shall help promote and build a
20 stronger IPR culture.

21 Finally, over this weekend itself, the
22 e-commerce policy was released. While we have

1 not had the opportunity to analyze it in detail,
2 the policy proposes anti-counterfeiting measures
3 to protect trademark owners, as well as
4 anti-piracy measures.

5 As mentioned, significant efforts have
6 been taken over the period of last year and in
7 light of these submissions, we recommend the
8 removal of the Indian government from the
9 priority watch list.

10 Moving to the second issue, as has
11 been consistently stated, the transfer of source
12 code presents an untenable risk of theft and
13 piracy, yet some governments implement source
14 code disclosure requirements as a minimum
15 requirement for legal market entry. These
16 requirements therefore prove as major
17 disincentives for international trade.

18 The broad policies of countries, of
19 such countries can be placed on the spectrum from
20 states which require mandatory source code
21 disclosure requirements for entry in the market.
22 Secondly the states which require source code

1 disclosure first off, they block you by the
2 public sector.

3 Thirdly, states which prefer open source
4 software over closed source software for the
5 government procurements and finally, we have
6 states which actively push for an international
7 regime where source code disclosure is
8 prohibited.

9 Russia, China and Nigeria fall under
10 the first category. Regarding the Russian
11 requirements, the practice of mandating source
12 code disclosure when the government itself is not
13 procuring such software is specifically
14 contentious.

15 It is as it also becomes a threat to
16 the various other countries, which might be using
17 the software to protect or otherwise in the
18 sensitive installations.

19 In the case of China, the new
20 cybersecurity law, which has been implemented
21 since 2017, has brought back the source code
22 disclosure requirement. Another notification at

1 the WTO also hints towards the same. This law is
2 also a move towards developing and applying
3 national technical standards and thereby is
4 counted to the obligations under the WTO
5 agreement on technical barriers of trade.

6 The Nigerian government continues to
7 have localization requirement across a broad
8 range of IT applications.

9 The states of Brazil and Indonesia
10 fall under the second category of mandating
11 disclosure for government procurements. India
12 and South Africa fall under the third category
13 where there is a policy preference of open source
14 software over closed source software when the
15 question is of government sector procurement.

16 However, this preference is waved off
17 when it is proven that the CSS is better than the
18 OSS for the purposes required. Therefore it can
19 be said that such of a requirement or preference
20 does not offer any threat to IP right,
21 intellectual property rights of these companies.

22 Finally there are various states which

1 fall under the fourth category, including the
2 United States of America, Japan, Canada, Chile,
3 Colombia, European Union and others who have
4 worked towards creating global security
5 environment in terms of source code disclosure
6 and recommend these efforts.

7 In light of these submissions, we
8 recommend that the steps may be taken on a case
9 by case basis with regards to these countries to
10 have a better international regime for tech
11 companies as well as app developers.

12 Thank you. We look forward to
13 understanding the USTR's 301 report in any manner
14 possible and I'm happy to answer any questions
15 that you may have.

16 CHAIR LEE: Thank you. The first
17 question comes from USTR.

18 MR. S. CHANG: Thank you for your
19 testimony. You just told us several key IP
20 reform improvements India has made in the past
21 year. Could you also tell us the top three
22 challenges that remain for India that it should

1 address in the coming year?

2 MR. SINGLA: With the challenges, I
3 would like to state that various members have
4 pointed to the data localization requirement,
5 which has come under the new policy. Secondly,
6 the e-commerce market place, which was released
7 just this week, it also mentions source code,
8 source code disclosure requirement, however, the
9 source code disclosure requirement is very
10 limited in nature.

11 It is basically in terms of AI
12 applications, as it mentions that a lot of
13 decisions will be made through artificial
14 intelligence.

15 And when it comes to these they might
16 lead to validation of consumer interest and
17 therefore, there might be a requirement for the
18 source code of -- for looking at the source code
19 because as you've seen previously as well,
20 artificial intelligence generally learns from the
21 current conditions, which might not be perfect,
22 and therefore there might be a requirement in

1 terms of fundamental rights violations or privacy
2 rights violations for the same.

3 Data localization, your AI source code
4 disclosure requirement, and thirdly I think the
5 delays in the U.S. -- in getting access to back
6 ends has been something that has been mentioned
7 by various other organizations.

8 CHAIR LEE: Thank you. The next
9 question is from the U.S. Patent and Trademark
10 Office.

11 MS. FERRITER: Thank you. Could
12 NALSAR comment on how it views long standing IP
13 challenges in India that are cited in past
14 special 301 reports?

15 These include, quote, those which make
16 it difficult for innovators to receive and
17 maintain patents in India, particularly for
18 pharmaceuticals enforcement actions and policies
19 that are insufficient to curb the problem,
20 copyright policies that do not properly
21 incentivize the creation and commercialization of
22 content, and an outdated and insufficient trade

1 secret legal framework, end quote.

2 MR. SINGLA: Well I will not comment
3 on the basis of NALSAR, but on the behalf of
4 NALSAR litigation project. With regards to
5 patents in terms of end price control, I would
6 like to renew attention to policy of Ministry of
7 Chemicals and Fertilizers through our related
8 January 3, 2019, under which patented new drugs
9 and orphaned drugs have been exempted from price
10 control for a period of five years from the date
11 of their commencement of commercial marketing.

12 This allows for another exception,
13 which will make Indian market attractive to
14 multinational pharmaceutical companies and
15 encourage them to introduce new drugs into India.
16 This also removes the localization requirement in
17 regards to this.

18 Was there a second part of this
19 question? With regards to the trade secret
20 requirement, there are other, under the Indian
21 civil procedure code there are other options
22 available for the companies to litigate in India.

1 However, it is true that there is no trade
2 secret, trade secret legislation, per se.

3 CHAIR LEE: Thank you very much. The
4 next question is from the Department of Justice.

5 MR. LAMBERTI: Hi, thank you. Thank
6 you for flying out from California for this and
7 appreciate your testimony. Your submission and
8 your testimony today describes a number of steps
9 that India has taken to create a friendly
10 domestic environment for IP-intensive industries.

11 However, other submissions and other
12 testimony earlier today describes India as
13 advocating for the erosion of intellectual rights
14 in multilateral fora. Where do you see the
15 disconnect, the inconsistency between the --

16 MR. SINGLA: What we do mention is
17 that until 2018, the USTR has always been putting
18 India on the priority watch list and that is of
19 course because of various reasons that India,
20 that the USTR has mentioned in its reports
21 consistently.

