

UNITED STATES TRADE REPRESENTATIVE

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SPECIAL 301 PUBLIC HEARING

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32nd ANNUAL REVIEW

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WEDNESDAY

FEBRUARY 26, 2020

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The Special 301 Committee met in Conference Rooms 1 and 2 of the U.S. Trade Representative Annex Building, 1724 F Street, N.W., Washington, D.C., at 10:00 a.m., Daniel Lee, Panel Chair, presiding.

PRESENT

DANIEL LEE, Acting Assistant U.S. Trade Representative, Office of Innovation and Intellectual Property
 JACOB EWERTD, Director for Innovation and Intellectual Property, Office of the U.S. Trade Representative
 IOANA DIFIORE, Foreign Affairs Officer, Office of Intellectual Property Enforcement, U.S. Department of State
 TAREK FAHMY, Director, Office of Intellectual Property Enforcement, U.S. Department of State
 STEVAN MITCHELL, Director, Office of Standards and Intellectual Property, International Trade Administration, U.S. Department of Commerce

JESSICA POMPER, International Trade Specialist,
International Trade Administration, U.S.
Department of Commerce

CARI BERDUT, Senior Counsel, U.S. Patent and
Trademark Office

KARIN FERRITER, Deputy Director for
International Affairs, U.S. Patent and
Trademark Office

JOE WERESZYNSKI, Department of Agriculture

CHRIS WESTON, Senior Counsel for Policy and
International Affairs, U.S. Copyright
Office

EMILY BLEIMUND, Director, Trade and Health,
Office of Global Affairs, U.S. Department
of Health and Human Services

LEENA KHAN, International Labor Advisor for
Trade Policy, Office of Trade and Labor
Affairs, U.S. Department of Labor

WON CHANG, International Economist, U.S.
Department of the Treasury

WITNESSES PRESENT

IVO KONSTANTINOV, Commercial Counselor and Trade
Attache, Government of Bulgaria

LEONOR OBANDO, IP Coordinator, Ministry of
Foreign Trade, Government of Costa Rica

JOSE CARLOS QUIRCE, Commercial Attache,
Government of Costa Rica

PANAGIOTIS DERMENTZOGLU, First Counselor for
Economic & Commercial Affairs, Government
of Greece

IWAN FREDDY HARI SUSANTO, Charges d'Affaires,
Embassy of Indonesia, Government of
Indonesia

DR. FREDDY HARRIS, DG of Intellectual Property,
Ministry of Law and Human Rights,
Government of Indonesia

BOKHYUN NAM, Director for Trade Affairs,
Ministry of Health and Welfare, Government
of Korea

DMYTRO ROMANOVYCH, Deputy Minister of Economic
Development, Trade, and Agriculture,
Government of Ukraine

TARAS KACHKA, Deputy Minister of Economic Development, Trade, and Agriculture, Government of Ukraine

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

CHRISTINA MITROPOULOS, Manager, Brand Protection & Manufacturing Initiatives, American Apparel and Footwear Association (AAFA)

SEAN FLYNN, Director of PIJIP, American University Washington College of Law, Program on Information Justice and Intellectual Property (PIJIP)

JUSTIN PINE, Senior Director, International Affairs, Biotechnology Innovation Organization (BIO)

LETICIA PHILLIPS, Consultant, Brazil National Confederation of Industry (CNI) & American Chamber of Commerce in Brazil (AmCham Brazil)

JOSEPH WHITLOCK, Director of Policy, Business Software Alliance (BSA), The Software Alliance

SIYAO LIU, China Chamber of International Commerce (CCOIC)

RACHAEL STELLY, Policy Counsel, Computer and Communications Industry Association (CCIA)

SHAWNA MORRIS, Senior Director, Consortium for Common Food Names (CCFN)

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

THOMAS VALENTE, Senior Director for Global Affairs, Intellectual Property Owners Association (IPO)

KEVIN ROSENBAUM, Counsel, International Intellectual Property Alliance (IIPA)

JAMES LOVE, Director, Knowledge Ecology International (KEI)

MARIANA F. JORGE, MFJ International, LLC

RYAN ONG, Director, International Business Policy, National Association of Manufacturers (NAM)

CHRIS MOORE, Deputy Vice President,
International, Pharmaceutical Research and
Manufacturers of America (PhRMA)

BURCU KILIC, Director, Digital Rights Program,
Public Citizen

ERIC SCHWARTZ, Counsel, SoundExchange

PAUL KILMER, Trademark Working Group (TWG)

KELLY ANDERSON, Director of International
Affairs, U.S. Chamber of Commerce, Global
Intellectual Property Center (GIPC)

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

2 10:05 a.m.

3 CHAIR LEE: Good morning, everyone.

4 My name is Daniel Lee and I'm the Acting
5 Assistant U.S. Trade Representative for
6 Innovation and Intellectual Property. I would
7 like to welcome everyone to the public hearing
8 for the annual Special 301 review.

9 The Special 301 review is a
10 statutorily mandated exercise we undertake each
11 year to develop an overall strategy, to ensure
12 adequate and effective intellectual property
13 rights protection and equitable market access in
14 foreign countries for United States persons that
15 rely on protection of intellectual property
16 rights, such as copyright and related rights,
17 trademarks, patents and trade secrets.

18 Ensuring that U.S. owners of
19 intellectual property, or IP, have a full and
20 fair opportunity to use and profit from their IP
21 is one of the trade priorities outlined in the
22 President's annual trade agenda.

1 This is the 32nd Annual Special 301
2 Review and 11th Public Hearing that USTR has
3 hosted in connection with the review.

4 I would like to note for the record
5 that today is Wednesday, February 26th, 2020 and
6 that this hearing is taking place at the Office
7 of the United States Trade Representative, or
8 USTR. We will make a transcript of today's
9 hearing available to the public on USTR's website
10 at www.ustr.gov.

11 Today's hearing is scheduled to go
12 until approximately 4:00 p.m. And we will break
13 for one hour and 25 minutes from 12:20 to 1:45.
14 We ask for everyone's cooperation with keeping
15 the hearing on track.

16 At this point, I would like to invite
17 colleagues on the hearing panel, all of whom
18 represent U.S. government agencies that serve on
19 the Special 301 Subcommittee to introduce
20 themselves. So we'll start here.

21 MR. EWERDT: Jacob Ewerdt, Director
22 for Innovation and Intellectual Property with the

1 Office of the U.S. Trade Representative.

2 MR. MITCHELL: Steve Mitchell, I
3 direct the Office of Standards of Intellectual
4 Property at the International Trade
5 Administration of Bureau of the Department of
6 Commerce.

7 MS. BERDUT: Cari Berdut, Senior
8 Counsel for Enforcement, Office of Policy and
9 International Affairs at the Patent and Trademark
10 Office.

11 MS. DIFIORE: Good morning. I'm Ioana
12 DiFiore, from Department of State, Office of
13 Intellectual Property Enforcement.

14 MS. BLEIMUND: Good morning. Emily
15 Bleimund, Director of Trade and Health, U.S.
16 Department of Health and Human Services Office of
17 Global Affairs.

18 MR. CHANG: Good Morning. My name is
19 Won Chang, Department of Treasury, International
20 Trade Office.

21 MR. WESTON: Good morning. I'm Chris
22 Weston, Senior Counsel for Policy and

1 International Affairs at the U.S. Copyright
2 Office.

3 MS. KHAN: Good morning. I'm Leena
4 Khan with the Department of Labor, Office of
5 Trade and Labor Affairs.

6 MR. WERESZYNSKI: Good morning. Joe
7 Wereszynski. I'm the Senior Policy Advisor for
8 Middle East and Africa at the U.S. Department of
9 Agriculture.

10 CHAIR LEE: Thanks. The Special 301
11 Subcommittee of the Trade Policy Staff Committee,
12 which is comprised of the agencies you've just
13 heard from and chaired by USTR, conducts the
14 annual Special 301 review every year.

15 The review is driven by stakeholder
16 contributions and by the contributions of
17 Washington-based U.S. government agencies and our
18 embassy-based personnel around the world.

19 The Subcommittee is currently in the
20 information gathering phase. On behalf of the
21 agencies here, we thank you for the views,
22 insights, opinions and factual information you

1 will share with us today.

2 The schedule of today's hearing is
3 comprised of interested parties. That is foreign
4 government officials, private sector interests
5 and civil society who have responded to USTR's
6 notice in the federal register published on
7 December 23rd, 2019. And voluntarily requested
8 the opportunity to appear at this public hearing.

9 As a reminder of today's hearing,
10 sorry. As a reminder, the purpose of today's
11 hearing is to provide the Special 301
12 Subcommittee with additional information that we
13 can use in the deliberations that will lead to
14 the publication of the 2020 Special 301 Report to
15 Congress, which will be on or about April 30th
16 this year.

17 This year we have received public
18 filings that address over 75 countries. And many
19 country-specific IP protection enforcement issues
20 that may negatively affect our bilateral trading
21 relationships.

22 Those filings are available to the

1 public at www.regulations.gov. And the Docket
2 Number is USTR 2019-0023.

3 The Special 301 Report is the result
4 of a congressionally mandated annual review of
5 the state of intellectual properties rights
6 protection and enforcement in trading partners
7 around the world, which the Office of the United
8 States Trade Representative conducts pursuant to
9 Section 182 of the Trade Act of 1974, as amended
10 by the Omnibus Trade and Competitiveness Act of
11 1988. And the Uruguay Rounds Agreement Act.

12 The provisions of Section 182 are
13 commonly referred to as the Special 301
14 provisions of the Trade Act. Hence, the Special
15 301 Report.

16 Specifically Section 182 of the Trade
17 Act requires that USTR identify countries that
18 deny adequate and effective protection of
19 intellectual property rights or deny fair and
20 equitable market access to U.S. persons who rely
21 on intellectual property protection.

22 The Statute requires USTR to determine

1 which, if any, countries should be identified as
2 priority foreign countries. Acts, policies or
3 practices that are the basis of the countries
4 identification as a priority foreign country can
5 be subject to the procedures set out in Sections
6 301 through 308 of the Trade Act.

7 In addition to the statutorily defined
8 priority foreign country destination, USTR
9 created the priority watch list, and watch list
10 categories, to assist the Administration in
11 pursuing the goals of the Special 301 provisions.
12 USTR is also charged with developing priority
13 watch list action plans where a country has been
14 on the priority watch list, without a change, for
15 at least one year.

16 So going into the format of today's
17 hearing. We will have, each party will have ten
18 minutes to testify. Each person will start with
19 five minutes of prepared statements leaving five
20 minutes for panel questions.

21 However, we will remain flexible
22 within the ten minute period making adjustments

1 as needed.

2 We will be watching the clock and will
3 interrupt with a time queue when one minute
4 remains from the allotted five minutes of
5 prepared statements.

6 The Panel will hold its questions
7 until the presenter concludes his or her
8 statement. In some cases, we have prepared
9 questions based on written filings. In others,
10 we will respond to your testimony today.

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

17 Again, we'll break once for one hour
18 and 25 minutes, from 12:20 to 1:45. And without
19 further delay, I would like to invite the
20 Government of Bulgaria to start us off. Please
21 come up.

22 Thank you. Please introduce yourself

1 with your name and organization for the record.
2 And begin your testimony.

3 MR. KONSTANTINOV: Thank you very
4 much. Good morning, everyone. My name is Ivo
5 Konstantinov, I-V-O, first name, last name, K-O-
6 N-S-T-A-N-T-I-N-O-V, representing the Government
7 of Bulgaria, as represented in Washington, D.C.
8 by the Embassy of Bulgaria to the United States,
9 in a progress report summarized by the ministry
10 of economy, the country's equivalent of the
11 Department of Commerce of the Government of
12 Bulgaria.

13 I would like to address the honorable
14 representatives of the Special 301 Committee with
15 gratitude for the opportunity to testify this
16 morning. And this is a progress report in the
17 second year after our exclusion and removal from
18 the Special 301 list, which is only a reason for
19 us to increase our efforts and take the matters
20 seriously as a motivation to enhance enforcement
21 even further.

22 We want to encourage with this also

1 other countries who are on the same path and
2 share with everyone, including our interested
3 U.S. interlocutors and other countries from
4 European Union and worldwide, that good
5 cooperation with the USTR and the interagency
6 interlocutors in other government agencies in
7 United States can bear fruit.

8 We have been implementing sort of a
9 roadmap that was recommended approximately five
10 years ago by the USTR, and an adjacent team with
11 representatives of Department of Justice, of
12 special measures that particularly my country was
13 supposed to take in improving IP enforcement, and
14 especially in some sensitive areas.

15 So I'm here to report a second
16 consequent year that we have been taking this
17 matter very, very seriously. And even though we
18 are not in the list anymore, we continue to
19 consider this as crucial because it's an
20 important basis for trade and investments.

21 Besides, our country is a thriving
22 startup and a thick hub for southeastern Europe,

1 has a stake already with its own software and
2 movie productions anyways.

3 What is important to share with you
4 today is that this year we have increased the
5 measures as recommended by our U.S. partners and
6 other partners from the European Union, Europol
7 and Eurojust, and our interagency committee on IP
8 enforcement. That includes the Ministry of
9 Culture, Ministry of Economy, the Combat
10 Organized Crime Unit and the National Police, and
11 most of all, the Attorney General.

12 Several things that are particularly
13 recommended by the U.S. side throughout the years
14 we have stepped up on implementing even further
15 this year, which is the implementation
16 universally of all district attorneys and
17 regional attorneys of the manual for IP
18 enforcement, issued and mandated by the Attorney
19 General of the Republic.

20 We have been conducting sting
21 operations with the Combat Organized Crime Unit
22 and Attorney General, especially for the newly

1 emerging IPTV illegal entertainment content
2 platforms ran by set top boxes, which is a new
3 trend that is gradually replacing the torrent
4 trackers in especially illicit entertainment
5 content.

6 And implementing and further
7 conducting training, not just domestically but
8 with Eurojust and Europol in the Netherlands for
9 prosecutors to enforce IP prosecution and IP law.
10 In the fast-changing technology, we still face
11 challenges with anonymizing service. GDPR
12 mandates that sometimes prevents us from very
13 fast measures of defacing. Sharing eBooks
14 through Facebook and Cloudflare hosting that
15 provides anonymizing services as well, which we
16 are tackling.

17 Most important of all, the elephant in
18 our room are two of the largest torrent tracking
19 servers that are operating in our country, whose
20 servers are outside of the country where our
21 National Police and Combat Organized Crime Unit
22 is preparing requests for legal assistants with

1 the U.S. side of defacing them and taking them
2 down from their host service here, which are here
3 in the United States. So this is new, this is
4 coming. And that's only one of the few remaining
5 open issues that we are still taking seriously
6 but are open.

7 We also working on the legislative
8 improvements on using samples as in the
9 indictments for the prosecutor's office. But
10 that is a big challenge because right now
11 Bulgarian law mandates that we take every single
12 infringement separately. And the only thing
13 we've managed to do this year was to restructure
14 indictments separately for IP infringements,
15 especially in the illegal entertainment content.

16 So we take the matter seriously, and
17 we continue the struggle. We're happy to be out
18 of the list and appreciate that.

19 CHAIR LEE: Thank you very much. I'd
20 like to start off with USTR first with questions.

21 MR. EWERDT: Your submission describes
22 multiple operations and arrests made by the

1 cybercrimes department. Is the cybercrimes
2 department fully staffed and operational, or are
3 there improvements that we can expect over the
4 next few years?

5 MR. KONSTANTINOV: I'm very glad you
6 asked. The staff of the cybercrime department in
7 the past two years have more than doubled -- 2.5
8 increase. It's up to 45. And especially
9 computer-related crimes has increased three times
10 its staff, allowing for more bandwidth and
11 capacity.

12 CHAIR LEE: Okay. Thank you. Next I
13 would like to turn to ITA.

14 MR. MITCHELL: Yes. Your submission
15 notes improvements in methodological guidelines
16 for work on files and cases involving IP crimes.
17 Can you elaborate on how these guidelines
18 improvements will actually improve IP
19 enforcement?

20 MR. KONSTANTINOV: That mostly
21 concerns the regional and district prosecutor
22 offices who have not been so technologically

1 savvy in a new electronic year of cloud hosting
2 of IP infringements, and some of whom who have
3 never prosecuted cases like that.

4 So the Attorney General's office, in
5 the Combat Organized Crime, have been conducting
6 and building capacity, especially the countryside
7 and the regional prosecutor's office, especially
8 in the smaller settlements. That's what this
9 actually means.

10 And in addition to that there have
11 been regional IP prosecutors that have been
12 appointed for every single county of the country
13 who are trained especially to prosecute and
14 indict IP infringements, especially very
15 technologically complicated ones.

16 CHAIR LEE: Thank you. If I could ask
17 you to turn off your microphone when you're not
18 testifying? Thank you. That helps with the
19 echo. Next I would like to turn to the U.S.
20 Copyright Office.

21 MR. WESTON: Hello. Your submission,
22 and I believe your testimony notes, that the

1 owners and operators of pirate websites often
2 conceal their identities and locations using a
3 reverse proxy service, such as Cloudflare. Have
4 Bulgarian officials worked with Cloudflare to
5 obtain this information in a manner that
6 facilitates its IP enforcement actions?

7 MR. KONSTANTINOV: I'm very glad you
8 asked. We have an excellent cooperation with
9 them. They're San Francisco-based. We exchange
10 information. We have a corporation agreement
11 with them. They provide all the information that
12 we need, but only for us to realize where the
13 service distributing illicit content is situated
14 physically.

15 The closing down, the cramping down of
16 the content now is a matter of forthcoming
17 judicial cooperation orders from our government
18 to the U.S. government in order to close servers
19 that are hosting and anonymizing illicit
20 entertainment content, which very frequently is
21 based here in the United States by the way. And
22 temporary measures are being done to, like

1 defacing and other forms, but they migrate very
2 often to other countries with anonymous servers,
3 like in Vietnam and Romania. So we are working
4 with Cloudflare very, very well actually.

5 CHAIR LEE: Thank you very much for
6 your testimony.

7 MR. KONSTANTINOV: I appreciate it.

8 CHAIR LEE: Thank you. Next I would
9 like to call the representative from the
10 Government of Costa Rica please. Welcome. If
11 you could introduce yourself for the record with
12 your name and organization that would be greatly
13 appreciated.

14 MS. OBANDO: Thank you. Good morning.
15 My name is Leonor Obando, and I am the
16 intellectual property coordinator at the Ministry
17 of Foreign Affairs, Costa Rica. Innovation,
18 education and thirst for knowledge are embedded
19 in our DNA. Consequently, Costa Rica has
20 intensely worked on establishing a legal and
21 institutional system that fosters these core
22 values and has implemented actions accordingly.

1 From the perspective of our country's
2 legal framework, important challenges have been
3 addressed. First, Costa Rica is party to 16
4 international treaties under WIPO. It has also
5 included IP commitments in its FDAs and has
6 undertaken important amendments of regulation.
7 So it's creating a strong and modern IPR
8 protection system consistent with the best
9 international standards.

10 Also amendments introduced over the
11 course of the last decade have enhanced
12 administrative civil and criminal measures for
13 IPRs protection, resulting in an effective and
14 pragmatic approach of their enforcement.

15 Data for 2019 shows that a number of
16 cases result regarding IPR infractions increased
17 by 66 percent over the course of the past three
18 years, demonstrating the country's commitment to
19 enforcement. Costa Rica's commitment, the
20 provisions for ISP's liability, in order to
21 provide them with a limitation of liability for
22 copyright infringed materials provided they

1 comply with a notice and takedown process in an
2 agile, prudential and reasonable manner.

3 The regulation on geographical
4 indication was also modified. It clarifies,
5 among other things, the provisions related to the
6 treatment of common names in compound GIs.
7 Furthermore, in order to create a strong and
8 efficient institutional framework, Costa Rica has
9 located important human and technological
10 resources. For instance, the quality and
11 consistency for the IP registration process and
12 registration time were improved by integrating
13 the country's databases with those at WIPO.

14 Also, government agencies have devoted
15 important resources in hiring the necessary
16 personnel to ensure timely registration of IPRs.
17 Last, but not least, Costa Rica firmly believes
18 that a solid and ineffective strategy for
19 enhancing protection in the long run is for
20 promoting a culture of awareness and respect to
21 IPRs.

22 Programs such as migrations are

1 worthy, target the younger students, have already
2 reached a figure equivalent of 20 percent of the
3 country's total population. Also, the copyright
4 registry designed an advertising strategy which
5 included social media campaign and ads in movie
6 theaters.

7 Multiple capacity building initiatives
8 targeting public officials and private
9 stakeholders have also been executed. Due to
10 intensity, work deployed through the years to
11 improve IPR protections, the 2019 Special 301
12 Report narrowed down the list of outstanding
13 issues to only two. I'm glad to convey that both
14 are being properly addressed.

15 Executive Decree 37549 of 2012
16 established the mandatory use of licensed
17 software by all government agencies.
18 Nevertheless, getting to know the state of
19 compliance has been challenging. In light of
20 this, an online platform of mandatory use was
21 created. In order to collect the necessary data
22 for the timely issuing of reports, this platform

1 is ready and will be launched next month.

2 While the first additional annual
3 report will be issued in the first part of 2021,
4 regarding the creation of a formal customs
5 regulation system for trademarks, the directorate
6 of customs issued guideline 04/2019 in September
7 of last year, establishing new rules and
8 providing a unified database for all customs
9 officials.

10 In sum, Costa Rica has made
11 substantial progress in the protection of IPRs
12 since the first inclusion of the USTRs watch
13 list. The government has devoted resources and
14 implemented policies to enhance institutional
15 capacity, reduce back loads and modernize illegal
16 and institutional framework.

17 This confirms our country's belief
18 that IPRs protection fosters innovation, and
19 knowledge creation, thus increase productivity
20 and support inclusive and sustainable economic
21 growth. Based on the significant progress made
22 in paperwork, the Government of Costa Rica

1 requests to be excluded from the USTR's watch
2 list for 2020. Thank you.

3 CHAIR LEE: Okay. Thank you for your
4 testimony. We'll start off with USTR with
5 questions. Thank you.

6 MR. EWERDT: Regarding border
7 enforcement, your written summation -- submission
8 and your testimony indicated that the directorate
9 general of customs is implementing a project
10 aimed at adjusting its internal processes to
11 improve the implementation of a trademark
12 recordation database. Can you further explain
13 what those internal processes are?

14 MS. OBANDO: Basically they used to
15 have just an Excel file that all customs
16 officials used in order to know who are the
17 representatives of the trademarks. Now they do
18 have a real database with all the information.

19 CHAIR LEE: Thank you. Next I will
20 turn to the U.S. Patent and Trademark Office.

21 MS. BERDUT: Thank you. In its
22 written submission, the International

1 Intellectual Property Alliance, IIPA, states that
2 online piracy of film and television material is
3 rapidly increasing in Costa Rica through a
4 variety of means, such as direct to home DTH
5 boxes, internet protocol TV, boxes and cable
6 piracy. Can you explain steps Costa Rica is
7 taking to reduce these modes of online piracy?

8 MS. OBANDO: Well we tried to figure
9 this out when we read the summation of the
10 Alliance. And we talked to stakeholders, to the
11 prosecutors, and there has not been any case
12 raised to our authorities.

13 So I would like to say that we are
14 open to listen to the alliance in worst-to-worst,
15 an improvement of our actions. And we can make
16 them -- we can make the necessary contact with
17 the competent authorities to raise -- to properly
18 address this issue.

19 CHAIR LEE: Thank you. Next I would
20 like to turn to the Department of Agriculture.

21 MR. WERESZYNSKI: In Costa Rica's
22 written submission it notes that it has updated

1 its geographical indications regulation through
2 executive decree 41572-J-COMEX, which clarifies
3 provisions related to opposition procedures and
4 the treatment of common names and compound terms.
5 Can you explain how the new executive decree is
6 being implemented and let us know how many
7 opposition proceedings have taken place since the
8 executive decree came out?

9 MS. OBANDO: Okay, no new requests for
10 registration of GI has been submitted during the
11 last year, so there are no opposition procedures
12 under these amended decrees. We have only one
13 registration, which was under the Lisbon
14 Agreement because we are part. So there are no
15 new GIs from other sources.

16 CHAIR LEE: Great. I would like to
17 next turn to the Department of Labor.

18 MS. KHAN: Thank you. Your submission
19 suggests that IP holders -- IP right holders are
20 not providing necessary documentation to
21 prosecute IP infringers.

22 Can you elaborate on the barriers to

1 cooperation with IP right holders that you are
2 seeing, and what is being done to address these
3 barriers?

4 MS. OBANDO: Okay. In some cases they
5 do not provide the power of attorney in order to
6 follow the processes. And a power of attorney is
7 needed because you need to know if somebody
8 really represents or is the representative of a
9 trademark. Besides, sometimes they appoint an
10 expert to make an informed report, and they do
11 not provide the reports. Those are the two
12 barriers.

13 What our prosecutor's office is doing
14 is having like capacity building activities with
15 the stakeholders to know why they are facing
16 these barriers. In some cases it is because it
17 is hard to find an expert to submit a report
18 regarding certain products. That's how we have
19 addressed this issue.

20 CHAIR LEE: Thank you very much. Next
21 I would like to call the representative from the
22 Government of Greece.

1 Welcome. Please state your name and
2 organization for the record, and begin your
3 testimony.

4 MR. DERMENTZOGLU: Good morning to
5 everybody. My name is Panagiotis Dermentzoglou.
6 I'm with the Embassy of Greece, Economic and
7 Commercial Affairs Section.

8 I have a read statement to make. And
9 I would like to apologize in advance, I'm timed
10 to be slightly above the five minutes so I hope
11 that this can be excused.

12 Members of the Special 301
13 Subcommittee, thank you very much for the
14 opportunity to present the testimony of the
15 Embassy of Greece in this year's Special 301
16 review. Greece remains committed to fighting
17 against IPR violations and building on the
18 progress it saved in 2018 as acknowledged in last
19 year's Special 301 Report, constantly addresses
20 existing challenges.

21 In this statement, I would like to
22 present developments on specific issues focusing

1 on the use of unlicensed software in the public
2 sector and enforcement against counterfeiting and
3 piracy. Regarding unlicensed software in the
4 public sector, according to the Ministry of
5 Development and Investments, two public
6 procurement standards have already been published
7 in the beginning of 2020.

8 Now in progress, regarding the
9 procurement of PC hardware with pre-installed
10 software covering the needs of ministries and
11 other public authorities. The two public
12 standards provide for the purchase of a total of
13 47,000 new PCS with pre-installed licensed MS
14 Windows.

