OFFICE OF THE
UNITED STATES TRADE REPRESENTATIVE

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2019 SPECIAL 301 PUBLIC HEARING

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WEDNESDAY
FEBRUARY 27, 2019

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

COMMITTEE MEMBERS
DANIEL LEE, Chair
EMILY BLEIMUND, U.S. Department of Health and Human Services
SUNG CHANG, Office of the U.S. Trade Representative
WON CHANG, U.S. Department of the Treasury
KARIN FERRITER, U.S. Patent and Trademark Office
BRAD GREENBERG, U.S. Copyright Office
DAVID HENRY, U.S. Department of State
OMAR KARAWA, U.S. Department of Agriculture
MATTHEW LAMBERTI, U.S. Department of Justice
STEVAN MITCHELL, U.S. Department of Commerce
MAUREEN M. PETTIS, U.S. Department of Labor
RACHEL SALZMAN, U.S. Department of Commerce
ANNE SNYDER, U.S. Department of Health and Human Services

GOVERNMENT WITNESSES
ALEJANDRO BILBAO LA VIEJA, Embassy of Bolivia
REZA PAHLEVI CHAIRUL, Embassy of the Republic of Indonesia
ALEJANDRA GASTELU-SOTOMAYOR, Ministry of International Trade and Integration, Government of Bolivia
IVO KONSTANTINOV, Embassy of the Republic of Bulgaria
BOKYUN NAM, Ministry of Health and Welfare, Government of the Republic of Korea
SCARLEY MARINA VALERIANO BARROSO, National Service for Intellectual Property, Government of Bolivia
VALERII ZHALDAK, Ministry of Economic Development and Trade, Government of Ukraine

NON-GOVERNMENT WITNESSES
JAIME CASTANEDA, Consortium for Common Food Names (CCFN)
GUAN JIAN, China Chamber of International Commerce (CCOIC)
TAN JIAN, China Chamber of International Commerce (CCOIC)
MARIANA JORGE, MFJ International, LLC
PAUL KILMER, Trademark Working Group
MARK LAUROESCH, Intellectual Property Owners Association (IPO)
JAMES LOVE, Knowledge Ecology International (KEI)
PETER MAYBARDUK, Public Citizen
CHRISTINA MITROPOULOS, American Apparel and Footwear Association (AAFA)
CHRIS MOORE, Pharmaceutical Research and Manufacturers of America (PhRMA)
ROGER MURRY, Alliance for Fair Trade with India (AFTI)
RYAN ONG, National Association of Manufacturers
JUSTIN PINE, Biotechnology Innovation Organization (BIO)

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

KEVIN ROSENBAUM, International Intellectual Property Alliance (IIPA)

BRIAN SCARPELLI, ACT/The App Association

NON-GOVERNMENT WITNESSES (cont'd)

MATTHEW SCHRUERS, Computer and Communications Industry Association (CCIA)

DAYAAR SINGLA, NALSAR Litigation Project (NLP)

ELLEN SZYMANSKI, U.S. Chamber of Commerce

JOSEPH WHITLOCK, BSA, The Software Alliance

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

10:04 a.m.

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

But, good morning. My name is Daniel Lee, and I am 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 every 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 right 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 top trade priorities outlined in the President's annual Trade Policy Agenda.

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

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

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

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

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

themselves. Maybe we can start at the end.

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

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

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

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

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

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

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

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

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

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

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

The Review is driven by stakeholder contributions and by contributions of Washington-based 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 that you will share with us today.

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

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

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

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

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

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

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 Competitive Act of 1988, and the Uruguay Round Agreements 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 the United States Trade Representative identify countries that deny adequate and effective protection of intellectual property rights, or that 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 a country's 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 designation, 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 change for at least one year.

The format of today's hearing is as follows: each party will be allotted ten minutes. 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 the written finding -- 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 will break for one hour from 12:20 to 1:20. And at this time I would like to invite the Government of Bolivia to start us off.

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

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

We are here on behalf of the Bolivian

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

I'm joined today by the Ambassador Pablo Canedo from the Embassy of Bolivia, the head of the Bolivian Authority of Intellectual Property, Ms. Scarley Valeriano, and the head of the Department of the Economics and Law at the Ministry of Foreign Affair of Bolivia.

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

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

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

enforcing intellectual property for this year.

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

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

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

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

granting intellectual property rights. Therefore, the direct beneficiaries are the holders of these rights.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. FERRITER: Thank you. Under

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

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

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

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

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

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

MR. KONSTANTINOV: I was about to do

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

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

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

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

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

have followed very closely in implementing in our country.

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

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

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

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

especially tripled the staff prosecuting IP-related cases.

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

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

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

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

There's 13 -- 30 imprisonments, one of

which effective and 29 conditionals related to IP breaches.

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

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

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

And I remain available for your questions.