22 What we are stating here is that India

1 has been, there has been a shift in terms of
2 India's policy towards IPR and as can be seen
3 through the various steps, it is continuously
4 moving towards providing a market which is
5 better, which enforces the intellectual
6 properties rights protection in a better, in a
7 better manner.

8 And therefore, we would appreciate
9 that if India is moved from priority watch list,
10 which also shows that the USTR is responding to
11 the manner in which India is working towards its
12 legislations as well as its policies in taking
13 steps. And hopefully this will be a further
14 incentive for the Indian state to continue
15 working on this issue.

16 CHAIR LEE: Thank you for your
17 testimony.

18 MR. SINGLA: Thank you.

19 CHAIR LEE: Next is the Pharmaceutical
20 Research and Manufacturers of America. Thank
21 you. Please state your name and organization for
22 the record and begin your testimony.

1 MR. MOORE: Thank you very much. I'm
2 Chris Moore with the Pharmaceutical Research and
3 Manufacturers of America. And on behalf of
4 bio-pharmaceutical innovators in the United
5 States and the more than 800,000 women and men
6 they employ across the country, PhRMA appreciates
7 this opportunity to testify before the Special
8 301 committee.

9 The United States leads the world in
10 medicines research and discovery. Intellectual
11 property, including patents and regulatory data
12 protection drives and sustains bio-pharmaceutical
13 innovation. It enables access to today's
14 medicines and promotes investment in tomorrow's
15 new treatments and cures.

16 Where markets are open and
17 intellectual property is protected and enforced,
18 PhRMA members have the predictability and
19 certainty necessary to research, develop and
20 deliver new medicines for patients who need them.

21 But today innovators face tremendous
22 challenges in major overseas markets that

1 threaten medical advances and put American jobs
2 and exports at risk.

3 Special 301 gives the administration
4 a powerful tool to identify and address severe
5 and pressing barriers abroad and to level the
6 playing field.

7 Special 301 is not only about
8 promoting adequate and effective intellectual
9 property protection overseas, it's also about
10 ensuring that our trading partners provide fair
11 market access for American inventions and that
12 they appropriately value new advances.

13 We urge the administration to use
14 Special 301 to address damaging market access
15 barriers in Japan, Canada and Korea that
16 significant harm to U.S. exports often through
17 practices that discriminate against American
18 innovators.

19 New policies in Japan use biased
20 criteria that would allow local companies to get
21 a competitive advantage and would discourage the
22 launch of competing products.

1 Proposed changes to Canada's pricing
2 policies are aimed solely at patent medicines and
3 would undervalue U.S. innovations. In Canada and
4 Korea, American innovators also face a range of
5 intellectual property challenges, including
6 inadequate patent term restoration. For these
7 reasons and others, we ask that Japan, Canada and
8 Korea be named priority foreign countries.

9 PhRMA submission also identifies top
10 intellectual property barriers and threats abroad
11 that require urgent action. In many cases these
12 threats are driven by or actively supported by
13 multilateral organizations.

14 Last year for example, Malaysia issued
15 a compulsory license for an innovative medicine,
16 a move that was not designed to address an urgent
17 public health challenge but rather to facilitate
18 the local development of a competing combination
19 product.

20 Final regulations Indonesia issued in
21 late December without any public consultation,
22 similarly, transformed compulsory licensing into

1 an industrial policy tool. Patent products that
2 are not manufactured in Indonesia can be
3 compulsory licensed.

4 Contrary to its own procedures, the
5 Colombian government accepted a petition for
6 review in December of 2017 that could result in a
7 compulsory licensing of patents protecting an
8 entire class of innovative medicines.

9 In Chile, an innovative medicine
10 developed in the United States is already at risk
11 of compulsory licensing and now Chilean lawmakers
12 are considering legislation that would grant the
13 health ministry extraordinary new powers to force
14 compulsory license decisions on the vaguest of
15 grounds.

16 For these reasons, we ask that
17 Malaysia be named a priority foreign country and
18 that Indonesia, Chile and Colombia be placed on
19 the priority watch list. Unfortunately, PhRMA
20 members are also facing growing intellectual
21 property barriers and threats in advanced
22 economies, including the European Union, Saudi

1 Arabia and the United Arab Emirates.

2 Despite its role in medical research,
3 the EU is days away from action that would
4 undermine innovation by allowing local companies
5 to make copies of patented medicines during the
6 period of supplemental protection for export or
7 stockpiling.

8 PhRMA asks that Saudi Arabia be placed
9 on the priority watch list and that the European
10 Union and the UAE at least be included on the
11 watch list.

12 We urge USTR to use all available
13 tools and leverage to address these and other
14 challenges outlined in our submission. We
15 particularly urge USTR and other federal agencies
16 to address market access and intellectual
17 property barriers in countries that are current
18 and prospective U.S. trade agreement partners, or
19 that are beneficiaries of the USGS peak program.

20 These existing agreements and
21 programs, as well as ongoing and pending
22 negotiations provide immediate opportunities to

1 address pressing market access and intellectual
2 property concerns and to enforce current rules.

3 Thank you for the opportunity to
4 testify today. We look forward to answering any
5 questions and to working with you to address the
6 serious concerns described in our submission for
7 the 2019 Special 301 report. Thank you.

8 CHAIR LEE: Thank you. We will start
9 with USTR.

10 MR. S. CHANG: Thank you. Your
11 submission and your testimony argues that
12 discriminatory pricing policies deny fair and
13 equitable market access. Could you please
14 explain the link further?

15 And also, are there examples where
16 companies have not sold products or where
17 companies have pulled out of specific markets due
18 to such policies?

19 MR. MOORE: The discriminatory
20 practices that are outlined in our submission are
21 very concerning for our members. They appear to
22 discriminate in certain cases between foreign and

1 domestic suppliers.

2 That is certainly the case in Japan,
3 has been the case in Korea. They also
4 discriminate between patented medicines and
5 generic drugs. That is the case in Canada.

6 There's real concern that these
7 controls will prevent products that are
8 manufactured in the United States from having the
9 same competitive opportunity to supply these
10 markets as domestic products.

11 We think that is a serious market
12 access barrier. The Special 301 statute requires
13 USTR to include countries on the list that are
14 preventing fair and equitable market access for
15 U.S. persons who depend on intellectual property
16 rights.

