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 EWERDT, 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 DERMENTZOGLOU, 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)

C-O-N-T-E-N-T-S

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

10:05 a.m.

CHAIR LEE: Good morning, everyone. My name is Daniel Lee and I'm the Acting Assistant U.S. Trade Representative for Innovation and Intellectual Property. I would like to welcome everyone to the public hearing for the annual Special 301 review.

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

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

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

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

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

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

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

Office of the U.S. Trade Representative.

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

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

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

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

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

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

International Affairs at the U.S. Copyright Office.

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

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

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

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

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

will share with us today.

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

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

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

Those filings are available to the

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

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

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

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

The Statute requires USTR to determine

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

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

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

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

as needed.

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

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

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

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

Thank you. Please introduce yourself

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

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

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

We want to encourage with this also

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIR LEE: Thank you very much for your testimony.

MR. KONSTANTINOV: I appreciate it.

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

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

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

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

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

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

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

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

Programs such as migrations are

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

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

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

is ready and will be launched next month.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Can you elaborate on the barriers to

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

According to the Hellenic Copyright

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

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

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

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

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

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

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

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

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

MR. EWERDT: U.S. companies have recognized the increase in counterfeit

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

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

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

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

discrepancy in the figures.

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

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

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

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

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

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

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

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

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

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

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

DR. HARRIS: Two minutes.

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

DR. HARRIS: Oh. Thank you.

CHAIR LEE: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

And the other side, according to job

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

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

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

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

And we produce the ministry of

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

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

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

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

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

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

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

CHAIR LEE: Thank you.

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

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

But before we came here I already

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

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

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

DR. HARRIS: Thank you.

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

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

Regarding the recent Special 301

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

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

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

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

criteria.

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

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

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

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

pharmaceutical companies.

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

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

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

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

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

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

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

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

(Foreign language spoken.)

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

final decision about ceiling prices.

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

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

(Foreign language spoken.)

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

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

Department of Health and Human Services.

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

(Foreign language spoken.)

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

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

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

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

Agriculture.

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

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

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

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

The official coordination was established between legislative and executive

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

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

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

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

On the first subject. Technically

pending issues in the sphere of collected management.

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

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

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

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

All procurement of software at the

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

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

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

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

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

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

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

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

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

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

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

in place.

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

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

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

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

What is the status of the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

measurable enhancement of IP protection in India.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Labor.

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

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

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

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

a framework for something much more.

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

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

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

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

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

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

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

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

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

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

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

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

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

AAFA commends the efforts of the

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

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

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

In order to effectively seize

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

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

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

Members continue to report that China is the primary source for counterfeiter supply

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

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

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

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

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

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

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

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

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

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

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

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

MS. MITROPOULOS: I think each of the

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. FLYNN: Okay, thank you. My name

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

(Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

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

Implicitly there has been a rule, I

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

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

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

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

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

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

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

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

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

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

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

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

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

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

And what we find is that --

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

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

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

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

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

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

MR. WESTON: Hi.

MR. FLYNN: Hi.

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

MR. FLYNN: Sure.

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

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

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

So, my reading of that fourth factor

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

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

CHAIR LEE: Thank you very much for your testimony.

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

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

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

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

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

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

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

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

economies.

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

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

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

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

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

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

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

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

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

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

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

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

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

and Russia?

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

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

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

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

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

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

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

So that's one thing to consider. Broadly speaking, not just for India.

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

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

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

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

MS. DIFIORE: Absolutely. Thank you.

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

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

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

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

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

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

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

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

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

Brazilian National Confederation of Industry, CNI.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

services called SpeedShare and private server service Speedbox VR.

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

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

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

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

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

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

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

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

MR. MITCHELL: Thank you so much.

MS. PHILLIPS: You're welcome.

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

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

MS. PHILLIPS: I unfortunately don't

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

MS. BLEIMUND: Sorry.

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

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

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

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

MS. DIFIORE: Please. Thank you.

CHAIR LEE: Thank you very much.

MS. PHILLIPS: You're welcome.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

serve to exclude foreign competitors and to favor domestic champions.

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

MR. EWERDT: Can you elaborate on how this trade barrier directly impacts the protection of intellectual property?

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

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

product safe and efficacious.

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

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

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

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

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

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

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

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

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

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

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

CHAIR LEE: Thank you very much for your testimony.

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

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

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

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

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

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

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

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

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

Through this hearing we wish to assist

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

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

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

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

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

explicitly emphasized the importance of IP protection on many occasions.

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

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

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

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

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

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

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

The State Intellectual Property Office

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

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

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

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

MS. LIU: Yes.

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

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

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

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

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

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

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

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

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

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

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

MR. EWERDT: Your written submission

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

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

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

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

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

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

MS. DIFIORE: Hi. CCOIC notes that

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

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

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

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

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

CHAIR LEE: Thank you very much for your testimony.

At this time, we will be breaking

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

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

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

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

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

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

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

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

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

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

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

mandatory disclosure of source code and other propriety data.

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

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

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

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

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

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

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

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

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

First, the Special 301 process should

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

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

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

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

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

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

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

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

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

Despite this, the EU moved forward

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

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

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

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

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

opportunities can be lost.

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

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

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

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

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

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

Directive, including France.

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

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

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

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

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

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

Can you elaborate on how, in your

view, Australia is not upholding its FTA obligations?

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

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

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

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

MR. MITCHELL: Your submission, as well

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

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

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

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

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

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

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

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

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

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

effectively counter their protectionist policies.

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

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

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

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

Now, imagine doing each of those with

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

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

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

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

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

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

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

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

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

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

farmers, and exporters.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIR LEE: Thank you very much for your testimony.

MS. MORRIS: Thank you.

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

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

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

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

about the China issue just after that.

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

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

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

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

consumers on the prevalence of counterfeit goods sold online.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. PRIEST: Nice.

CHAIR LEE: -- from the Department of Labor.

MS. KHAN: Thank you.

MR. PRIEST: Sure.

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

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

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

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

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

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

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

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

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

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

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

MR. PRIEST: Yes, thank you.

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

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

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

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

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

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

In our comments to the Subcommittee,

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

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

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

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

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

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

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

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

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

Although we've been pleased to see

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

still exists. Now, we have a national law.

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

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

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

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

with other countries.

CHAIR LEE: Excellent. Thank you for your testimony.

MR. VALENTE: Thank you.

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

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

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

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

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

representing the U.S. copyright-based industries.

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

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

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

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

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

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

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

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

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

There are those who ask you to dilute

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

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

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

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

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

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

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

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

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

to market access for American creators.

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

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

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

Our trading partners should be doing much more to foster and encourage such cooperation and to develop best practices to

reduce the use of infringing sites and to increase traffic to legitimate copyrighted materials.

Finally, all efforts to address copyright infringement will be unsuccessful if legitimate products and services cannot be brought into market to meet consumer demand. U.S. officials should continue to strive to eliminate or phase out market access barriers.

Special 301 remains a cornerstone of the U.S. effort to advance modern levels of protection for copyright. We look forward to our continued work with USTR and other government agencies to advance these goals.

CHAIR LEE: Thank you. We have some questions and we'll start with USTR.

MR. EWERDT: Regarding Ukraine's recent reforms to its collective management organization regime, or CMOs, are you aware of any prosecutions of owners of rogue CMOs?

MR. ROSENBAUM: Thank you for that question. Ukraine has been a problem in this

area for many years, as USTR is well aware. I am not aware of any efforts to prosecute rogue CMOs, but let me get back to you. I'll check and get back to you on that. Thank you for the question.

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

MR. WESTON: Thank you. IIPA did not recommend South Africa for the Special 301 list in 2019. But this year, IIPA recommends placing South Africa on the Priority Watch List.

Is the basis of this recommendation solely the proposed Copyright Amendment Bill and Performers' Protection Bill or have other conditions in the country changed since last year?

MR. ROSENBAUM: Thank you very much for that question. I believe we did recommend Priority Watch List for South Africa last year, in the lead-up.

At the time, that bill, those two bills were on their way through Parliament and I believe after the process were subsequently

passed, and they're now sitting on the President's desk.

Those bills are incredibly destructive, or would be if enacted, to our industries. So, the situation in South Africa is not good currently.