15 According to the Ministry of Digital
16 Governments, furthermore, the Greek government
17 has initiated a process for obtaining Microsoft
18 products and services through an enterprise
19 agreement for the purchase of 10,000 licenses of
20 Office 365, 13,000 licenses of Office Standard,
21 20,000 server licenses, 500 personal Microsoft
22 support and 400 personal hours of advisory

1 services. The total cost of the enterprise
2 agreement is estimated at approximately 37
3 million Euros. A request for proposal is
4 completed, whereas a public standard is to be
5 announced in the coming weeks.

6 Regarding enforcement against
7 counterfeiting and piracy. According to the
8 ministry of development and investments,
9 secretarial general for trade and consumer
10 protection, market control and combating illicit
11 trade are high priorities of the Greek
12 government. Statistical data obtained through
13 the official ministry control mechanism shows
14 notable results of enforcement actions between
15 August 2019 through January 2020, such as
16 increase of inspection of prosecutions, ceased
17 goods and of total fines.

18 Notably, a draft bill is expected to
19 become law by the end of March 2020 establishing
20 the new joint interagency for market control and
21 the fight against illicit trade, including IPR
22 infringements and implementing important

1 institutional changes, such as enhanced
2 corporation among Greek enforcement authorities,
3 such as police port, police customs, et cetera,
4 and the use of intelligent services, national and
5 international.

6 In addition, a new regulation in
7 existing legislation regarding illicit trade in
8 counterfeit goods introduces for the first time
9 in Greece for high fines for counterfeiting that
10 treats up to a 100,000 euros, whereas the means
11 for distributing counterfeits will also be
12 ceased.

13 According to the ministry of citizen
14 protection, Greek police headquarters, the policy
15 against crime program 2020-2024, provides that
16 the protection of IPR is among the current key
17 priorities of the Greek police, which constantly
18 implements targeted actions in order to control
19 and combat IPR crimes.

20 In this context, special police teams
21 operate in major, excuse me, over centers in
22 order to clamp down on the illicit trade of

1 goods. Statistical data for 2019 showed 66,000
2 related inspections increased from last year,
3 6,000 infringement cases decreased, 15,000 ceases
4 of counterfeit goods and over 1 million euros in
5 administrative fines.

6 In addition, Greek police divisions
7 for financial and cybercrime are collaborating
8 with several other authorities in Greece and
9 overseas participating in a series of
10 international organizations coordinated by
11 Europol, Interpol and the European Union
12 Intellectual Property Office.

13 According to the Greek independent
14 authority for public revenue, secretarial general
15 for customs, in compliance with the UN
16 international legislation, significant results
17 can be achieved in the fight against trafficking
18 of counterfeit or falsified products. In 2019 a
19 total of 4,000 inspections were conducted, 170
20 infringements were identified, and a total of 20
21 million items of counterfeit or falsified
22 products were ceased.

1 In EU context, Greece implements the
2 respective EU legislation concerning customs
3 enforcement of IPR to tackle trafficking of
4 counterfeit or falsified products. At national
5 level, customs services implemented provisions of
6 law to tackle trafficking of falsified or
7 counterfeit products in the domestic market.

8 Article 39 of the said law defines
9 simplified procedures for intensifying
10 inspections and destroying counterfeit products.
11 Furthermore, on the basis of the national customs
12 code, in case of an IPR infringement, customs
13 authorities may impose administrative fines of up
14 to 20,000 Euros.

15 Overall, Greek Custom Services
16 participate regularly in joint operations
17 conducted by new institutions, such as all of
18 Interpol --- excuse me, Europol. Or
19 international agencies such as Worldwide Customs
20 Organization, Interpol and Select. The five said
21 joint operations were conducted in 2019.

22 According to the Hellenic Copyright

1 Organization, significant developments in 2019
2 include the following: the committee for the
3 identification of copyright and related rights,
4 infringement on the Internet was established
5 under law for fighting against copyright online
6 infringement cases through an extra judicial
7 mechanism.

8 Within a maximum of 60 days, a right
9 holder who applies to the committee regarding
10 works made available on the Internet illegally
11 can have the works immediately removed or access
12 to them blocked, depending on the case.

13 This committee started operating
14 September 2018. And so far it has issued 11
15 decisions, whereas at the same time access to 64
16 websites has been restricted. The ministry of
17 culture and sports is also implementing a series
18 of measures on copyright protection, including
19 dynamic site blocking.

20 The Hellenic Copyright Organization is
21 reporting detailed statistical data on actions
22 providing piracy of copyrighted works in the

1 observatory for piracy, a specifically created
2 website updated twice a year.

3 As shown in the data, Greek courts are
4 very strict in upholding the law as the
5 imposition of fines and cases of copyright
6 infringement has been constantly increasing.

7 In conclusion, we would like to
8 underline that in the context of the ongoing U.S.
9 Greece threat is a dialogue, and the actual level
10 of bilateral relations, Greece is fully committed
11 to working with the United States on IPR issues.

12 CHAIR LEE: Thank you very much. If
13 I could ask you to turn off your microphone for
14 just a second. Thank you.

15 Generally speaking, I think we'd like
16 to try to keep the testimony to five minutes.
17 That allows time for the panelists to ask some
18 questions. I think we have time for maybe one,
19 maybe two questions. So I'd like to start off
20 with USTR.

21 MR. EWERTD: U.S. companies have
22 recognized the increase in counterfeit

1 enforcement trainings for customs officers and
2 police in Greece, but they have also expressed
3 concerns that the number of searches and seizures
4 of counterfeit goods has decreased over the past
5 few years. Can you explain why the number of
6 searches and seizures of counterfeit goods has
7 decreased even though the training has increased?

8 MR. DERMENTZOGLOU: According to the
9 information that we received, that we have
10 received and I have just presented to you,
11 seizures have been relatively steady to
12 increasing. So I am not so sure whether the
13 sources that we are referring to are the same or
14 maybe are differing in figures.

15 In any case, I would -- as I'm not
16 really, you understand, this is a lot of
17 information that we have received from a number
18 of agencies. And there was really not a lot of
19 time to really go into detail into every single
20 item of this information.

21 I'm happy to return back to you, to
22 get back to you with a clarification of this

1 discrepancy in the figures.

2 CHAIR LEE: Thank you very much. Next
3 I would like to call up the representative from
4 the Government of Indonesia. Is someone here
5 from the Government of Indonesia?

6 While we wait, I'm wondering: is the
7 Government of Korea available to testify first,
8 or if you prefer to wait we can wait, but if
9 you're ready, we can go ahead with the Government
10 of Korea first.

11 Oh, sorry, I think the Indonesian
12 government representatives are ready, so sorry.
13 Thank you for your flexibility. Hi, welcome. If
14 you could please state your name and organization
15 for the record and begin your testimony.

16 MR. FREDDY HARI SUSANTO: Good
17 morning, everyone. My name is Iwan Freddy Hari
18 Susanto. I am the Charges d'Affaires for the
19 Indonesian Embassy in Washington, D.C. I am
20 accompanied by my colleague, Mr. Freddy Harris,
21 Director for Intellectual Property from the
22 Indonesian government. Today we both would like

1 to provide testimony on the Indonesian government
2 status and updates and policies on Special 301
3 review public hearing.

4 Ladies and gentlemen, first of all,
5 allow me to extend our appreciation for the
6 opportunity to work with the USTR on the Special
7 301 review for considering on intellectual
8 property rights. Indonesia believes that there
9 is substantial room for expanding our trade
10 relations, considering the U.S., being the
11 largest economy in the world. And for that,
12 Indonesia also possesses one of the largest
13 domestic markets in Asia. While serving as a hub
14 for the Southeast Asia and East Asian region and
15 experiencing growth rates over 5 percent in the
16 past 10 years, the full potential of trade
17 between Indonesia and the U.S. have not been met.
18 Our trade total is approaching \$29 billion, while
19 at the same time the U.S. trade deficit has
20 consistently narrowed.

21 This can contribute, among others,
22 because of Indonesia's continuous efforts in

1 sending several, by admissions, to the U.S. to
2 purchase additional agriculture, energy and
3 technology products to promote free, fair and
4 reciprocal trade relations with the U.S.

5 For technical and more detailed
6 information about our policies and objects on how
7 we deal with intellectual property protection,
8 I'd like to invite my colleague, Mr. Freddy, to
9 continue this information.

10 DR. HARRIS: Thank you. I am Freddy,
11 Director General of Intellectual Property,
12 Ministry of Law and Human Rights, Republic of
13 Indonesia. I will write the testimony, so if I
14 would know how long that we have time?

15 CHAIR LEE: You have approximately two
16 minutes left for the testimony part, and then
17 there will be questions --

18 DR. HARRIS: Two minutes.

19 CHAIR LEE: -- from the panel for
20 about five minutes.

21 DR. HARRIS: Oh. Thank you.

22 CHAIR LEE: Thank you.

1 DR. HARRIS: -- two minutes. Because
2 we have three pages. Actually now, since three
3 years ago, we've already make some progress, and
4 a good cooperation with some of the United States
5 institutions. So we also -- this is very
6 important occasion, that's why we came here and
7 make the testimony. Because as we know, United
8 States already take in more than 10 years.

9 So man, this is very important for us
10 to give the information and to share the
11 information that we've already make some
12 progress, especially on IP related to the trades
13 here.

14 According to our government, that the
15 IP policy now is already -- make some progress.
16 In the first, the problem of the --- and now we
17 also know, we already, the government notes is,
18 also wants to make some exchanges with the
19 omnibus law in Indonesia.

20 And the other is also, according to an
21 implementation of ministry of regulation at
22 ministry of law regulation, we're ready to

1 renewable, yes. To give some, what's open for
2 investors.

3 And also, last month is also, we all
4 did in force of the enforcement with the custom
5 and the police here to enforce the infringements
6 of what the trademark products are, the
7 standards. Trademark is American trademarks.
8 And the last is also we already closed some
9 websites who sold the infringements -- who sold
10 the infringements, illegal movies, yeah. More
11 than 1,000.

12 We also corporation, make corporation
13 with the minister of information. And the other
14 is also according to the police, we handle more -
15 -- in 2019 we handle more than 47 applications,
16 cases. And also now is already settle about 20
17 cases, and the other is still running.

18 May I have 30 seconds? Okay. Thank
19 you. So according to this, special reviews of
20 the 301, we hope in the next year now, yes, with
21 United States, we are very welcoming improvement
22 our market access and strong enforcement of IPR

1 protection, which we also provide to allow the
2 largest presidential democracies with the huge
3 opportunity to full achieve the economic and
4 trade investment potentially. Thank you very
5 much.

6 CHAIR LEE: Thank you very much for
7 your testimony. We have some questions from the
8 Panel, and we will start with USTR.

9 MR. EWERDT: A draft job creation
10 omnibus bill was recently submitted to the
11 Indonesian parliament that will, if passed,
12 eliminate the local manufacturing and use
13 requirements contained in Article 20 of the
14 patent law. Will there be a formal process for
15 interested parties to submit comments on the
16 draft job creation omnibus bill?

17 DR. HARRIS: Thank you. According to
18 omnibus law, because we are responsible for the
19 IP, for the IP, with the omnibus law we want to
20 stress the articles that have a problem with the
21 sums, patent holders. Yes.

22 And the other side, according to job

1 creations, because the ministry have so many,
2 multiple labor associations, and this is still
3 ongoing with the government, and initiate of
4 omnibus law is from the government.

5 CHAIR LEE: Thank you very much. Next
6 I would like to turn to the U.S. Patent and
7 Trademark Office.

8 MS. BERDUT: Good morning. U.S.
9 companies have also raised other concerns with
10 Indonesia's patent law, including narrow
11 patentability criteria, disclosure requirements
12 with respect to traditional knowledge, and
13 genetic resources in licensing recordal
14 requirements. Can you explain the Indonesian
15 government's plans to address these concerns?

16 DR. HARRIS: Thank you. According to
17 the patent law, the Article of 20, actually, we
18 decided to solve some limitation problems,
19 certain limitation problem because it's the egg.
20 So we want to extend the meaning of the Article
21 20 now.

22 And we produce the ministry of

1 regulation means, according to the patent
2 holders, so they can extend until we have make a
3 new draft of patent law. Means now we also
4 already discussed with the stakeholders, that's
5 like an MCHC in Jakarta. Also USPTO and USTR.

6 So, it's already solved. Not
7 permanently. But we hope if we already protest
8 the omnibus law, some of the problem is already
9 settled.

10 According to what the traditional
11 knowledge, also the compulsory license, actually
12 the United States already signed the TRIPS
13 agreement. Means, according to the administer of
14 regulation, now we already were the appointee
15 that according to the TRIPS, the requirement is
16 related to the TRIPS. Thank you.

17 CHAIR LEE: Thank you. We have one
18 final question from our Department of the
19 Treasury.

20 MR. CHANG: Hi. In your written
21 submission Indonesia stated that it is in the
22 process of drafting a presidential regulation

1 replacing the presidential regulation Number 44
2 of 2016 on the negative investment list as an
3 implementing regulation for Law Number 33 of 2009
4 regarding film. Can you provide further
5 information on this draft presidential
6 regulation?

7 Would this presidential regulation
8 address longstanding concerns stemming from the
9 2009 film law, including local screen quotas and
10 prohibitions on dubbing of imported films?

11 CHAIR LEE: Thank you.

12 DR. HARRIS: Thank you. According to
13 Indonesian regulation related to the films, in
14 this regulation we have a requirement, a minimum
15 requirement, for the theater who take the movies,
16 as local movies, in 50 percent.

17 But actually, it's not implementing
18 for ten years. And in 2019 there is not the
19 presidential regulation but this initial
20 education regulation that produce the ministry
21 regulation.

22 But before we came here I already

1 discussed with the director of movie and culture,
2 so means they want to make some consideration
3 movement.

4 And also, they want to change this
5 regulation because the regulation actually is not
6 implemented because according to market, initial
7 movie now is already selling more than 52
8 percent. Means, it's open in this year. Thank
9 you.

10 CHAIR LEE: Thank you very much.
11 We'll move on to the next testifier. If we could
12 have the Government of Korea representatives come
13 up that would be great.

14 DR. HARRIS: Thank you.

15 CHAIR LEE: Welcome. Please state
16 your name and organization for the record. And
17 begin your testimony.

18 MR. NAM: Good morning, everyone. I
19 am Bokhyun Nam, director for Trade Affairs at the
20 Ministry of Health and Welfare of the Republic of
21 Korea.

22 Regarding the recent Special 301

1 review, PhRMA and BIO requested the USTR to
2 remark Korea as a priority foreign country.
3 There are arguments mainly focused on four
4 matters. I'd like to address each of these
5 matters.

6 First, drug pricing and reimbursement
7 system. In order to better understand Korea,
8 Korea's approach to drug pricing is important to
9 know how Korea's health insurance system works.

10 Korea's health insurance system is a
11 universal public health care system. Which
12 guarantees every citizen access to quality health
13 care services. Therefore, Korea's drug pricing
14 must be consistent with the health insurance
15 system.

16 At the same time, the Korean
17 government has operation system to recognize and
18 rework. The very innovative new drugs. That is
19 to say, Korea is committed to protecting the
20 valuable, innovative new drugs to the maximum
21 extent by using current facilities and
22 pharmaceutical economic variation of objective

1 criteria.

2 Accordingly, we believe that the
3 argument, which state that Korea violate
4 intellectual property right of available new
5 drugs is based on this understanding of our
6 system.

7 Second, the premium price encouraged
8 for global innovative new drugs. Regarding the
9 revised policy, which came into effect on January
10 1st, 2019. There have been concerns from the
11 U.S. pharmaceutical industry that its
12 qualification criteria are still too strict for
13 drug makers to qualify for and obtain critical
14 benefit.

15 However, I'd like to state the fact
16 that two applications have been submitted since
17 the revision. One of the subsequently met the
18 qualifications for premium pricing while the
19 other is currently under review.

20 This proves the fairness and
21 effectiveness of the price, and also the fact
22 that the policy does not discriminate against the

1 pharmaceutical companies.

2 Third, Korea's risk sharing automated
3 system. The Korean government has paid attention
4 to those who test from the U.S. pharmaceutical
5 industry and taken steps to improve the system by
6 extending two serious conditions. As part of the
7 reform, serious disease products are now included
8 in the RSA.

9 The last is Korea's independent leader
10 process. Through IRP the Korean government
11 provides an institutional mechanism that allows
12 pharmaceutical companies to speak up.

13 However, to the request from the U.S.
14 pharmaceutical industry to apply IRP to price
15 negotiations, the Korean government has
16 continuously made it clear that price negotiated
17 by, between the measurement, health insurance
18 service and pharmaceutical companies are not
19 subject to IRP.

20 This is because they are mutual
21 argument made between parties on equal footing.
22 The Korean government will keep making effort to

1 operate our policies in a fair, reasonable and
2 nondiscriminatory manner and are consistent with
3 the current FTA. Thank you for listening. I'm
4 happy to answer any questions.

5 CHAIR LEE: Thank you very much.
6 We'll start with questions from USTR.

7 MR. EWERDT: If a pharmaceutical
8 company is not satisfied with the price ceiling
9 that has been set by the health insurance review
10 and assessment service, or HIRA, for the
11 reimbursement price, is the pharmaceutical
12 company able to challenge this decision, and if
13 so, has there been an instance where HIRA has
14 changed the price ceiling based on a challenge by
15 a pharmaceutical company?

16 MR. NAM: For Korea communication
17 purpose I want to accompany my interpreter.

18 (Foreign language spoken.)

19 MR. NAM: So, HIRA conducts
20 assessments regarding clinical usefulness. And
21 also they conduct PE analysis. Therefore they
22 just suggest the ceiling price is not just a

1 final decision about ceiling prices.

2 So, before having price negotiations
3 with the NHIS, National Health Insurance Service,
4 pharmaceutical companies have adequate
5 opportunities to speak of their opinions
6 regarding drug prices.

7 MR. EWERTD: And the second question
8 was, has there been an instance where HIRA has
9 changed the price ceiling, or its suggestion of a
10 price ceiling, based on input by a pharmaceutical
11 company? Or a challenge by a pharmaceutical
12 company?

13 (Foreign language spoken.)

14 MR. NAM: So, HIRA provides adequate
15 opportunities to pharmaceutical companies
16 regarding material submission and speaking of
17 their opinions. And so after HIRA, after making
18 ceiling prices, ceiling prices up, pharmaceutical
19 can raise an independent review or they can apply
20 to assessments regarding drug pricing.

21 CHAIR LEE: Thank you. We're going to
22 try to squeeze in one quick question from our

1 Department of Health and Human Services.

2 MS. BLEIMUND: Thank you. You noted
3 that two companies had applied for premium
4 pricing under the new criteria that were
5 established last year. Can you just confirm, you
6 said one of the companies did meet the criteria.
7 Can you confirm, was that a domestic company or a
8 foreign company? Thank you.

9 (Foreign language spoken.)

10 MR. NAM: Those two applications are
11 all submitted by European companies, so there is
12 no domestic company at all.

13 CHAIR LEE: Thank you for your
14 testimony. Next I would like to invite the
15 Government of Ukraine representatives to come up.

16 Welcome. If you could begin your
17 testimony with stating your name and
18 organizations for the record, that would be
19 great. Thank you.

20 MR. ROMANOVYCH: Thank you. Thank you
21 I am Dmytro Romanovych, Deputy Administrator of
22 the Ministry of Economy Development Rate and

1 Agriculture.

2 MR. KACHKA: Taras Kachka, Deputy
3 Administer for the Development of Economy Trade
4 and Agricultural Trade, Representative of
5 Ukraine.

6 MR. ROMANOVYCH: We can start? Okay,
7 thank you. First of all, I want to excuse, I
8 want to ask for excuse if I will take a bit more
9 than five minutes. Ukraine made remarkable
10 achievements in the IPR sphere. This is a great
11 opportunity to report on them.

12 On behalf of the Government of Ukraine
13 let me express the upmost respect for the Office
14 of the United States Trade Representative, for
15 other U.S. government institutions and for all
16 the participants of this event.

17 As of today, IP still remain one of
18 the priorities of the state policy of Ukraine.
19 It's in the agenda of the president's office, the
20 government, and the parliament.

21 The official coordination was
22 established between legislative and executive

1 branches of power. Parliamentary commentary of
2 economic development is responsible for IPR
3 sphere and its main kind of project for the
4 ministry of economic development.

5 Inside of the Ukrainian parliament,
6 the interparty group of members called
7 intellectually created. And it's helped very
8 much with dealing with the IP sphere. That has
9 already left positive outcomes in the form of
10 adopted legislative acts.

11 The program of activities of the
12 cabinet of ministry of Ukraine for 2020 includes
13 a standalone goal, 7.8. Owners of works and
14 inventions are protected under CFR amelioration.
15 It's among the goals of the ministry of economy.

16 Our work on IPR infringements issues
17 has taken place on the following areas. For
18 technically pending issues in the sphere of
19 collection management, working with unlicensed
20 software issues and third, strengthening
21 intellectual property rights enforcement.

22 On the first subject. Technically

1 pending issues in the sphere of collected
2 management.

3 In 2019 16 CMOs were registered. An
4 accreditation process is ongoing there and it is
5 planned to be complete this year in 2020.

6 Six CMO were accredited, in
7 particular, in four spheres of debt collective
8 management and two spheres of extended collective
9 management. The competition regarding two
10 remaining spheres of extended collective
11 management is going on.

12 The division for labor customs
13 organization report form was approved that will
14 permit, to designate newly opened competition of
15 the most representative organization, the
16 accredited one in the relevant sphere of the
17 mandated or extensive collective management.

18 As for their unlicensed software,
19 Ukraine takes all possible measures aiming at
20 prevention of the use of unlicensed software,
21 executive authorities and in general.

22 All procurement of software at the

1 executive authorities are approved by the state
2 agency and are conducted through the transparent
3 procedure with the use of our portal, so it's
4 reasonable, transparent and you can check it.
5 And it's allowed to buy the unlicensed software
6 through it.

7 The threshold for procurement was
8 pretty low. Around \$8,000. And will be even
9 lower starting from March. It will be \$2,000.
10 So almost every procurement procedure will go
11 through the electronic options.

12 All of this prevents violation on
13 rights of the, rights holder during the purchase
14 of the software. We're in permanent contract
15 with Microsoft Ukraine, Oracle and other
16 providers through American Chamber of Commerce.
17 We are working with them on a lot of legislative
18 and implementation issues in the permanent
19 contract.

20 As for the strengthening intellectual
21 property rights enforcement. First, IP
22 legislation. The Ukrainian parliament adopted

1 the following laws in the field IP. First, on
2 layout of semiconductors products under
3 geographical indications and on amending tax
4 quarters regarding IPR's protection at
5 transporting goods across the customs border of
6 Ukraine. The ministry is current supporting the
7 following draft laws. Regarding inventions and
8 related models under forming a patent legislation
9 registry.

10 The second one. Regarding trademarks
11 in industrial design, including patent trolling,
12 and own establishment of the national
13 intellectual property authority. All of them was
14 worded in the first reading with the
15 constitutional majority gives us a lot of comfort
16 regarding the second reading that should have on
17 this here. The new draft law on copyright is
18 developed by ministry of economic development and
19 will be published for public discussion.

20 Activity of the national policy. In
21 2019 the representatives of the policy Q20 285
22 criminal proceedings based on crimes related to

1 IPRs infringement. In particular, 145 related to
2 the corporate, 65 criminal procedures related to
3 illegal use of marks for in services, 22 to
4 illegal distribution of discs, 17 to industrial
5 property objects. Especially I want to
6 strengthen that to 35 private production lines,
7 for infringing copyright were shut down.

8 As for the custom procedures, the
9 custom register under the existing Ukraine
10 contain more than 4,000 IPR objects. There are
11 6,875 cases of suspension of customs clearance of
12 goods in 2019.

13 As I already mentioned, the new, the
14 amendments to the custom quarter to improve the
15 IPR protection on the customs is approved in
16 October 2019.

17 As for high IPR court, legally it was
18 established in 2017, so institutional
19 arrangements are finalizing. So the personal
20 composition is formed, the competition for
21 vacancy for judges are held and the
22 organizational preparation is already, also took

1 in place.

2 The last thing I want to mention that
3 we improved the trademark protection in the
4 internet. In particular, in domain names.

5 Agreement on domain names was the
6 resolution between WIPO and UA administration
7 that was concluded in 2018. The relevant
8 regulation entered into the effect in the
9 beginning of 2019. And in the end of 2019 it
10 become active for domain of certain levels. So
11 we are able to protect the trademarks in the
12 internet. Thank you.

13 CHAIR LEE: Thanks a lot. Thank you.
14 We'll start with questions from USTR.

15 MR. EWERDT: In your written
16 submission you note that during parliamentary
17 sessions last December, the national strategy of
18 IP sphere development for 2020 through 2025 was
19 discussed. And that the relevant recommendations
20 to implement the strategy are under development
21 for consideration by the Rada.

22 What is the status of the

1 recommendations and will the draft
2 recommendations be shared for stakeholder input?

3 MR. ROMANOVYCH: This recommendation
4 is with, right now, within the community,
5 relevant committee of the parliament. And as far
6 as I am informed, it will be passed to the
7 consideration of the parliament in your
8 responses.

9 CHAIR LEE: Thank you. The next
10 question is from our Copyright Office.

11 MR. WESTON: Hi. Regarding concerns
12 raised by stakeholders with the current
13 Collective Management Organization, or CMO
14 regime, can you confirm that the Government of
15 Ukraine will work on addressing these concerns
16 within the larger copyright bill reform efforts?

17 MR. ROMANOVYCH: Yes, absolutely. So
18 we have already prepared the draft law that
19 addressing at least some of the issues. I don't
20 know what exact comments on your side but we are
21 working closely with all the CMOs that is
22 existing in Ukraine on improving the law.

1 As well, we are in contact with the
2 U.S. Embassy and other relevant stakeholders in
3 this sphere, so we are open. And the draft law
4 that is already prepared will be published for
5 public discussion, so it will be available for
6 all the parties to comment.

7 CHAIR LEE: Thank you very much. We
8 have one last question from our Treasury
9 Department.

10 MR. CHANG: Thank you. You noted that
11 Ukraine has taken measures to prevent the use of
12 unlicensed software by government entities. Does
13 Ukraine also plan to take measures to prevent the
14 use of unlicensed software by the general public
15 as well?

16 MR. ROMANOVYCH: Thank you for this
17 question. Yes, absolutely. So we have the
18 institution of the IP inspectors that is
19 responsible for it. And they react on the claims
20 and make inspections to check this for instance.
21 So we plan to strengthen this function of course.
22 But yes, this institution has already existed.

1 CHAIR LEE: Thank you so much for your
2 testimony today. Next I would like to invite the
3 Alliance for Fair Trade with India to come up.

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

7 MR. MURRY: Good morning. My name is
8 Roger Murry and I am with the Alliance for Fair
9 Trade with India.

10 So, dealings for fair trade with
11 India, or AFTI, is a diverse group of trade
12 associations that support increased action to
13 address the many barriers to trade investment
14 that U.S. companies face in India, including
15 those adversely impacted by India's intellectual
16 property policies. I want to thank the panel for
17 its work to advance stronger intellectual
18 property policies around the globe. And
19 particularly in India.