17 It also gives some guidance in terms
18 of what would constitute a market access barrier
19 including whether these are barriers that appear
20 to violate international agreements, that appear
21 to be discriminatory, non-tariff trade barriers.
22 We think that's the case with respect to the

1 countries and the practices that we've
2 highlighted.

3 MR. S. CHANG: Thank you for that
4 answer. Going back to the last part of my
5 question, if possible, could you please give us
6 some concrete examples of where your member
7 companies have pulled out of specific countries
8 due to such pricing policies?

9 MR. MOORE: For our members, we're
10 producing products that are different than other
11 products might be. They're products that are
12 required by patients for their health. And so
13 the last thing that any of our members want to do
14 is to pull out of a country.

15 We also face the challenge under trade
16 rules and intellectual property rules globally
17 that if we fail to supply a product that is
18 protected by a patent in a country, that product
19 can then be compulsory licensed for failure to
20 work the patent.

21 And so that's a very serious concern
22 as well. So our members are constantly striving

1 to be able to supply these products but given
2 some of the new proposals that have been cited in
3 our submission, the types of cuts that we're
4 looking at, the discriminatory nature of those
5 cuts, I think that's going to make it very, very
6 difficult for a number of our members.

7 CHAIR LEE: Thank you. Next is a
8 question from the Treasury Department.

9 MR. W. CHANG: Thanks for your
10 testimony. Over the past two years since the
11 issuance of India's national IP policy, how does
12 PhRMA evaluate India's implementation of the
13 policy? What recommendations do you have to the
14 government of India for implementation of the
15 policy going forward? Thanks.

16 MR. MOORE: Well we have been in many
17 discussions with the Indian government. It's
18 always our goal to try to engage constructively
19 with governments around opportunities to create
20 the right environment for bio-pharmaceutical
21 innovation in their countries.

22 And some of the challenges that our

1 industry continues to face in the Indian market
2 make that very difficult. The inability to
3 maintain and enforce patents that we have in that
4 country because of challenges with the
5 enforcement procedures, things like Session 3D
6 make it very difficult for our companies to get
7 patents in India.

8 We aren't able to secure regulatory
9 data protection in India. It's very difficult to
10 do clinical trials in India both for our member
11 companies but also for Indian generic drug
12 companies.

13 And so all of those things are issues
14 that we have brought to the Indian government and
15 we look forward to concrete steps to resolve
16 those issues.

17 CHAIR LEE: Thank you very much for
18 your testimony. Next is Public Citizen.

19 MR. MAYBARDUK: Thanks very much,
20 members of the committee, good to see many of you
21 again, and let me start by saying I appreciate
22 that yours is a challenging and delicate job,

1 that this is a long day, and that you take some
2 criticism. So I thank you for hearing from us.

3 Public Citizen is a nonprofit,
4 consumer advocate --

5 CHAIR LEE: Sorry. Let me just
6 interrupt for just a second. Could you state
7 your name --

8 MR. MAYBARDUK: My name for the
9 record. Yes.

10 CHAIR LEE: -- for the, for the
11 record? Thank you.

12 MR. MAYBARDUK: Yes, sir. Peter
13 Maybarduk. I'm the director of our Access to
14 Medicines Program. We've been seeing each other
15 here for many years. So Public Citizen is a
16 nonprofit, consumer advocacy organization. We
17 accept no money from any government and no money
18 from any business. Our 500,000 members and
19 supporters are U.S. consumers.

20 As the director of our Access to
21 Medicines Program, I work with partners across
22 the United States and around the world to make

1 medicines affordable and available through tools
2 and policy and law and our submission that you
3 have that draws on our experience providing
4 technical assistance to public agencies
5 particularly in developing countries on patent
6 and other IP rules to protect access to
7 medicines.

8 But it is worth saying that we are
9 working more and more in the United States these
10 days, given the pain that people living here are
11 feeling from increasing medicine prices.

12 Of the latest Kaiser survey suggests
13 that 24 percent of Americans either themselves or
14 within their family are self-rationing their
15 prescriptions.

16 They are failing to fill prescriptions
17 precisely because of cost, because of the high
18 price of pharmaceuticals in the United States,
19 fully one-quarter of the U.S. population.

20 This is according to Harvard and
21 Politico, drug pricing, the number one issue that
22 Americans have for the U.S. Congress at the

1 moment.

2 You ask Democratic oriented voters,
3 Republican identified voters, you find that both
4 at the moment list drug pricing ahead of every
5 other salient issue that Congress might address.
6 They're really hoping for strong action to make
7 medicines affordable here at home.

8 Now in this context we would note that
9 the Trump administration, we've actually seen
10 take some modest and positive steps towards
11 lowering drug prices. However, when we analyze
12 the good and bad of administration policy, the
13 practice of blaming other countries for high
14 prices here constitutes the ugly in the good, bad
15 and ugly of those practices.

16 We're concerned that the Special 301
17 report from last year seemed to follow that
18 aggressive approach, merely criticizing foreign
19 practices that are designed simply to make
20 medicines affordable. The report reflects,
21 quote, the resolve of the administration to call
22 out foreign countries, which we took to be some

1 very interesting language.

2 Well some context about this approach.
3 There is no logical reason, let alone evidence to
4 think that people in the United States will pay
5 less for medicine if the U.S. government works to
6 compel other countries to pay more.

7 That's crazy talk. That's not how
8 business works. Companies are working to
9 maximize revenue in every market, and they are
10 not pricing to recover research and development
11 cost, but rather to recoup revenue.

12 That's not just how all industries
13 work. That's also what the U.S. government found
14 in its own reports on the subject. HHS in 2016
15 had a report on prescription drug spending in
16 innovation that identified the simple and obvious
17 revenue maximization model.

18 One recent study found that
19 prescription drug corporations receive 176
20 percent of global R&D costs from the excess
21 profits they make charging high prices in the
22 United States alone.

1 But what does make pharma pricing
2 different from other sectors is that the
3 patent-based industry operates without typical
4 competitive constraints and in the USA without
5 even government negotiating powers that check on
6 price. So while there's an extent to which we
7 pay for innovation and of course taxpayers put in
8 \$30 billion a year for the National Institutes of
9 Health publicly funded by medical research and
10 development, there's a greater extent to which we
11 pay for monopoly, it's the monopoly conditions of
12 the not quite markets for pharmaceuticals that
13 make prices so high.