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

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

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

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

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

Can you please explain the seeming discrepancy?

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

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

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

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

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

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

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

seized to determine if it is infringing.

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

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

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

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

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

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

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

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

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

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

CHAIR LEE: All right. We have time

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

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

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

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

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

And as the Attorney General's office

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

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

CHAIR LEE: Thank you very much for your testimony.

MR. KONSTANTINOV: Appreciate it.

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

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

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

I would like to thank USTR for

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

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

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

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

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

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

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

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

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

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

includes provisions of public patrol to report on pirated products.

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

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

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

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

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

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

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

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

And then initiating review of existing

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

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

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

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

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

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

And finally, is Indonesia committed to

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

Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

But again, --

MR. LAMBERTI: On the website, yeah.

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

CHAIR LEE: Great. Thank you for your testimony.

MR. CHAIRUL: Thank you, Mr. Lee.

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

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

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

Korea.

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

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

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

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

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

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

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

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

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

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

Lastly, that the intellectual property rights of innovative new drugs are not impeded. Second, Korea's premier pricing policy for global innovative new drugs, Korea amended on December 31, 2018, implemented the premier pricing policy consistent with those of FTA which is fair, reasonable, and nondiscriminatory.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

reload in the system of collective management in Ukraine.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

judges appointed.

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

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

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

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

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

finalized.

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

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

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

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

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

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

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

Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

But again, maybe -- well, our

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

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

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

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

CHAIR LEE: Thank you very much.

MR. ZHALDAK: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

widely. They can be basic and well known.

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

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

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

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

That re-published app will look and

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

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

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

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

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

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

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

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

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

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

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

Could you please elaborate on these policies and their effects?

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

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

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

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

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

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

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

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

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

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

circumvention of technological protection measures.

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

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

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

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

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

MR. MURRY: Good morning.

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

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

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

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

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

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

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

Now we commend these actions and ask

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

To implement the WIPO Internet Treaties India needs to adopt multiple amendments to the Copyright Act. However, despite these important but measured steps, the Government of India has yet to meaningfully address numerous onerous and longstanding shortcomings to its IPR regime identified in the 2018 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 seed technology.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

India's compulsory licensing policies?

MR. MURRY: Thanks for the question. Kind of high-level, compulsory licensing policy is a bit like discussion of royalty caps proposals where the mention, the existence of the willingness to proceed down that path can chill the investment environment, can chill the intellectual property environment.

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

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

So those are some concerns where we

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. MURRY: Thank you, all.

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

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

AAFA appreciates the opportunity to testify before the Special 301 Committee. 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 a thousand

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

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

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

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

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

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

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

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

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

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

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

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.

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

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

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

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

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

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

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

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

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

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

AAFA appreciates this opportunity to raise these concerns and we look forward to working with USTR to address these 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.

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

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

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

However, you do not make any

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

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

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

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

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

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

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

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

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

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

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

Department.

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

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

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

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

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

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

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

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

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

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

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

goods.

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

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

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

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

MS. PETTIS: Okay, great. Thank you.

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

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

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

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

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

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

agriculture and industrial and environmental sectors.

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

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

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

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

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

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

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

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

abroad.

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

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

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

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

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

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

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

In some cases, there is no legislation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

to undermine intellectual property rights.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

And we are among the most innovative

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

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

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

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

The scorecard measures each countries

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIR LEE: Okay, thank you. We'll

begin questions with USTR.

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

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

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

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

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

And let me just preface with an

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

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

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

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

The cybersecurity classified

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

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

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

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

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

We would refer you more broadly to our

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

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

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

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

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

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

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

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

CHAIR LEE: Thank you very much for your testimony.

MR. WHITLOCK: Thank you.

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

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

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

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

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

In 2018, in order to establish a

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

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

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

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

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

countries.

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

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

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

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

For instance, the Supreme People's

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. G. JIAN: Thank you.

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

MR. SCHRUERS: Sure. Matt Schruers for the Computer and Communications Industry Association.

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

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

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

submission.

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

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

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

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

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

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

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

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

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

are which.

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

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

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

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

There is no limit to the rents that

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

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

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

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

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

For example, you identify concerns

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

Are you equally concerned about all trading partners you mentioned?

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

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

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

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

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

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

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

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

non-expressive or non-consumptive uses."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

efforts and to hold our trading partners to their commitments.

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

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

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

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

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

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

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

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

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

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

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

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

obligations concerning GIs in the 2012 EU Singapore FTA.

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

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

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

CHAIR LEE: Okay. Thank you. Next,

we have a question from the Department of Agriculture.

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

Could you please elaborate on this?

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

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

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

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

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

CHAIR LEE: Thank you very much for your testimony.

MR. CASTANEDA: Certainly.