They needed copyright reform efforts to take place, but unfortunately, the copyright reform efforts that have moved forward would make things worse. And so, that's why we're sounding the alarm on this. And we did last year as well.

And they're currently just in limbo, they could be passed at any time, these bills, and they would have all kinds of contractual requirements that would essentially make it impossible to produce content in the country.

There are exceptions and limitations that are clearly outside the scope of the three-step test and other issues, in terms of rights, a lack of rights, that meet the requirements of the Internet Treaties.

So, they -- South Africa would be

well-served by restarting its copyright reform process, this time bringing in the full range of stakeholders.

They did not consider the views of local artists, local creators, who protested when these bills were introduced. So as I said, they'd be well-served to restart the process over, and that's what we're seeking in South Africa.

CHAIR LEE: All right. Thank you very much for your testimony.

MR. ROSENBAUM: Thank you.

CHAIR LEE: Next is Knowledge Ecology International. Welcome and please begin your testimony by stating your name and organization.

MR. LOVE: My name is James Love with Knowledge Ecology International. I'm going to start on medical technologies.

The Pharmaceutical Manufacturers Association, BIO, the U.S. Chamber of Commerce, the National Association of Manufacturers, the Alliance for Fair Trade with India, and a few

other organizations are asking the United States to take measures to extend and expand monopolies and otherwise raise prices for medical inventions in foreign countries.

The scope of the demands is broad. The USTR is being asked to discipline the breaking of global norms, the use of exceptions that exist in those norms, thinking about using those norms, and finally, any attempt to influence those norms in ways that are not favored by big drug companies.

The drug company-backed asks are framed in terms of U.S. having an interest in promoting biomedical innovation and U.S. jobs in this sector. That argument holds some water, but also leaves a lot out.

The measures proposed by the drug companies present obvious conflicts with policies to curb anti-competitive practices and to promote health, affordability, and more equal access.

Also worth noting, the measures that will raise foreign prices on drugs to treat

cancer and other illnesses are unpopular in the foreign countries where they are targeted. When the U.S. pressures countries to raise drug prices, the U.S. incurs costs, both politically and economically.

When a trade policy favors one particular sector of the economy at the expense of others, there's a cost to the other sectors. That's something to put on the table.

The U.S. can't ask every country to do everything one industry sector wants, since every time the U.S. makes a demand, there's an opportunity cost.

The pharma industry has an insatiable appetite for new rent-seeking norms and actions, but governments can and should, and they need to consider alternatives that don't pit affordability, access, and equality against innovation.

For several years, drug companies have lobbied against efforts at the World Health Organization to set global norms for funding

research and development.

More recently, drug companies have lobbied against global norms on the transparency of pharmaceutical markets and more aggressively against the transparency of R&D costs.

It's in our interest, the interest of the United States, that foreign governments expand public sector financing of biomedical research.

The U.S. government does a laudable job of funding billions of dollars in biomedical research as a public good and spends billions every year to subsidize clinical trials.

The U.S. should push other countries to raise the level of their biomedical R&D spending and clinical trial subsidies and this could have a more pronounced positive impact on innovation than higher prices for drugs, vaccines, and gene and cell therapies.

In the past two decades, pharma has opposed all efforts to pivot from IPR to R&D regarding the focus of trade policy. To be sure,

the pharma sector wants to claim that its policies are designed to enhance R&D spending, but when proposals have been made to create even soft norms in R&D funding or to address a lack of transparency in R&D spending, pharma has mobilized opposition.

The large biomedical companies understand, perhaps better than some government officials, that a focus on R&D rather than IPR could undermine policies that protect price gouging and eliminate their biggest price gouging defense.

While it's true that price gouging can spur innovation, so can lots of other cheaper and less harmful measures, such as expanded R&D subsidies, enhanced government funding direct research, or incentives like market entry awards that are de-linked from prices or monopolies.

One reason the U.S. government needs to rethink the strategy of cross-border funding of biomedical R&D is the U.S. is consistently the biggest victim of excessive pricing and

anti-competitive practices, and is facing the significant aging of our population over the next 15 years, which will add more fiscal stress to an already costly and globally most costly healthcare system.

Among the reforms being considered to address the crises in affordability medicines are those would de-link R&D cost. And in particular, the incentives to invest in R&D.

More generally, this is about de-linking the incentives for the use of monopolies and replacing them with things like market entry awards.

I want to mention on the aging of the population, the United States Bureau of Census estimates we have about 52 million people 65 years or older right now. And they think that will raise to around 95 million by the year 2060.

The percent of the population over 65, which is now 16 percent, is expected to exceed 23 percent. If policymakers are not taking this into account, we are ignoring where we are headed.

The United States is also not the only country that supplies new medical inventions. We're often paying foreign countries for new drug, cell, or gene therapies.

Novartis, a Swiss firm, owns the first CAR-T therapy, as well as the Lexterna gene therapy.

Roche, another Swiss firm, has reaped tens of billions of dollars from U.S. cancer patients, including the treatment my wife takes, which is an invoice for more than $470,000 a year.

Korea, Japan, and Singapore have extensive biotech programs. China is investing heavily in new treatments, including cell and gene therapies.

ClinicalTrials.gov lists 470 clinical trials mentioning chimeric antigen receptor for CAR-T treatments. Of these, 204 of the trials are taking place in the United States, while 208 are taking place in China.

Patent thickets in the United States

in CAR-T gene therapy and CRISPR and the high cost of licensing patents are creating barriers to entry in the United States.

We have to consider the use of compulsory license or expanded exceptions to patents used in the treatment of humans to overcome these problems.

It's also worth reflecting on some of the other issues relevant to the industry 301 submissions, particularly those dealing with local working and technology transfer obligations.

In the United States, the government is now expressing concern over the lack of national capacity to manufacture pharmaceutical APIs or finished products domestically, including in the context of potential coronavirus pandemic.

KEI also expects the U.S. Congress to examine the need to mandate technology transfer for biologics, drugs, vaccines, and cell and gene therapies, in order to overcome the current lack of competition or to address safety concerns for

biosimilars or biogenerics.

I will submit for the record an attachment that provides estimates for the distribution of income for 96 countries, including data on the per capita of income by country, within country.

Indonesia came up earlier, 80 percent of the population in Indonesia has a per capita income of just over $200.

I'll just end with the last thing on copyright to say that we note that BSA is seeking broader global protections for fair use and other exceptions as it concerns text and data mining on the context that non-consumptive reproductions are necessary for the development of AI-related technologies.

In its submission, BSA urges the United States to continue such exceptions to foster innovation and creativity and to maintain the U.S. leadership in AI. We agree with BSA on this topic.

On education materials, we note that

many of the publishers who are seeking policies that are restrictive on exceptions in education are European publishers and not American publishers. Thank you.

CHAIR LEE: Thank you. I think we have a little bit of time for questions. Why don't we start with USTR?

MR. EWERDT: What specific trade-related IP developments that have occurred since April 2019 should this Committee consider as it conducts the Special 301 review this year?

MR. LOVE: I think you need to look at the patent landscape on the recently introduced cell and gene therapies and on CRISPR technologies.

If you look at, for example, small molecules versus biologic drugs, I think what you're seeing right now is an order of magnitude more patents on biologic drugs as opposed to small molecules.

You're seeing a similar but somewhat different thing in terms of new cell and gene

therapies and CRISPR technologies. And there's a proliferation of patents in these areas.

And the cost of acquiring the IP in those areas is much higher than I've seen it for drugs in the past. And I think that the idea that you're sort of promoting global norms against compulsory licensing and exceptions to this area is not very strategic in terms of where the science is going.

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

MR. LOVE: Thank you.

CHAIR LEE: Next, we have MFJ International LLC. Please begin your testimony by stating your name and organization for the record.

MS. JORGE: Thank you. Good afternoon, my name is Mariana Jorge, from MFJ International. Thank you for the opportunity to testify today.

MFJ is a small consulting firm with a significant focus on increasing access to affordable drugs. This testimony is not made on

behalf of any client.

Access to affordable medication has become one of the top policy priorities in the U.S., with real bipartisan support. This high priority was reflected in the State of the Union address and in the administration's Blueprint to Lower Drug Prices, which quotes President Trump as saying, one of my greatest priorities is to reduce the price of prescription drugs.

Nevertheless, U.S. trade policy has been slow to adjust to emerging government priorities and the Special 301 Report is very much an example of this.