20 As in recent years, AFTI joins many
21 U.S. organizations coined for USTR to, again,
22 place India on the priority watch list.

1 Reflecting the range of IP concerns that have not
2 yet been addressed. But today's hearing comes
3 hours after President Trump returned from his
4 state visit to India where he and Prime Minister
5 Modi agreed to initiate negotiations for a bigger
6 deal. And I do want to briefly comment on that
7 and the role that the Special 301 Report can play
8 in facilitating that.

9 AFTI believes that such talks must
10 address intellectual property rights. We ask
11 that this year's report provide our negotiators a
12 roadmap to accelerate the positive, if modest
13 trajectory on IP policy, that has emerged from
14 India's national IPR policy. Which came out in
15 2016. Many serious hurdles remain that directly
16 limit market access in place, U.S. innovative
17 industries at a disadvantage.

18 These hurdles also hold back India
19 innovators, creators and entrepreneurs and rob
20 India of critical trade and investment that could
21 move India's economy forward. Bilateral trade
22 talks can and should lead to substantive and

1 measurable enhancement of IP protection in India.

2 AFTI is encouraged in 2020 by the
3 progress India has made over the past year. If
4 often preliminary and in discrete areas. India
5 has, since 2015, more than tripled the number of
6 patent examiners, which has cut examination times
7 in half. A December court ruling should solidify
8 patent rights for computer related inventions
9 where India has been making progress in recent
10 years.

11 In November, Japan and India began a
12 pilot Patent Prosecution Highway program, which
13 is India's first such agreement with a major IP
14 office. Although it is limited by the number of
15 patents it will take each year and the scope of
16 patents. So there is room for improvement.

17 We've also been encouraged by, and
18 continue to increase an injunctive style relief
19 for disabling and infringing content online.

20 However, despite these important but
21 measured steps, the Government of India has yet
22 to meaningfully address numerous and onerous

1 longstanding shortcomings to its IPR regime
2 identified in the 2019 and prior Special 301
3 Reports. These include major hurdles to patent
4 protections for innovative medicines, pressure to
5 localize manufacturing and price controls on
6 medical devices and agriculture biotechnology.
7 Our comments detail, our written comments detail
8 these priority challenges more fully.

9 AFTI continues to believe that
10 together our governments can advance strong
11 intellectual property rights that promote
12 innovation, trade and investment. India's
13 regional competitors have not stood still as
14 countries like China have strengthened
15 intellectual property rights and regulation.

16 In the last few years, China has made
17 progress strengthening core IP protections with
18 improvements in areas such as patents, trade
19 secrets and trademarks. The IP chapter in the
20 U.S. China agreement, when fully implemented,
21 will create stark contrast between the Chinese
22 and India IPR regimes for American rights

1 holders. The bilateral talks announced yesterday
2 create the opportunity to close this widening
3 competitiveness gap between India and China.

4 In conclusion, thank you for your
5 tireless work to protect the intellectual
6 property rights of American's. AFTI looks
7 forward to seeing the positive impact that this
8 year's Special 301 Report will have on upcoming
9 bilateral negotiations. I'm happy to answer any
10 questions you might have.

11 CHAIR LEE: Thank you very much.
12 We'll start with USTR.

13 MR. EWERDT: Your written submission
14 cites concerns from the USTR 2019 Special 301
15 Report on adequate trade secret protection. And
16 the proposed cooperation on improving India's
17 trade secret regime has failed. Do you have any
18 suggestions for successfully collaborating with
19 the Government of India to improve India's trade
20 secret regime?

21 MR. MURRY: Well, I think the trade
22 policy forum and the IP dialogue within that has

1 made repeated attempts to enhance trade secret
2 protection. And I think we certainly have taken
3 a look at the IP chapter in the Phase 1 U.S.
4 China agreement. So that's certainly what a good
5 end result could look like.

6 But I think it's, this exercise today,
7 this year's 301 Report, and just continue
8 pressure. And I guess unfortunately I don't have
9 any specific suggestions. But I also can say
10 that our members have been engaging directly with
11 their Indian industry counterparts, with Indian
12 government officials trying to provide that
13 second track engagement. And hopefully that will
14 yield a better understanding of the importance of
15 trade secrets and will assist in
16 government-to-government consultations.

17 CHAIR LEE: Thank you. And this goes
18 for all the witnesses. To the extent that you
19 have follow-up input, we do have the post hearing
20 submissions as well as just any sort of follow-up
21 that you'd like to do separately from that as
22 well. Next I'd like to turn to the Department of

1 Labor.

2 MS. KHAN: AFTI's submission urges
3 India to engage more robustly with the United
4 States on matters that would help promote
5 American innovation. What are some specific ways
6 that AFTI believes that the government of India
7 can engage in making meaningful improvements?

8 MR. MURRY: I think I really have to,
9 I think that the state visit yesterday, that
10 concluded yesterday, is a historic opportunity to
11 raise the profile of government-to-government
12 engagement on intellectual property.

13 We firmly hope that intellectual
14 property will be part of the bigger trade talks.
15 And we have been engaging at a lower level while
16 the GSP focused trade talks have been ongoing for
17 the past year and a half plus.

18 And I think there is a lot of
19 potential to re-engage on intellectual property.
20 I know that there has been talk about
21 reinstatement of the IP dialogue. But I think
22 actually what the two leaders have said provides

1 a framework for something much more.

2 CHAIR LEE: Okay, thank you. We'll
3 turn next to the U.S. Patent and Trademark
4 Office.

5 MS. BERDUT: Thank you. AFTI
6 expresses concerns with the burdens that Section
7 8 of India's patent act places on foreign patent
8 applicants. Given the historical basis of
9 Section 8, does AFTI have suggestions on how to
10 modernize or improve Section 8, to remove the
11 burdens on foreign applicants?

12 MR. MURRY: Our members have been
13 engaging directly with the Government of India,
14 providing feedback for, I think on a regular
15 basis, over years. And so we're going to
16 continue to do that. But I think I would like to
17 follow up, submit written comments to provide a
18 little, few extra ideas.

19 CHAIR LEE: Thank you very much. We
20 will move on to the next witness. I'd like to
21 ask the representative from the American Apparel
22 and Footwear Association to come up.

1 Thank you. Please state your name and
2 organization for the record and begin your
3 testimony.

4 MS. MITROPOULOS: Christina
5 Mitropoulos with the American Apparel and
6 Footwear Association.

7 AAFA appreciates the opportunity to
8 testify before the Special 301 Committee today.
9 AAFA is the national trade association
10 representing apparel, footwear, travel goods and
11 other sewn products companies and their
12 suppliers, which compete in the global market.

13 We represent more than 1,000 world
14 famous name brands, their management and
15 shareholders, our industries nearly four million
16 U.S. workers and its contribution of \$400 billion
17 in annual U.S. retail sales.

18 AAFA's brand protection council
19 vigorously pursues brand protection efforts with
20 the focus on the global war against counterfeit
21 apparel, footwear, accessories and other supplier
22 products. The issues and recommendations

1 identified in our submission are a result of the
2 input provided directly by AAFA brand protection
3 council members.

4 While I'm prepared to talk about any
5 of the issues raised in written submission, out
6 of the interest of time today I'd like to focus
7 on two significant trading partners, Mexico and
8 China.

9 The U.S. trade ties to Canada and
10 Mexico are critical. In fact, more than 12
11 million American jobs depend on trade with Canada
12 and Mexico. AAFA recently applauded the passage
13 of the U.S. Mexico, Canada agreement and
14 encouraged President Trump to sign the bill into
15 law and implement the agreement quickly.

16 Through the USMCA the U.S., Mexico and
17 Canada reached an agreement on a modernized high
18 standard IP chapter that provides strong and
19 effective protection and enforcement of rights
20 critical to driving innovation, creating economic
21 growth and supporting American jobs.

22 AAFA commends the efforts of the

1 administration in USTR to ensure that IP
2 protection and enforcement against counterfeit
3 and pirated goods are a top priority in America's
4 trade relationships. AAFA members see Mexico in
5 particular as an increasingly important market as
6 they look to expand selling and production
7 operations there following the future
8 implementation of the USMCA.

9 However, AAFA members believe that
10 Mexico has not taken adequate steps to protect
11 American intellectual property. And for that
12 reason should be placed on USTR's 2020 priority
13 watch list.

14 We are disappointed to make this
15 recommendation in light of our longstanding
16 partnership with Mexico under NAFTA and now
17 USMCA. In addition to the issues flagged in
18 AAFA's submissions, members note that they have
19 experienced issues pursuing large scale cases of
20 infringement based on cost associated with
21 Mexico's injunctive process.

22 In order to effectively seize

1 merchandise, a brand must offer up a guarantee
2 based on the declared value or market price of
3 each product, which is the price per unit times
4 the amount of goods seized.

5 With a high volume of goods seized,
6 this number easily climbs to a figure that is
7 unrealistic for most, if not all brands, to
8 support leaving brands with no other option but
9 to allow the goods to be released. In light of
10 the USMCA, we encourage the Mexican government to
11 take necessary steps to address these IP right
12 deficiencies. Now I'd like to focus my remaining
13 time on China.

14 As AAFA has mentioned in previous
15 submissions and testimony, China is an invaluable
16 trading partner for our members and for the
17 apparel and footwear industry. Trade barriers,
18 such as tariffs on U.S. apparel, accessories and
19 footwear imports from China, harms consumers by
20 raising costs for basic necessities.

21 Members continue to report that China
22 is the primary source for counterfeit supply

1 chains, from manufacturing to distribution.
2 China has also not shown significant progress in
3 addressing the registration of trademarks in bad
4 faith.

5 It is also important to highlight that
6 many third-party marketplaces don't vet
7 counterfeit goods from China or have appropriate
8 and efficient takedown methods. We encourage
9 USTR to hold the Chinese government accountable
10 for IP right deficiencies.

11 The highly anticipated Phase 1 China
12 trade deal offered some promising provisions for
13 the stronger Chinese legal protections of
14 American intellectual property. We are hopeful
15 that if China implements parts of the trade deal
16 it will address some, if not many, of these
17 issues raised by our members.

18 While there are significant IP
19 concerns in China, we stress, as we have in the
20 past, that steps to address Chinese IP practices
21 must be taken in a manner that ensures that
22 supply chains and the U.S. jobs that support them

1 are not interrupted by U.S. actions or Chinese
2 retaliation.

3 AAFA appreciates this opportunity to
4 raise these concerns and we look forward to
5 working with USTR to address IP issues. We
6 consider this to be an ongoing process and will
7 provide USTR with updated information as our
8 members bring them to our attention. And I will
9 now take any questions you might have, thank you.

10 CHAIR LEE: Thank you very much.

11 We'll start with USTR.

12 MR. EWERDT: Your comments focus on
13 countries that produce counterfeits and on
14 countries where corruption prevents the effective
15 enforcement of trademarks. You do not identify
16 countries that are major hubs for trans-shipment
17 of counterfeit goods, nor did AAFA identify any
18 free trade zones in its 2019 notorious market
19 submission. In terms of priority for AAFA
20 members, is the role of trans-shipment hubs in
21 the global counterfeit trade of relatively low
22 priority?

1 MS. MITROPOULOS: Certainly a priority
2 for our members. And as I mentioned at the
3 beginning of my testimony, this submission
4 references countries that members flagged during
5 this input process. And obviously free trade
6 zones and trans-shipment hubs are of significant
7 importance to our members. And I can definitely
8 go back to them and flag any issues, or countries
9 that are of issue for them.

10 CHAIR LEE: Thank you very much. The
11 next question comes from the Department of Labor.

12 MS. KHAN: Thank you. As you've
13 indicated in your testimony, AAFA recommends that
14 certain countries be put, that produce
15 counterfeit goods be placed on the 2020 priority
16 watch list, including Mexico, China, as well as
17 Indonesia, Turkey, Pakistan and the Philippines.

18 Which countries would you say are most
19 responsible for the losses that your members have
20 faced from losing market share to counterfeit
21 products?

22 MS. MITROPOULOS: I think each of the

1 countries that we identified as priority watch
2 list countries for the 2020 list are of
3 significance to our members. I don't think
4 members place them on a certain scale. But I can
5 definitely go back to our members and ask if they
6 prioritize certain countries over others. But
7 including these countries in our submission
8 obviously reflect that these countries are of
9 significance to our members.

10 CHAIR LEE: Thank you very much. Next
11 we have a question from ITA.

12 MR. MITCHELL: This question concerns
13 AAFA's observations about Spain. In AAFA's
14 submission, you recognize that lower volumes of
15 street level counterfeit sales are occurring in
16 Spain. And you note specifically that, and I
17 quote, members have received better information
18 from officials that has allowed them to connect
19 online sellers to the on the ground targets in a
20 timely manner.

21 My question was whether you think that
22 Spain's actions to address these counterfeit

1 problems can be replicated in other countries to
2 address other similar issues?

3 MS. MITROPOULOS: As you know, AAFA
4 identified Spain on the notorious markets list,
5 as well as in our submission for last year's
6 Special 301 process. And I think given the
7 increasing focus and pressure that our members
8 and our counterparts in the EU placed on Spain,
9 they were able to see progress.

10 And I do believe that working with
11 local and government officials enabled them to
12 see progress. So I do think that definitely
13 could be replicated with other countries that are
14 experiencing an influx of street vendors selling
15 counterfeit apparel and footwear products.

16 CHAIR LEE: Thank you. I think we
17 have time for one last question. From the State
18 Department.

19 MS. DIFIORE: Hi. On the Philippines
20 your members raised questions that the National
21 Bureau of Investigation and the IP Office need to
22 implement radical changes to their processes in

1 order for brand owners to continue taking
2 enforcement actions. Can you further explain
3 what specific steps the Philippines should take
4 to improvement IP enforcement?

5 MS. MITROPOULOS: As we noted in our
6 submission, I think a lot of the concerns that
7 members raised relate to paying storage fees for
8 seized goods. So I think that ties into the
9 processes that brand owners are looking for
10 changes. But I can go back to membership and see
11 if they have any additional recommendations or
12 suggestions as to what would further this
13 process.

14 CHAIR LEE: Thank you. And thank you
15 for your testimony today. Next I'd like to invite
16 the representative from the American University,
17 Washington College of Law Program on information
18 justice and intellectual property to come up.

19 Welcome. And please begin your
20 testimony by stating your name and organization
21 for the record.

22 MR. FLYNN: Okay, thank you. My name

1 is Sean Flynn. I'm a professor at American
2 University Washington College of Law. I direct
3 our program on Information Justice and
4 Intellectual Property. I've testified here many
5 times before, although not in the last few years,
6 so it's good to be back in front of you all. I
7 notice a couple of new faces, couple of old ones.
8 I mean, repeat ones.

9 (Laughter.)

10 MR. FLYNN: But I'm here to talk
11 primarily about the complaint by IIPA against
12 South Africa. And that complaint primarily
13 involves South Africa's proposed -- not yet
14 implemented -- new copyright reform legislation.

15 So, I think perhaps the most
16 interesting and telling page of the IIPA
17 complaint -- at least in the way I printed them
18 out -- comes right in the end of the two or 300
19 or so pages that they submitted to you. Which is
20 misleadingly labeled on the packet page 3.

21 And my first kind of general comment
22 after reading through a lot of the submissions is

1 please adopt a page limit in future proceedings
2 like this. There is really an incredible amount
3 of repetition within the complaints before you.

4 So that chart contains -- if you go
5 down the right-hand -- or the left-hand column --
6 a request for South Africa to be listed at the
7 second highest level as a priority watch list
8 country. But then if you run along the row you
9 will find that South Africa has not been listed
10 at any level since 1999.

11 So, I think that brings to you two key
12 questions that you need to answer in regards to
13 the IIPA complaint. And I encourage you to ask
14 them since they're coming after me.

15 So the first is, what changed in 1999.
16 And the second, of course, is what's changed
17 since then to alter the process.

18 So what happened in 1999? So in 1999
19 was the year that an Executive Order was passed
20 by the Clinton Administration that banned USTR
21 from applying trade pressure to Sub-Saharan
22 African countries, to pressure them to adopt

1 TRIPS-plus measures that reduce access to needed
2 AIDS medications.

3 At the time, as you probably know,
4 South Africa was being watch listed for having
5 passed the law allowing parallel importation of
6 medicines.

7 That trade pressure was in the face of
8 overwhelming evidence that patents in South
9 Africa were driving exclusionary pricing of AIDS
10 medication. So at the time the prices of AIDS
11 medicines in South Africa was three times the GDP
12 per capita in that country.

13 That lead to a massive outcry, both in
14 the United States and in South Africa. Literally
15 from Seattle to Cape Town. And many, many
16 protests in between.

17 And the result was the Executive Order
18 that I mentioned. Now, since that Executive
19 Order, no Sub-Saharan African country has been
20 listed on the Special 301 watch list for
21 anything.

22 Implicitly there has been a rule, I

1 would say, that USTR has operated under, that
2 countries in Sub-Saharan Africa may adopt TRIPS
3 compliant measures, flexibilities to promote both
4 access to medicines but also access to knowledge
5 without coming under USTR trade pressure.

6 So the question before you is whether
7 the IIPA made a substantial enough complaint to
8 alter that implicit policy.

9 So, what's happened since then? So
10 you're presented with an invitation from IIPA to
11 sanction South Africa for passing a law that's
12 not yet been signed by the president, that
13 implements the WIPO internet treaties, the
14 Marrakesh treaty and the Beijing treaty and
15 couples that with an expansion of limitations and
16 exceptions for libraries, archives and museums,
17 and incorporates a U.S.-style fair use clause.

18 Now, I appeared at a hearing a few
19 weeks ago, GSP hearing, in which there were at
20 least ten people who testified in favor of that
21 bill and gave you an extensive record of the
22 various provisions from other countries, very few

1 of which are on the Special 301 watch list, if
2 any, that have similar provisions in their loss.

3 So Germany, for instance, has similar
4 abilities of the government to regulate
5 contracts. Most of Europe has similar reversion
6 rights, for instance. Et cetera.

7 And so I'm happy to talk more about
8 those specifics, but I think the upshot is this.
9 All of the provisions that IIPA complains about
10 have analogs in other countries, most of which
11 the U.S. is not complaining about here.

12 And for that reason, USTR should
13 continue its implicit policy and refuse to list
14 USTR -- or any other African country, for that
15 matter -- on this year's Special 301 list. So
16 I'm happy to open up to further questions.

17 CHAIR LEE: Thank you. And we'll
18 begin questions with USTR.

19 MR. EWERDT: You mentioned in your
20 submission that South Africa's introduction of a
21 U.S.-style fair use provision will make it easier
22 for U.S. companies to trade in technology and

1 services that rely on fair use. Can you explain
2 specifically how this provision will make it
3 easier for U.S. companies to trade in these
4 technologies and services and whether the
5 legitimate interests of right holders is
6 considered in your analysis?

7 MR. FLYNN: Yes, sure. So, we've
8 actually done some empirical research on this
9 regard. So, we've created what's called the user
10 rights database, which is available on our
11 website, www.pijip.org.

12 And that index looks at 30 or 40
13 different countries of different development
14 levels and looks at how they've opened their
15 copyright exceptions over time. Including, but
16 not only, by adopting fair use type standards.

17 And what we find in that data -- and
18 we've back loaded it back to 1970 to 2016. And
19 so by doing that it enables econometric analysis,
20 looking at the before and after effects of
21 opening copyright exceptions.

22 And what we find is that --

1 controlling further factors -- investments by the
2 technology industry increase in countries that
3 open their exceptions to a broader range of
4 purposes, et cetera.

5 And the reason for that is -- perhaps
6 self-explanatory, and I know some of the CCIA and
7 other associations will be here today to discuss
8 -- but there are many kinds of products and
9 services that you cannot develop without a fair
10 use provision or another specific exception for
11 that purpose.

12 I mean, you can take, for instance,
13 text and data mining for the purpose of machine
14 learning and artificial intelligence. You can
15 only develop that kind of technology and fibers
16 in probably eight or nine countries around the
17 world today.

18 I mean, the number is growing, but
19 it's fairly limited. So if you have a copyright
20 law that doesn't have an open general exception,
21 doesn't have a specific exception for text and
22 data mining, then you just can't do that kind of

1 work in that country. There's many other
2 examples as well.

3 CHAIR LEE: Thank you. Next I'd like
4 to turn to the U.S. Copyright Office.

5 MR. WESTON: Hi.

6 MR. FLYNN: Hi.

7 MR. WESTON: The fourth factor I'm
8 going to talk about, the fair use.

9 MR. FLYNN: Sure.

10 MR. WESTON: The fourth factor in
11 South Africa's fair use style provision looks to
12 the, quote, substitution effect on the potential
13 market, unquote.

14 Do you think that this provision will
15 conflict with the normal exploitation of the work
16 and therefore violate the three-step test because
17 uses that effect the market of the work may be
18 considered a fair use?

19 MR. FLYNN: No, I don't. And the
20 reason is, because it doesn't do so in the U.S.,
21 right?

22 So, my reading of that fourth factor

1 is it's just a extrapolation of our own case law.
2 So that looks like it comes from the Google Books
3 case. So that kind of substitution language is
4 the way U.S. courts currently apply U.S. law.

5 South Africa doesn't have to apply
6 U.S. law, but I'm just pointing out that I
7 believe that that particular phrasing is
8 reflecting the law that we already have in our
9 own country. So no, I don't think it causes any
10 conflict as it doesn't here.

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

13 Next we have the Biotechnology
14 Innovation Organization. Welcome. Please begin
15 your testimony by stating your name and
16 organization for the record.

17 MR. PINE: Okay, great. Good morning.
18 My name is Justin Pine, I'm a patent attorney and
19 Senior Director at BIO.

20 BIO is the world's largest
21 Biotechnology Trade Organization with a
22 membership comprising more than 1,000

1 biotechnology companies. The vast majority of
2 our members are small-, medium-sized enterprises.
3 And they are increasingly looking to expand
4 globally.

5 I would like to in these brief
6 comments extenuate their perspective on the
7 issues raised in our submission. This
8 perspective is an important highlight given the
9 role these companies have in contributing to
10 local economies in so many parts of our country,
11 in the role they have driving innovation.

12 In the human health space, for
13 example, SMEs account for over 70 percent of
14 treatments in the global clinical pipeline.

15 Generally, it is becoming more
16 difficult for our companies to secure patents.
17 Particularly due to restrictive patentability
18 criteria, among other factors.

19 Furthermore, there are limitation on
20 companies' abilities to obtain regulatory data
21 protection for biologics. These are challenges
22 that cut across both developing and developed

1 economies.

2 Even after obtaining some meaningful
3 IP rights, countries identified in our submission
4 employ policies that significantly undermine the
5 value of IP assets. For example, countries
6 undermine IP rights by eliminating the
7 availability of enforcement mechanisms through
8 market access barriers, force localization
9 policies, and draconian price controls.

10 These policy challenges devastate the
11 emerging biotech sector, limiting the ability for
12 companies to expand globally and to continue
13 raising funds necessary to support their R&D
14 endeavors.

15 Perhaps most notable from our 301
16 submission this year compared to 2019 is how we
17 have elevated challenges in key developed
18 markets. Mainly Canada, Japan and South Korea.

19 These are countries where there is a
20 great expectation of having reasonable market
21 access for innovative IP protective products.
22 These developed countries with strong economies

1 and capacities of their own and high standards of
2 living should be at the forefront of nations
3 acting responsibility with appropriate evaluation
4 and reimbursement for biotech innovations.

5 For example, the Japanese and South
6 Korean governments' condition preferential
7 pricing policies on various performance
8 requirements, including localized manufacturing
9 and R&D joint partnerships with domestic firms.

10 SMEs lack the necessary resources and
11 pipeline to satisfy the localization requirements
12 and are thus excluded from the full pricing
13 premium. These policies effectively discriminate
14 against SMEs, hinder access to innovative
15 therapies and may encourage U.S.-based companies
16 to out-license early stage drug development,
17 transfer technology and intellectual property
18 assets, change prices in these countries in order
19 to ensure their innovative products are
20 appropriately valued.

21 Finally, compulsory licensing threats
22 loom in Malaysia without any apparent will to

1 resolve the issue in a fair and transparent
2 process for the rights holder. These tactics are
3 also being used in other countries, such as Chile
4 and Colombia.

5 Sadly, these compulsory licensing
6 mechanisms are not employed to solve actual
7 health emergencies or address exceptional
8 circumstances, but rather as an industrial policy
9 to promote the local pharmaceutical industries.

10 So with that I'll conclude. And I'd
11 like to thank USTR and the interagency for your
12 efforts, and I'll do my best to answer any
13 questions you may have.

14 CHAIR LEE: Thank you very much.
15 We'll start with USTR.

16 MR. EWERTD: BIO has requested that
17 USTR designate Canada, Japan, Malaysia and South
18 Korea as priority foreign countries. Can you
19 explain how the acts, policies and practices of
20 these countries are more problematic for your
21 members than countries you requested to be placed
22 on the priority watch list, such as China, India

1 and Russia?

2 MR. PINE: Sure. Well, as I mentioned
3 in my opening remarks, there's a higher
4 expectation in some regards when we're looking at
5 Canada, South Korea and Japan.

6 Malaysia, for example, sort of a
7 separate but significant issue for our sector
8 around compulsory licensing. Something that we
9 single out as well.

10 It's an issue that's been lingering
11 now for over a year without any movement.
12 Certainly hasn't been any -- much of a
13 transparent process to resolve the issue and so
14 that's why Malaysia is on as a priority foreign
15 country.

16 CHAIR LEE: All right, the next
17 question is from the U.S. Patent and Trademark
18 Office.

19 MS. BERDUT: Thank you. Regarding
20 India, BIO suggests the development of a
21 notification and early resolution mechanism for
22 patent disputes. Are the recent efforts to

1 facilitate notification via increased
2 transparency and cooperating sufficient or do you
3 have other specific recommendations?

4 MR. PINE: So, yes, one recommendation.
5 Generally that's mentioned several times in the
6 report is around patent linkage, mechanisms and
7 having some clear and transparent process by
8 which there is patent linkage with the regulatory
9 agencies and countries.

10 So that's one thing to consider.

11 Broadly speaking, not just for India.

12 CHAIR LEE: All right, thank you. The
13 next question comes from the State Department.

14 MS. DIFIORE: Thank you. Regarding
15 Korea's patent term restoration, or PTR process,
16 BIO's submission indicates that an apparel of the
17 BTR length may result in the loss of the entire
18 PTR.

19 Is this a recent concern and does BIO
20 know how many appeals result in the loss of the
21 entire PTR and the factors that result in the
22 loss?