14 However, our country is beginning to
15 seriously question and challenge this status quo.
16 Many types of reform are active in Congress right
17 now, are active with the administration. We'll
18 probably see the limiting and banning this year
19 of particular pharma industry abuses, thanks in
20 part to the leadership of Republic Senator Chuck
21 Grassley.

22 Even compulsory licensing, a hot topic

1 today, there are at least two bills in Congress
2 favoring the use of compulsory licenses in the
3 United States. One already has the support of
4 full half the members of the House Democratic
5 Caucus, half. So these are not marginal issues
6 in our own country any longer. There are bills
7 to reduce exclusivity periods and serious efforts
8 to patent reform.

9 I see that I only have a minute, so
10 I'll have to move rather quickly but it's worth
11 noting that again, here in the United States,
12 Baltimore City has requested compulsory licenses
13 as a remedy for the opioid addiction crisis for
14 treatments for naloxone. Louisiana has explored
15 this for Hepatitis C, the same drug that's being
16 criticized for Malaysia's action effectively do
17 the same thing that Louisiana's looking to do.
18 The interest of U.S. elected leaders should lead
19 to a softening of U.S. pressure against similar
20 policies abroad.

21 Now it is worth addressing the
22 mandate, the Trade Act of 1974 briefly. You

1 asked about discrimination. Our understanding
2 with the prior speaker, if pricing policies
3 neither discriminate against American firms, in
4 particular, nor violate an international
5 agreement, it is inappropriate to include them in
6 Special 301. Patented, distinguishing between a
7 patented and a generic product is not
8 discrimination, as regards trade practice. It's
9 policy. It's smart policy.

10 Current administration will leave
11 office eventually and it looks as those at least
12 some subsequent governments will see these issues
13 quite differently if we follow the track of U.S.
14 politics today on drug pricing, we think that we
15 should exercise some caution in our approach
16 regarding such globally explosive issue and how
17 we target our trading partners and how far we
18 stray from our own values at home, not least
19 given that many people's lives are at stake.

20 Balance of our comments you can find
21 in our submission and I will answer your
22 questions.

1 CHAIR LEE: Thank you. The first
2 question comes from USTR.

3 MR. S. CHANG: Thank you for your
4 testimony. With respect to the Malaysia
5 compulsory licensing issues, how does Public
6 Citizen respond to stakeholders' comments that
7 the Malaysian government's actions undermine the
8 current research and development model for
9 innovative medicines?

10 MR. MAYBARDUK: Well again, we're
11 looking at doing the same thing in the United
12 States today, as a first matter. But also Gilead
13 in that case -- and this is detailed in our
14 comments -- Gilead in that case had licensed its
15 product, which is a Hepatitis C cure, a very
16 expensive Hepatitis C cure that is critically
17 important for the 500,000 Malaysians that are
18 living with Hepatitis C today, had licensed that
19 product for generic competition in many countries
20 but not in Malaysia.

21 Malaysia sought to expand essentially
22 the competitive territory for that product by

1 pursing government use license, and it was
2 through pursuit of the government use of those
3 patents that Gilead subsequently decided to, as I
4 understand it, extend its, extend the licenses to
5 Malaysia as a territory. So this is Malaysia
6 working to induce more procompetitive behavior
7 from the patent holders successfully in a way
8 that can help them actually end the Hepatitis C
9 epidemic.

10 CHAIR LEE: Okay. Next is a question
11 from the Department of Health and Human Services.

12 MS. SNYDER: Your submission suggests
13 that the Special 301 report should not criticize
14 countries for a lack of transparency or due
15 process unless such criticism clearly articulates
16 the alleged violation of a TRIPS standard. Is
17 TRIPS the only standard that should apply, or
18 would you consider them to fall within the market
19 access prong of the report's legislative mandate
20 if the policies cause disproportionate harm to
21 foreign companies?

22 MR. MAYBARDUK: Well I think that the

1 standards -- so the trade act states for IP
2 provision, that violate provisions of
3 international law or international grievance
4 which both the U.S. and foreign country are
5 parties, so a trade agreement standard would also
6 apply, a NAFTA standard would seemingly also
7 apply. Or constitute discriminatory, non-tariff
8 trade barriers.

9 So I think our standard there, again,
10 you know, it's not, it's not discrimination to
11 distinguish between patented or generic products.
12 It's good policy. You should distinguish them in
13 price and cost. It's also not entirely clear to
14 me whether it's merely a matter of foreign firms
15 versus domestic, though it'd be interesting to
16 converse on that. As opposed to American firms
17 in particular.

18 But I think we have to look at where,
19 you know, where there's an overlay of
20 coincidence. If the distinction that's being
21 drawn is the patent, that's not discrimination.
22 That is a, that is policy. Sorry, does that

1 answer your question?

2 MS. SNYDER: I think that gets to most
3 of it.

4 CHAIR LEE: Thank you. We have a
5 final question from the State Department.

6 MR. HENRY: This question relates to
7 your comments regarding pricing. Your submission
8 mentioned that, quote, there's no evidence to
9 suggest that high prices for innovated medicines
10 are rooted in high research and development costs
11 that the rest of the world does not sufficiently
12 support, end quote.

13 However, the study cited in your
14 submission in support of this statement, instead
15 seems to suggest that higher prices paid by U.S.
16 patents, taxpayers and businesses subsidize
17 pharmaceutical R&D for the rest of the world.
18 Could you clarify how Public Citizen views this?

19 MR. MAYBARDUK: Americans pay
20 outrageous prices for pharmaceuticals, higher
21 than just about every country in the world.
22 However, most other countries pay prices that are

1 far too high also. So the premium pricing that
2 people living in the United States are paying is
3 going to the industry but is not necessarily
4 going directly to R&D costs because prices aren't
5 coming from R&D costs.

6 Prices are coming from revenue
7 maximization under conditions where you have a
8 monopoly on an essential product. The government
9 isn't sitting down to negotiate with you, and
10 there are no disciplines on price. You charge
11 whatever you can. They're not tied to R&D costs.
12 It's not to say that R&D is not expensive, and we
13 fully support a broad range of policies to drive
14 R&D toward the medical needs that people have but
15 there isn't a direct nexus between what the price
16 of a product is and what the investment that went
17 into that, went into that product may be.

18 And if we try and change pricing
19 aboard, it will have zero effect on pricing for
20 Americans because we'll still see revenue
21 maximization in all markets.