And while President Trump, HHS, FDA, and others have made deliberate efforts to increase competition in the pharmaceutical market, some of the agreements negotiated by the USTR and the Special 301 Reports focus on provisions that will do exactly the opposite, broaden and lengthen the monopolies granted to pharmaceutical companies, thus delaying or deterring the launch of generic and biosimilar

drugs and with that, the chances of lowering drug prices.

Today, generics fill 90 percent of the prescriptions in the U.S. but represent only 22 percent of drug spending, thus contributing $292 billion in savings in 2018 alone.

Thus, the generic industry plays a critical role to ensure access to more affordable drugs. Having reached a point of saturation in the U.S. market, the U.S. generic industry has become a global player.

During the negotiations of the TPP and the USMCA, one of the conflictive issues was the exclusivity for biologics. Biologics are complex drugs that are among the most expensive in the market, with prices often above $100,000 per patient per year, and in one case, over $200 million.

Numbers provided by former FDA Commissioner Gottlieb offer a sobering perspective. While less than two percent of Americans use biologics, they represent 40

percent of the total spending on prescription drugs.

Moreover, they represent 70 percent of the growth in drug spending between 2010 and 2015 and they are forecasted to be the fastest growing segment of drug spending in the coming years.

However, efforts to increase competition for biologics are undermined by trade policies that support the adoption of long exclusivities for biologic drugs.

We congratulate the USTR and the U.S. Congress for reaching a bipartisan agreement on this matter in the USMCA. The FTC concluded that there is not evidence about the lack of patentability of biologics, it was mentioned about how many patents are on these drugs.

This seems to be confirmed by a review of biosimilar drugs approved so far in the United States. While 26 biosimilars have been approved, only 14 have been launched.

One of the reasons for the failure of launch some of these products seems to be

litigation initiated by originator companies or because companies have reached settlement agreements as a result of litigation.

Concerns over competition of these drugs were expressed by Commissioner Gottlieb in the following terms. Competition is for the most part anemic. It is anemic because litigation has delayed market access for biosimilar drugs.

In addition, the investment required to develop biosimilar products is much higher than for generics. Again, Commissioner Gottlieb said, while it can cost about $10 million to develop a generic version of a small molecule drug, the complexity of manufacturing and testing biosimilars typically cost between $100 and $250 million per program.

Finally, the FDA recognizes that creating efficient economies of scale for biosimilars require a global market.

Therefore, today, I am requesting that the USTR take a fresh look at this issue in the understanding that, one, more than 30 years after

the release of the first Special 301 Report, the report should not focus on continuing to ratchet up the standards of IP protection, but on ensuring that all countries provide adequate and effective protection in compliance with their international obligations.

Two, the Special 301 Report cannot be a reflection of a wish list of one side of the pharmaceutical industry at the expense of the other, consumers, and payers.

Three, in the past 30 years, the U.S. pharmaceutical industry has dramatically changed and today, the generic and biosimilar industry is global and needs access to foreign markets to be able to provide new biosimilar medications in the U.S. Failure to have such access will put its development and sustainability at risk.

Four, U.S. trade policy must be consistent with other government priorities, which is, in the case of health, is clearly bipartisan, lowering drug prices.

And finally, U.S. trade policy must

support the efforts of other government agencies to achieve this important goal, not undermine them.

CHAIR LEE: Thank you very much. We have some questions and we will start with USTR.

MR. EWERDT: In your submission, you state that, quote, further increasing the levels of intellectual property protection in other markets would result in the adoption of new non-tariff barriers to entry for the generic and biosimilar industry, end quote.

Aside from ensuring market entry for biosimilars, you do not discuss particular policies or practices that deny adequate and effective protection of IP rights or deny fair and equitable market access to U.S. persons who rely on IP protection.

Can you provide specific examples of policies or practices in other countries that you think should be highlighted in the 2020 Special 301 Report?

MS. JORGE: Yes. I am a true believer

in intellectual property, but it has to be balanced with competition. This is not just me saying it, the FTC report has a report on this issue and says, in order to promote innovation, it has to be a balance between IP and competition.

We have to remember that IP is not an end in itself, it's a medium to an end and the end is innovation.

So, everything that breaks that balance between protection and competition, that is what create non-tariff barriers.

So we are recognizing, we have 20-year patent terms, but if we keep extending the patents through patent extensions unlimited, to also extend different type of patents, to do the evergreening, to do exclusivity for biologics, exclusivity for this, exclusivity for pediatrics, I mean, the competition is being shrinking and shrinking and shrinking.

And guess who is on the other side? All of us and all of our families. And we are

not creating more innovation, we are, I'm sorry for the term, but I think it's graphic, we are creating fat cows that do not need to work hard to create new things to bring to the market.

We want innovation, we want cures for illnesses, but we do not create just big fat cows that do not need to work for it. We want balance between innovation, between protection of intellectual property and access. And I think we have lost the perspective that not always more IP is better.

CHAIR LEE: Okay. Thank you. The next question is from HHS.

MS. BLEIMUND: Thank you. I think, on a related note, in your submission, you state that while the Special 301 statute requires USTR to identify countries that deny adequate and effective protection of IP rights, you say there is now, quote, an assumption that more intellectual property is always better.

Keeping in mind the legislative mandate for the Special 301 Report, how do you

suggest the United States use the report to advance the administration's policy goals related to IP protection and enforcement?

MS. JORGE: Thank you. Well, the very first thing I will say, I don't know if anybody was watching TV last night, something was going on. Well, in-between what was going on, there was an ad from the President about increasing competition for biosimilars, okay?

So, I think we have to look at what the priorities for the government are and whether what was designed 30 years ago still apply. It's like we are in one room, but the whole scenario has changed and we are acting like the scenario has not changed.

The whole priorities and the situation where we were when it was '89 has changed. And we cannot pretend that more IP and more IP and more IP, we are becoming slaves of interest groups that are just seeking their own benefit.

They do have to seek their own benefit, I'm not saying they are not doing what

they have to do, but the government has to look after the common good. The government has to look after all of us.

And so, going back to your question, how to do it, I think we have to relook at the Special 301 and we have to look at what the situation is now.

Thirty years ago, in '89, it was only five years after Hatch-Waxman passed. Guess what? The generic industry was completely focused into developing internally.

I know, because it took me four heads of the generic industry to understand that these kind of provisions was going to hurt them. But we went from, in '85 or '84, it was 21 percent of generic utilization in this country. When Hatch-Waxman passed, they have to focus in growing internally.

Now, they have to have access to other markets. And instead, the Special 301 are locking them by establishing barriers to entry to U.S. products.

And if we don't generate that extra money, we cannot generate the $100 to $250 million that Gottlieb says it takes to develop a biosimilar.

So, if we block those markets, we are blocking solutions to access to really expensive drugs, and like cancer drugs, for our own citizens.

CHAIR LEE: Thank you very much for your testimony.

MS. JORGE: Thank you for the opportunity.

CHAIR LEE: Excellent. Next, we have the National Association of Manufacturers. All right. Please state your name and organization for the record.

MR. ONG: There we go, with the mic on this time. Ryan Ong, with the National Association of Manufacturers. Thank you.

Members of the Special 301 Committee, thank you for the opportunity to testify today on behalf of the National Association of

Manufacturers, the NAM, and the more than 14,000 manufacturers that we represent.

Manufacturers in the United States have created an innovation engine that has reshaped the world around us. New technologies and products have brought us energy independence, new lifesaving medicines, and more efficient automobiles.

As we speak, countless other innovative manufactured products are being developed and refined to improve people's lives and secure our nation's global manufacturing leadership.

Innovation and intellectual property fuel that manufacturing industry and its ability to propel the American economy forward, but our businesses and products remain targets for other countries seeking to steal our innovative ideas and undercut those advancements. And sadly, this trend is not getting better, it's getting worse.

A 2017 report by the Commission on the Theft of American Intellectual Property found

that stolen ideas, brands, and inventions drain up to $600 billion from the U.S. economy, a shocking figure that's nearly double that of the Commission's report from four years prior.

Undercutting American innovation harms U.S. businesses, jobs, and workers in the process.