1 MR. PINE: So, on that specific
2 detail, I'll have to -- I'd like to be able to
3 get back to you. I don't have details on that.

4 MS. DIFIORE: Absolutely. Thank you.

5 CHAIR LEE: All right, next I'd like
6 to turn to the Treasury Department.

7 MR. CHANG: As to China -- based on
8 the experience of your companies and on the
9 ground experience to date -- have you seen any
10 indications of changes to practices that are the
11 subject of concern in your submission?

12 MR. PINE: Certainly we have -- our
13 submission mentions a bit about the Phase 1
14 agreement and potential for that agreement to
15 address some of our concerns.

16 I think your question maybe goes to
17 more of the practical elements in terms of if
18 we're seeing anything. We haven't really seen
19 much yet in terms of policy changes in China. So
20 that's something that we'll continue to monitor
21 and look forward to collaborating with you all
22 on.

1 CHAIR LEE: Thank you very much for
2 your testimony. Next I'd like to invite the
3 representative -- or representatives -- from the
4 Brazil National Confederation of Industry and
5 American Chamber of Commerce in Brazil.

6 Thank you very much. If you could
7 please begin your testimony by stating your name
8 and organization -- or organizations -- for the
9 record. Thank you.

10 MS. PHILLIPS: Good morning. My name
11 is Leticia Phillips and I am a consultant for the
12 American Chamber of Commerce for Brazil, AmCham
13 Brazil.

14 Good morning, Assistant USTR Lee,
15 ladies and gentlemen on the Panel. Thank you for
16 the opportunity to come before you today to offer
17 our testimony on the Special 301 annual review.

18 My name is Leticia Phillips and I'm a
19 U.S.-based consultant for the American Chamber of
20 Commerce for Brazil, AmCham Brazil. And today I
21 speak on behalf of AmCham Brazil and its
22 partnering organization on this endeavor, the

1 Brazilian National Confederation of Industry,
2 CNI.

3 We have submitted detailed comments to
4 the record, but in the interest of time my
5 remarks today will be very brief.

6 I just wanted to call your attention
7 to five significant improvements in the IP system
8 and Brazil that has happened in 2019, which
9 illustrate the firm and longstanding commitment
10 of the private and public sectors in Brazil to
11 improve the intellectual property protection and
12 innovation environment in the country.

13 First, the Brazilian plan to fight
14 patent backlog. Brazil has launched, in 2019, a
15 comprehensive federal plan to reduce the patent
16 pendency by at least 80 percent by 2021 and to
17 issue patent final office actions, on average, in
18 less than two years from the designation request.

19 In the first six months of the plan,
20 backlog was already reduced by 18 percent, which
21 indicates that Brazil's National Institute for
22 Industrial Property, INPI, is on track to meet

1 its goal and to stand on equal footing with its
2 foreign counterparts.

3 Second point, U.S. and Brazil
4 implemented an expanded PPH agreement. On
5 December 1st, 2019, the United States Patent and
6 Trademark Office and Brazil's INPI put into
7 effect a new Patent Prosecution Highway agreement
8 that significantly expands their prior agreement.

9 Existing restrictions to applications
10 and the specific technological fields were lifted
11 and annual caps were increased. Such initiative
12 will contribute to fostering innovation and to
13 reduce patent backlog in the country.

14 Third, Brazil joining the Madrid
15 Protocol. Brazil has joined the WIPO-
16 administered international trademark system.

17 The Madrid Protocol has entered into
18 effect for Brazil on October 2nd, 2019 and will
19 lead to cheaper, less bureaucratic and more agile
20 procedures for trademark registration in the
21 country with positive spillover to the work
22 conducted by INPI.

1 Fourth, piracy and specialized IPR
2 enforcement units, the fight against piracy and
3 illicit trade was strengthened as a result of
4 intensive cooperation among the several Brazilian
5 enforcement units.

6 The National Council for Combating
7 Piracy and Crimes Against Intellectual Property
8 of the Ministry of Justice has spearheaded
9 enforcement operations in partnership with
10 several law enforcement units, resulting in
11 massive shutdowns of IPR-infringing websites,
12 apps and facilities.

13 Fifth, and last point, pro-IPR
14 judicial environment. The judicial courts have
15 clearly shown that Brazil is a pro-IPR
16 environment country.

17 On a leading case, the Brazilian
18 Superior Court of Justice has ruled in favor of
19 agricultural innovation in Brazil by
20 acknowledging that generic engineered products
21 are protected by patent -- by domestic patent
22 law.

1 Considering the relevant and
2 successful efforts undertaken by the Brazilian
3 public and business sectors in order to
4 strengthen the promotion, protection and
5 enforcement of IPR in Brazil, as well as the
6 intensified cooperation in the era of IP and the
7 trust building between the governments of Brazil
8 and the United States, we respectfully request
9 that Brazil be excluded from the watch list on
10 the next Special 301 Report.

11 Thank you for your attention. And
12 please count on AmCham Brazil and CNI as your
13 source of credible information regarding
14 Brazilian IPR systems. Thank you so much.

15 CHAIR LEE: Thank you. We have a few
16 questions, and we'll start with USTR.

17 MR. EWERDT: Your submission notes
18 that Brazil has strengthened its fight against
19 piracy and increased enforcement of IP
20 protection. Can you elaborate further on the
21 enforcement operations that you noted and the
22 cooperation between Brazilian enforcement units?

1 MS. PHILLIPS: Sure. I think we
2 submitted at least three operations. And I think
3 they are all coordinated by the Ministry of
4 Justice and with the use of the Federal Police of
5 Brazil. And depending on the raids, they have
6 coordination with the civil and military police
7 in the country.

8 I think one of the most important ones
9 was that in November of this past year, an
10 operation between the CNCP and the Secretariat of
11 Integrated Operations against digital piracy
12 resulted in 30 search warrants in 12 different
13 Brazilian states, 210 infringing websites and 100
14 infringing apps were taken down. And there were
15 many arrests.

16 This operation was also supported by
17 ANCINE, which is the Brazilian film agency.

18 Another very important operation was
19 Operation Copyright that took place in January of
20 last year, where Brazilian federal authorities
21 executed raids to seize computers and hardware
22 from administrators of notorious infringing

1 services called SpeedShare and private server
2 service Speedbox VR.

3 In this operation, these sites --
4 these combined sites attract 104 million annual
5 visits and more than four -- they had more than
6 400,000 registered users.

7 Criminal charges were presented
8 against SpeedShare Operations in September of
9 last year, totaling in 21 individuals involved.

10 I think that we can elaborate on more
11 of these operations to you and submit in the
12 post-hearing submissions.

13 CHAIR LEE: Thank you very much. The
14 next question is from ITA.

15 MR. MITCHELL: Oh yes, thank you for
16 your orderly presentation of the five
17 improvements. You mentioned that implementing an
18 expanded PPH agreement and acceding to the Madrid
19 Protocol are steps toward improving the IP
20 regime.

21 Do you have data to support the other
22 three areas of improvements that you've

1 highlighted fighting patent backlogs, cooperating
2 between enforcement units and implementing a
3 pro-IP judicial environment?

4 MS. PHILLIPS: I am sure that AmCham
5 and ANCINE in Brazil have that data, and if they
6 don't, they can go after that data and I will
7 follow up with the post-hearing submission to
8 you.

9 MR. MITCHELL: Thank you so much.

10 MS. PHILLIPS: You're welcome.

11 CHAIR LEE: All right, the next
12 question is from the Department of Health and
13 Human Services.

14 MS. BLEIMUND: Your submission
15 mentions that the INPI ANVISA interagency
16 ordinance -- number 10/2017 -- is an agreement
17 that helps expedite the examination of
18 pharmaceutical applications. Can you share with
19 us industry's response to the scope of ANVISA's
20 current role and whether it has affected the
21 approval of pharmaceutical patents?

22 MS. PHILLIPS: I unfortunately don't

1 have the details for you, but I'll be happy to
2 submit in follow-up comments.

3 MS. BLEIMUND: Sorry.

4 CHAIR LEE: Thank you. And I think we
5 have time for one more question. From the State
6 Department please.

7 MS. DIFIORE: Hi. You mentioned that
8 Brazil implemented the Madrid Protocol in October
9 2019 to provide more agile procedures for
10 trademark registrations.

11 Have you seen any notable results or
12 improvements in the past few months?

13 MS. PHILLIPS: Yes. We have seen that
14 the process for Brazilian brands and
15 international brands have been -- has speed up in
16 Brazil. And we are very happy to see that Brazil
17 finally joined, and this is filing to ---
18 enforcement in the country. And I'll be happy to
19 provide more comments for you in post-hearing
20 submissions.

21 MS. DIFIORE: Please. Thank you.

22 CHAIR LEE: Thank you very much.

1 MS. PHILLIPS: You're welcome.

2 CHAIR LEE: Next, I'd like to invite
3 the representative from BSA, The Software
4 Alliance.

5 Welcome. Please begin your testimony
6 by stating your name and organization for the
7 record.

8 MR. WHITLOCK: Thank you. My name is
9 Joseph Whitlock and I'm with BSA, The Software
10 Alliance.

11 BSA represents business software
12 companies and enterprise cloud computing service
13 providers active in the development of emerging
14 technologies, including artificial intelligence,
15 quantum and blockchain.

16 Our members make significant
17 investments in innovation and IPR in the United
18 States. BSA members invest over \$80 billion in
19 R&D in the United States annually.

20 The enterprise software industry is
21 highly IP intensive. BSA members accounted for
22 47 percent of all patents issued by the USPTO in

1 2018 to the top ten patent recipients, regardless
2 of country of origin. So that's including
3 non-U.S. entities.

4 Out of all of the American
5 headquartered companies in the top ten U.S.
6 patent grantees in 2018, BSA members accounted
7 for over 80 percent of the patents issued.

8 BSA members are also software
9 publishers and invest heavily in the creation of
10 copyrighted content, holding some of the most
11 valuable copyrighted innovations and productivity
12 tools in the world. And our members are numbered
13 among some of the most -- the world's most
14 valuable brands.

15 And why do I mention this? This is to
16 underscore the point that BSA members qualify as
17 United States persons who rely on intellectual
18 property protection.

19 The 301 statute has two prongs, as you
20 know. The denial of adequate and affective
21 intellectual property rights protection and the
22 denial of fair and equitable market access to

1 U.S. persons, like BSA members who rely on IPR
2 protection.

3 Instead of focusing on specific
4 countries for my testimony, I'd like to discuss
5 broad trends under both of these prongs. Under
6 the prong of IPR protection and enforcement, this
7 issue continues to be a serious challenge for
8 BSA.

9 In our 2018 Global Software Survey
10 that included 20,000 respondents, it was
11 determined that the commercial value of
12 unlicensed software is nearly \$50 billion
13 annualized.

14 Furthermore, the consequences of the
15 widespread use of unlicensed software around the
16 world are severe, causing --- resulting in an
17 estimate of over \$359 billion in damage from
18 malware every year.

19 With regards to the second prong
20 regarding market access -- fair and equitable
21 market access for U.S. persons who rely on IPR,
22 even as some countries around the world have

1 gradually improved elements of their IPR
2 protection regimes, we have seen a dramatic
3 worsening of other innovation-related market
4 access barriers.

5 We've seen a veritable explosion in
6 new types of barriers to innovation that simply
7 didn't exist four or five years ago. What I'm
8 referring to primarily, and predominately, are
9 barriers to the cross-border transfer of data and
10 data localization barriers.

11 And these barriers are barriers that
12 don't just affect BSA member companies, they
13 affect companies in every sector of the economy.
14 Any company with international operations is
15 affected by these types of barriers.

16 So that includes automotive,
17 aerospace, advance manufacturing, agriculture,
18 pharmaceuticals, film production and finance.

19 These barriers can prevent
20 multinational researchers and engineers from
21 collaborating in basic R&D to develop new
22 products, striking at the very heart of the

1 inventive process and the root of the innovation
2 cycle. These barriers interfere with the ability
3 to conduct clinical trials, like cross population
4 groups, undermining the search for tomorrow's
5 cures.

6 And this way they strike at the core
7 ability to invent and acquire IP rights. These
8 barriers also interfere or prevent companies from
9 identifying and servicing customers from
10 marketing products, from processing invoices.
11 And in this way they interfere with the enjoyment
12 of IP rights.

13 Five years ago there were very few, if
14 any, such barriers around the world. Today these
15 innovation barriers exist in China, Indonesia,
16 India, Vietnam, Russia and many other countries.

17 And I, unfortunately, predict that one
18 year from now the situation will be materially
19 worse than it is today.

20 Cross-border data transfers and data
21 localization barriers harm developing and
22 developed countries alike, undermine jobs and

1 efficiency and are a drag on innovation. And
2 most importantly, for our purposes, they deny
3 U.S. persons who rely on IPR fair and equitable
4 market access.

5 We respectfully submit that these
6 issues merit consideration and discussion in the
7 2020 Special 301 Report. Thank you for the
8 opportunity to testify today.

9 CHAIR LEE: Thank you very much. We
10 have a number of questions for you, and we will
11 start with USTR.

12 MR. EWERDT: BSA's submission
13 identifies the countries of Brazil, China, India,
14 Korea, Thailand and Vietnam as countries that
15 are, quote, using or proposing to use security
16 concerns to justify de facto trade barriers, end
17 quote.

18 Can you identify concrete parameters
19 for when security measures may be justified and
20 can you elaborate on how this trade barrier
21 directly impacts the protection of intellectual
22 property?

1 MR. WHITLOCK: Thank you. Let me
2 begin by answering this question in relation to
3 several of the countries that you mentioned, and
4 speak at a broader, principle-based level.

5 Security-related, cybersecurity
6 measures are a top priority for BSA and its
7 membership. A robust cybersecurity framework is
8 critical to building the trust of consumers and
9 of users alike across the innovation spectrum.

10 And BSA itself has developed a
11 cybersecurity framework to promote the most
12 robust software security development processes
13 possible.

14 The challenge is when cybersecurity
15 measures are used as disguised restrictions on
16 trade. This type of scenario will often arise in
17 circumstances in which a country may choose to
18 impose mandatory national standards that are at
19 odds with or inconsistent with internationally
20 accepted standards.

21 And so from a technical barriers to
22 trade perspective, these types of measures can

1 serve to exclude foreign competitors and to favor
2 domestic champions.

3 And I believe in our testimony we've
4 identified some of those cases, but we'll go
5 through it and make a supplementation after the
6 fact if that would be helpful.

7 MR. EWERTD: Can you elaborate on how
8 this trade barrier directly impacts the
9 protection of intellectual property?

10 MR. WHITLOCK: Yes. So, I think I
11 have to elaborate on the trade barrier in a
12 couple of different ways.

13 You asked about the protection of
14 intellectual properties. So to the extent that
15 measures that impose data transfer restrictions
16 prevent companies from transferring the results
17 of their R&D out of a country and back to cross-
18 border teams, it interferes with the ability to
19 conceive and reduce to practice and complete
20 patent applications, the ability to conduct core
21 R&D, the ability to, in some contexts, conduct
22 the type of R&D that's necessary to prove a

1 product safe and efficacious.

2 So that type of data barrier does
3 indeed directly affect the protection of IPR in
4 that context. But I think, just to elaborate --
5 expand a bit on the question, under the statute,
6 the focus is on barriers that affect U.S. persons
7 who rely on intellectual property rights,
8 barriers that impact the fair and equitable
9 market access to countries around the world.

10 And that's a much broader standard
11 than simply the impact of data barriers on
12 intellectual property itself.

13 CHAIR LEE: Thank you very much. The
14 next question comes from the Treasury Department.

15 MR. CHANG: Okay. So, BSA recommends
16 Argentina be moved from priority watch list to
17 watch list, but BSA does not note improvements
18 that its members have seen in Argentina over the
19 past year.

20 Can BSA provide some examples on how
21 Argentina's IP has improved and why it should be
22 moved to the watch list?

1 MR. WHITLOCK: We will provide a
2 supplementation in writing to that effect.

3 CHAIR LEE: Okay, I think we have time
4 for one more question from the U.S. Copyright
5 Office.

6 MR. WESTON: Hi. BSA notes that,
7 quote, data suggests that the use of unlicensed
8 software by enterprises is declining in Korea.
9 But you still remain concerned about, quote,
10 persistent under-licensing of software in a
11 variety of sectors and industries, end quote.

12 Is there data available that supports
13 these concerns, or can you elaborate on what is
14 precisely triggering these concerns?

15 MR. WHITLOCK: In regards to the
16 statistical questions regarding specific sectors,
17 I will have to supplement on that.

18 I would note that our recommendation
19 with respect to Korea's status relates to the
20 variety of trade barriers and IP protection and
21 enforcement concerns. And the data-related trade
22 barriers in Korea are significant.

1 CHAIR LEE: Thank you very much for
2 your testimony.

3 The final testimony we have before the
4 lunch break is from the China Chamber of
5 International Commerce. If the representative or
6 representatives could come up, that would be
7 great.

8 Welcome. Please begin your testimony
9 by stating your name and organization.

10 MS. LIU: Sure. Thank you so much.
11 Mr. Chairman, members of the Special 301
12 Subcommittee, my name is Siyao Liu,
13 representative of the China Chamber of
14 International Commerce, CCOIC.

15 Thank you for the opportunity for me
16 to testify here today. CCOIC is a national
17 organization in China with more than 240,000
18 members covering various sectors.

19 Our main functions include promoting
20 international economic and trade cooperation,
21 expressing interests and concerns of Chinese
22 business stakeholders to international

1 organizations and Chinese and foreign
2 governments, participating in the formulation and
3 promotion of international economic and trade
4 rules and advocating social responsibilities and
5 good practices among its members.

6 This is the third time that we have
7 participated in the Special 301 review
8 proceeding. We are pleased to see that the USTR
9 in the 2019 Special 301 Report affirmed the key
10 developments of China in the field of
11 intellectual property in 2018.

12 However, we regret to note that there
13 are still some misunderstandings of Chinese
14 regulations, judiciary and enforcement or related
15 policies for protecting intellectual property.
16 And USTR fails to fully consider our submission.

17 We and our members have intuitive
18 feelings and experienced the substantial progress
19 that China has made in respect of protection of
20 intellectual property rights. Particularly in
21 recent years.

22 Through this hearing we wish to assist

1 the U.S. government to gain a more comprehensive
2 and accurate understanding of China's
3 intellectual property rights protection, law
4 enforcement and the related market access. And
5 therefore, to make a more objective and fair
6 assessment of the same.

7 We believe an objective and impartial
8 assessment of China's IP protection is important
9 for China and the United States to carry out
10 constructive cooperation in the field of
11 intellectual property rights, which will in turn
12 benefit the people of both countries.

13 As we have elaborated in our written
14 comments submitted in February, since 2019, China
15 has made even greater achievements in providing
16 legal protection for domestic and foreign IP
17 routers, including those from the United States.

18 We therefore appeal to the USTR to
19 remove China from the priority watch list in the
20 2020 Special 301 Report.

21 First, China attaches great importance
22 to IP protection. President Xi Jinping has

1 explicitly emphasized the importance of IP
2 protection on many occasions.

3 He stressed that China would intensify
4 efforts to enhance international cooperation in
5 IP protections, focus on creating the business
6 environment that respects the value of knowledge,
7 fully improve the legal framework for protecting
8 IP, enhance the protection of lawful rights and
9 interests of foreign IP owners, eradicate the
10 forced technology transfer and improve protection
11 of trade secrets.

12 Second, China makes outstanding
13 progress in legislation of IP. The new trademark
14 law takes effect on November 1st, 2019, which
15 strengthens the crackdown on malicious trademark
16 registration and increases the punitive
17 compensation for trademark infringements.

18 The regulations on patent agency and
19 the guideline for patent examination came into
20 effect, which are beneficial to support
21 enterprises innovation, lighten the enterprises
22 and stimulate market vitality and creativity.

1 The Anti-Unfair Competition Law is
2 amended that electronic intrusion is included as
3 one of the means of infringement and the acts of
4 abetting, seducing and helping others to obtain
5 trade secrets is also included in the acts of
6 infringing trade secrets.

7 The Foreign Investment Law prevents
8 the compulsory transfer of technology in the way
9 of technical cooperation and protects the IP
10 rights of foreign investors and foreign invested
11 enterprises.

12 Third, the level of administrative
13 enforcement of IP rights continues to improve.
14 2019 is the first year after the reform of
15 China's IP enforcement system.

16 In order to strengthen the enforcement
17 of IP rights and severely crack down on
18 violations of IP rights, such as trademarks,
19 patents, copyrights and geographical indications
20 while strengthening the supervision of
21 enforcement.

22 The State Intellectual Property Office

1 launches a series of special actions, such as
2 Thunder, Escort, traceability and a purification.

3 Besides, the National Copyright
4 Administration jointly launched its fourth 2019
5 special action with the other three departments
6 to crack down on online infringement and piracy,
7 which deter malicious infringement and
8 counterfeiting and constantly optimize the
9 environment for IP protection.

10 Sir, may I have some -- like one or
11 two more minutes?

12 CHAIR LEE: If you could try to wrap
13 up --

14 MS. LIU: Yes.

15 CHAIR LEE: -- in the next 30 seconds
16 please.

17 MS. LIU: Sure. Fourth, the judiciary
18 protection of IP rights continues to increase.

19 In order to further implement the
20 requirements of improving the trial system for IP
21 and optimize allocation of judiciary resources,
22 required by the outline of the National

1 Intellectual Property Strategy, the Supreme
2 People's Court of China set up the IP Court and
3 began to informally hear appeal cases of
4 professional and technical IP civil and
5 administrative cases on a national scale, on
6 January 1st, 2019.

7 Fifth, China continues to ease the
8 market access for foreign investments. The
9 Foreign Investment Law emphasizes the management
10 of areas other than the active list of foreign
11 investments in accordance with the principle of
12 equal treatment to domestic and foreign
13 investors.

14 Sixth, the first phase of single U.S.
15 trade and negotiation has reached a preliminary
16 agreement. China and the United States signed
17 the economic and trade agreements between the
18 government of the U.S. and the government of
19 China on January 5th, 2020.

20 In particular, certainly proper
21 arrangements have been made in the agreements on
22 IP issues confirmed by the United States in the

1 report, such as trade secrets, patent and
2 pharmaceutical related IP, geographical
3 indications, piracy and counterfeiting in
4 ecommerce platforms, enforcement against the
5 pirated and the counterfeit ones and technology
6 transfer.

7 We hope that USTR will give full
8 consideration to China's commitment in the
9 agreement and respect the achievements of China
10 and the U.S. in the first phase of trade
11 negotiation. Thank you for your time.

12 CHAIR LEE: Thank you. Just as a
13 general announcement, just to remind people of
14 the format, it is five minutes for testimony so
15 that we can have five minutes for panel
16 questions. To the extent that testifiers can
17 stick to that, I think that would be helpful for
18 the panel to be able to have a chance to ask
19 questions to gain further information.

20 With that, I would like to turn first
21 to USTR for the first question. Thank you.

22 MR. EWERDT: Your written submission

1 mentions China's counterfeiting hotline. Are
2 there statistics on the number of complaints that
3 are made to this hotline and the resolution of
4 each complaint?

5 MS. LIU: Thank you for the question.
6 We will provide a detailed and complete response
7 to that question in the post-hearing submission.

8 CHAIR LEE: Thank you. The next
9 question is from ITA.

10 MR. MITCHELL: U.S. parties report
11 that enforcement of IP rights in China has become
12 increasingly difficult with the rise of ecommerce
13 platforms. What efforts are the Chinese
14 government making to prevent the sale and
15 distribution of counterfeit goods through these
16 platforms?

17 MS. LIU: Thank you for the question.
18 Again, we will provide some detailed response in
19 the post-hearing submissions. Thank you so much.

20 CHAIR LEE: Thank you. The next
21 question comes from the State Department.

22 MS. DIFIORE: Hi. CCOIC notes that

1 China may compel licenses from foreign parties
2 through its standards regime. Will these Chinese
3 national standards deviate from international
4 standards and international standards pricing?

5 MS. LIU: Thank you. So as to the
6 Chinese standards we will, again, provide more
7 detailed information in the post-hearing
8 submissions. Thank you.

9 CHAIR LEE: All right, thank you. And
10 one final question is from the U.S. Patent and
11 Trademark Office.

12 MS. BERDUT: Thank you. In your
13 opinion, where can improvements be made to
14 China's judicial system to ensure timeliness,
15 fair judgement and compliance with intellectual
16 property verdicts?

17 MS. LIU: Thank you for the question.
18 We will, again, provide the information in the
19 post-hearing submissions. Thank you.

20 CHAIR LEE: Thank you very much for
21 your testimony.

22 At this time, we will be breaking

1 until 1:45 p.m. So you're free to take a short
2 break.

3 I would like to remind everyone that
4 security procedures do take a little bit of time,
5 and that we will be starting promptly at 1:45, so
6 please take that into account when you return.

7 Thank you.

8 (Whereupon, the above-entitled matter
9 went off the record at 12:24 p.m. and resumed at
10 1:45 p.m.)

11 CHAIR LEE: Good afternoon, everyone.
12 I'd like to reconvene, as promised, at 1:45.
13 Because there's been some people who were not
14 here this morning, I just want to quickly go over
15 the format again.

16 Each party has been allotted ten
17 minutes. We'll start with five minutes of
18 prepared statements, leaving five minutes for
19 Panel questions.

20 We will try to remain flexible, but,
21 again, with the purpose of trying to give the
22 Panel as much information, the Subcommittee as

1 much information as possible, we'd like to try to
2 stick with the five minutes and five minutes.

3 So, with that, we will pick up with
4 the Computer and Communications Industry
5 Association. Please come forward, and once you
6 settle in, please state your name and
7 organization for the record and begin your
8 testimony.

9 MS. STELLY: Thank you. Good
10 afternoon, my name is Rachael Stelly and I serve
11 as a policy counsel for the Computer and
12 Communications Industry Association. Thank you
13 for this opportunity to convey CCIA's views in
14 regards to the 2020 Special 301 Report.

15 CCIA is a trade association of
16 internet and technology firms, many of whom
17 export goods and services that are regulated by
18 the domestic IP laws of our trading partners.

19 Additionally, as rights holders, CCIA
20 members value intellectual property protection
21 and the need for adequate protection enforcement
22 measures. These provisions include that prohibit

1 mandatory disclosure of source code and other
2 propriety data.

3 These strong U.S. exporters are
4 discouraged from entering new markets that lack
5 IP rules that enable innovation and reduce legal
6 uncertainty.

7 A strong intellectual property system
8 is one that reflects the needs of all
9 participants in the content creation, discovery,
10 and distribution supply chains.

11 The U.S. should promote policies that
12 reflect this needed dynamic, including through
13 U.S. free trade agreements and increased
14 discussions with key trading partners.

15 In particular, the U.S. should
16 continue to build upon the success of the U.S.-
17 Mexico-Canada Agreement to open markets for IP-
18 reliant digital services.