22 CHAIR LEE: Thank you for your

1 testimony.

2 MR. MAYBARDUK: Thank you. If I may
3 just really briefly, I understand that one of the
4 questions today has been what would we like to
5 see U.S. charge, or what do we see as sort of the
6 appropriate range of the report. And I think it
7 is worth just saying really briefly that there
8 are criminal defenses defined under TRIPS, both
9 in trademark counterfeit and copyright piracy.

10 CHAIR LEE: So we do have the
11 opportunity for a post comment, or sorry, post
12 hearing submissions from people who testified, so
13 that maybe something an area that you pursue for
14 any sort of post hearing filings.

15 MR. MAYBARDUK: Very good.

16 CHAIR LEE: Thank you. Next is the
17 Trademark Working Group.

18 MR. KILMER: Good afternoon. I'm Paul
19 Kilmer appearing on behalf of the Trademark
20 Working Group. Thank you for the opportunity
21 again to address trademark issues that affect
22 U.S. brand owners.

1 What we did this year as we did in
2 past years is ask our members what trademark laws
3 and practices abroad cost you the most time and
4 money. And the list starts with, as it did last
5 year, China in general. One issue that came to
6 the top this year are trademark squatters and
7 pirates who are now becoming, not only more
8 prevalent in China but also starting to practice
9 their trade in the United States and in other
10 foreign countries.

11 Another concern was that China is
12 considering eliminating relative grounds refusals
13 in trademark examination. This is an issue we
14 face in other countries and what it does is force
15 brand owners to bring more oppositions and
16 invalidation proceedings than if the trademark
17 offices would do relative grounds in what we call
18 likelihood of confusion, examination, during the
19 examination phase.

20 The absence of default judgments is
21 also costing American companies a lot of money in
22 China. Many of the serial trademark pirates and

1 squatters will file applications and then not
2 bother to defend oppositions or invalidation
3 proceedings, and yet the U.S. company must submit
4 evidence and arguments and spend a good deal of
5 money in cases where the applicant, many times a
6 pirate or squatter doesn't bother to show up and
7 defend their application.

8 The failure to give due weight to
9 witness declarations by U.S. companies, in other
10 words, affidavits, the Chinese trademark office
11 as well as the TRAB gives no weight to such
12 declarations even if the contents of the
13 declaration is not challenged in a proceeding.

14 The elimination of direct appeals to
15 the TRAB from the CTMO, another issue we've
16 raised in the past, which is costing U.S. brand
17 owners a lot of money because what that means is
18 the mark they have challenged becomes registered.
19 It is entitled to all the presumptions of
20 registration. And then the trademark owner is
21 forced to bring a brand-new proceeding, rather
22 than an appeal. And this costs a great deal more

1 time and money.

2 China also has still a great many
3 burdensome formalities in the Beijing IP court,
4 as well as in other contentious proceedings.
5 They remain very inflexible in terms of accepting
6 goods and service descriptions, especially in
7 high technology and new technology fields, which
8 we're trying to address somewhat in the TM5
9 process, but it is slow in coming.

10 The failure to allow amendment of
11 applications challenged in contentious
12 proceedings, in oppositions and invalidation
13 proceedings is causing a lot of problems with
14 brand owners in situation in which they might be
15 able to otherwise settle the case. If you allow
16 amendment during contentious proceedings
17 sometimes the parties can decide, well, my goods
18 really don't compete with your goods. Or my mark
19 really isn't that similar to yours. They enter
20 into an agreement and yet the trademark office
21 will not allow you to amend your goods and
22 services in the challenged application during the

1 course of those contentious proceedings.

2 India is another nation that does come
3 up quite a bit in our discussions with
4 participants. The inability to obtain quick
5 seizures of counterfeit goods under Section 115
6 of the Indian Trademark Act is particularly
7 troublesome and is causing brand owners to not be
8 able to seriously control counterfeiting in India
9 in some situations.

10 Also the pendency of thousands of
11 oppositions, rectification proceedings and
12 cancellation proceedings brought more than three
13 years ago continues to be a serious issue.
14 License recordation and registered user
15 requirements is another issue that comes up
16 constantly. The absence of certification mark
17 registration in countries ranging from Algeria to
18 Yemen is another issue that our members bring up
19 regularly.

20 Failure of countries to accept letters
21 of consent and coexistence agreements is another
22 major issue. Failure by some countries, in fact

1 many countries to accept multiclass trademark
2 applications continues to be a problem. There
3 are more than 35 such nations listed in our
4 report. There are many more issues listed in our
5 submission, including failure to recognize
6 letters of protest. Nations that do not
7 recognize the doctrine of excusable nonuse to
8 maintain trademark registrations and many more.

9 Thank you for your time. I would
10 enjoy hearing your questions.

11 CHAIR LEE: Thank you very much. The
12 first question is from USTR.

13 MR. S. CHANG: Thank you. Your
14 submission highlights certain trademark laws or
15 practices in Central Asia, which may merit
16 special attention. Is there a particular law or
17 practice which your members consistently
18 highlight as particularly problematic in the
19 region as a whole?

20 MR. KILMER: There are many nations in
21 Central Asia that still don't have opposition
22 proceedings, where you file a trademark

1 application, you're not really allowed to --
2 someone else files a trademark application.
3 You're not really allowed to contest it until
4 it's registered. And many of our members have
5 commented that, you know, they have to wait,
6 allow registration and again all the presumptions
7 that flow from registration before they can take
8 effective action.

9 I'd say that's probably the number one
10 issue in those nations.

11 CHAIR LEE: Great. Thank you. The
12 next question is from the U.S. Patent and
13 Trademark Office.

14 MS. FERRITER: Thank you. Have you
15 seen any Middle East and North Africa regional or
16 individual improvements or deteriorations in
17 trademark processes since last year? If you
18 could fix one thing in the MENA region or one
19 issue in a specific MENA country, what would it
20 be? And what is the one complaint you hear most
21 regarding trademark processes in the MENA region?

22 MR. KILMER: Yeah. I mean the

1 legalization requirement is one that affects many
2 nations in the MENA area. Some even have what
3 they call super legalization. After you go
4 through the whole process of legalizing documents
5 in the United States, then you need to go to that
6 nation and within the nation, legalize again. It
7 is -- it's something we don't find outside of
8 that region at all.

9 Another thing that affects our members
10 profoundly is the cost involved in registering
11 marks in many of those countries. Some of the
12 fees charged to file trademark applications are
13 extremely high and remain extremely high. So we
14 do hear a good deal about that as well.