The NAM's formal Special 301 submission details a full list of recommendations to protect manufacturing IP. We recommend eight countries for the Priority Watch List and six additional countries for the Watch List as the focus for this year's report. This includes longstanding priorities, such as China and India, and emerging challenges, such as Argentina and Saudi Arabia.

Although the United States faces a multitude of IP threats from foreign actors, today I'd like to focus quickly on three: counterfeiting, trade secret theft, and threats to IP emanating from work streams at international organizations.

First, manufacturers continue to battle a growing tide of fake products sold in the United States. Counterfeiters increasingly abuse online channels, exploit weaknesses in the international postal system, and transship through free trade zones to flood the United States with fake and unsafe products.

The administration has focused welcome attention on these issues with its recent report on combating counterfeiting, as well as initial steps towards implementation, but significant work remains to benefit American manufacturers, large and small.

Second, companies face sophisticated physical and electronic attempts by bad actors to steal trade secrets. A 2014 study estimated that the economic loss from trade secret theft is between one and three percent of U.S. GDP, which would translate to a loss of between $180 and $500 billion.

This makes it hard, challenging, difficult for U.S. companies to export and

compete in countries around the world, particularly small and medium-sized companies for whom trade secrets are often their most important competitive asset.

Finally, actors and initiatives at international organizations increasingly seek to weaken critical IP protections in the name of other important policy priorities, such as public health and environmental protection.

These remain critical priorities, but it's important to understand that these types of efforts overlook the importance of innovation in finding powerful solutions to these very challenges and create barriers and false narratives that hinder the very progress they claim to promote.

The United States has long made vigorous protection of IP rights at home and abroad a cornerstone of our manufacturing competitiveness, but we must do more in the face of these and other challenges.

It is more critical now than ever

before that the United States strongly defend intellectual property and innovation around the world in all available and appropriate forums.

We must make strategic use of available options, working collaboratively across agencies to address IP challenges through both existing channels, as well as new tools.

This must include not only active use of Special 301 related tools, such as country classifications, out-of-cycle reviews, and results-oriented action plans, but the U.S. government must also prioritize intellectual property protections in current and future trade negotiations, leverage IP-friendly international organizations and fora to push for stronger IP rules, and expand capacity-building and enforcement collaboration programs with foreign governments.

To our U.S. government colleagues, we strongly support your work to continue to pursue a level playing field for American manufacturers to compete in the increasingly global economy.

Every day, manufacturers across the country are transforming their operations to achieve greater efficiency, productivity, and competitiveness, while working to create a better tomorrow we all dream of.

None of that is possible without U.S. leadership driving strong rules to protect our innovation and IP, as well as robust enforcement efforts. The success of our industry and the strength of our economy depend on it.

Thank you. With that, I'm happy to answer any questions you have.

CHAIR LEE: Thank you very much. We indeed do have questions, and we'll start with USTR.

MR. EWERDT: Regarding your written submission, you state that USTR should address legislative efforts that could undermine existing patent term restoration, specifically noting the EU's revisions to its SPC regime.

Can you further explain this statement and what does NAM see as the critical steps here?

MR. ONG: Sure, I appreciate that question. What we see in a variety of global markets are efforts to use domestic legislation and other regulatory tools to be able to place increased limitations or boundaries on the ability of companies to be able to generate and use regulatory data that's critical for producing products that come to market and products that help to serve the interests and needs of customers and consumers.

Within the European Union, the process of discussion over SPC and the appropriate balance is a longstanding issue, it's one that's picked up legislative momentum in recent years. And it's not alone, we see similar legislative moves in other critical markets.

It remains fundamentally important on these and issues that pop up market-to-market that the U.S. government, that USTR, and that each of you in your interagency jurisdictions, as you're engaging with European counterparts on these issues, look for ways to be able to pursue

legislative reform and change, to be able to ensure strong protection for IP and the regulatory protection that, again, makes it possible for innovative companies to bring these products to market.

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

MS. FERRITER: Thank you. With respect to China your written submission stated, and I quote, trademark squatting issues also remain a problem and not one covered well under existing law.

As of November 1, 2019, Article 4 of China's Amended Trademark Law provides grounds for rejection and opposition of bad faith trademarks. And again, I quote, without intent to use, end quote.

Has the new provision been of any use to rights holders? Thank you.

MR. ONG: Thank you as well. The legislative change that you're referring, I think

for our manufacturers was seen as a welcome step, an important recognition of the nature of this problem, as well as providing access to some additional tools to be able to address the issue.

Given the relatively recent nature of that change, I think our manufacturing members that are monitoring this issue are watching very closely to ensure that in practice, manufacturers that experience challenges with trademark squatting or other bad faith trademark actions can adequately use those provisions to be able to address those issues.

And that's something that I think will take some additional time. I'm happy to remain engaged with you and your colleagues as we continue to hear further from our manufacturing members.

CHAIR LEE: Thank you. It looks like we have time for one more question and it will be from ITA.

MR. MITCHELL: In its submission, your organization has commented that, quote,

international organizations increasingly seek to weaken IP protections in the name of other policy priorities, such as public health or environmental protection.

Can you identify specific examples of such instances?

MR. ONG: Sure, absolutely. I'll provide a good example from 2016, one we still continue to see reverberate in policy discussions today.

And that's the UN High Level Panel on Access to Medicines. This was a panel set up at the recommendation of the UN Secretary General to look at an important issue that we've been speaking a good bit about today, that being best ways to be able to ensure access to lifesaving medications in markets around the world.

In practice, what we saw from the workings of that panel was a fairly one-sided discussion that focused purely on intellectual property, as opposed to an opportunity for a robust discussion of the range of barriers that

can often help to prevent meaningful access to these products in global markets, trained healthcare personnel, cold chain logistics, local tariff protections, trade barriers, and these types of issues.

And so, the end report that was released had a similarly problematic one-sided focus.

The U.S. government at that point in time, and this was under the previous administration, was extremely helpful in delivering a strong interagency rebuttal and response to that report, pointing out U.S. work and engagement to address these issues meaningfully, but also the problematic nature of both process and content on the back end.

We continue to see, however, in a variety of agencies, the World Health Organization and others, attempts to be able to use that report and its findings as a basis for specific additional work streams that have a similarly, I would say, one-sided approach to

these issues.

CHAIR LEE: All right. Thank you very much for your testimony.

MR. ONG: Thank you.

CHAIR LEE: Next is the Pharmaceutical Research and Manufacturers of America. All right. Please begin by stating your name and organization for the record.

MR. MOORE: I am Chris Moore with the Pharmaceutical Research and Manufacturers of America.

And on behalf of biopharmaceutical innovators in the United States and the more than 800,000 women and men they employ across the country, PhRMA appreciates the opportunity to testify before the Special 301 Committee.

Where markets are open and intellectual property is protected and enforced, PhRMA members have the predictability and certainty necessary to research, develop, and deliver new medicines and vaccines for patients who need them.

Today, America's biopharmaceutical innovators are playing a critical role in the global response to the COVID-19 virus and are pioneering groundbreaking therapies that are revolutionizing the treatment of many other devastating diseases and conditions.

But urgent challenges abroad are threatening future medical advances for patients and putting American jobs and exports at risk.

Around the world, a growing array of governments are free-riding on American investments and failing to provide fair market access for medicines developed in this country.

We urge the administration to use Special 301 to address damaging market access barriers in Japan, Canada, and Korea and elsewhere that are harming U.S. exports, often through practices that discriminate against American innovators.

New rules in Japan have been developed without sufficient stakeholder input, are not science-based and systematically devalue U.S.

products. Key elements of the new rules discriminate against U.S. companies in favor of domestic competitors.

Unprecedented recent changes to Canada's pricing regulations are aimed solely at devaluing patented medicines as a condition for market access. In Korea, pricing practices harm the rights of American innovators.

These barriers are devastating important overseas markets and they are part of an increasing and increasingly damaging trend of foreign free-riding, as highlighted in a report released by the Council of Economic Advisors earlier this month.

The Council's report finds that ending overseas free-riding and reducing foreign price controls would increase innovation, leading to greater competition and lower prices for U.S. patients.

Special 301 is a critical opportunity to prioritize this problem for urgent action. For the reasons outlined in our written

submission, we ask that Japan, Canada, and Korea be named Priority Foreign Countries.