19 The USMCA should continue to be the
20 gold standard going forward in planning trade
21 talks with the UK, EU, and Kenya, and the U.S.
22 should replicate provisions in the IP Chapter

1 that reflect U.S. law regarding copyright safe
2 harbors.

3 These provisions on copyright
4 intermediary liability are important to guard
5 against distortive liability measures coming out
6 of the EU, which I will touch upon in these
7 remarks.

8 It is also important that any
9 discriminatory practices under the guise of
10 intellectual property that target U.S. exporters
11 should be identified and discouraged through
12 annual reports, including both the National Trade
13 Estimates Report and the Special 301 Report.

14 The remainder of my remarks will
15 discuss two key themes addressed in CCIA's
16 written submission. First, the need for USTR to
17 support comprehensive implementation of
18 intermediary liability protections abroad, and
19 second, the continued concern about the rise of
20 ancillary rights in foreign markets, including
21 the now EU-wide press publishers' right.

22 First, the Special 301 process should

1 address departures from international norms
2 regarding online copyright intermediary liability
3 protection.

4 U.S. firms operating as online
5 intermediaries, effectively almost all popular
6 internet services, face an increasingly hostile
7 environment in a variety of international
8 markets, impeding U.S. internet companies from
9 expanding services abroad.

10 These adverse conditions manifest
11 through court decisions and new copyright
12 regulations targeting U.S. firms.

13 For example, the EU Copyright
14 Directive, finalized in 2019, places unreasonable
15 and, in some cases, technically impractical
16 obligations on a wide range of service providers,
17 including filtering obligations. Implementation
18 of the Directive in the EU member states in
19 upcoming months will result in a loss of market
20 access by U.S. firms.

21 The Special 301 process serves as a
22 valuable tool to identify areas where liability

1 rules fall short and USTR should identify
2 failures to implement a clear and predictable
3 intermediary liability regime that provides all
4 stakeholders an adequate process for protecting
5 content without overburdening internet services.

6 Second, CCIA raises concerns regarding
7 the spread of ancillary copyright in foreign
8 markets in the form of a new press publishers'
9 right and related regulatory initiatives. These
10 provisions contravene international copyright
11 commitments.

12 As CCIA has noted previously,
13 ancillary protection is a violation of
14 international copyright obligations under the
15 Berne Convention regarding freedom of quotation.

16 Studies have concluded that the
17 creation of these new rights is not likely to
18 achieve the desired goals of proponents by
19 examining previous unsuccessful national attempts
20 to establish these rules, such as in Spain and
21 Germany.

22 Despite this, the EU moved forward

1 with the EU-wide press publishers' right in the
2 recent Directive. CCIA written comments go into
3 further details regarding recent country
4 implementation proposals pursuant to the
5 Directive and concerns regarding fragmentation
6 across member states.

7 Before concluding, I'd also like to
8 briefly note the importance of other countries
9 developing fair use style measures that are
10 reflective of U.S. law.

11 CCIA strongly encourages USTR to
12 reject arguments that seek to undermine
13 countries' pursuit of similar rules, such as the
14 case with South Africa's recent changes to its
15 own copyright law.

16 In conclusion, the Special 301 process
17 should place greater emphasis upon discriminatory
18 practices directed at U.S. internet services that
19 create new rights for domestic industries.

20 When countries fail to implement norms
21 that facilitate digital trade or fail to adhere
22 to commitments made to protect them, U.S. export

1 opportunities can be lost.

2 Discriminatory practices under the
3 guise of intellectual property that target U.S.
4 exports should be identified and discouraged by
5 USTR in the 2020 Special 301 Report.

6 Thank you very much and I look forward
7 to your questions.

8 CHAIR LEE: Thank you very much. We'll
9 start with questions with USTR.

10 MR. EWERDT: CCIA lists the European
11 Union as a region of concern in your submission.
12 Are you recommending that individual EU member
13 countries be listed in the Special 301 Report or
14 that the EU itself be listed? And if so, for
15 what statutory reasons?

16 MS. STELLY: Thank you for the
17 question. CCIA's written comments don't
18 recommend placing any countries on specific watch
19 lists, we don't take a position on that.

20 Our comments identify both the EU, but
21 then, we've also raised concerns with how
22 countries have started implementing the

1 Directive, including France.

2 And I'm happy to provide further
3 comments on how other countries are looking to
4 implement key parts of the Directive in post-
5 hearing comments.

6 CHAIR LEE: Thank you very much. Next,
7 we have a question from the State Department.

8 MR. FAHMY: Hello. Regarding China,
9 can you describe your concerns about the e-
10 commerce law and what impact you've seen since
11 the law's entry into force?

12 MS. STELLY: Thank you for that
13 question. I'll have to clarify in our post-
14 hearing comments on that. Thank you.

15 CHAIR LEE: All right. And we have a
16 question from the U.S. Copyright Office.

17 MR. WESTON: Thank you. CCIA's
18 submission claims that Australia is not upholding
19 its obligation to provide liability limitations
20 for service providers, as outlined in the U.S.-
21 Australia Free Trade Agreement.

22 Can you elaborate on how, in your

1 view, Australia is not upholding its FTA
2 obligations?

3 MS. STELLY: Thank you for that
4 question. We've raised concerns with Australia
5 for a number of years regarding their failure to
6 fully comply with the provisions in the U.S.-
7 Australia Free Trade Agreement.

8 From our understanding and our
9 reading, this is something that the Australian
10 government has also acknowledged, that the
11 provisions that have sought to implement the
12 intermediary law obligations in the Free Trade
13 Agreement don't go far enough to include all
14 services that are covered under this Agreement.

15 So, it only refers to what they refer
16 to as carriage service providers, and that's not
17 as expansive as what's required in the Free Trade
18 Agreement. And it's also not as expansive as
19 what is outlined in U.S. law.

20 CHAIR LEE: Thank you. And a final
21 question from ITA.

22 MR. MITCHELL: Your submission, as well

1 as your testimony, called for the need for USTR
2 to support comprehensive implementation of
3 intermediary liability protections abroad,
4 particularly where required by free trade
5 agreements.

6 Can you identify a particular
7 instances or countries in which you think USTR
8 could have made more robust efforts in supporting
9 comprehensive implementation of intermediary
10 protections?

11 MS. STELLY: Thank you for that
12 question. As I mentioned in response to the
13 previous question, we think Australia is an area
14 where there is a failure to fully comply with the
15 intermediary protections in the Free Trade
16 Agreement.

17 Our comments also identify Colombia as
18 well, as having not fully complied with the
19 intermediary obligations.

20 And then, in addition, to follow up on
21 the Australia as well, Australia had an
22 opportunity, they recently amended their

1 copyright law on the intermediary protections,
2 but they failed to fully go far enough that makes
3 them compliant with the FTA obligation.

4 CHAIR LEE: All right. Thank you very
5 much. Next, we have the Consortium for Common
6 Food Names. Thank you. Please begin by stating
7 your name and organization for the record.

8 MS. MORRIS: Sorry, redo. Shawna
9 Morris, with the Consortium for Common Food
10 Names. Thank you for having me here today.

11 The Consortium for Common Food Names
12 appreciates the opportunity to bring attention to
13 trade barriers harming our members. My testimony
14 today will highlight in particular the European
15 Union's aggressive campaigns to stifle trade
16 through the misuse of geographical indications.

17 The U.S. government has long worked to
18 thwart the EU's efforts to monopolize the use of
19 common food names. We strongly urge a continued
20 opposition to the EU's misuse of GIs to impair
21 competition and call for the importance of
22 deploying an expanded set of tools to most

1 effectively counter their protectionist policies.

2 I'd like to begin by asking you to
3 consider how often you yourselves rely on
4 everyday product terms to make purchasing
5 decisions. And that's part of why I have, not
6 samples, but props here with me today.

7 When you go to the grocery store to
8 find ingredients for a recipe, do you usually
9 look for the products that it actually calls for
10 or pick unfamiliar terms and simply hope they'll
11 work out?

12 As you stock your cart with wine for
13 a party that you're hosting, do you use the
14 common names of wine types, varietal terms like
15 Cabernet, Chardonnay, and Pinot Noir, to help you
16 select which bottles to purchase, particularly if
17 you're trying a new winery?

18 And when you look at a menu and pick
19 a salad or a burger, do you check out the type of
20 cheese on it in deciding whether to keep it or
21 request a substitution of that product?

22 Now, imagine doing each of those with

1 terms you've never heard of, particularly if your
2 waiter isn't familiar with the novel word either
3 or there's no cheese or wine expert at your local
4 grocery store to quiz about what an unfamiliar
5 product might taste like.

6 Food manufacturers, importers,
7 distributors, retailers, restaurants, and
8 consumers, all these groups rely heavily on the
9 use of numerous generic terms to make sense of
10 what products to purchase and what consumers are
11 likely to prefer as well.

12 The EU's common refrain that the U.S.
13 should just abandon the use of common food names
14 dramatically understates the challenge that U.S.
15 companies would face in abiding by a gag order.
16 Such restrictions amount to far more than simply
17 the cost of creating and printing new labels.

18 Rather, it would represent a ground-up
19 reeducation process, forcing non-European
20 competitors to splinter their collective efforts
21 to build consumer awareness around a common
22 product category, while EU producers would

1 continue to reap the rewards of decades of
2 investments by others.

3 Over the past several years, the EU
4 has erected numerous non-tariff trade barriers
5 under the guise of registering its geographical
6 indications.

7 Those barriers impose unjustified
8 restrictions that seek to eliminate competition
9 from American-made goods. They're detailed in
10 our written comments.

11 This campaign is as deliberate as it
12 is destructive and effectively combating it will
13 require continued vigilance and a coordinated
14 U.S. government effort.

15 We commend USTR for recognizing the
16 serious threat these trade barriers represent in
17 the 2019 Special 301 review, which called
18 attention to the EU's highly concerning GI
19 agenda.

20 We also appreciate the actions the
21 U.S. has taken so far to protect American jobs
22 and the legitimate rights of food manufacturers,

1 farmers, and exporters.

2 However, the EU has made it clear it
3 will continue its government-driven efforts to
4 expand these restrictions and the U.S. government
5 must use all tools at its disposal to boldly
6 advance common name safeguards in the strongest
7 manner possible.

8 To most effectively do so, we urge the
9 U.S. government to expand its actions in the
10 coming year to keep doors open around the world
11 for fair competition and secure explicit
12 commitments assuring the future use of specific
13 generic food and beverage terms targeted by EU
14 monopolization efforts in order to reject the use
15 of GIs as barriers to trade.

16 Specifically, we encourage you to
17 build upon the type of framework established in
18 USMCA, whereby market access rights were clearly
19 affirmed for a non-exhaustive list of commonly
20 used product names.

21 We appreciate the administration's
22 clear and determined focus on pursuing a level

1 playing field for U.S. companies and on tearing
2 down trade barriers that hinder U.S.
3 competitiveness.

4 We look forward to continuing to
5 partner together in order to keep markets open
6 for American-made products. Thank you.

7 CHAIR LEE: Thank you. We will start
8 with questions with USTR.

9 MR. EWERTD: Can CCFN provide an
10 estimated dollar value for the impact of the EU's
11 global GI policies on U.S. industry? Or can CCFN
12 provide a dollar value for losses in specific
13 markets, such as Canada, Japan, or Korea, where
14 the EU has established an FTA with GI
15 protections?

16 MS. MORRIS: Thank you for that. We'd
17 be happy to submit as follow-up to the hearing
18 the answers on the specific markets that you
19 cited.

20 Globally, we conducted a study last
21 year that estimated the impact of restrictions on
22 the broad range of names being targeted, only in

1 the cheese sector alone, if they were to be put
2 in place, both globally and the U.S., on the
3 order of \$20 billion.

4 Certainly, we view the toll that the
5 logical conclusion of what the EU is working to
6 put in place is quite significant, both here at
7 home and around the world.

8 CHAIR LEE: Thank you. The next
9 question is from USDA.

10 MR. WERESZYNSKI: In your submission,
11 you raise concerns regarding the ongoing EU-
12 Australia FTA. You noted that, as part of the
13 negotiations, Australia published a list of EU
14 GIs for opposition.

15 Have your members experienced
16 difficulty during this opposition process? And
17 if so, what?

18 MS. MORRIS: The difficulty our members
19 have experienced is simply the fact that they're
20 having to point out the obvious.

21 The vast majority of the terms at
22 issue during the opposition process, which saw, I

1 believe, over 400 oppositions submitted into the
2 Australian government, are already generically
3 used in the Australian market.

4 These are terms that, whether
5 Australian or U.S., companies shouldn't have had
6 the burden to prove should remain generic. These
7 should have been terms that the Australian
8 government took the burden upon themselves to
9 clearly and up front indicate no restrictions
10 would be imposed and make clear that those were
11 off the table at the outset.

12 Australia has a fully functioning
13 intellectual property process for trademarks,
14 which includes GIs, and that avenue is the one
15 that should be being used by EU GI applicants
16 instead.

17 CHAIR LEE: Thank you. The next
18 question is from ITA.

19 MR. MITCHELL: Can CCFN provide any
20 examples of products that have been blocked due
21 to the EU's traditional specialty guaranteed
22 program?

1 MS. MORRIS: Not at this time. This is
2 an area that, at this point in the process, we
3 have continued to monitor, since we have seen
4 what's happened with the geographical indications
5 program and the newly, as of a few years ago,
6 restrictive nature of the traditional specialties
7 guarantee program indicates we may see similar
8 barriers in the future.

9 One that we had been particularly
10 concerned about included a TSG for mozzarella.
11 That appears to be grandfathered in to not be
12 location-specific, which we appreciate.

13 So, we'll continue to keep an eye on
14 it and keep the interagency committee informed if
15 that changes. Thanks.

16 CHAIR LEE: Great. We have the next
17 question from PTO.

18 MS. FERRITER: Thank you. In your
19 submission, you note that in 2016, Indonesia
20 issued text proposing changes to its GI
21 regulations and that the proposal contained a
22 number of highly troubling provisions with

1 penalties and scope that appear to be even more
2 draconian than those employed in the EU.

3 Have these proposed changes been
4 finalized? Can you further explain how the
5 proposals are more draconian than the EU's GI
6 regime?

7 MS. MORRIS: Thank you. The EU's GI
8 regime, for all the faults it has, at least on
9 paper, has an application and opposition process.
10 Whether that's legitimately followed or not,
11 we'll set aside. But those are some of the
12 failings that we noted in the Indonesia system as
13 well.

14 In particular, the draconian pieces,
15 I believe related to the outsized degree of
16 penalties, including jail time for violations,
17 that we thought, frankly, would pose very
18 significant burdens, particularly on this topic,
19 where companies often are quite surprised to find
20 out that terms that they viewed as generic are in
21 fact restricted in a market, when they've been
22 operating in good faith.

1 We, unfortunately, are not aware of
2 what the final version of that looks like at this
3 point.

4 CHAIR LEE: Thank you very much for
5 your testimony.

6 MS. MORRIS: Thank you.

7 CHAIR LEE: Next, we have the Footwear
8 Distributors and Retailers of America. Welcome.
9 Please begin your testimony by stating your name
10 and organization for the record.

11 MR. PRIEST: My name is Matt Priest,
12 I'm the President and CEO of the Footwear
13 Distributors and Retailers of America.

14 FDRA is the footwear industry's trade
15 and business association. We represent the
16 industry and we come here every single year to
17 testify at this important hearing and we're
18 grateful for the opportunity to be here again
19 today.

20 I'd like to highlight several global
21 IP trends and touch on some of the themes of our
22 written submission, and then, kind of talk more

1 about the China issue just after that.

2 Now, with the significant rise of e-
3 commerce, footwear companies have seen a
4 substantial increase in both unauthorized sales
5 and counterfeiting.

6 Brands usually have little information
7 on these offenders, because platforms generally
8 do not share the information they have on these
9 sellers with the rights holders and it is
10 impossible for brands to get in touch with each
11 and every online seller suspected of selling
12 counterfeits to ask for additional information
13 and pictures.

14 We appreciate the administration's
15 efforts to address this key issue, including the
16 release of recommendations by the Department of
17 Homeland Security in accordance with the
18 President's April 2019 Memorandum on Combating
19 Trafficking in Counterfeit and Pirated Goods.

20 We look forward to working with the
21 administration on these efforts, including ways
22 to increase enforcement, as well as better inform

1 consumers on the prevalence of counterfeit goods
2 sold online.

3 And for this 2020 Special 301 Report,
4 we encourage the Committee to closely examine the
5 ways in which current e-commerce channels
6 directly impact IP protection and enforcement
7 globally.

8 Moreover, counterfeiters currently
9 take advantage of a loophole to evade CBP by
10 shipping labels and trademark tags separately
11 from infringing products and attach them to the
12 infringing products in the U.S. to avoid seizure
13 by Customs.

14 If the labels are seized by Customs,
15 the more valuable fake shoes still get in,
16 because under current law, Customs is authorized
17 to seize counterfeit trademark shoes, but cannot
18 seize a shoe that is clearly a copy of a
19 trademark shoe absent the presence of a logo or
20 distinguishing tag.

21 Bipartisan legislation, S.2987, the
22 Counterfeit Goods Seizure Act of 2019 has been

1 introduced in the Senate, that will directly
2 address this issue by giving Customs authority to
3 seize based on design patent infringement.

4 A number of countries already do this,
5 such as Mexico, Japan, South Korea, and the
6 European Union. So, we urge the administration
7 to work with Congress to enact this legislation
8 as soon as possible to give Customs authority to
9 address this critical issue for footwear
10 companies and consumers.

11 In addition, there are enforcement
12 gaps that still are prevalent. Infringers often
13 use express mail and postal services to deliver
14 counterfeit goods in small packages. This makes
15 it more challenging for enforcement officials to
16 confiscate these goods.

17 When Customs and Border Protection
18 seizes counterfeit products and alerts the rights
19 holders, the rights holders, in many cases, never
20 go further than the seizure of the product,
21 because of a lack of information. We need better
22 information sharing.

1 Customs officials may lack sufficient
2 training or knowledge to consider trade duress as
3 a basis for seizure. In today's 21st century
4 retail environment, the way that a brand presents
5 a shoe, from its appearance to its packaging, is
6 a critical part of the customer experience.

7 Moreover, I think a general theme for
8 all the countries that we talk about in our
9 submission, and we do not recommend one way or
10 the other how you should rank them in your
11 report, there are a number of trends that are
12 prevalent across many of them.

13 One, penalties are often inadequate to
14 deter criminal enterprises for engaging in
15 trademark counterfeiting operations. At times,
16 the judicial systems in developing nations lack
17 transparency and independence, making it
18 difficult for rights holders to pursue claims.

19 Counterfeiters now commonly register
20 domains that advertise and sell counterfeit
21 goods. Many of these counterfeiters use a
22 country code top-level domain to avoid detection

1 and to avoid the reach of the U.S. judicial
2 system.

3 The theft of trade secrets has become
4 an increasingly important issue for global brands
5 because, at times, foreign governments are either
6 complicit in or even participate in the theft of
7 trade secrets.

8 So, lastly, with my one minute left,
9 I'm going to pivot to the China agreement. We
10 believe the Phase 1 trade agreement with China is
11 an important first step, absolutely, to get the
12 Chinese to agree to a number of different
13 provisions that we've been calling for, and many
14 others have been calling for, for quite some
15 time, was an important first step.

16 We hope the administration will work
17 quickly on Phase 2, so that, one, we can
18 eliminate footwear tariffs, I know not the
19 purview of this body, but also, further
20 strengthen IP protection in China.

21 This is key for U.S. footwear
22 companies, because China has a dynamic and

1 growing market of footwear consumers and they're
2 eager to buy U.S. brands and it serves as a key
3 footwear production hub and a design center for
4 many of our brands.

5 China has also integrated the use of
6 technology and e-commerce at an incredible pace
7 and scope to deliver products to Chinese
8 consumers. Today, this vast Chinese market
9 involves nearly one-fifth the world's population,
10 as we know.

11 Now, China has made a number of
12 significant improvements in its protection and
13 enforcement of IP rights. And now, we're
14 entering a critical phase, as the Phase 1
15 agreement takes hold and we start to implement
16 the agreement.

17 It's really important the
18 administration holds the Chinese feet to the
19 fire, to their commitments on this, because we
20 are excited about what they've agreed to, but it
21 all comes down to enforcement, which I know is a
22 priority of the Trump Administration.

1 So, with that, I'll pause there and
2 welcome any questions that you might have.

3 CHAIR LEE: Thank you. We'll begin
4 with questions with the USTR.

5 MR. EWERDT: Can you give us an idea of
6 the estimated loss in dollar value to American
7 workers and American businesses in the footwear
8 industry due to the proliferation of counterfeit
9 goods on e-commerce platforms?

10 MR. PRIEST: Yes, it's a great
11 question. We've never put a number to it, but it
12 is in the multiple billions of dollars.

13 The challenge that we have is with the
14 platforms, and I think the administration has
15 done a really good job of thinking through how
16 the platforms can be more responsible as they
17 move goods around and deliver those goods to
18 consumers.

19 But the fact of the matter is, every
20 day, we have multitude of examples where you
21 cannot tell from one shoe to the next if one's
22 counterfeit and one's not.

1 We have orthotic inserts, we have a
2 company that has orthotic inserts that have been
3 counterfeited and are sold on e-commerce
4 platforms in the United States. These are for
5 health and safety.

6 So, it's vitally important that as an
7 organization, as an industry, that we work with
8 the administration, particularly as DHS has
9 pointed out in its report, on public awareness
10 and consumer awareness and working collectively
11 across a variety of different industries to
12 ensure the public understands that just because
13 it was fulfilled by said platform services,
14 fulfillment services, does not mean that it's a
15 legitimate good.

16 And so, my hope is that this report,
17 the memorandum the President put out last year,
18 and then, the subsequent reports will continue to
19 drive conservation in a positive way, and I think
20 we're seeing that, the fruit of that labor.

21 CHAIR LEE: Thank you. Speaking of
22 labor, the next question comes --

1 MR. PRIEST: Nice.

2 CHAIR LEE: -- from the Department of
3 Labor.

4 MS. KHAN: Thank you.

5 MR. PRIEST: Sure.

6 MS. KHAN: In your written testimony,
7 you state that China is the number one source of
8 counterfeit and pirated goods imported into the
9 United States, with best-selling knockoff
10 footwear from best-selling American brands.

11 And you further state that the
12 provinces of Guangdong, Zhejiang, and Fujian pose
13 particular challenges for footwear brands,
14 because all three are major footwear hubs,
15 producing both legitimate footwear, as well as
16 counterfeit products.

17 With respect to the production of
18 counterfeit products, can you give us any idea,
19 either by percentage or dollar value, of the
20 losses that your members are facing from
21 counterfeit footwear production in China?

22 MR. PRIEST: Yes, that's a really good

1 question. And again, I think it's in the
2 billions of dollars, because I think that the
3 prevalence of these brands globally is so easy
4 now.

5 What used to be a localized
6 experience, meaning you would be in the local
7 city, whether it's in China or it's, heck, here
8 in the United States, in New York, you go to what
9 you know is to be counterfeit and you buy the
10 product and the quality would be so-so, but hey,
11 you might have what looks like is a legitimate
12 brand.

13 That has been kind of put on the
14 steroids and then, blasted all over the world.
15 So, it is not difficult to go on Reddit, to go on
16 Amazon, to go on other platforms and easily
17 ascertain, not only counterfeit goods that are
18 made in these provinces that you mentioned, but
19 also very high quality counterfeit goods.

20 And the challenge for our brands is
21 working with the U.S. government, working with
22 Customs in particular, to educate them on new

1 trends, on new styles, on what the hot sellers
2 are.

3 So, not every shoe is going to be
4 knockoff-worthy, if you will, but for those that
5 are out there, ensuring that the U.S. government
6 is aware of what is legitimate product and what
7 is illegitimate producing coming in and being
8 able to enforce that, I know it's a monumental
9 task, but it's, I think, key to the information
10 piece in ensuring the product made in those
11 provinces you referenced don't make their way
12 over to the U.S. marketplace.

13 CHAIR LEE: All right. Thank you so
14 much for your testimony.

15 MR. PRIEST: Yes, thank you.

16 CHAIR LEE: Next up is the Intellectual
17 Property Owners Association. Please begin with
18 saying your name and organization.

19 MR. VALENTE: Sure. My name is Tom
20 Valente. I'm with the Intellectual Property
21 Owners Association. I'm the Senior Director for
22 Global Affairs at IPO.

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

8 IPO is an international trade
9 association. We represent companies and
10 individuals in all industries and fields of
11 technology who own or are interested in IP
12 rights.

13 IPO's membership includes about 175
14 companies and close to 12,000 individuals who are
15 involved in the association. IPO's members make
16 vital contributions to America's economic success
17 by developing the advances that drive exports and
18 create jobs.

19 Innovators assume considerable risks
20 and rely on IP to protect investments in new
21 technology.

22 In our comments to the Subcommittee,

1 IPO notes numerous deficiencies in and challenges
2 presented by IP laws around the world. It also
3 notes some improvements that have been made on
4 issues previously raised.

5 We thank you for your work that has
6 made these improvements possible and we remain
7 optimistic that further progress can be made in
8 2020 and beyond.

9 My testimony today will address two
10 impediments to appropriate protection of IP
11 rights abroad. The first is inadequate
12 protection of trade secrets. The second is
13 compulsory licensing.

14 First, regarding inadequate protection
15 of trade secrets. Protecting trade secrets
16 around the world continues to remain a top
17 priority for IPO members.

18 When trade secret laws are deficient
19 or nonexistent, this enables competitors to use
20 an innovator's hard-earned knowledge without the
21 cost of or the risks associated with developing
22 it.

1 Many countries fail to provide
2 adequate enforcement mechanisms and punishments
3 to prevent, deter, and remedy trade secret theft.

4 Some examples include India, which
5 lacks civil and criminal statutory protection for
6 trade secrets. It allows contractual obligations
7 to be the primary vehicle for protecting trade
8 secrets, but they require a close relationship
9 between the trade secret owner and the would-be
10 misappropriator. Of course, bad actors who
11 choose to steal information rather than innovate
12 are often not in privity with trade secret
13 owners.

14 Russia offers nominal weak and
15 unpredictable protection for trade secrets,
16 leaving little protection for U.S. innovators
17 doing business in the country.

18 And in China, our members face high
19 burdens of proof, limited discovery, and damages
20 issues when seeking to enforce their trade
21 secrets.

22 Although we've been pleased to see

1 recent upgrades in China, such as the expanded
2 availability of injunctive relief in China's
3 amended civil procedure framework, more needs to
4 be done.

5 We are encouraged by Section B of the
6 Phase 1 economic and trade agreement between the
7 U.S. and China, which if fully implemented will
8 substantial improve trade secret protection in
9 China.