15 CHAIR LEE: Okay. Thank you very
16 much. The next question is from the Department
17 of Labor.

18 MS. PETTIS: Thank you for your
19 testimony. Your submission mentions that serial
20 trademark pirates or squatters in China are a
21 growing and costly problem for your stakeholders.
22 Could you further elaborate on the process being

1 experimented by the Chinese -- the China
2 Trademark Office to address this issue, and your
3 view on the potential effectiveness of this
4 process?

5 MR. KILMER: The China Trademark
6 Office has begun to implement what they call a
7 blacklist. And one can make a filing with the
8 China Trademark Office, pointing out a particular
9 person or company that has engaged in the
10 practice of large-scale trademark squatting. The
11 CTMO is at this point in time, anyway, as far as
12 I know, informally making a list of some of those
13 individuals and companies.

14 Unfortunately what tends to happen is
15 the squatter changes its stripes. It forms a new
16 company under a different name and then continues
17 the practice under that name or under the name of
18 a different individual. So it's still is
19 something that our members are very concerned
20 about and is still seeing more of them than we
21 would like to see. Although certainly the
22 Chinese government has taken some steps to try to

1 curb the practice.

2 CHAIR LEE: All right. The next
3 question will be from the U.S. Patent and
4 Trademark Office.

5 MS. FERRITER: Thank you. Your
6 submission mentions that serial trademark pirates
7 or squatters -- or sorry. Sorry. I was not
8 paying attention.

9 MR. KILMER: No, no, not a problem.
10 I can answer it again. I'll try to answer it in
11 a different way.

12 MS. FERRITER: No, no. I have lots of
13 questions to ask. Could you elaborate on the
14 types of formalities required of trademark owners
15 in the Gulf region, including Kuwait, Saudi
16 Arabia, and the UAE? How much of the burden do
17 these formalities place on the Trademark Working
18 Group participants?

19 MR. KILMER: Right. There are quite
20 a number, and we covered the legalization
21 already, but the requirement of recording
22 registered users is another one. Most of the

1 countries in that region, if you have licensed
2 users, they require you to record those licensed
3 users with the government before you really get
4 the full benefit of your trademark rights.

5 Some nations actually will deny you
6 the ability to protect your trademark if you
7 don't record your license. Some will actually
8 keep you from enforcing your license against your
9 licensees. So it's a very tricky thing. A lot
10 of U.S. companies frankly are not aware of some
11 of those requirements or the impact, if they fail
12 to record their license agreements.

13 CHAIR LEE: Thank you very much for
14 your testimony.

15 MR. KILMER: Thank you.

16 CHAIR LEE: Next is the U.S. Chamber
17 of Commerce. Thank you. Please state your name
18 and organization for the record and begin your
19 testimony.

20 MS. SZYMANSKI: Sure. My name is
21 Ellen Szymanski. I'm the executive director at
22 the Global Innovation Policy Center at the U.S.

1 Chamber of Commerce. First, thank you for the
2 opportunity to testify today.

3 The countries included in our
4 submission we based on geopolitical importance,
5 market size, and maybe there might be a
6 particular IP issue that we wanted to highlight.
7 And we hope we've provided enough information on
8 those countries, but I'm sure you have questions
9 or clarifications, and of course we'll be very
10 responsive in responding to those questions
11 today, but also after the hearing.

12 In addition to the countries that we
13 highlighted by name, we've also supplemented our
14 submission by our U.S. Chamber International IP
15 Index. And it's a scorecard that looks at the --
16 50 economies around the world, which is about 90
17 percent of GDP, and takes a look at their IP
18 system, so hopefully that can be informative to
19 you.

20 Our research from the index shows a
21 lot of socioeconomic benefits that accrue from a
22 high IP standard. And just to highlight a few,

1 if you have a high standard IP system, you're 53
2 percent more likely to experience increased R&D
3 investment in your economy, 55 percent more
4 likely to adopt new technology, and 30 percent
5 more likely to get your innovations funded.

6 In today's knowledge-based economy, IP
7 is critical. Some of the countries -- some of
8 our country's largest trading partners have taken
9 small steps in the right direction. And I'd like
10 to point to India for example. It's introduced
11 reforms to align its IP environment with the
12 international system, and it's addressing its
13 patent backlog.

14 Recognizing this potential, we
15 partnered with the U.S.-India Business Council
16 and the India Federation of Indian Chambers of
17 Commerce and Industry to launch the first ever
18 Track 1.5, U.S.-India IP dialog. And we thank
19 the U.S. PTO and the rest of the U.S. government
20 for their support in that initiative.

21 Despite positive developments we've
22 seen around the world, the challenges for IP

1 owners abroad remain. Lack of enforcement to
2 protect copyright holders, misapplication of
3 competition policy, price controls, compulsory
4 licenses, undermining the IP protection through
5 multilateral organizations is examples of some of
6 those issues.

7 For example, the Chilean congress is
8 considering a bill that would amend the grounds
9 for compulsory licensing, setting a troubling
10 precedent. All of this is -- all of these types
11 of undermining of the IP system end up favoring
12 domestic commercial interests at the expense of
13 innovators, creators, and consumers around the
14 world.

15 But I'd like to end on a positive
16 note. The USMCA and the forthcoming FTAs provide
17 an opportunity to strengthen IP protection. To
18 illustrate the strengths of the IP chapter of the
19 new NAFTA, GIPC benchmarked it against the IP
20 standards in our index. The research revealed
21 that the original NAFTA scored a mere 48 percent
22 on our index, but USMCA will score 80 percent.

1 We commend the negotiation team on the
2 completion of USMCA, and we're working hard to
3 educate members of Congress on the benefits of
4 the agreement. Thank you very much.

5 CHAIR LEE: Thank you. We'll begin
6 questions with USTR.

7 MR. S. CHANG: Thank you. Your
8 submission states that several developing
9 countries, quote, continue to take steps in the
10 wrong direction, end quote, including Malaysia.
11 What specific problematic steps has Malaysia
12 taken, and with respect to the Malaysian
13 compulsory licensing issue included in your
14 submission, what are your views and what steps
15 should Malaysia take to resolve them?