PhRMA's submission also identifies top intellectual property barriers and threats abroad that require urgent action. In many cases, these threats are being driven or actively supported by multilateral organizations.

For example, Malaysia has issued a compulsory license for an innovative medicine, a move that was not designed to address a public health challenge, but rather to facilitate the local development of a competing product.

While there has been progress in Brazil, Chilean lawmakers are in the final stages of considering legislation that would grant the Health Ministry extraordinary new powers to force compulsory license decisions on the vaguest of grounds.

Contrary to its own procedures, the Colombian government continues to review a petition that could result in the compulsory licensing of patents protecting an entire class

of innovative medicines.

Saudi Arabia has knowingly facilitated the infringement of breakthrough treatments by approving the marketing of competing products during the period of patent or regulatory data protection.

Rather than seek to improve its intellectual property protection and enforcement regime, Saudi Arabia has proposed compulsory licensing and data protection regulations that would deny any predictability and certainty for innovators.

We ask that Malaysia be named a Priority Foreign Country and that Chile, Colombia, and Saudi Arabia be placed on the Priority Watch List. We further call for meaningful out-of-cycle reviews for Chile and Colombia.

Unfortunately, PhRMA members are also facing growing intellectual property and market access barriers and threats in some of our country's largest overseas markets, including the

European Union and Mexico.

The European Union has already put American innovators at a competitive disadvantage by weakening its supplementary protection system for new medicines. This sends a negative signal for the pending review of orphan and pediatric protections.

Mexico has consistently failed to establish effective systems for the protection and enforcement of patents and regulatory test data. New procurement rules threaten to further limit market opportunities for American innovative medicines.

For these reasons and others, PhRMA asks that the European Union and Mexico be included on the Watch List and that an out-of-cycle review be conducted for Mexico.

We urge you to develop and implement concrete action plans and to use all available tools and leverage to address these serious and pressing challenges, as well as those outlined in our submission.

We particularly urge you to address market access and IP barriers in countries that are current or prospective U.S. trade agreement partners or that are beneficiaries of the U.S. trade agreement GSP program.

These existing agreements and programs provide immediate opportunities to address pressing challenges and concerns. We appreciate the opportunity to testify today.

CHAIR LEE: Thank you. We have some questions and we will begin with USTR.

MR. EWERDT: This year, PhRMA is requesting that four countries be designated as Priority Foreign Countries, Canada, Japan, Korea, and Malaysia.

First, are each of these countries equally problematic for your members? And second, how does PhRMA distinguish between these countries and those that it nominated for the Priority Watch List?

MR. MOORE: Thank you for the question. We follow the Special 301 statutory criteria as

we're developing our submission.

We are looking at the most serious and egregious intellectual property and market access barriers abroad that have the greatest impact on our industry.

And so, we are looking at those issues and attempt to prioritize them, both in terms of the countries that are included in our submission and in the proposals that we make for the different designations.

We also are following the statutory criteria as we consider what countries should be Priority Foreign Countries, looking at the criteria that you will have to use to evaluate whether those countries can be named Priority Foreign Countries.

So, we are looking at violations of international rules, non-tariff, discriminatory non-tariff barriers and the like, that are outlined in the statute.

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

MR. FAHMY: Thank you very much. On Malaysia, and you noted in your testimony that Malaysian government utilized a non-transparent process to issue a compulsory license on a U.S. patented medicine.

You also talked a little bit about the considerations that you used to recommend that they be a Priority Foreign Country.

Could you talk a little bit more, though, about any engagement that you've had with the government of Malaysia and what the response has been?

MR. MOORE: Sure. And in all of these cases, we always seek to try to work out any concerns directly with the government.

And in the first instance, in Malaysia, we know that it was very difficult for us to engage the government during the period of time when we knew that they were considering this unfortunate action.

We have sought to engage the Malaysian government since then, both to reverse the

decision that they made, but also to put in place procedures that would address some of the deficiencies that we saw in this instance.

We have not been successful in achieving those objectives with the government, but we stand ready to continue to work with whatever the new government will be in that country to continue that conversation.

CHAIR LEE: We'll try to squeeze in one last question, and it comes from the PTO.

MS. FERRITER: Thank you. Regarding South Korea, your organization indicated that Health Insurance and Review Assessments, or HIRA, have revised the premium pricing policy for global innovative drugs.

What is the criteria for a pharmaceutical to be classified as a global innovative drug to qualify for the premium prices?

MR. MOORE: The concerns that we've outlined in our submission in Korea are very serious.

And as we've pointed out there, part of the way that Korea determines the price of medicines and, therefore, the opportunity for those medicines to enter the market is it does so by direct comparison of patented medicines, innovative medicines, with off-patent generic medicines.

And so, that has an effect of depressing the prices initially, and then there are additional actions that are taken by the government, as outlined in our submission, to further effect the price of those products.

We were concerned that Korea was providing some opportunity for domestic companies to get a price premium in the market that was not extended to overseas firms.

We know that that was addressed in recent trade discussions between the United States and Korea. Unfortunately, Korea has not resolved that in a satisfactory way and we continue to have the concerns that are outlined in our submission.

CHAIR LEE: Thank you for your testimony.

MR. MOORE: Thank you.

CHAIR LEE: Next is Public Citizen. Welcome and please begin your testimony by stating your name and organization.

MS. KILIC: Hi, my name is Burcu Kilic. B-U-R-C-U, K-I-L-I-C. I work for Public Citizen's Global Access to Medicine Program. Public Citizen appreciates opportunity to testify on behalf of its more than 500,000 members and supporters. Public Citizen is a nonprofit consumer advocacy organization with a 50-year history of representing consumer interests.

We work with partners across the United States and around the world to make medicines affordable and available for all through tools in policy and law. Our testimony draws upon comments that we submitted and our experiences working on the ground with government agencies, civil society organizations, and academic and patient groups.

Recent Special 301 Reports have seemed to follow an increasingly aggressive approach of expressly criticizing foreign practices designed to make medicines accessible and affordable. Take compulsory licenses, for instance. Every year, since the late 1980s, U.S. pharmaceutical companies and their allies have been complaining about not only the actual issues of compulsory licenses, but also policy discussions of the licenses.

Unfortunately, in 2019 Special 301 Report, USTR adopts pharma's narrative on compulsory licenses, quote, actions by trading partners to unfairly issue, threaten to issue, or encourage others to issue compulsory licenses raise serious concerns. Such actions can undermine a patent holder's IP, reduce incentives to invest in research and development for new treatments and cures, unfairly shift the burden for funding such research and development to American patients and those in other markets that properly respect IP, and discourage the

introduction of important new medicines into effected markets.

I would like to clarify a few issues here. Compulsory licensing allows government to authorize generic competition with patented medicines in exchange for royalty payments to patent holders. It's a standard and longstanding flexibility included in the TRIPS Article 31. It doesn't undermine patent holders IP rights, as patents are not absolute. They are granted, subject to compulsory licensing and government use rights, which have been lawful under international law for nearly 125 years.

They are not available only in extremely limited circumstances. Under the TRIPS agreement, members have the right to issue licenses on grounds they determine appropriate, including to address diseases they believe important, address unreasonably high prices, and secure alternative sources to supply.

Number of compulsory licenses ever issued by developing countries are very limited.

In fact, the United States, which has a very open government use statute, may be the world's most flagrant user of compulsory licensing across technology sectors. It's absurd to claim that American patients face higher prices and less innovative drugs because of compulsory licenses. There is no necessary link between a decline in drug prices here and a price increase in another country, or case of price hike linked to a compulsory license issued anywhere in the world.

The politics of drug pricing and patents are changing quickly. Reducing the high drug prices and making drugs affordable have become a major political concern, and the rare departures on cost are rarely around.

Three of the four candidates for the Democratic presidential nomination this year expressly support compulsory licensing of patents to make medicines affordable, and the majority of House Democrats support a bill to use compulsory licensing as a leverage in Medicare price negotiations. Yesterday the Center for Disease

Control and Prevention warned that Americans should brace for the likelihood that the coronavirus will spread to communities in the United States.

The CDC said, it's not much of a question if this will happen in this country anymore, but the question of when this will happen. It's scary. We urgently need safe and effective treatments for coronavirus. This is the third time in the history, in last 20 years, that a coronavirus has made the leap from animals to humans, SARS coronavirus in 2002, MERS coronavirus in 2012, and the novel coronavirus in 2019.