10 We urge you to continue to encourage
11 our trading partners to adopt and implement much
12 needed trade secrets upgrades to safeguard
13 American knowhow.

14 Secondly, compulsory licensing
15 undermines the economic incentives created by the
16 IP system for investment in the R&D that leads to
17 innovation.

18 Yet, efforts to impose compulsory
19 licensing appear to be increasing, including that
20 countries that have issued compulsory licenses in
21 recent years have included Indonesia, Malaysia,
22 and Russia.

1 In December 2019, Argentina passed an
2 emergency law that increases the likelihood of
3 compulsory licenses being issued in that country.
4 Further, national policies in countries such as
5 India and South Africa are supportive of
6 compulsory licensing.

7 More innovation, not less, is needed
8 to meet the challenges of our age and the costs
9 associated with the research and development
10 needed for science to progress are often quite
11 high and compulsory licensing devalues the IP
12 that is necessary to encourage that investment.

13 We again thank the Subcommittee for
14 its efforts to promote the protection of IP
15 rights globally, which will sustain and grow
16 America's economy. I welcome any questions.

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

19 MR. EWERDT: Regarding Brazil, can you
20 describe the current impact of ANVISA, the
21 National Health Surveillance Agency, on patent
22 examination and whether the agreement between

1 ANVISA and INPI, the National Institute of
2 Industrial Property, has been effective in
3 limiting ANVISA's role?

4 MR. VALENTE: So, thank you for your
5 question. In IPO's view, the fact that ANVISA
6 has to review all the pharmaceutical patent
7 applications and continues to be involved in this
8 process does cause us some concern.

9 We recognize that there is a recent
10 agreement that an unfavorable opinion from ANVISA
11 on patentability issues is no longer binding on
12 INPI, but we are still somewhat concerned and so,
13 we'd like to continue to monitor that.

14 CHAIR LEE: Thank you. The next
15 question is from the Labor Department.

16 MS. KHAN: On Indonesia, you note that
17 while the Ministry of Law and Human Rights
18 revised its compulsory licensing regulation,
19 there are further concerns and fundamental issues
20 that need to be addressed.

21 Can you please explain what those
22 concerns and fundamental issues are?

1 MR. VALENTE: Sure. IPO welcomes the
2 improvement made by Indonesia. The new
3 regulation seems to require more details and a
4 fairer system for trying to look at the
5 compulsory licensing issue.

6 But as part of that regulation, there
7 is still a working requirement. The working
8 requirements always concern us. What does
9 working mean in a country? Does importation
10 qualify for working? And so, that is one
11 particular issue I know that is of concern to us.

12 I think we're very just concerned
13 overall about this trend of compulsory licensing.
14 And one of the things that we want to see is more
15 details, less ambiguity in all these countries
16 about when a compulsory license is going to be
17 imposed.

18 Because right now, with respect to a
19 number of the countries that I mentioned earlier,
20 it's not clear that the rules are very clear.
21 They're often ambiguous, which leaves a lot up in
22 the air for the rights holder.

1 CHAIR LEE: Thank you very much. The
2 next question is from the U.S. Patent and
3 Trademark Office.

4 MS. FERRITER: Thank you. In your
5 submission, you identify China specifically when
6 discussing the problem of protecting trade
7 secrets. And you just went into some detail as
8 to China's shortcomings.

9 But what are some proposed solutions
10 or further proposed solutions to address China's
11 shortcomings in this area? And are there any
12 countries that can serve as an example for others
13 of how you would like to see trade secrets
14 protected? Thank you.

15 MR. VALENTE: Sure, thank you for the
16 question. Of course, our model for protecting
17 trade secrets would be the United States. We'd
18 like to see the other countries model themselves
19 after the U.S.

20 Now, the U.S. has -- we're no longer
21 a state-by-state jurisdiction on trade secrets,
22 although that ability to implicate state law

1 still exists. Now, we have a national law.

2 As far as China, we are very
3 encouraged by the Phase 1 trade agreement. The
4 issue in particular of the shifting of the burden
5 of proof is extremely important to us.

6 As you know, previously in China, as
7 in many countries, one of the main issues is
8 discovery, that they don't have a discovery
9 system like the U.S. does. And so, how does
10 someone prove their trade secrets have been
11 stolen?

12 And so, having the shifting of the
13 burden of proof so that the trade secrets holder
14 is able to make a very basic showing and then,
15 have the alleged trade secret infringer have to
16 come forward with evidence, to us, that's
17 extremely important.

18 So, we would like to see how that
19 plays out in China. The enforcement is going to
20 be very important. But then, in addition, that
21 and the other provisions of the Phase 1 agreement
22 seem like they would be ones we'd like to see

1 with other countries.

2 CHAIR LEE: Excellent. Thank you for
3 your testimony.

4 MR. VALENTE: Thank you.

5 CHAIR LEE: Next is the International
6 Intellectual Property Alliance. When you're
7 ready, please begin your testimony by stating
8 your name and organization.

9 MR. ROSENBAUM: Thank you. I am Kevin
10 Rosenbaum, counsel to the International
11 Intellectual Property Alliance, the IIPA.

12 Thank you for the opportunity to
13 present the views of the IIPA in this year's
14 Special 301 process.

15 We applaud the U.S. government for
16 making the 301 review a catalyst for positive
17 change to address the challenges faced by the
18 U.S. creative industries in key markets abroad.
19 We welcome the chance to participate again in
20 this important annual dialogue.

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

1 representing the U.S. copyright-based industries.

2 The core copyright industries
3 combined, according to a December 2018 study,
4 contribute over \$1.3 trillion to the U.S.
5 economy, provide 5.7 million jobs, and nearly
6 seven percent of GDP.

7 Our members comprise over 3,200
8 companies producing and distributing materials
9 protected by copyright laws throughout the world.

10 To reach foreign markets through
11 legitimate state of the art distribution
12 channels, these companies rely on copyright
13 protection and enforcement that meet current
14 global standards and fast evolving best practices
15 and the elimination of market access barriers.

16 Progress in these areas advances U.S.
17 trade goals while enabling our trading partners
18 to develop and expand their own cultural and
19 creative output.

20 The ultimate objective is to promote
21 markets where the creative industries can bring
22 even more products and services than they

1 currently offer in an increasing variety of ways
2 from a greater diversity of players before an
3 ever growing global audience.

4 Advancing that objective is a proven
5 means to grow U.S. exports, create good American
6 jobs, and enhance U.S. global competitiveness.
7 With this broad vision in mind, IIPA has
8 participated in every Special 301 review since
9 the 1988 Trade Act created this process.

10 Given some of the other comments
11 provided, it is worth reviewing the specific
12 statutory language and purpose of the Special 301
13 review, namely, to identify foreign countries
14 that deny adequate and effective protection of
15 intellectual property rights or deny fair and
16 equitable market access to U.S. persons who rely
17 on intellectual property protection.

18 It is critical for the Special 301
19 process to maintain this focus on intellectual
20 property protection, in our case, copyright
21 protection and enforcement.

22 There are those who ask you to dilute

1 this focus, to weaken protections and
2 enforcement, in order to accommodate the
3 perceived interests of business sectors that, by
4 their own words, depend on expanding the zone
5 where copyright protections do not apply.

6 This is not what Congress intended
7 when it created the Special 301 process. It is
8 not consistent with the clear statutory language
9 of Special 301 and is not the approach that has
10 made Special 301 so successful.

11 The Special 301 process is not the
12 place to advocate that our trading partners
13 weaken their copyright regimes, especially in
14 countries where legitimate rights holders cannot
15 get a toehold due to grossly inadequate copyright
16 protection or enforcement.

17 In this year's submission, IIPA
18 recommends that 19 countries be identified in the
19 2020 Special 301 Report, including 11 countries
20 for inclusion on the Priority Watch List.

21 Our submission highlights five legal
22 reforms that our trading partners should focus on

1 to adequately and effectively address all forms
2 of piracy in a fast-changing technological
3 environment.

4 Most fundamentally, U.S. trading
5 partners must both accede to and fully implement
6 the WIPO Internet Treaties, which set global
7 minimum standards for copyright protections in
8 the digital environment.

9 The U.S. government should press U.S.
10 trading partners to adhere to well-established
11 global norms, including the requirement to
12 confine all exceptions and limitations to
13 copyright protections within the well-established
14 three-step test.

15 The U.S. government should also ensure
16 that our trade agreements realize the goal of
17 opening foreign markets to U.S. goods and
18 services dependent on copyright protection,
19 including by ensuring our trading partners
20 implement the agreements in manner that does not
21 erode protection, prevent licensing of legitimate
22 content on commercial terms, or create barriers

1 to market access for American creators.

2 Our submission also lists five
3 enforcement challenges confronting the U.S.
4 copyright industries seeking to compete in
5 overseas markets, starting of course with
6 internet and mobile network piracy, an
7 overarching challenge for all businesses that
8 depend on copyright.

9 We applaud the U.S. government for
10 establishing an annual review of notorious
11 markets, which has made a significant
12 contribution to combating systematic online
13 copyright theft.

14 And we urge you to redouble efforts to
15 encourage our trading partners to adopt legal
16 frameworks to prevent the operation or emergence
17 of illegal services, including by fostering
18 cooperation among all industries in the online
19 supply chain.

20 Our trading partners should be doing
21 much more to foster and encourage such
22 cooperation and to develop best practices to

1 reduce the use of infringing sites and to
2 increase traffic to legitimate copyrighted
3 materials.

4 Finally, all efforts to address
5 copyright infringement will be unsuccessful if
6 legitimate products and services cannot be
7 brought into market to meet consumer demand.
8 U.S. officials should continue to strive to
9 eliminate or phase out market access barriers.

10 Special 301 remains a cornerstone of
11 the U.S. effort to advance modern levels of
12 protection for copyright. We look forward to our
13 continued work with USTR and other government
14 agencies to advance these goals.

15 CHAIR LEE: Thank you. We have some
16 questions and we'll start with USTR.

17 MR. EWERDT: Regarding Ukraine's recent
18 reforms to its collective management organization
19 regime, or CMOs, are you aware of any
20 prosecutions of owners of rogue CMOs?

21 MR. ROSENBAUM: Thank you for that
22 question. Ukraine has been a problem in this

1 area for many years, as USTR is well aware. I am
2 not aware of any efforts to prosecute rogue CMOs,
3 but let me get back to you. I'll check and get
4 back to you on that. Thank you for the question.

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

7 MR. WESTON: Thank you. IIPA did not
8 recommend South Africa for the Special 301 list
9 in 2019. But this year, IIPA recommends placing
10 South Africa on the Priority Watch List.

11 Is the basis of this recommendation
12 solely the proposed Copyright Amendment Bill and
13 Performers' Protection Bill or have other
14 conditions in the country changed since last
15 year?

16 MR. ROSENBAUM: Thank you very much for
17 that question. I believe we did recommend
18 Priority Watch List for South Africa last year,
19 in the lead-up.

20 At the time, that bill, those two
21 bills were on their way through Parliament and I
22 believe after the process were subsequently

1 passed, and they're now sitting on the
2 President's desk.

3 Those bills are incredibly
4 destructive, or would be if enacted, to our
5 industries. So, the situation in South Africa is
6 not good currently.

7 They needed copyright reform efforts
8 to take place, but unfortunately, the copyright
9 reform efforts that have moved forward would make
10 things worse. And so, that's why we're sounding
11 the alarm on this. And we did last year as well.

12 And they're currently just in limbo,
13 they could be passed at any time, these bills,
14 and they would have all kinds of contractual
15 requirements that would essentially make it
16 impossible to produce content in the country.

17 There are exceptions and limitations
18 that are clearly outside the scope of the
19 three-step test and other issues, in terms of
20 rights, a lack of rights, that meet the
21 requirements of the Internet Treaties.

22 So, they -- South Africa would be

1 well-served by restarting its copyright reform
2 process, this time bringing in the full range of
3 stakeholders.

4 They did not consider the views of
5 local artists, local creators, who protested when
6 these bills were introduced. So as I said,
7 they'd be well-served to restart the process
8 over, and that's what we're seeking in South
9 Africa.

10 CHAIR LEE: All right. Thank you very
11 much for your testimony.

12 MR. ROSENBAUM: Thank you.

13 CHAIR LEE: Next is Knowledge Ecology
14 International. Welcome and please begin your
15 testimony by stating your name and organization.

16 MR. LOVE: My name is James Love with
17 Knowledge Ecology International. I'm going to
18 start on medical technologies.

19 The Pharmaceutical Manufacturers
20 Association, BIO, the U.S. Chamber of Commerce,
21 the National Association of Manufacturers, the
22 Alliance for Fair Trade with India, and a few

1 other organizations are asking the United States
2 to take measures to extend and expand monopolies
3 and otherwise raise prices for medical inventions
4 in foreign countries.

5 The scope of the demands is broad.
6 The USTR is being asked to discipline the
7 breaking of global norms, the use of exceptions
8 that exist in those norms, thinking about using
9 those norms, and finally, any attempt to
10 influence those norms in ways that are not
11 favored by big drug companies.

12 The drug company-backed asks are
13 framed in terms of U.S. having an interest in
14 promoting biomedical innovation and U.S. jobs in
15 this sector. That argument holds some water, but
16 also leaves a lot out.

17 The measures proposed by the drug
18 companies present obvious conflicts with policies
19 to curb anti-competitive practices and to promote
20 health, affordability, and more equal access.

21 Also worth noting, the measures that
22 will raise foreign prices on drugs to treat

1 cancer and other illnesses are unpopular in the
2 foreign countries where they are targeted. When
3 the U.S. pressures countries to raise drug
4 prices, the U.S. incurs costs, both politically
5 and economically.

6 When a trade policy favors one
7 particular sector of the economy at the expense
8 of others, there's a cost to the other sectors.
9 That's something to put on the table.

10 The U.S. can't ask every country to do
11 everything one industry sector wants, since every
12 time the U.S. makes a demand, there's an
13 opportunity cost.

14 The pharma industry has an insatiable
15 appetite for new rent-seeking norms and actions,
16 but governments can and should, and they need to
17 consider alternatives that don't pit
18 affordability, access, and equality against
19 innovation.

20 For several years, drug companies have
21 lobbied against efforts at the World Health
22 Organization to set global norms for funding

1 research and development.

2 More recently, drug companies have
3 lobbied against global norms on the transparency
4 of pharmaceutical markets and more aggressively
5 against the transparency of R&D costs.

6 It's in our interest, the interest of
7 the United States, that foreign governments
8 expand public sector financing of biomedical
9 research.

10 The U.S. government does a laudable
11 job of funding billions of dollars in biomedical
12 research as a public good and spends billions
13 every year to subsidize clinical trials.

14 The U.S. should push other countries
15 to raise the level of their biomedical R&D
16 spending and clinical trial subsidies and this
17 could have a more pronounced positive impact on
18 innovation than higher prices for drugs,
19 vaccines, and gene and cell therapies.

20 In the past two decades, pharma has
21 opposed all efforts to pivot from IPR to R&D
22 regarding the focus of trade policy. To be sure,

1 the pharma sector wants to claim that its
2 policies are designed to enhance R&D spending,
3 but when proposals have been made to create even
4 soft norms in R&D funding or to address a lack of
5 transparency in R&D spending, pharma has
6 mobilized opposition.

7 The large biomedical companies
8 understand, perhaps better than some government
9 officials, that a focus on R&D rather than IPR
10 could undermine policies that protect price
11 gouging and eliminate their biggest price gouging
12 defense.

13 While it's true that price gouging can
14 spur innovation, so can lots of other cheaper and
15 less harmful measures, such as expanded R&D
16 subsidies, enhanced government funding direct
17 research, or incentives like market entry awards
18 that are de-linked from prices or monopolies.

19 One reason the U.S. government needs
20 to rethink the strategy of cross-border funding
21 of biomedical R&D is the U.S. is consistently the
22 biggest victim of excessive pricing and

1 anti-competitive practices, and is facing the
2 significant aging of our population over the next
3 15 years, which will add more fiscal stress to an
4 already costly and globally most costly
5 healthcare system.

6 Among the reforms being considered to
7 address the crises in affordability medicines are
8 those would de-link R&D cost. And in particular,
9 the incentives to invest in R&D.

10 More generally, this is about
11 de-linking the incentives for the use of
12 monopolies and replacing them with things like
13 market entry awards.

14 I want to mention on the aging of the
15 population, the United States Bureau of Census
16 estimates we have about 52 million people 65
17 years or older right now. And they think that
18 will raise to around 95 million by the year 2060.

19 The percent of the population over 65,
20 which is now 16 percent, is expected to exceed 23
21 percent. If policymakers are not taking this into
22 account, we are ignoring where we are headed.

1 The United States is also not the only
2 country that supplies new medical inventions.
3 We're often paying foreign countries for new
4 drug, cell, or gene therapies.

5 Novartis, a Swiss firm, owns the first
6 CAR-T therapy, as well as the Lexterna gene
7 therapy.

8 Roche, another Swiss firm, has reaped
9 tens of billions of dollars from U.S. cancer
10 patients, including the treatment my wife takes,
11 which is an invoice for more than \$470,000 a
12 year.

13 Korea, Japan, and Singapore have
14 extensive biotech programs. China is investing
15 heavily in new treatments, including cell and
16 gene therapies.

17 ClinicalTrials.gov lists 470 clinical
18 trials mentioning chimeric antigen receptor for
19 CAR-T treatments. Of these, 204 of the trials
20 are taking place in the United States, while 208
21 are taking place in China.

22 Patent thickets in the United States

1 in CAR-T gene therapy and CRISPR and the high
2 cost of licensing patents are creating barriers
3 to entry in the United States.

4 We have to consider the use of
5 compulsory license or expanded exceptions to
6 patents used in the treatment of humans to
7 overcome these problems.

8 It's also worth reflecting on some of
9 the other issues relevant to the industry 301
10 submissions, particularly those dealing with
11 local working and technology transfer
12 obligations.

13 In the United States, the government
14 is now expressing concern over the lack of
15 national capacity to manufacture pharmaceutical
16 APIs or finished products domestically, including
17 in the context of potential coronavirus pandemic.

18 KEI also expects the U.S. Congress to
19 examine the need to mandate technology transfer
20 for biologics, drugs, vaccines, and cell and gene
21 therapies, in order to overcome the current lack
22 of competition or to address safety concerns for

1 biosimilars or biogenerics.

2 I will submit for the record an
3 attachment that provides estimates for the
4 distribution of income for 96 countries,
5 including data on the per capita of income by
6 country, within country.

7 Indonesia came up earlier, 80 percent
8 of the population in Indonesia has a per capita
9 income of just over \$200.

10 I'll just end with the last thing on
11 copyright to say that we note that BSA is seeking
12 broader global protections for fair use and other
13 exceptions as it concerns text and data mining on
14 the context that non-consumptive reproductions
15 are necessary for the development of AI-related
16 technologies.

17 In its submission, BSA urges the
18 United States to continue such exceptions to
19 foster innovation and creativity and to maintain
20 the U.S. leadership in AI. We agree with BSA on
21 this topic.

22 On education materials, we note that

1 many of the publishers who are seeking policies
2 that are restrictive on exceptions in education
3 are European publishers and not American
4 publishers. Thank you.

5 CHAIR LEE: Thank you. I think we have
6 a little bit of time for questions. Why don't we
7 start with USTR?

8 MR. EWERDT: What specific
9 trade-related IP developments that have occurred
10 since April 2019 should this Committee consider
11 as it conducts the Special 301 review this year?

12 MR. LOVE: I think you need to look at
13 the patent landscape on the recently introduced
14 cell and gene therapies and on CRISPR
15 technologies.

16 If you look at, for example, small
17 molecules versus biologic drugs, I think what
18 you're seeing right now is an order of magnitude
19 more patents on biologic drugs as opposed to
20 small molecules.

21 You're seeing a similar but somewhat
22 different thing in terms of new cell and gene

1 therapies and CRISPR technologies. And there's a
2 proliferation of patents in these areas.

3 And the cost of acquiring the IP in
4 those areas is much higher than I've seen it for
5 drugs in the past. And I think that the idea
6 that you're sort of promoting global norms
7 against compulsory licensing and exceptions to
8 this area is not very strategic in terms of where
9 the science is going.

10 CHAIR LEE: All right. Thank you for
11 your testimony.

12 MR. LOVE: Thank you.

13 CHAIR LEE: Next, we have MFJ
14 International LLC. Please begin your testimony by
15 stating your name and organization for the
16 record.

17 MS. JORGE: Thank you. Good afternoon,
18 my name is Mariana Jorge, from MFJ International.
19 Thank you for the opportunity to testify today.

20 MFJ is a small consulting firm with a
21 significant focus on increasing access to
22 affordable drugs. This testimony is not made on

1 behalf of any client.

2 Access to affordable medication has
3 become one of the top policy priorities in the
4 U.S., with real bipartisan support. This high
5 priority was reflected in the State of the Union
6 address and in the administration's Blueprint to
7 Lower Drug Prices, which quotes President Trump
8 as saying, one of my greatest priorities is to
9 reduce the price of prescription drugs.

10 Nevertheless, U.S. trade policy has
11 been slow to adjust to emerging government
12 priorities and the Special 301 Report is very
13 much an example of this.

14 And while President Trump, HHS, FDA,
15 and others have made deliberate efforts to
16 increase competition in the pharmaceutical
17 market, some of the agreements negotiated by the
18 USTR and the Special 301 Reports focus on
19 provisions that will do exactly the opposite,
20 broaden and lengthen the monopolies granted to
21 pharmaceutical companies, thus delaying or
22 deterring the launch of generic and biosimilar

1 drugs and with that, the chances of lowering drug
2 prices.

3 Today, generics fill 90 percent of the
4 prescriptions in the U.S. but represent only 22
5 percent of drug spending, thus contributing \$292
6 billion in savings in 2018 alone.

7 Thus, the generic industry plays a
8 critical role to ensure access to more affordable
9 drugs. Having reached a point of saturation in
10 the U.S. market, the U.S. generic industry has
11 become a global player.

12 During the negotiations of the TPP and
13 the USMCA, one of the conflictive issues was the
14 exclusivity for biologics. Biologics are complex
15 drugs that are among the most expensive in the
16 market, with prices often above \$100,000 per
17 patient per year, and in one case, over \$200
18 million.

19 Numbers provided by former FDA
20 Commissioner Gottlieb offer a sobering
21 perspective. While less than two percent of
22 Americans use biologics, they represent 40

1 percent of the total spending on prescription
2 drugs.

3 Moreover, they represent 70 percent of
4 the growth in drug spending between 2010 and 2015
5 and they are forecasted to be the fastest growing
6 segment of drug spending in the coming years.

7 However, efforts to increase
8 competition for biologics are undermined by trade
9 policies that support the adoption of long
10 exclusivities for biologic drugs.

11 We congratulate the USTR and the U.S.
12 Congress for reaching a bipartisan agreement on
13 this matter in the USMCA. The FTC concluded that
14 there is not evidence about the lack of
15 patentability of biologics, it was mentioned
16 about how many patents are on these drugs.

17 This seems to be confirmed by a review
18 of biosimilar drugs approved so far in the United
19 States. While 26 biosimilars have been approved,
20 only 14 have been launched.

21 One of the reasons for the failure of
22 launch some of these products seems to be

1 litigation initiated by originator companies or
2 because companies have reached settlement
3 agreements as a result of litigation.

4 Concerns over competition of these
5 drugs were expressed by Commissioner Gottlieb in
6 the following terms. Competition is for the most
7 part anemic. It is anemic because litigation has
8 delayed market access for biosimilar drugs.

9 In addition, the investment required
10 to develop biosimilar products is much higher
11 than for generics. Again, Commissioner Gottlieb
12 said, while it can cost about \$10 million to
13 develop a generic version of a small molecule
14 drug, the complexity of manufacturing and testing
15 biosimilars typically cost between \$100 and \$250
16 million per program.

17 Finally, the FDA recognizes that
18 creating efficient economies of scale for
19 biosimilars require a global market.

20 Therefore, today, I am requesting that
21 the USTR take a fresh look at this issue in the
22 understanding that, one, more than 30 years after

1 the release of the first Special 301 Report, the
2 report should not focus on continuing to ratchet
3 up the standards of IP protection, but on
4 ensuring that all countries provide adequate and
5 effective protection in compliance with their
6 international obligations.

7 Two, the Special 301 Report cannot be
8 a reflection of a wish list of one side of the
9 pharmaceutical industry at the expense of the
10 other, consumers, and payers.

11 Three, in the past 30 years, the U.S.
12 pharmaceutical industry has dramatically changed
13 and today, the generic and biosimilar industry is
14 global and needs access to foreign markets to be
15 able to provide new biosimilar medications in the
16 U.S. Failure to have such access will put its
17 development and sustainability at risk.

18 Four, U.S. trade policy must be
19 consistent with other government priorities,
20 which is, in the case of health, is clearly
21 bipartisan, lowering drug prices.

22 And finally, U.S. trade policy must

1 support the efforts of other government agencies
2 to achieve this important goal, not undermine
3 them.

4 CHAIR LEE: Thank you very much. We
5 have some questions and we will start with USTR.

6 MR. EWERDT: In your submission, you
7 state that, quote, further increasing the levels
8 of intellectual property protection in other
9 markets would result in the adoption of new
10 non-tariff barriers to entry for the generic and
11 biosimilar industry, end quote.

12 Aside from ensuring market entry for
13 biosimilars, you do not discuss particular
14 policies or practices that deny adequate and
15 effective protection of IP rights or deny fair
16 and equitable market access to U.S. persons who
17 rely on IP protection.

18 Can you provide specific examples of
19 policies or practices in other countries that you
20 think should be highlighted in the 2020 Special
21 301 Report?

22 MS. JORGE: Yes. I am a true believer

1 in intellectual property, but it has to be
2 balanced with competition. This is not just me
3 saying it, the FTC report has a report on this
4 issue and says, in order to promote innovation,
5 it has to be a balance between IP and
6 competition.

7 We have to remember that IP is not an
8 end in itself, it's a medium to an end and the
9 end is innovation.

10 So, everything that breaks that
11 balance between protection and competition, that
12 is what create non-tariff barriers.

13 So we are recognizing, we have 20-year
14 patent terms, but if we keep extending the
15 patents through patent extensions unlimited, to
16 also extend different type of patents, to do the
17 evergreening, to do exclusivity for biologics,
18 exclusivity for this, exclusivity for pediatrics,
19 I mean, the competition is being shrinking and
20 shrinking and shrinking.

21 And guess who is on the other side?
22 All of us and all of our families. And we are

1 not creating more innovation, we are, I'm sorry
2 for the term, but I think it's graphic, we are
3 creating fat cows that do not need to work hard
4 to create new things to bring to the market.

5 We want innovation, we want cures for
6 illnesses, but we do not create just big fat cows
7 that do not need to work for it. We want balance
8 between innovation, between protection of
9 intellectual property and access. And I think we
10 have lost the perspective that not always more IP
11 is better.