16 MS. SZYMANSKI: That is the main issue
17 on Malaysia. I think our submission goes into a
18 number of other areas. But certainly the
19 compulsory license in Malaysia is very troubling.
20 So I think that, you know, there's been a number
21 of questions on Malaysia and on compulsory
22 licensing themselves, and on price controls and

1 many of those types of steps that are undermining
2 the IP system.

3 I want to make one additional point
4 beyond I think what some of my colleagues have
5 made. If you look at what happened in Europe as
6 an example of what happened when they started
7 price controls. Before price controls in Europe,
8 they invested 24 percent more in R&D investment
9 and IP. After price controls, they invest 40
10 percent less.

11 So we need to protect intellectual
12 property here in the United States and abroad
13 because we have to create that pipeline and
14 secure that pipeline of new medicines so we can
15 address some of the challenges in our health care
16 system.

17 CHAIR LEE: Thank you. The next
18 question is from the U.S. Patent and Trademark
19 Office.

20 MS. FERRITER: Thank you. IIPA
21 submission characterizes South Africa's recent
22 policy actions on intellectual property reform as

1 potentially undermining the modern marketplace by
2 failing to establish a clear, legal framework.

3 While at the same time, South Africa's score on
4 the U.S. Chamber's IP Index improved marginally.
5 Why is that?

6 MS. SZYMANSKI: We absolutely agree
7 with the assessment from IIPA, first of all, and
8 our submission does go through the IP policy and
9 some of the troubling aspects of it. And we've
10 spent a lot of time in South Africa talking to
11 the government about that. So I wanted to say we
12 definitely agree with that statement.

13 As far as the index goes, we added a
14 number of criteria in the index, and South Africa
15 did well on some of those indicators. The index
16 is ranked on 45 indicators that are all measured
17 equally. They all have the same points in the
18 index. So as a result you might have something
19 that's very troubling, but it's only going to
20 reduce a country's score marginally. And the
21 same for, they may have taken a huge step in
22 let's say the areas of trademark, but that's only

1 going to increase their score marginally.

2 So we -- so that's why sometimes, you
3 know, there might be great uproar on a policy in
4 a particular country, but it's really only a
5 marginal difference on our index.

6 CHAIR LEE: Okay. Thank you. The
7 next question is from the International Trade
8 Administration of the Commerce Department.

9 MS. SALZMAN: Thank you. In your
10 submission you stated that Japan's new health
11 technology assessment system is cause for alarm
12 because, and I quote, since it has the potential
13 to significantly undervalue the principle of fair
14 value for innovation, end quote. And that's from
15 Page 64. Could you please elaborate on this new
16 system and how it would impair the efficacy of
17 Japan's system?

18 MS. SZYMANSKI: Sure. I probably
19 don't know the system as well as some of my
20 colleagues, so I would like to take the
21 opportunity to give you additional information
22 after the hearing.

1 But what I would say relating to
2 Japan's system and many others, we have to
3 understand that innovation is not an aha moment
4 and then we have a new product. There's a lot of
5 investment that goes into it, high risk
6 investment. And the other thing that concerns me
7 internationally but in the United States as well
8 is that investment in new medicines is not a
9 guarantee.

10 It's not a guarantee that that
11 investment will go into medicines, and it's not a
12 guarantee that that investment will go into your
13 invention. You have to create a stable and
14 predictable IP system that's going to attract it.
15 And so there are a number of highly developed
16 countries that we find are implementing policies
17 that are really going to have an effect on the
18 innovative pipeline of medicines, so Japan,
19 Canada and a number of others.

20 CHAIR LEE: Thank you. And we have
21 time for one more question from the Department of
22 Agriculture.

1 MR. KARAWA: Thank you for your
2 submission and your comments so far. In your
3 submission you highlight the link between IP
4 intensive industries and job creation. Do you
5 find that this argument helps when talking to
6 foreign governments about the importance of
7 strong IP policies?

8 MS. SZYMANSKI: Yes, I do. In our IP
9 index, we look at socioeconomic indicators, such
10 as job creation, and we actually have 29 of them.
11 And so when we go to governments and we talk to
12 them about why it's important to have an IP
13 system, it has to be a benefit to them. It has
14 to be a benefit to their economy. And when we're
15 able to show the statistical correlation between
16 a high IP standard and job creation or, as I
17 mentioned, getting innovation funding, or, you
18 know, attracting foreign investment, that's a
19 much better argument. It's much more persuasive.

20 CHAIR LEE: Thank you very much for
21 your testimony. Next and last, we have the
22 U.S.-India Strategic Partnership Forum. Thank

1 you. Please state your name and organization for
2 the record and begin your testimony.

3 MR. BJORKMAN: Good afternoon. I'm
4 Neil Bjorkman. I'm with the U.S.-India Strategic
5 Partnership Forum. I have the privilege of going
6 last, so I'll try to be brief, and I'll try to
7 not rely too much on my notes.

8 Briefly, we are an organization that
9 is dedicated to deepening strategic and economic
10 ties with India. We were founded by John
11 Chambers and a number of prominent CEOs,
12 including the CEOs of Pepsi, MasterCard,
13 Medtronic, Adobe and others. And the first point
14 I'll make is that despite trade tensions with
15 India, which are quite longstanding, U.S.
16 companies are in it for the long term when it
17 comes to India.

18 They've been in India for over 100
19 years. They do a lot of research and
20 development. They work very closely with the
21 government of India and consider themselves good
22 corporate citizens. Point number two, and this

1 is something I think that's been echoed by almost
2 everyone, which is that innovation is really the
3 key to economic success.

4 You know, the old saying, adapt or
5 die. Right? And it's imperative for governments
6 around the world to protect those innovators. So
7 we very much appreciate the 301 process, as it is
8 a form of leverage and it does help American
9 companies protect their intellectual property
10 abroad. My third point is more of a quick
11 observation about the good and maybe the not so
12 good in terms of India's recent actions in the IP
13 space.

14 I think on the good side we're seeing
15 India raise awareness about the importance of IP.
16 So CIPAM, which is the Cell for IPR Promotion
17 under DIPP educated 100,000 students. There were
18 trainings that took place for over 58 officials
19 at the Ministry of Micro, Small and Medium
20 Enterprises, which I affectionately call MSME.

21 Also we've seen -- we've done some of
22 our own work on the ground. We actually on the

1 14th of December hosted a roundtable discussion
2 on piracy prevention, new media, and new
3 challenges in partnership with CIPAM and DIPP.
4 And the roundtable brought together diverse
5 stakeholders from both the public and private
6 sectors to talk about global best practices.