The pharmaceutical industry, meanwhile, has brought the claim that the monopoly-based patent system is the most effective tool to reward and incentivize innovation, that it fulfills the promise of breakthroughs in treatment and cures for scores of debilitating or life-threatening illnesses around the world.

Yet the monopoly model hasn't driven significant industry investment in infectious diseases, including coronaviruses. Consider the industry pipeline for coronaviruses, like SARS and MERS before the last outbreak. I'm wrapping up.

Last week, 46 members of Congress sent a letter to President Donald Trump highlighting the disease burden, and they ask him to ensure that any vaccine or treatment be accessible, available and affordable for all Americans. According to the letter, NIH has spent nearly $700 million on coronavirus research and development. The representatives urge, we should not grant any manufacturer a blank check to monopolize the coronavirus vaccine or treatment developed with public taxpayer support.

Without aggressive action to protect public health, we are fearful that Americans and people in lower and middle income countries will not be adequately protected against current and future coronavirus outbreaks. Not only American

companies, but also Chinese companies and authorities are racing to crash-develop vaccines and therapies to combat the virus. The world relies heavily on China for supplies of many essential medications.

There is a serious chance, not all certain, but realistic, either that the United States may adopt those policies it has long criticized under Special 301. This should commence caution in the Special 301 review today. The U.S. government should not criticize our trading partners for assessing their disease burden and considering or issuing compulsory licenses, both of which are consistent with their international obligations in intellectual property and trade.

It seems it's in our best interest to begin muting criticism of access to medicines policies. This way, our government lessens the risks of charges of hypocrisy, and more importantly keeps up with the country and its needs.

CHAIR LEE: Thank you. We're going to switch it up and actually not start with USTR for questions, we'll go with the Copyright Office for a question on --

MS. KILIC: Okay.

CHAIR LEE: -- copyright issues in your submission.

MS. KILIC: Yes.

MR. WESTON: Hi. Public Citizen's public submission states that the wording of the South African fair use provision mimics --

MS. KILIC: Yes.

MR. WESTON: -- the wording of its U.S. equivalent. In fact, there seem to be two critical differences between the two statutes, namely, the South African bill Article 12A limits the effect of the use on the potential market factor to, quote, the substitution effect on the potential market, unquote, and it codifies the serving a purpose different from that of the work effected as a sub-factor in the purpose and character of the use factor.

Given these two changes, how does Public Citizen see the South African bill protecting the right to create adaptations guaranteed under Articles 12 and 14 of the Berne Convention? Does Public Citizen assert that substitution effect on the potential market is compliant with the three-step test requirement to not conflict with the normal exploitation of the work? And if so, how?

MS. KILIC: Okay. This is a very interesting discussion. I was here for the GSP review, and I testified on behalf of South Africa because we also work on access to knowledge.

And this is a very interesting question. And during my testimony, I mentioned that it was a great like surprise to me that I was like sitting there and trying to defense a country for adopting fair use, which is very, very American institution. And I'm a European-trained intellectual property lobbyer. And in Europe, we are not big fan of American IP policies. But there is only one concept which we

love and we admire, that's fair use.

And it has always been the U.S. policy to promote fair use. I was like -- I was very -- I could follow the TPP negotiations very closely. And at that time, USTR, like, USTR proposed the flexible version of the fair use in the TPP negotiations. And at that time, they were very, very proud of that.

Things have changed, but it is kind of like disappointing that we are questioning countries' policies which promote access to knowledge or education, because that's what South Africa needs. And we can provide you more on the details of the South African law and how it complies with Article 13 of the TRIPS Agreement.

CHAIR LEE: Thank you very much for your testimony. Next is SoundExchange. All right. Please begin by stating your name and organization for the record.

MR. SCHWARTZ: Thank you, Mr. Chairman and members of the Special Committee. I'm Eric Schwartz, counsel to SoundExchange. And we very

much appreciate the opportunity to present the views of SoundExchange in this year's Special 301 review.

SoundExchange is a nonprofit organization formed by and for the recorded music industry to administer royalties for digital transmissions of recorded music. It serves as a critical backbone to today's digital music industry. The organization collects and distributes digital performance royalties in the U.S. and abroad on behalf of more than 202,000 recording artists and master rightsowners' accounts. It collects these royalties on behalf of major and independent record labels, performers and their representatives, and unions representing musical performers.

Since its founding in 2003, SoundExchange has paid out more than $6 billion in royalties to over 170,000 artists and rightsholders globally. It currently administers royalties from over 3,000 digital radio services.

SoundExchange is focused in the

Special 301 review on particular market access barriers that have been imposed on American musical performers and producers in a handful of countries where a full payment of royalties has been denied for uses of American sound recordings on traditional broadcasts, public performances, and some digital uses.

In the territories we focus on, local performers and musical producers are being fully compensated for such uses, while American performers and producers are being denied payments for the exact same uses. This discriminatory treatment is a denial of full national treatment in contravention to the purpose and principals of national treatment obligations found in multilateral treaties and trade agreements and other bilateral commitments to the United States.

The territories identified in this filing for review are: the United Kingdom, Australia, Canada, France, Japan and the Netherlands, collectively referred to in the

filing as the Six Territories. In total, SoundExchange collected $1.127 billion and dispersed $953 million in 2018 in the United States. SoundExchange collects moneys in the United States which it disperses for American and foreign performers and producers in 89 other countries, including in each of the Six Territories.

Payment of non-nationals in the U.S. is based on national treatment. This should be the case in the Six Territories as well. National treatment is a bedrock underlying principal of all copyright and neighboring rights treaties and has been since 1886 in the Berne Convention.

As adopted in many subsequent treaties and trade agreements, it requires works and recordings of non-national authors, producers, and performers to be protected at a minimum at the same level of protection as the works and recordings of national authors and producers and performers.

SoundExchange is paying performers and producers in all Six Territories for all streaming services and digital radio uses for which SoundExchange collects for American performers and producers and at the exact same rates as for domestic recordings. In contrast, American performers and producers are being denied some of their moneys from the Six Territories.

In short, U.S. copyright law does not discriminate in its treatment of foreign producers and performers, nor does it deny access to and the ability to collect royalties for uses in the United States. In the absence of full national treatment, the total amount of moneys being denied to American performers in these Six Territories is $170 million annually.

From these Six Territories in 2018, SoundExchange received approximately $3.8 million, while making a combined payment of $100 million. The details of how national treatment is being denied in each of the Six Territories is

found in our written submission. For all the reasons detailed in the written submission, SoundExchange recommends that Canada be retained on the Watch List.

At present, Canadian users do not pay public performance royalties to American producers or performers for traditional broadcasts, public performances, or digital services, including payments for the use of older recordings, even though these same users do make payments to Canadian performers and producers.

The USMCA, once fully implemented, will require Canada to provide full national treatment in accordance with Article 20.8 of the agreement. I would just conclude by saying, for the other countries, SoundExchange recommends that USTR should prioritize this issue and engage in bilateral discussions with each of these countries, with the goal of each country applying full national treatment for American producers and performers.

Again, we appreciate the opportunity

today to testify, and I look forward to working with you on these issues.

CHAIR LEE: Thank you. We have some follow-up questions, beginning with USTR.

MR. EWERDT: Besides national treatment, are there other concerns that affect U.S. CMOs, and what are the ways you think that we can address these issues?

MR. SCHWARTZ: Well just generally, the problems with CMOs that pertain outside of SoundExchange, good governance, transparency, accountability. As you know from other filings in the 301 process, other countries, Russia, Ukraine, and a host of others have denied American rightsholders their payments, either because there's no good governance, there's no transparency, there's no auditing of payments and the like.

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

MR. WESTON: Thank you. Your submission and your testimony recommends that

Canada be retained on the Watch List in the 2020 Special 301 Report. I know you've just touched on this in your testimony, but do you think that the implementation of USMCA will fully address the issues that you have raised?

MR. SCHWARTZ: The short answer is yes. The national treatment obligation is -- I would refer to it as airtight. It applies to both equitable remuneration as well as to protection and enforcement of national treatment obligations.