12 CHAIR LEE: Okay. Thank you. The next
13 question is from HHS.

14 MS. BLEIMUND: Thank you. I think, on
15 a related note, in your submission, you state
16 that while the Special 301 statute requires USTR
17 to identify countries that deny adequate and
18 effective protection of IP rights, you say there
19 is now, quote, an assumption that more
20 intellectual property is always better.

21 Keeping in mind the legislative
22 mandate for the Special 301 Report, how do you

1 suggest the United States use the report to
2 advance the administration's policy goals related
3 to IP protection and enforcement?

4 MS. JORGE: Thank you. Well, the very
5 first thing I will say, I don't know if anybody
6 was watching TV last night, something was going
7 on. Well, in-between what was going on, there
8 was an ad from the President about increasing
9 competition for biosimilars, okay?

10 So, I think we have to look at what
11 the priorities for the government are and whether
12 what was designed 30 years ago still apply. It's
13 like we are in one room, but the whole scenario
14 has changed and we are acting like the scenario
15 has not changed.

16 The whole priorities and the situation
17 where we were when it was '89 has changed. And
18 we cannot pretend that more IP and more IP and
19 more IP, we are becoming slaves of interest
20 groups that are just seeking their own benefit.

21 They do have to seek their own
22 benefit, I'm not saying they are not doing what

1 they have to do, but the government has to look
2 after the common good. The government has to
3 look after all of us.

4 And so, going back to your question,
5 how to do it, I think we have to relook at the
6 Special 301 and we have to look at what the
7 situation is now.

8 Thirty years ago, in '89, it was only
9 five years after Hatch-Waxman passed. Guess
10 what? The generic industry was completely
11 focused into developing internally.

12 I know, because it took me four heads
13 of the generic industry to understand that these
14 kind of provisions was going to hurt them. But
15 we went from, in '85 or '84, it was 21 percent of
16 generic utilization in this country. When
17 Hatch-Waxman passed, they have to focus in
18 growing internally.

19 Now, they have to have access to other
20 markets. And instead, the Special 301 are
21 locking them by establishing barriers to entry to
22 U.S. products.

1 And if we don't generate that extra
2 money, we cannot generate the \$100 to \$250
3 million that Gottlieb says it takes to develop a
4 biosimilar.

5 So, if we block those markets, we are
6 blocking solutions to access to really expensive
7 drugs, and like cancer drugs, for our own
8 citizens.

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

11 MS. JORGE: Thank you for the
12 opportunity.

13 CHAIR LEE: Excellent. Next, we have
14 the National Association of Manufacturers. All
15 right. Please state your name and organization
16 for the record.

17 MR. ONG: There we go, with the mic on
18 this time. Ryan Ong, with the National
19 Association of Manufacturers. Thank you.

20 Members of the Special 301 Committee,
21 thank you for the opportunity to testify today on
22 behalf of the National Association of

1 Manufacturers, the NAM, and the more than 14,000
2 manufacturers that we represent.

3 Manufacturers in the United States
4 have created an innovation engine that has
5 reshaped the world around us. New technologies
6 and products have brought us energy independence,
7 new lifesaving medicines, and more efficient
8 automobiles.

9 As we speak, countless other
10 innovative manufactured products are being
11 developed and refined to improve people's lives
12 and secure our nation's global manufacturing
13 leadership.

14 Innovation and intellectual property
15 fuel that manufacturing industry and its ability
16 to propel the American economy forward, but our
17 businesses and products remain targets for other
18 countries seeking to steal our innovative ideas
19 and undercut those advancements. And sadly, this
20 trend is not getting better, it's getting worse.

21 A 2017 report by the Commission on the
22 Theft of American Intellectual Property found

1 that stolen ideas, brands, and inventions drain
2 up to \$600 billion from the U.S. economy, a
3 shocking figure that's nearly double that of the
4 Commission's report from four years prior.

5 Undercutting American innovation harms
6 U.S. businesses, jobs, and workers in the
7 process.

8 The NAM's formal Special 301
9 submission details a full list of recommendations
10 to protect manufacturing IP. We recommend eight
11 countries for the Priority Watch List and six
12 additional countries for the Watch List as the
13 focus for this year's report. This includes
14 longstanding priorities, such as China and India,
15 and emerging challenges, such as Argentina and
16 Saudi Arabia.

17 Although the United States faces a
18 multitude of IP threats from foreign actors,
19 today I'd like to focus quickly on three:
20 counterfeiting, trade secret theft, and threats
21 to IP emanating from work streams at
22 international organizations.

1 First, manufacturers continue to
2 battle a growing tide of fake products sold in
3 the United States. Counterfeiters increasingly
4 abuse online channels, exploit weaknesses in the
5 international postal system, and transship
6 through free trade zones to flood the United
7 States with fake and unsafe products.

8 The administration has focused welcome
9 attention on these issues with its recent report
10 on combating counterfeiting, as well as initial
11 steps towards implementation, but significant
12 work remains to benefit American manufacturers,
13 large and small.

14 Second, companies face sophisticated
15 physical and electronic attempts by bad actors to
16 steal trade secrets. A 2014 study estimated that
17 the economic loss from trade secret theft is
18 between one and three percent of U.S. GDP, which
19 would translate to a loss of between \$180 and
20 \$500 billion.

21 This makes it hard, challenging,
22 difficult for U.S. companies to export and

1 compete in countries around the world,
2 particularly small and medium-sized companies for
3 whom trade secrets are often their most important
4 competitive asset.

5 Finally, actors and initiatives at
6 international organizations increasingly seek to
7 weaken critical IP protections in the name of
8 other important policy priorities, such as public
9 health and environmental protection.

10 These remain critical priorities, but
11 it's important to understand that these types of
12 efforts overlook the importance of innovation in
13 finding powerful solutions to these very
14 challenges and create barriers and false
15 narratives that hinder the very progress they
16 claim to promote.

17 The United States has long made
18 vigorous protection of IP rights at home and
19 abroad a cornerstone of our manufacturing
20 competitiveness, but we must do more in the face
21 of these and other challenges.

22 It is more critical now than ever

1 before that the United States strongly defend
2 intellectual property and innovation around the
3 world in all available and appropriate forums.

4 We must make strategic use of
5 available options, working collaboratively across
6 agencies to address IP challenges through both
7 existing channels, as well as new tools.

8 This must include not only active use
9 of Special 301 related tools, such as country
10 classifications, out-of-cycle reviews, and
11 results-oriented action plans, but the U.S.
12 government must also prioritize intellectual
13 property protections in current and future trade
14 negotiations, leverage IP-friendly international
15 organizations and fora to push for stronger IP
16 rules, and expand capacity-building and
17 enforcement collaboration programs with foreign
18 governments.

19 To our U.S. government colleagues, we
20 strongly support your work to continue to pursue
21 a level playing field for American manufacturers
22 to compete in the increasingly global economy.

1 Every day, manufacturers across the
2 country are transforming their operations to
3 achieve greater efficiency, productivity, and
4 competitiveness, while working to create a better
5 tomorrow we all dream of.

6 None of that is possible without U.S.
7 leadership driving strong rules to protect our
8 innovation and IP, as well as robust enforcement
9 efforts. The success of our industry and the
10 strength of our economy depend on it.

11 Thank you. With that, I'm happy to
12 answer any questions you have.

13 CHAIR LEE: Thank you very much. We
14 indeed do have questions, and we'll start with
15 USTR.

16 MR. EWERDT: Regarding your written
17 submission, you state that USTR should address
18 legislative efforts that could undermine existing
19 patent term restoration, specifically noting the
20 EU's revisions to its SPC regime.

21 Can you further explain this statement
22 and what does NAM see as the critical steps here?

1 MR. ONG: Sure, I appreciate that
2 question. What we see in a variety of global
3 markets are efforts to use domestic legislation
4 and other regulatory tools to be able to place
5 increased limitations or boundaries on the
6 ability of companies to be able to generate and
7 use regulatory data that's critical for producing
8 products that come to market and products that
9 help to serve the interests and needs of
10 customers and consumers.

11 Within the European Union, the process
12 of discussion over SPC and the appropriate
13 balance is a longstanding issue, it's one that's
14 picked up legislative momentum in recent years.
15 And it's not alone, we see similar legislative
16 moves in other critical markets.

17 It remains fundamentally important on
18 these and issues that pop up market-to-market
19 that the U.S. government, that USTR, and that
20 each of you in your interagency jurisdictions, as
21 you're engaging with European counterparts on
22 these issues, look for ways to be able to pursue

1 legislative reform and change, to be able to
2 ensure strong protection for IP and the
3 regulatory protection that, again, makes it
4 possible for innovative companies to bring these
5 products to market.

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

9 MS. FERRITER: Thank you. With respect
10 to China your written submission stated, and I
11 quote, trademark squatting issues also remain a
12 problem and not one covered well under existing
13 law.

14 As of November 1, 2019, Article 4 of
15 China's Amended Trademark Law provides grounds
16 for rejection and opposition of bad faith
17 trademarks. And again, I quote, without intent
18 to use, end quote.

19 Has the new provision been of any use
20 to rights holders? Thank you.

21 MR. ONG: Thank you as well. The
22 legislative change that you're referring, I think

1 for our manufacturers was seen as a welcome step,
2 an important recognition of the nature of this
3 problem, as well as providing access to some
4 additional tools to be able to address the issue.

5 Given the relatively recent nature of
6 that change, I think our manufacturing members
7 that are monitoring this issue are watching very
8 closely to ensure that in practice, manufacturers
9 that experience challenges with trademark
10 squatting or other bad faith trademark actions
11 can adequately use those provisions to be able to
12 address those issues.

13 And that's something that I think will
14 take some additional time. I'm happy to remain
15 engaged with you and your colleagues as we
16 continue to hear further from our manufacturing
17 members.

18 CHAIR LEE: Thank you. It looks like
19 we have time for one more question and it will be
20 from ITA.

21 MR. MITCHELL: In its submission, your
22 organization has commented that, quote,

1 international organizations increasingly seek to
2 weaken IP protections in the name of other policy
3 priorities, such as public health or
4 environmental protection.

5 Can you identify specific examples of
6 such instances?

7 MR. ONG: Sure, absolutely. I'll
8 provide a good example from 2016, one we still
9 continue to see reverberate in policy discussions
10 today.

11 And that's the UN High Level Panel on
12 Access to Medicines. This was a panel set up at
13 the recommendation of the UN Secretary General to
14 look at an important issue that we've been
15 speaking a good bit about today, that being best
16 ways to be able to ensure access to lifesaving
17 medications in markets around the world.

18 In practice, what we saw from the
19 workings of that panel was a fairly one-sided
20 discussion that focused purely on intellectual
21 property, as opposed to an opportunity for a
22 robust discussion of the range of barriers that

1 can often help to prevent meaningful access to
2 these products in global markets, trained
3 healthcare personnel, cold chain logistics, local
4 tariff protections, trade barriers, and these
5 types of issues.

6 And so, the end report that was
7 released had a similarly problematic one-sided
8 focus.

9 The U.S. government at that point in
10 time, and this was under the previous
11 administration, was extremely helpful in
12 delivering a strong interagency rebuttal and
13 response to that report, pointing out U.S. work
14 and engagement to address these issues
15 meaningfully, but also the problematic nature of
16 both process and content on the back end.

17 We continue to see, however, in a
18 variety of agencies, the World Health
19 Organization and others, attempts to be able to
20 use that report and its findings as a basis for
21 specific additional work streams that have a
22 similarly, I would say, one-sided approach to

1 these issues.

2 CHAIR LEE: All right. Thank you very
3 much for your testimony.

4 MR. ONG: Thank you.

5 CHAIR LEE: Next is the Pharmaceutical
6 Research and Manufacturers of America. All
7 right. Please begin by stating your name and
8 organization for the record.

9 MR. MOORE: I am Chris Moore with the
10 Pharmaceutical Research and Manufacturers of
11 America.

12 And on behalf of biopharmaceutical
13 innovators in the United States and the more than
14 800,000 women and men they employ across the
15 country, PhRMA appreciates the opportunity to
16 testify before the Special 301 Committee.

17 Where markets are open and
18 intellectual property is protected and enforced,
19 PhRMA members have the predictability and
20 certainty necessary to research, develop, and
21 deliver new medicines and vaccines for patients
22 who need them.

1 Today, America's biopharmaceutical
2 innovators are playing a critical role in the
3 global response to the COVID-19 virus and are
4 pioneering groundbreaking therapies that are
5 revolutionizing the treatment of many other
6 devastating diseases and conditions.

7 But urgent challenges abroad are
8 threatening future medical advances for patients
9 and putting American jobs and exports at risk.

10 Around the world, a growing array of
11 governments are free-riding on American
12 investments and failing to provide fair market
13 access for medicines developed in this country.

14 We urge the administration to use
15 Special 301 to address damaging market access
16 barriers in Japan, Canada, and Korea and
17 elsewhere that are harming U.S. exports, often
18 through practices that discriminate against
19 American innovators.

20 New rules in Japan have been developed
21 without sufficient stakeholder input, are not
22 science-based and systematically devalue U.S.

1 products. Key elements of the new rules
2 discriminate against U.S. companies in favor of
3 domestic competitors.

4 Unprecedented recent changes to
5 Canada's pricing regulations are aimed solely at
6 devaluing patented medicines as a condition for
7 market access. In Korea, pricing practices harm
8 the rights of American innovators.

9 These barriers are devastating
10 important overseas markets and they are part of
11 an increasing and increasingly damaging trend of
12 foreign free-riding, as highlighted in a report
13 released by the Council of Economic Advisors
14 earlier this month.

15 The Council's report finds that ending
16 overseas free-riding and reducing foreign price
17 controls would increase innovation, leading to
18 greater competition and lower prices for U.S.
19 patients.

20 Special 301 is a critical opportunity
21 to prioritize this problem for urgent action.
22 For the reasons outlined in our written

1 submission, we ask that Japan, Canada, and Korea
2 be named Priority Foreign Countries.

3 PhRMA's submission also identifies top
4 intellectual property barriers and threats abroad
5 that require urgent action. In many cases, these
6 threats are being driven or actively supported by
7 multilateral organizations.

8 For example, Malaysia has issued a
9 compulsory license for an innovative medicine, a
10 move that was not designed to address a public
11 health challenge, but rather to facilitate the
12 local development of a competing product.

13 While there has been progress in
14 Brazil, Chilean lawmakers are in the final stages
15 of considering legislation that would grant the
16 Health Ministry extraordinary new powers to force
17 compulsory license decisions on the vaguest of
18 grounds.

19 Contrary to its own procedures, the
20 Colombian government continues to review a
21 petition that could result in the compulsory
22 licensing of patents protecting an entire class

1 of innovative medicines.

2 Saudi Arabia has knowingly facilitated
3 the infringement of breakthrough treatments by
4 approving the marketing of competing products
5 during the period of patent or regulatory data
6 protection.

7 Rather than seek to improve its
8 intellectual property protection and enforcement
9 regime, Saudi Arabia has proposed compulsory
10 licensing and data protection regulations that
11 would deny any predictability and certainty for
12 innovators.

13 We ask that Malaysia be named a
14 Priority Foreign Country and that Chile,
15 Colombia, and Saudi Arabia be placed on the
16 Priority Watch List. We further call for
17 meaningful out-of-cycle reviews for Chile and
18 Colombia.

19 Unfortunately, PhRMA members are also
20 facing growing intellectual property and market
21 access barriers and threats in some of our
22 country's largest overseas markets, including the

1 European Union and Mexico.

2 The European Union has already put
3 American innovators at a competitive disadvantage
4 by weakening its supplementary protection system
5 for new medicines. This sends a negative signal
6 for the pending review of orphan and pediatric
7 protections.

8 Mexico has consistently failed to
9 establish effective systems for the protection
10 and enforcement of patents and regulatory test
11 data. New procurement rules threaten to further
12 limit market opportunities for American
13 innovative medicines.

14 For these reasons and others, PhRMA
15 asks that the European Union and Mexico be
16 included on the Watch List and that an
17 out-of-cycle review be conducted for Mexico.

18 We urge you to develop and implement
19 concrete action plans and to use all available
20 tools and leverage to address these serious and
21 pressing challenges, as well as those outlined in
22 our submission.

1 We particularly urge you to address
2 market access and IP barriers in countries that
3 are current or prospective U.S. trade agreement
4 partners or that are beneficiaries of the U.S.
5 trade agreement GSP program.

6 These existing agreements and programs
7 provide immediate opportunities to address
8 pressing challenges and concerns. We appreciate
9 the opportunity to testify today.

10 CHAIR LEE: Thank you. We have some
11 questions and we will begin with USTR.

12 MR. EWERDT: This year, PhRMA is
13 requesting that four countries be designated as
14 Priority Foreign Countries, Canada, Japan, Korea,
15 and Malaysia.

16 First, are each of these countries
17 equally problematic for your members? And
18 second, how does PhRMA distinguish between these
19 countries and those that it nominated for the
20 Priority Watch List?

21 MR. MOORE: Thank you for the question.
22 We follow the Special 301 statutory criteria as

1 we're developing our submission.

2 We are looking at the most serious and
3 egregious intellectual property and market access
4 barriers abroad that have the greatest impact on
5 our industry.

6 And so, we are looking at those issues
7 and attempt to prioritize them, both in terms of
8 the countries that are included in our submission
9 and in the proposals that we make for the
10 different designations.

11 We also are following the statutory
12 criteria as we consider what countries should be
13 Priority Foreign Countries, looking at the
14 criteria that you will have to use to evaluate
15 whether those countries can be named Priority
16 Foreign Countries.

17 So, we are looking at violations of
18 international rules, non-tariff, discriminatory
19 non-tariff barriers and the like, that are
20 outlined in the statute.

21 CHAIR LEE: Thank you. The next
22 question comes from the State Department.

1 MR. FAHMY: Thank you very much. On
2 Malaysia, and you noted in your testimony that
3 Malaysian government utilized a non-transparent
4 process to issue a compulsory license on a U.S.
5 patented medicine.

6 You also talked a little bit about the
7 considerations that you used to recommend that
8 they be a Priority Foreign Country.

9 Could you talk a little bit more,
10 though, about any engagement that you've had with
11 the government of Malaysia and what the response
12 has been?

13 MR. MOORE: Sure. And in all of these
14 cases, we always seek to try to work out any
15 concerns directly with the government.

16 And in the first instance, in
17 Malaysia, we know that it was very difficult for
18 us to engage the government during the period of
19 time when we knew that they were considering this
20 unfortunate action.

21 We have sought to engage the Malaysian
22 government since then, both to reverse the

1 decision that they made, but also to put in place
2 procedures that would address some of the
3 deficiencies that we saw in this instance.

4 We have not been successful in
5 achieving those objectives with the government,
6 but we stand ready to continue to work with
7 whatever the new government will be in that
8 country to continue that conversation.

9 CHAIR LEE: We'll try to squeeze in one
10 last question, and it comes from the PTO.

11 MS. FERRITER: Thank you. Regarding
12 South Korea, your organization indicated that
13 Health Insurance and Review Assessments, or HIRA,
14 have revised the premium pricing policy for
15 global innovative drugs.

16 What is the criteria for a
17 pharmaceutical to be classified as a global
18 innovative drug to qualify for the premium
19 prices?

20 MR. MOORE: The concerns that we've
21 outlined in our submission in Korea are very
22 serious.

1 And as we've pointed out there, part
2 of the way that Korea determines the price of
3 medicines and, therefore, the opportunity for
4 those medicines to enter the market is it does so
5 by direct comparison of patented medicines,
6 innovative medicines, with off-patent generic
7 medicines.

8 And so, that has an effect of
9 depressing the prices initially, and then there
10 are additional actions that are taken by the
11 government, as outlined in our submission, to
12 further effect the price of those products.

13 We were concerned that Korea was
14 providing some opportunity for domestic companies
15 to get a price premium in the market that was not
16 extended to overseas firms.

17 We know that that was addressed in
18 recent trade discussions between the United
19 States and Korea. Unfortunately, Korea has not
20 resolved that in a satisfactory way and we
21 continue to have the concerns that are outlined
22 in our submission.

1 CHAIR LEE: Thank you for your
2 testimony.

3 MR. MOORE: Thank you.

4 CHAIR LEE: Next is Public Citizen.
5 Welcome and please begin your testimony by
6 stating your name and organization.

7 MS. KILIC: Hi, my name is Burcu Kilic.
8 B-U-R-C-U, K-I-L-I-C. I work for Public Citizen's
9 Global Access to Medicine Program. Public
10 Citizen appreciates opportunity to testify on
11 behalf of its more than 500,000 members and
12 supporters. Public Citizen is a nonprofit
13 consumer advocacy organization with a 50-year
14 history of representing consumer interests.

15 We work with partners across the
16 United States and around the world to make
17 medicines affordable and available for all
18 through tools in policy and law. Our testimony
19 draws upon comments that we submitted and our
20 experiences working on the ground with government
21 agencies, civil society organizations, and
22 academic and patient groups.

1 Recent Special 301 Reports have seemed
2 to follow an increasingly aggressive approach of
3 expressly criticizing foreign practices designed
4 to make medicines accessible and affordable.
5 Take compulsory licenses, for instance. Every
6 year, since the late 1980s, U.S. pharmaceutical
7 companies and their allies have been complaining
8 about not only the actual issues of compulsory
9 licenses, but also policy discussions of the
10 licenses.

11 Unfortunately, in 2019 Special 301
12 Report, USTR adopts pharma's narrative on
13 compulsory licenses, quote, actions by trading
14 partners to unfairly issue, threaten to issue, or
15 encourage others to issue compulsory licenses
16 raise serious concerns. Such actions can
17 undermine a patent holder's IP, reduce incentives
18 to invest in research and development for new
19 treatments and cures, unfairly shift the burden
20 for funding such research and development to
21 American patients and those in other markets that
22 properly respect IP, and discourage the

1 introduction of important new medicines into
2 effected markets.

3 I would like to clarify a few issues
4 here. Compulsory licensing allows government to
5 authorize generic competition with patented
6 medicines in exchange for royalty payments to
7 patent holders. It's a standard and longstanding
8 flexibility included in the TRIPS Article 31. It
9 doesn't undermine patent holders IP rights, as
10 patents are not absolute. They are granted,
11 subject to compulsory licensing and government
12 use rights, which have been lawful under
13 international law for nearly 125 years.

14 They are not available only in
15 extremely limited circumstances. Under the TRIPS
16 agreement, members have the right to issue
17 licenses on grounds they determine appropriate,
18 including to address diseases they believe
19 important, address unreasonably high prices, and
20 secure alternative sources to supply.

21 Number of compulsory licenses ever
22 issued by developing countries are very limited.

1 In fact, the United States, which has a very open
2 government use statute, may be the world's most
3 flagrant user of compulsory licensing across
4 technology sectors. It's absurd to claim that
5 American patients face higher prices and less
6 innovative drugs because of compulsory licenses.
7 There is no necessary link between a decline in
8 drug prices here and a price increase in another
9 country, or case of price hike linked to a
10 compulsory license issued anywhere in the world.

11 The politics of drug pricing and
12 patents are changing quickly. Reducing the high
13 drug prices and making drugs affordable have
14 become a major political concern, and the rare
15 departures on cost are rarely around.

16 Three of the four candidates for the
17 Democratic presidential nomination this year
18 expressly support compulsory licensing of patents
19 to make medicines affordable, and the majority of
20 House Democrats support a bill to use compulsory
21 licensing as a leverage in Medicare price
22 negotiations. Yesterday the Center for Disease

1 Control and Prevention warned that Americans
2 should brace for the likelihood that the
3 coronavirus will spread to communities in the
4 United States.

5 The CDC said, it's not much of a
6 question if this will happen in this country
7 anymore, but the question of when this will
8 happen. It's scary. We urgently need safe and
9 effective treatments for coronavirus. This is
10 the third time in the history, in last 20 years,
11 that a coronavirus has made the leap from animals
12 to humans, SARS coronavirus in 2002, MERS
13 coronavirus in 2012, and the novel coronavirus in
14 2019.

15 The pharmaceutical industry,
16 meanwhile, has brought the claim that the
17 monopoly-based patent system is the most
18 effective tool to reward and incentivize
19 innovation, that it fulfills the promise of
20 breakthroughs in treatment and cures for scores
21 of debilitating or life-threatening illnesses
22 around the world.

1 Yet the monopoly model hasn't driven
2 significant industry investment in infectious
3 diseases, including coronaviruses. Consider the
4 industry pipeline for coronaviruses, like SARS
5 and MERS before the last outbreak. I'm wrapping
6 up.

7 Last week, 46 members of Congress sent
8 a letter to President Donald Trump highlighting
9 the disease burden, and they ask him to ensure
10 that any vaccine or treatment be accessible,
11 available and affordable for all Americans.
12 According to the letter, NIH has spent nearly
13 \$700 million on coronavirus research and
14 development. The representatives urge, we should
15 not grant any manufacturer a blank check to
16 monopolize the coronavirus vaccine or treatment
17 developed with public taxpayer support.

18 Without aggressive action to protect
19 public health, we are fearful that Americans and
20 people in lower and middle income countries will
21 not be adequately protected against current and
22 future coronavirus outbreaks. Not only American

1 companies, but also Chinese companies and
2 authorities are racing to crash-develop vaccines
3 and therapies to combat the virus. The world
4 relies heavily on China for supplies of many
5 essential medications.

6 There is a serious chance, not all
7 certain, but realistic, either that the United
8 States may adopt those policies it has long
9 criticized under Special 301. This should
10 commence caution in the Special 301 review today.
11 The U.S. government should not criticize our
12 trading partners for assessing their disease
13 burden and considering or issuing compulsory
14 licenses, both of which are consistent with their
15 international obligations in intellectual
16 property and trade.

17 It seems it's in our best interest to
18 begin muting criticism of access to medicines
19 policies. This way, our government lessens the
20 risks of charges of hypocrisy, and more
21 importantly keeps up with the country and its
22 needs.

1 CHAIR LEE: Thank you. We're going to
2 switch it up and actually not start with USTR for
3 questions, we'll go with the Copyright Office for
4 a question on --

5 MS. KILIC: Okay.

6 CHAIR LEE: -- copyright issues in your
7 submission.

8 MS. KILIC: Yes.

9 MR. WESTON: Hi. Public Citizen's
10 public submission states that the wording of the
11 South African fair use provision mimics --

12 MS. KILIC: Yes.

13 MR. WESTON: -- the wording of its U.S.
14 equivalent. In fact, there seem to be two
15 critical differences between the two statutes,
16 namely, the South African bill Article 12A limits
17 the effect of the use on the potential market
18 factor to, quote, the substitution effect on the
19 potential market, unquote, and it codifies the
20 serving a purpose different from that of the work
21 effected as a sub-factor in the purpose and
22 character of the use factor.