7 As others have mentioned, we've seen
8 the patent process overall improve, so the number
9 of patents granted increased by 14 percent. The
10 overall number of claims pending examination
11 dropped from over 200,000 to 130,000 this year.
12 We saw the claims that were actually processed
13 and filed increased by -- or sorry -- patent
14 examinations increase by 51 percent.

15 In terms of problem areas, patent
16 infringement is still a big problem, and often
17 infringement is not detected until the violating
18 product hits the marketplace, which is far too
19 late. We also see that Indian law still allows
20 third-party manufacturers to commercialize copies
21 of an innovator's product even if those copies
22 violate the patent.

1 Also and finally the national pharma
2 policy in 2017 allows for the use of CL,
3 compulsory licenses. There's also the ability to
4 control prices on patented products. And the
5 final point I'll make is simply that the U.S.
6 government of course has to balance what's
7 happening in the trade sphere with what's
8 happening in the strategic sphere. So as much as
9 we're siloed here today with a trade discussion,
10 ultimately the President of the United States
11 would have to weigh in on what to do, or, you
12 know, if something were to come out of a 301,
13 what to do about it.

14 Of course, on the strategic side, the
15 relationship is extremely strong. India is our
16 major defense partner and we do more military
17 exercise with India than with any other country,
18 and of course it acts as a balancing check
19 against other actors in a very unstable region.
20 Thank you.

21 Oh, my apologies. My final point is
22 our recommendation would be to have the

1 governments convene an IP dialog, and we would be
2 happy to facilitate any private sector
3 participation in that dialog. Thanks.

4 CHAIR LEE: Thank you very much. The
5 first question comes from USTR.

6 MR. S. CHANG: Thank you for your
7 testimony. You commend India for its
8 implementation of the national IP policy. What
9 areas should India prioritize for future
10 implementation of that policy?

11 MR. BJORKMAN: Well I think broadly
12 speaking, it's increased enforcement, increased
13 awareness building, increased training. I think
14 that's -- some of those are easier said than
15 done. They require time, effort, and money.

16 CHAIR LEE: Thank you. The next
17 question comes from the Justice Department.

18 MR. LAMBERTI: Good afternoon. USISPF
19 cites the creation of India's commercial courts
20 as a positive step towards improving India's
21 intellectual property regime. Could you please
22 describe the experiences of members of the forum

1 with IP cases, specific IP cases in India's
2 commercial courts? And could you also describe
3 the types of cases heard by these courts? Is it
4 a broad range of IP cases including patents,
5 trademarks, copyrights, and trade secrets?

6 MR. BJORKMAN: Thank you. I did not
7 have the pen for that discussion, so for that
8 part of our submission if I could perhaps provide
9 something in writing at a later time, I'd
10 appreciate that.

11 MR. LAMBERTI: That's fine. Thank
12 you.

13 MR. BJORKMAN: Thank you.

14 CHAIR LEE: Thank you. Next is a
15 question from the U.S. Copyright Office.

16 MR. GREENBERG: Your submission notes
17 that the Indian film industry earns about \$2
18 billion a year but loses \$700 million a year due
19 to piracy. How much does piracy in India cost
20 U.S. stakeholders, and what efforts should the
21 government of India take aside from just a
22 camcording prohibition and amending the copyright

1 law to ensure adequate protection against
2 circumvention of technological protection
3 measures?

4 MR. BJORKMAN: I'm not sure about the
5 specific number as it relates to the United
6 States. Certainly there are large U.S. companies
7 that have a big footprint in India in the media
8 space. 21st Century Fox comes to mind right
9 away. And on the second one, if I could get back
10 to you, I'd appreciate that.

11 CHAIR LEE: Thank you very much. The
12 next question is from the U.S. Patent and
13 Trademark Office.

14 MS. FERRITER: Thank you. India has
15 enacted dedicated IP crime units in -- and I'm
16 sorry if I'm mispronouncing these names --
17 Telangana and Maharashtra, and there are plans to
18 expand that program.

19 What experience have your members had
20 in working with these units? And in addition,
21 what areas would you suggest for capacity
22 building and training to improve their resources

1 to assist right holders in enforcing their IP
2 rights?

3 MR. BJORKMAN: So I'm not exactly sure
4 on what the relationship is right now with our
5 members and those specific units. But I'd be
6 happy to get back to you.

7 CHAIR LEE: Great. Thank you. We
8 have time for one last question, and it comes
9 from the International Trade Administration of
10 the Commerce Department.

11 MS. SALZMAN: Thank you. USISPF
12 submission notes several recent improvements in
13 India's patent regime over the past year,
14 including the digitized Indian patent office, the
15 draft amended patent rules and streamlined
16 pre-grant patent opposition review procedures.
17 Which patent reform has been most meaningful for
18 USISPF members?

19 MR. BJORKMAN: Again, I'm going to
20 have to have an internal discussion to try to
21 figure that out. Thank you.

22 CHAIR LEE: Thank you very much for

1 your testimony.

2 MR. BJORKMAN: Appreciate it.

3 CHAIR LEE: All right. On behalf of
4 the Special 301 Subcommittee, thank you all for
5 taking time out of your day to have this exchange
6 with us. We appreciate the comprehensive
7 research, the thought, and the problem-solving
8 efforts that went into the written submissions
9 and oral testimonies that we heard today.

10 As mentioned before, post-hearing
11 briefs by interested parties that testified today
12 are optional, and if you are interested, please
13 follow the instructions on the agenda or in the
14 original Federal Register notice at
15 Regulations.gov with the Docket Number
16 USTR-2018-0037. The Special 301 docket will
17 reopen this afternoon and will remain open until
18 11:59 p.m. Eastern Time on March 5th.

19 In addition, a transcript and the
20 video of today's hearing will be available free
21 of charge at USTR's website at www.ustr.gov. We
22 will do our best to get that posted within the

1 next two weeks. So thanks again, everyone,
2 including my colleagues on the panel and those
3 who testified today, for your contributions, your
4 time, and your attention.

5 Finally, a special thanks to the
6 personnel at USTR who took -- took care of
7 today's logistics and setup. Ladies and
8 gentlemen, the 2019 Special 301 hearing is now
9 adjourned.

10 (Whereupon, the above-entitled matter
11 went off the record at 3:27 p.m.)
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This is to certify that the foregoing transcript

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Before: USTR

Date: 02-27-19

Place: Washington, DC

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