And the President, of course, has to certify to Congress that Canada is in full compliance with the USMCA before it goes into force. And we would certainly recommend that that certification be withheld until Canada makes clear that it's going to make these payments, which has been estimated -- I've heard estimates somewhere around $20-25 million a year for the denial of payments that they're making to Canadian rights holders, and by the way, other foreign nationals from Rome Convention countries.

CHAIR LEE: All right. Thank you. And we have a question from the State Department.

MR. FAHMY: Thank you very much. You discussed already your recommendation for Canada both in the submission and in the testimony. But for the other countries, UK, Australia, France, Japan and the Netherlands, you discuss the engaging in bilateral discussions with each of these countries.

Can you clarify exactly what that means and whether you're actually recommending that any of these countries be placed on any of the lists, or any other designation?

MR. SCHWARTZ: Sure. I mean realistically placement on the list of some of these countries is an option. A better option, of course, in any bilateral context, in any future FTAs, that the USMCA national treatment language should be incorporated into those agreements.

That would lock up the full national treatment obligations that the copyright

treaties, the WPPT or other agreements, allow carve-outs for full national treatment. Otherwise, just to engage in bilateral discussions on full national treatment with the countries, if that's more effective.

Just my almost three decades of working on 301 issues tells me that sometimes placement on lists is effective, and sometimes there are other more effective ways to engage with countries, and this may be one of those instances.

CHAIR LEE: Okay. Thank you very much for your testimony.

MR. SCHWARTZ: Thank you.

CHAIR LEE: Next up is the Trademark Working Group. Welcome.

MR. KILMER: Thank you.

CHAIR LEE: If you can begin your testimony by stating your name and organization, --

MR. KILMER: Certainly.

CHAIR LEE: -- that would be great.

MR. KILMER: Paul Kilmer, on behalf of the Trademark Working Group. Again, we appreciate the opportunity to present the observations of our participants as to those trademark laws and practices that cost them the most time and money.

This year's matters of most concern to our participants, default judgments. The absence of default judgments in opposition and in validation proceedings in jurisdictions such as China, the EU and Brazil cost U.S. companies many millions of dollars a year in prosecuting proceedings brought against trademark pirates and squatters, who have shown no interest in defending their applications or registrations.

Second issue, ex parte relative grounds refusals. During trademark examination, the European Union and its members, among other jurisdictions, do not reject trademark applications on relative grounds -- that is based on likelihood of confusion with previously registered or applied for marks. This costs U.S.

businesses many millions of dollars a year in unnecessary opposition proceedings.

Certification mark registration. There are still dozens of nations, from Algeria to Yemen, that do not have certification mark registration systems. Other nations, such as Australia, France, India and the United Kingdom, allow certification mark registrations, but impose burdens on applicants that render it difficult if not impossible to maintain a single global certification regime.

Ex officio border measures. Nations such as Ecuador, Malaysia and Nigeria do not have, or do not have effective, ex officio border measures that allow trademark owners to post their registered marks with a custom authority empowered to thereafter seize incoming counterfeit goods.

Statutory and enhanced damages. Nations that do not provide for enhanced or statutory damages for either blatant infringement or counterfeiting essentially provide a free pass

for the most egregious types of piratical conduct. These nations include Brazil, Egypt, Nigeria, Pakistan, Saudi Arabia, South Africa, Turkey, Ukraine and the United Arab Emirates.

Coined and well-known mark protection. Nations that do not have robust protection for inherently strong or well-known marks often allow registration and use of such marks by others, in relation to products or services for which their legitimate owner has not attained registration. Nations such as Nigeria offer no protection for well-known marks. Nations such as China severely restrict well-known mark protection.

Mandatory license recordation and registered user requirements. These requirements place an unnecessary burden and expense on trademark owners and set a trap for the unwary. Such provisions are in place in nations such as Brazil, Indonesia, Israel, Mexico, Nigeria, Pakistan, South Korea and Thailand.

Formalities. Onerous formalities, such as legalization, imposed by a number of

nations, including China, Jordan, Lebanon and the United Arab Emirates, place an unnecessary burden on trademark owners. Such nations should be encouraged to either accept notarized document or join the Hague Apostille Convention.

Letters of consent and coexistence agreements. Failure by nations to accept or give force to letters of consent or coexistence agreements prevents companies in the marketplace from assisting trademark offices in determining what marks truly will cause a likelihood of confusion. Relevant nations include Argentina, Brazil, China, Japan, South Korea and Thailand.

Multi-class registration. Failure to allow multi-class trademark applications in more than 35 nations, including Argentina, Egypt, Pakistan, the Philippines, Saudi Arabia and South Africa, increases the cost of an administrative burden on trademark owners in relation to both filing and maintenance of their registrations.

Quite a number of other issues are addressed in our annual 301 submission, which is

before you. Thank you again for this opportunity.

CHAIR LEE: Excellent. Thank you. We have some follow-up questions, and we'll begin with USTR.

MR. EWERDT: Your submission expresses the burden that the absence of default judgments places on U.S. companies. Can you elaborate more on what these default judgments would look like and the best way to ensure their implementation?

MR. KILMER: Right. This is a question that's been raised a number of times in different forums. Basically, at bottom, we were just looking for any response from a trademark applicant that it is still interested in its application. That's the first phase.

In the United States, the situation is a bit different, because here we require defendants -- applicants to answer oppositions and if they don't answer them, judgment is entered against them. But as a first step in countries that are unfamiliar with default

practice, we would simply recommend the trademark office contact the applicant and ask them if they're still interested in their application.

Even at that level, we believe that about 60 percent of the opposition proceedings in China, for example, could be avoided simply through a simple mechanism such as that. In fact, we find that about 30 to 40 percent of Chinese applicants give a false address in their applications, so they can't even be contacted officially if an opposition proceeding is filed.

And the opposition is then published in the official, what we would call the official gazette. And the trademark applicant never sees that notice, because they aren't watching the official gazette on a day-to-day basis. So I would estimate that a good 60 percent of trademark oppositions in China, for example, would be resolved on default judgment.

Now what does that do for the trademark office, and what does it do for the country? It does a lot for U.S. owners because

we don't have to file evidence, and we don't have to prove our case. What it does for the country, and China is a great example, is if they instituted default judgments for, let's say, 60 percent -- I would say more -- of the proceedings were done on default judgment, it would allow them to put resources into examination.

Now I believe in 2018, the figure in China was something like 7 million-plus trademark applications, and the processing time was getting quite lengthy. They've made some improvements in that regard. But you can imagine taking away 60 percent of the opposition proceedings, in some way devoting those resources to examination, how much more quickly applications would get through the process.

And then legitimate trademark owners would have the advantage of that. And those legitimate trademark owners these days do include an awful lot of Chinese companies, not just U.S. companies.

CHAIR LEE: Thank you. The next

question is from the Treasury Department.

MR. CHANG: Thank you. Of the various concerns that you've identified with respect to China, which are the highest priorities?

MR. KILMER: Yes. I think the default judgment issue that we've just discussed. I also think the formalities, the legalization, especially for the Beijing IP Court, although they're trying to work on that, I still think that's a very significant issue for them.

The mandatory license recordation really is not an issue for them, but the formalities definitely are. And I would really say the formalities and default judgment, of the things I've mentioned, are probably the most significant and would probably help to save the most money and time on behalf of U.S. companies.

CHAIR LEE: Could you just follow up a little bit on the formalities piece --

MR. KILMER: Sure.

CHAIR LEE: -- specifically related to China?

MR. KILMER: Yes. In China, to -- in fact, I just went through this painful process with a client, but we're before the Beijing IP Court in an invalidation proceeding. We had to submit a certificate of good standing. We had to submit a power of attorney. We had to submit an interest certificate, all of which had to be fully legalized through the Chinese Consulate, the embassy here in Washington.

Due to the virus situation, the Consulate, which used to take two weeks to do these things, is now taking something closer to four weeks in many cases. So we're actually going to have late filed documents because of the formalities requirement.

Frankly, based on the Phase 1 agreement with China, there are some provisions in there that they've agreed to that might now allow them to adopt at least the Hague Apostille Convention, which would speed things up dramatically.

CHAIR LEE: Thank you very much for

your testimony.

MR. KILMER: Thank you.

CHAIR LEE: Our last testifier today is the U.S. Chamber of Commerce. Welcome. Please state your name and organization for the record and begin your testimony.