1 Given these two changes, how does
2 Public Citizen see the South African bill
3 protecting the right to create adaptations
4 guaranteed under Articles 12 and 14 of the Berne
5 Convention? Does Public Citizen assert that
6 substitution effect on the potential market is
7 compliant with the three-step test requirement to
8 not conflict with the normal exploitation of the
9 work? And if so, how?

10 MS. KILIC: Okay. This is a very
11 interesting discussion. I was here for the GSP
12 review, and I testified on behalf of South Africa
13 because we also work on access to knowledge.

14 And this is a very interesting
15 question. And during my testimony, I mentioned
16 that it was a great like surprise to me that I
17 was like sitting there and trying to defense a
18 country for adopting fair use, which is very,
19 very American institution. And I'm a
20 European-trained intellectual property lobbyist.
21 And in Europe, we are not big fan of American IP
22 policies. But there is only one concept which we

1 love and we admire, that's fair use.

2 And it has always been the U.S. policy
3 to promote fair use. I was like -- I was very --
4 I could follow the TPP negotiations very closely.
5 And at that time, USTR, like, USTR proposed the
6 flexible version of the fair use in the TPP
7 negotiations. And at that time, they were very,
8 very proud of that.

9 Things have changed, but it is kind of
10 like disappointing that we are questioning
11 countries' policies which promote access to
12 knowledge or education, because that's what South
13 Africa needs. And we can provide you more on the
14 details of the South African law and how it
15 complies with Article 13 of the TRIPS Agreement.

16 CHAIR LEE: Thank you very much for
17 your testimony. Next is SoundExchange. All
18 right. Please begin by stating your name and
19 organization for the record.

20 MR. SCHWARTZ: Thank you, Mr. Chairman
21 and members of the Special Committee. I'm Eric
22 Schwartz, counsel to SoundExchange. And we very

1 much appreciate the opportunity to present the
2 views of SoundExchange in this year's Special 301
3 review.

4 SoundExchange is a nonprofit
5 organization formed by and for the recorded music
6 industry to administer royalties for digital
7 transmissions of recorded music. It serves as a
8 critical backbone to today's digital music
9 industry. The organization collects and
10 distributes digital performance royalties in the
11 U.S. and abroad on behalf of more than 202,000
12 recording artists and master rightsowners'
13 accounts. It collects these royalties on behalf
14 of major and independent record labels,
15 performers and their representatives, and unions
16 representing musical performers.

17 Since its founding in 2003,
18 SoundExchange has paid out more than \$6 billion
19 in royalties to over 170,000 artists and
20 rightsholders globally. It currently administers
21 royalties from over 3,000 digital radio services.

22 SoundExchange is focused in the

1 Special 301 review on particular market access
2 barriers that have been imposed on American
3 musical performers and producers in a handful of
4 countries where a full payment of royalties has
5 been denied for uses of American sound recordings
6 on traditional broadcasts, public performances,
7 and some digital uses.

8 In the territories we focus on, local
9 performers and musical producers are being fully
10 compensated for such uses, while American
11 performers and producers are being denied
12 payments for the exact same uses. This
13 discriminatory treatment is a denial of full
14 national treatment in contravention to the
15 purpose and principals of national treatment
16 obligations found in multilateral treaties and
17 trade agreements and other bilateral commitments
18 to the United States.

19 The territories identified in this
20 filing for review are: the United Kingdom,
21 Australia, Canada, France, Japan and the
22 Netherlands, collectively referred to in the

1 filing as the Six Territories. In total,
2 SoundExchange collected \$1.127 billion and
3 dispersed \$953 million in 2018 in the United
4 States. SoundExchange collects moneys in the
5 United States which it disperses for American and
6 foreign performers and producers in 89 other
7 countries, including in each of the Six
8 Territories.

9 Payment of non-nationals in the U.S.
10 is based on national treatment. This should be
11 the case in the Six Territories as well.

12 National treatment is a bedrock underlying
13 principal of all copyright and neighboring rights
14 treaties and has been since 1886 in the Berne
15 Convention.

16 As adopted in many subsequent treaties
17 and trade agreements, it requires works and
18 recordings of non-national authors, producers,
19 and performers to be protected at a minimum at
20 the same level of protection as the works and
21 recordings of national authors and producers and
22 performers.

1 SoundExchange is paying performers and
2 producers in all Six Territories for all
3 streaming services and digital radio uses for
4 which SoundExchange collects for American
5 performers and producers and at the exact same
6 rates as for domestic recordings. In contrast,
7 American performers and producers are being
8 denied some of their moneys from the Six
9 Territories.

10 In short, U.S. copyright law does not
11 discriminate in its treatment of foreign
12 producers and performers, nor does it deny access
13 to and the ability to collect royalties for uses
14 in the United States. In the absence of full
15 national treatment, the total amount of moneys
16 being denied to American performers in these Six
17 Territories is \$170 million annually.

18 From these Six Territories in 2018,
19 SoundExchange received approximately \$3.8
20 million, while making a combined payment of \$100
21 million. The details of how national treatment
22 is being denied in each of the Six Territories is

1 found in our written submission. For all the
2 reasons detailed in the written submission,
3 SoundExchange recommends that Canada be retained
4 on the Watch List.

5 At present, Canadian users do not pay
6 public performance royalties to American
7 producers or performers for traditional
8 broadcasts, public performances, or digital
9 services, including payments for the use of older
10 recordings, even though these same users do make
11 payments to Canadian performers and producers.

12 The USMCA, once fully implemented,
13 will require Canada to provide full national
14 treatment in accordance with Article 20.8 of the
15 agreement. I would just conclude by saying, for
16 the other countries, SoundExchange recommends
17 that USTR should prioritize this issue and engage
18 in bilateral discussions with each of these
19 countries, with the goal of each country applying
20 full national treatment for American producers
21 and performers.

22 Again, we appreciate the opportunity

1 today to testify, and I look forward to working
2 with you on these issues.

3 CHAIR LEE: Thank you. We have some
4 follow-up questions, beginning with USTR.

5 MR. EWERDT: Besides national
6 treatment, are there other concerns that affect
7 U.S. CMOs, and what are the ways you think that
8 we can address these issues?

9 MR. SCHWARTZ: Well just generally, the
10 problems with CMOs that pertain outside of
11 SoundExchange, good governance, transparency,
12 accountability. As you know from other filings
13 in the 301 process, other countries, Russia,
14 Ukraine, and a host of others have denied
15 American rightsholders their payments, either
16 because there's no good governance, there's no
17 transparency, there's no auditing of payments and
18 the like.

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

21 MR. WESTON: Thank you. Your
22 submission and your testimony recommends that

1 Canada be retained on the Watch List in the 2020
2 Special 301 Report. I know you've just touched
3 on this in your testimony, but do you think that
4 the implementation of USMCA will fully address
5 the issues that you have raised?

6 MR. SCHWARTZ: The short answer is yes.
7 The national treatment obligation is -- I would
8 refer to it as airtight. It applies to both
9 equitable remuneration as well as to protection
10 and enforcement of national treatment
11 obligations.

12 And the President, of course, has to
13 certify to Congress that Canada is in full
14 compliance with the USMCA before it goes into
15 force. And we would certainly recommend that
16 that certification be withheld until Canada makes
17 clear that it's going to make these payments,
18 which has been estimated -- I've heard estimates
19 somewhere around \$20-25 million a year for the
20 denial of payments that they're making to
21 Canadian rights holders, and by the way, other
22 foreign nationals from Rome Convention countries.

1 CHAIR LEE: All right. Thank you. And
2 we have a question from the State Department.

3 MR. FAHMY: Thank you very much. You
4 discussed already your recommendation for Canada
5 both in the submission and in the testimony. But
6 for the other countries, UK, Australia, France,
7 Japan and the Netherlands, you discuss the
8 engaging in bilateral discussions with each of
9 these countries.

10 Can you clarify exactly what that
11 means and whether you're actually recommending
12 that any of these countries be placed on any of
13 the lists, or any other designation?

14 MR. SCHWARTZ: Sure. I mean
15 realistically placement on the list of some of
16 these countries is an option. A better option,
17 of course, in any bilateral context, in any
18 future FTAs, that the USMCA national treatment
19 language should be incorporated into those
20 agreements.

21 That would lock up the full national
22 treatment obligations that the copyright

1 treaties, the WPPT or other agreements, allow
2 carve-outs for full national treatment.
3 Otherwise, just to engage in bilateral
4 discussions on full national treatment with the
5 countries, if that's more effective.

6 Just my almost three decades of
7 working on 301 issues tells me that sometimes
8 placement on lists is effective, and sometimes
9 there are other more effective ways to engage
10 with countries, and this may be one of those
11 instances.

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

14 MR. SCHWARTZ: Thank you.

15 CHAIR LEE: Next up is the Trademark
16 Working Group. Welcome.

17 MR. KILMER: Thank you.

18 CHAIR LEE: If you can begin your
19 testimony by stating your name and organization,

20 --

21 MR. KILMER: Certainly.

22 CHAIR LEE: -- that would be great.

1 MR. KILMER: Paul Kilmer, on behalf of
2 the Trademark Working Group. Again, we
3 appreciate the opportunity to present the
4 observations of our participants as to those
5 trademark laws and practices that cost them the
6 most time and money.

7 This year's matters of most concern to
8 our participants, default judgments. The absence
9 of default judgments in opposition and in
10 validation proceedings in jurisdictions such as
11 China, the EU and Brazil cost U.S. companies many
12 millions of dollars a year in prosecuting
13 proceedings brought against trademark pirates and
14 squatters, who have shown no interest in
15 defending their applications or registrations.

16 Second issue, ex parte relative
17 grounds refusals. During trademark examination,
18 the European Union and its members, among other
19 jurisdictions, do not reject trademark
20 applications on relative grounds -- that is based
21 on likelihood of confusion with previously
22 registered or applied for marks. This costs U.S.

1 businesses many millions of dollars a year in
2 unnecessary opposition proceedings.

3 Certification mark registration.

4 There are still dozens of nations, from Algeria
5 to Yemen, that do not have certification mark
6 registration systems. Other nations, such as
7 Australia, France, India and the United Kingdom,
8 allow certification mark registrations, but
9 impose burdens on applicants that render it
10 difficult if not impossible to maintain a single
11 global certification regime.

12 Ex officio border measures. Nations
13 such as Ecuador, Malaysia and Nigeria do not
14 have, or do not have effective, ex officio border
15 measures that allow trademark owners to post
16 their registered marks with a custom authority
17 empowered to thereafter seize incoming
18 counterfeit goods.

19 Statutory and enhanced damages.

20 Nations that do not provide for enhanced or
21 statutory damages for either blatant infringement
22 or counterfeiting essentially provide a free pass

1 for the most egregious types of piratical
2 conduct. These nations include Brazil, Egypt,
3 Nigeria, Pakistan, Saudi Arabia, South Africa,
4 Turkey, Ukraine and the United Arab Emirates.

5 Coined and well-known mark protection.
6 Nations that do not have robust protection for
7 inherently strong or well-known marks often allow
8 registration and use of such marks by others, in
9 relation to products or services for which their
10 legitimate owner has not attained registration.
11 Nations such as Nigeria offer no protection for
12 well-known marks. Nations such as China severely
13 restrict well-known mark protection.

14 Mandatory license recordation and
15 registered user requirements. These requirements
16 place an unnecessary burden and expense on
17 trademark owners and set a trap for the unwary.
18 Such provisions are in place in nations such as
19 Brazil, Indonesia, Israel, Mexico, Nigeria,
20 Pakistan, South Korea and Thailand.

21 Formalities. Onerous formalities,
22 such as legalization, imposed by a number of

1 nations, including China, Jordan, Lebanon and the
2 United Arab Emirates, place an unnecessary burden
3 on trademark owners. Such nations should be
4 encouraged to either accept notarized document or
5 join the Hague Apostille Convention.

6 Letters of consent and coexistence
7 agreements. Failure by nations to accept or give
8 force to letters of consent or coexistence
9 agreements prevents companies in the marketplace
10 from assisting trademark offices in determining
11 what marks truly will cause a likelihood of
12 confusion. Relevant nations include Argentina,
13 Brazil, China, Japan, South Korea and Thailand.

14 Multi-class registration. Failure to
15 allow multi-class trademark applications in more
16 than 35 nations, including Argentina, Egypt,
17 Pakistan, the Philippines, Saudi Arabia and South
18 Africa, increases the cost of an administrative
19 burden on trademark owners in relation to both
20 filing and maintenance of their registrations.

21 Quite a number of other issues are
22 addressed in our annual 301 submission, which is

1 before you. Thank you again for this
2 opportunity.

3 CHAIR LEE: Excellent. Thank you. We
4 have some follow-up questions, and we'll begin
5 with USTR.

6 MR. EWERDT: Your submission expresses
7 the burden that the absence of default judgments
8 places on U.S. companies. Can you elaborate more
9 on what these default judgments would look like
10 and the best way to ensure their implementation?

11 MR. KILMER: Right. This is a question
12 that's been raised a number of times in different
13 forums. Basically, at bottom, we were just
14 looking for any response from a trademark
15 applicant that it is still interested in its
16 application. That's the first phase.

17 In the United States, the situation is
18 a bit different, because here we require
19 defendants -- applicants to answer oppositions
20 and if they don't answer them, judgment is
21 entered against them. But as a first step in
22 countries that are unfamiliar with default

1 practice, we would simply recommend the trademark
2 office contact the applicant and ask them if
3 they're still interested in their application.

4 Even at that level, we believe that
5 about 60 percent of the opposition proceedings in
6 China, for example, could be avoided simply
7 through a simple mechanism such as that. In
8 fact, we find that about 30 to 40 percent of
9 Chinese applicants give a false address in their
10 applications, so they can't even be contacted
11 officially if an opposition proceeding is filed.

12 And the opposition is then published
13 in the official, what we would call the official
14 gazette. And the trademark applicant never sees
15 that notice, because they aren't watching the
16 official gazette on a day-to-day basis. So I
17 would estimate that a good 60 percent of
18 trademark oppositions in China, for example,
19 would be resolved on default judgment.

20 Now what does that do for the
21 trademark office, and what does it do for the
22 country? It does a lot for U.S. owners because

1 we don't have to file evidence, and we don't have
2 to prove our case. What it does for the country,
3 and China is a great example, is if they
4 instituted default judgments for, let's say, 60
5 percent -- I would say more -- of the proceedings
6 were done on default judgment, it would allow
7 them to put resources into examination.

8 Now I believe in 2018, the figure in
9 China was something like 7 million-plus trademark
10 applications, and the processing time was getting
11 quite lengthy. They've made some improvements in
12 that regard. But you can imagine taking away 60
13 percent of the opposition proceedings, in some
14 way devoting those resources to examination, how
15 much more quickly applications would get through
16 the process.

17 And then legitimate trademark owners
18 would have the advantage of that. And those
19 legitimate trademark owners these days do include
20 an awful lot of Chinese companies, not just U.S.
21 companies.

22 CHAIR LEE: Thank you. The next

1 question is from the Treasury Department.

2 MR. CHANG: Thank you. Of the various
3 concerns that you've identified with respect to
4 China, which are the highest priorities?

5 MR. KILMER: Yes. I think the default
6 judgment issue that we've just discussed. I also
7 think the formalities, the legalization,
8 especially for the Beijing IP Court, although
9 they're trying to work on that, I still think
10 that's a very significant issue for them.

11 The mandatory license recordation
12 really is not an issue for them, but the
13 formalities definitely are. And I would really
14 say the formalities and default judgment, of the
15 things I've mentioned, are probably the most
16 significant and would probably help to save the
17 most money and time on behalf of U.S. companies.

18 CHAIR LEE: Could you just follow up a
19 little bit on the formalities piece --

20 MR. KILMER: Sure.

21 CHAIR LEE: -- specifically related to
22 China?

1 MR. KILMER: Yes. In China, to -- in
2 fact, I just went through this painful process
3 with a client, but we're before the Beijing IP
4 Court in an invalidation proceeding. We had to
5 submit a certificate of good standing. We had to
6 submit a power of attorney. We had to submit an
7 interest certificate, all of which had to be
8 fully legalized through the Chinese Consulate,
9 the embassy here in Washington.

10 Due to the virus situation, the
11 Consulate, which used to take two weeks to do
12 these things, is now taking something closer to
13 four weeks in many cases. So we're actually
14 going to have late filed documents because of the
15 formalities requirement.

16 Frankly, based on the Phase 1
17 agreement with China, there are some provisions
18 in there that they've agreed to that might now
19 allow them to adopt at least the Hague Apostille
20 Convention, which would speed things up
21 dramatically.

22 CHAIR LEE: Thank you very much for

1 your testimony.

2 MR. KILMER: Thank you.

3 CHAIR LEE: Our last testifier today is
4 the U.S. Chamber of Commerce. Welcome. Please
5 state your name and organization for the record
6 and begin your testimony.

7 MS. ANDERSON: Sure. I am Kelly
8 Anderson, I'm with the U.S. Chamber's Global
9 Innovation Policy Center. So we thank you so
10 much for the opportunity to testify on the
11 Chamber's Special 301 submission. I must admit,
12 as somebody with an A last name, I'm used to
13 coming first at things, but I'm happy to be here
14 on behalf of the Chamber to close out your day.

15 So the Chamber's submission highlights
16 both systemic and country-specific challenges.
17 And in my testimony today, I want to highlight
18 some of the issues that are top-of-mind for the
19 Chamber's member companies.

20 So our Chamber's Special 301
21 submission is informed by our two signature
22 research products, our International IP Index,

1 which hopefully you all are familiar with, and
2 our Creativity and Innovation Access Barometer.
3 Our International IP Index is now in its eighth
4 edition. It represents 53 economies, covering
5 over 90 percent of global GDP. The Index
6 evaluates the IP criteria across 50 unique
7 indicators, which we developed with industry as
8 those that they believe are indicative of
9 countries with robust IP systems.

10 So while the Index evaluates the
11 strengths and weaknesses of the country's IP
12 ecosystem, at the Chamber, we recognize that the
13 presence or absence of IP laws is just one piece
14 of the puzzle. In fact, our members have
15 witnessed how a country's investment in IP-driven
16 innovative and creative sectors can be undone by
17 negative market interventions.

18 So the Chamber's Innovation and
19 Creativity Access Barometer evaluates policies
20 beyond traditional IP laws that limit the
21 availability of innovative or creative products,
22 services, and technologies in global markets.

1 The Barometer specifically looks at localization
2 policies, forced technology transfer, local
3 content requirements, and pricing and
4 reimbursement policies that prevent consumers
5 from accessing 21st century innovation in markets
6 around the world. And we'll ask that full copies
7 of both those reports are submitted for the
8 record as well.

9 So building upon the Chamber's
10 research products, the Special 301 submission
11 highlights a number of emerging challenges on IP
12 which our companies face. So first, we recognize
13 that free trade agreements provide a critical
14 mechanism to elevate IP standards in global
15 markets. The 2020 Index illustrates how the
16 countries with FTAs with the U.S. have
17 significantly more robust and effective IP
18 systems than those without them.

19 I should start by saying, we
20 appreciate all the great work that USTR did to
21 negotiate what we believe was a truly 21st
22 century IP chapter in the USMCA. However, the

1 Chamber was disappointed and saw the USMCA as a
2 significant missed opportunity to elevate the IP
3 standards of two of the world's largest trading
4 partners with the final deal that was reached in
5 December.

6 As the Administration begins to focus
7 on future agreements with the UK, the EU, Japan
8 and Kenya, we believe that USMCA should not be
9 used as a template for future agreements as the
10 provisions do not any longer represent 21st
11 century IP protection.

12 Second, our members are concerned
13 about the erosion of IP in developed markets. In
14 Australia, Canada, the EU and Japan, the
15 governments have pursued regulations which
16 undermine life sciences IP in the name of cost
17 containment. These policies not only diminish
18 the value of American IP in these markets, but
19 may reduce the availability of new medical
20 innovations for patients.

21 Third, while emerging markets are
22 taking steps to address longstanding IP

1 challenges, it won't surprise you to hear me say
2 that challenges remain. In China, the government
3 has acknowledged a need to bolster its protection
4 of IP and implemented reforms to reorganize its
5 IP institutions and introduce legislation to
6 strengthen China's IP framework.

7 However, China's regulatory
8 environment is increasingly emphasizing
9 industrial policy outcomes that raise the cost
10 and create uncertainty for U.S. companies
11 operating in China. The ongoing trade
12 negotiations between the U.S. and China provide
13 an opportunity to address systemic challenges on
14 IP and technology transfer that prevent us from
15 realizing the full potential of the bilateral
16 relationship.

17 Additionally, in India, the Ministry
18 of Commerce and Industry has taken incremental
19 steps to improve the national IP environment
20 since the inception of the National IP Policy in
21 2016. But work remains to be done to enforce
22 patent terms, institute a coherent vision on

1 trade secrets protection, and establish a solid
2 technology transfer mechanism.

3 So in conclusion, many governments are
4 in fact increasingly recognizing the importance
5 of IP to their economic and social development,
6 and the Chamber truly stands as a partner to help
7 countries address these outstanding concerns, to
8 help place them on the path to becoming true
9 knowledge-based economies.

10 The Chamber greatly appreciates USTR's
11 dedication to furthering IP protection in markets
12 around the world, and we believe it is critical
13 that the U.S. government work together with other
14 nations to prevent a further deterioration of IP
15 standards abroad.

16 We look forward to working with you
17 and our trading partners to securing meaningful
18 IP commitments, to create jobs, support
19 innovation, create access to technology, and
20 protect consumers, both in the United States and
21 in markets around the world. Thank you.

22 CHAIR LEE: Thank you very much. We

1 have some follow-up questions, beginning with
2 USTR.

3 MR. EWERDT: First of all, thank you to
4 the U.S. Chamber for putting in the time and
5 effort of publishing the annual International IP
6 Index. Your Special 301 submission highlights 16
7 countries and the EU, while your International IP
8 Index evaluates 53 countries. Some of the
9 countries highlighted in your Special 301
10 submission, such as Japan, are given high scores
11 in your Index.

12 Some countries that are given the
13 lowest scores in your Index, such as Venezuela
14 and Argentina, are not included -- or Algeria,
15 Venezuela and Algeria -- are not included in your
16 Special 301 submission. How did the Chamber
17 choose which countries to highlight in its
18 Special 301 submission and which countries to
19 omit?

20 MS. ANDERSON: Sure. I love a good
21 question that involves the Index, so thank you
22 for that. So when we came up with the Index, the

1 goal for the country coverage was that we wanted
2 to have geographic diversity, countries from all
3 different levels of economic development, from
4 all around the world. So we have quite a broad
5 number of economies that are included in that
6 report.

7 We identified the countries in our
8 Special 301 submission based on where our
9 members' top concerns are. So while obviously
10 the Index highlights that there are challenges in
11 countries like Algeria and Venezuela, the
12 countries that we outline in our submission are
13 those where our IP-intensive companies are
14 seeking to operate and facing significant
15 challenges.

16 CHAIR LEE: Thank you. The next
17 question is from the State Department.

18 MR. FAHMY: Thank you very much. On
19 Saudi Arabia, you recognized in your submission
20 that the notorious pirate service beoutQ has been
21 offline now for approximately six months. Is
22 that something that we should consider, that the

1 beoutQ issue is resolved for the purposes of the
2 2020 consideration for the 301 Report?

3 MS. ANDERSON: Yes, thank you for the
4 question. So I will admit that I'm not the Saudi
5 Arabia expert on the team, but with the
6 conversations that we've had with some folks on
7 the ground, we were happy to see that it was
8 offline, but we think it's a situation that needs
9 to continue to be monitored.

10 As I think we see that when a site
11 comes offline somewhere, it can easily pop back
12 up. So that's something that the Chamber's
13 members are closely monitoring.

14 CHAIR LEE: Thank you. The next
15 question is from the U.S. Patent and Trademark
16 Office.

17 MS. FERRITER: Thank you. The Chamber
18 states that the EU's General Data Protection
19 Regulation, or GDPR, has a significant impact on
20 U.S. stakeholders, as it affects the WHOIS
21 database by limiting the personal information
22 that domain name registries and registrars can

1 provide in order to be compliant with the GDPR's
2 heightened level of privacy, and thereby
3 hampering copyright online enforcement. Can you
4 explain this statement further?

5 MS. ANDERSON: Sure. So I'll admit
6 that I'm not familiar with the specifics of that
7 specific part of the submission, but I can reach
8 out to my colleagues that handle GDPR and get
9 back to you with an answer for the record.

10 CHAIR LEE: Okay. We have one final
11 question from the U.S. Copyright Office.

12 MR. WESTON: Thank you. The copyright
13 industry points to India's statutory licensing
14 scheme as the main reason behind lower
15 broadcasting revenues for producers and
16 performers. Accordingly, the Chamber recommends
17 that the Indian government limit the Copyright
18 Board's role to collective administration instead
19 of the current system of granting and pricing
20 licenses. Can you further explain this
21 suggestion?

22 MS. ANDERSON: Sure. So we have been

1 engaged in the Indian market for as long as the
2 GIPC has been around, which is since 2007. I
3 think that the Index shows that we've seen a lot
4 of positive progress when it comes to the Indian
5 government slowly investing in IP protection.
6 And one of the things that we recognize is that
7 they are taking some positive steps on copyright.

8 The specifics of the policy that you
9 recommend, I'm not totally familiar with, so
10 again I'm happy to get back with you with some
11 specifics.

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

14 MS. ANDERSON: Thank you.

15 CHAIR LEE: All right. On behalf of
16 the Special 301 Subcommittee, I would like to
17 thank all the participants for taking time out of
18 your day to have this exchange with us. We
19 appreciate the comprehensive research, thought,
20 and problem-solving efforts that went into your
21 written submissions and oral testimony.

22 Regarding post-hearing comments, the

1 Special 301 docket will reopen this afternoon and
2 remain open until 11:59 p.m. Eastern Time on
3 March 5th. Post-hearing briefs by interested
4 parties that testified today are optional.
5 Please follow the instructions on the agenda or
6 in the original Federal Register Notice, which is
7 at regulations.gov at docket number
8 USTR-2019-0023.

9 A transcript and video of today's
10 hearing will be available at USTR.gov. We will
11 do our best to get that posted within the next
12 two weeks. So again, thank you, everyone,
13 including my colleagues on the panel and those
14 who testified today, for your contributions and
15 your time and attention.

16 Finally, I just want to give a special
17 thanks to personnel at USTR who took care of
18 today's logistics and setup. So in conclusion,
19 ladies and gentlemen, the 2020 Special 301 is now
20 adjourned. Thank you.

21 (Whereupon, the above-entitled matter
22 went off the record at 3:55 p.m.)

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In the matter of: Special 301 Public Hearing

Before: USTR

Date: 02-26-20

Place: Washington, DC

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