MS. ANDERSON: Sure. I am Kelly Anderson, I'm with the U.S. Chamber's Global Innovation Policy Center. So we thank you so much for the opportunity to testify on the Chamber's Special 301 submission. I must admit, as somebody with an A last name, I'm used to coming first at things, but I'm happy to be here on behalf of the Chamber to close out your day.

So the Chamber's submission highlights both systemic and country-specific challenges. And in my testimony today, I want to highlight some of the issues that are top-of-mind for the Chamber's member companies.

So our Chamber's Special 301 submission is informed by our two signature research products, our International IP Index,

which hopefully you all are familiar with, and our Creativity and Innovation Access Barometer. Our International IP Index is now in its eighth edition. It represents 53 economies, covering over 90 percent of global GDP. The Index evaluates the IP criteria across 50 unique indicators, which we developed with industry as those that they believe are indicative of countries with robust IP systems.

So while the Index evaluates the strengths and weaknesses of the country's IP ecosystem, at the Chamber, we recognize that the presence or absence of IP laws is just one piece of the puzzle. In fact, our members have witnessed how a country's investment in IP-driven innovative and creative sectors can be undone by negative market interventions.

So the Chamber's Innovation and Creativity Access Barometer evaluates policies beyond traditional IP laws that limit the availability of innovative or creative products, services, and technologies in global markets.

The Barometer specifically looks at localization policies, forced technology transfer, local content requirements, and pricing and reimbursement policies that prevent consumers from accessing 21st century innovation in markets around the world. And we'll ask that full copies of both those reports are submitted for the record as well.

So building upon the Chamber's research products, the Special 301 submission highlights a number of emerging challenges on IP which our companies face. So first, we recognize that free trade agreements provide a critical mechanism to elevate IP standards in global markets. The 2020 Index illustrates how the countries with FTAs with the U.S. have significantly more robust and effective IP systems than those without them.

I should start by saying, we appreciate all the great work that USTR did to negotiate what we believe was a truly 21st century IP chapter in the USMCA. However, the

Chamber was disappointed and saw the USMCA as a significant missed opportunity to elevate the IP standards of two of the world's largest trading partners with the final deal that was reached in December.

As the Administration begins to focus on future agreements with the UK, the EU, Japan and Kenya, we believe that USMCA should not be used as a template for future agreements as the provisions do not any longer represent 21st century IP protection.

Second, our members are concerned about the erosion of IP in developed markets. In Australia, Canada, the EU and Japan, the governments have pursued regulations which undermine life sciences IP in the name of cost containment. These policies not only diminish the value of American IP in these markets, but may reduce the availability of new medical innovations for patients.

Third, while emerging markets are taking steps to address longstanding IP

challenges, it won't surprise you to hear me say that challenges remain. In China, the government has acknowledged a need to bolster its protection of IP and implemented reforms to reorganize its IP institutions and introduce legislation to strengthen China's IP framework.

However, China's regulatory environment is increasingly emphasizing industrial policy outcomes that raise the cost and create uncertainty for U.S. companies operating in China. The ongoing trade negotiations between the U.S. and China provide an opportunity to address systemic challenges on IP and technology transfer that prevent us from realizing the full potential of the bilateral relationship.

Additionally, in India, the Ministry of Commerce and Industry has taken incremental steps to improve the national IP environment since the inception of the National IP Policy in 2016. But work remains to be done to enforce patent terms, institute a coherent vision on

trade secrets protection, and establish a solid technology transfer mechanism.

So in conclusion, many governments are in fact increasingly recognizing the importance of IP to their economic and social development, and the Chamber truly stands as a partner to help countries address these outstanding concerns, to help place them on the path to becoming true knowledge-based economies.

The Chamber greatly appreciates USTR's dedication to furthering IP protection in markets around the world, and we believe it is critical that the U.S. government work together with other nations to prevent a further deterioration of IP standards abroad.

We look forward to working with you and our trading partners to securing meaningful IP commitments, to create jobs, support innovation, create access to technology, and protect consumers, both in the United States and in markets around the world. Thank you.

CHAIR LEE: Thank you very much. We

have some follow-up questions, beginning with USTR.

MR. EWERDT: First of all, thank you to the U.S. Chamber for putting in the time and effort of publishing the annual International IP Index. Your Special 301 submission highlights 16 countries and the EU, while your International IP Index evaluates 53 countries. Some of the countries highlighted in your Special 301 submission, such as Japan, are given high scores in your Index.

Some countries that are given the lowest scores in your Index, such as Venezuela and Argentina, are not included -- or Algeria, Venezuela and Algeria -- are not included in your Special 301 submission. How did the Chamber choose which countries to highlight in its Special 301 submission and which countries to omit?

MS. ANDERSON: Sure. I love a good question that involves the Index, so thank you for that. So when we came up with the Index, the

goal for the country coverage was that we wanted to have geographic diversity, countries from all different levels of economic development, from all around the world. So we have quite a broad number of economies that are included in that report.

We identified the countries in our Special 301 submission based on where our members' top concerns are. So while obviously the Index highlights that there are challenges in countries like Algeria and Venezuela, the countries that we outline in our submission are those where our IP-intensive companies are seeking to operate and facing significant challenges.

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

MR. FAHMY: Thank you very much. On Saudi Arabia, you recognized in your submission that the notorious pirate service beoutQ has been offline now for approximately six months. Is that something that we should consider, that the

beoutQ issue is resolved for the purposes of the 2020 consideration for the 301 Report?

MS. ANDERSON: Yes, thank you for the question. So I will admit that I'm not the Saudi Arabia expert on the team, but with the conversations that we've had with some folks on the ground, we were happy to see that it was offline, but we think it's a situation that needs to continue to be monitored.

As I think we see that when a site comes offline somewhere, it can easily pop back up. So that's something that the Chamber's members are closely monitoring.

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

MS. FERRITER: Thank you. The Chamber states that the EU's General Data Protection Regulation, or GDPR, has a significant impact on U.S. stakeholders, as it affects the WHOIS database by limiting the personal information that domain name registries and registrars can

provide in order to be compliant with the GDPR's heightened level of privacy, and thereby hampering copyright online enforcement. Can you explain this statement further?

MS. ANDERSON: Sure. So I'll admit that I'm not familiar with the specifics of that specific part of the submission, but I can reach out to my colleagues that handle GDPR and get back to you with an answer for the record.

CHAIR LEE: Okay. We have one final question from the U.S. Copyright Office.

MR. WESTON: Thank you. The copyright industry points to India's statutory licensing scheme as the main reason behind lower broadcasting revenues for producers and performers. Accordingly, the Chamber recommends that the Indian government limit the Copyright Board's role to collective administration instead of the current system of granting and pricing licenses. Can you further explain this suggestion?

MS. ANDERSON: Sure. So we have been

engaged in the Indian market for as long as the GIPC has been around, which is since 2007. I think that the Index shows that we've seen a lot of positive progress when it comes to the Indian government slowly investing in IP protection. And one of the things that we recognize is that they are taking some positive steps on copyright.

The specifics of the policy that you recommend, I'm not totally familiar with, so again I'm happy to get back with you with some specifics.

CHAIR LEE: Thank you very much for your testimony.

MS. ANDERSON: Thank you.

CHAIR LEE: All right. On behalf of the Special 301 Subcommittee, I would like to thank all the participants for taking time out of your day to have this exchange with us. We appreciate the comprehensive research, thought, and problem-solving efforts that went into your written submissions and oral testimony.

Regarding post-hearing comments, the

Special 301 docket will reopen this afternoon and remain open until 11:59 p.m. Eastern Time on March 5th. Post-hearing briefs by interested parties that testified today are optional. Please follow the instructions on the agenda or in the original Federal Register Notice, which is at regulations.gov at docket number USTR-2019-0023.

A transcript and video of today's hearing will be available at USTR.gov. We will do our best to get that posted within the next two weeks. So again, thank you, everyone, including my colleagues on the panel and those who testified today, for your contributions and your time and attention.

Finally, I just want to give a special thanks to personnel at USTR who took care of today's logistics and setup. So in conclusion, ladies and gentlemen, the 2020 Special 301 is now adjourned. Thank you.

(Whereupon, the above-entitled matter went off the record at 3:55 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Special 301 Public Hearing

Before: USTR

Date: 02-26-20

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

Court Reporter