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

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

CHAIR LEE: All right, everyone. Thank

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

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

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

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

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

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

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

Brands usually have little information on these offenders, because platforms to not share the information they have on these sellers with the rights-holders. 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. In fact, many individuals and entities selling counterfeit goods on these platforms do so using false identities, making it impossible for brands to take action.

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

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

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

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

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

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

In today's 21st century retail

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

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

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

Also, 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.

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

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

So as the U.S. works to strengthen IP

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

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

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

MR. PRIEST: Yes, in our written

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIR LEE: Thank you very much for your testimony.

MR. PRIEST: Thank you.

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

MR. LAUROESCH: Good afternoon. My name

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

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

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

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

IP to protect investments in new technology.

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

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

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

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

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

undermine the innovative incentive provided by IP protection.

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

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

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

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

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

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

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

trade secret upgrades to safeguard American know-how.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

highlight any particular ranking.

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

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

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

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

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

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

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

MR. ROSENBLUM: Thank you. My name is Kevin Rosenblum, I am counsel for the International Intellectual Property Alliance. 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 this Special 301 review a catalyst for positive change to address the challenges faced by the U.S. creative copyright industries in key markets abroad. We welcome the chance to participate, again, in this crucial annual dialog.

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

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

Our members are the Association of American Publishers, the Entertainment Software Association, the Independent Film & Television Alliance, the Motion Picture Association of America, and the Recording Industry Association of America.

These associations comprise over 3200 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 four main elements: Consistent modern standards of copyright protection, efficient copyright enforcement, sound legal structures for licensing, 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 creative and cultural 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 mobile 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 this Special 301 review, namely to identify, quote, 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, unquote.

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 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, and it is not consistent with the clear and statutory language of Special 301. This is not the approach that has made Special 301 so successful and the Special 301 process is not the place to advocate that our trading partners weaken their copyright regimes, especially in countries where legitimate copyright 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 2019 Special 301 Report. All these are listed in our hearing statement, with capsule summaries, under are 10 companies we recommend for inclusion on the priority watch list. Argentina, Chile, China, India, Mexico, Russia, South Africa, Taiwan, Ukraine, and Vietnam.

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

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

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

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

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

Our submission also lists six enforcement challenges confronting 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. SUNG CHANG: Thank you for your testimony. What trade-related IP developments that have occurred since April of 2018 should this committee consider as it conducts this Special 301 review this year?

MR. LOVE: Well, I think what's happening in Europe right now in terms of the copyright reform is something, again as I mention in our written submission, is really problematic from our point of view.

We publish things around the world. I think other people do too, and it's hard to think of the copyright law of one country as being only a national thing right now, and certainly American companies are involved and the big platforms in social media. But I think that that's one area.

You should take note of the fact that

the European Union is about ready to issue compulsory licenses on their patent extensions for export to third-party countries, something the U.S. might consider looking at as well.

The SCP reform, which I think are the first part of the EU is the idea that if a monopoly exists in the European Union because of patent extension, it doesn't exist outside the European Union. They want the European companies to be able to supply those markets with products, even if they can't supply them within the EU. That's something that might -- maybe some American companies might want to take advantage of if you had a similar approach.

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

MR. WON CHANG: Thank you for your submission. Your public submission comments on the Special 301 process and notes that USYR should, quote, refrain its focus and use the process to develop and outline and policies and norms that it wants to promote. Do you have any

specific suggestions for any individual countries nominated for or previously included in the Special 301 Report?

MR. LOVE: Well, I will mention, as I think I have mentioned several times in the past, I think it doesn't do you a service if you keep putting Canada on the anti-piracy list, because they have probably one of the lowest rates of piracy on the planet. So it's sort of weird to me that you would go after Canada consistently.

But from our point, in terms of reshaping the norms, I think that the real interest that the Americans have in the pharmaceutical area in medical and technology in general is innovation. And I think you should focus on whether or not the policies of countries are engaged in it, are enhancing the rate of innovation and whether there's, but redefine the free rider issue.

The free rider issue should not be, you have patent extensions, you have, you know, you grant evergreening patents and stuff. It

should be what collections of things do you do to support innovation? We have the NIH, we have BARDA, we have research and development programs in the Navy, in the Army, Veterans Administration, all kinds of different places in the U.S. Government, and those things are a huge engine for innovation in the United States.

There's a lot of countries, for example Switzerland, a lot of countries that do very little in terms of funding the basic science that the rest of the world basically takes advantage of. We have open access publishing, for example, on articles funded by the NIH, which other countries, some do but some don't.

I think there are policies that would be good for innovation and good for science, to respond to your question, that are trade related. And I think that if the shift is more about innovation, not just IPR, I know this is an IPR list, but the companies themselves are bringing up direct pricing, for example, which is not an IPR issue, so I think it's fair for me to bring

up these other issues.

CHAIR LEE: Thank you. The next question is from the Department of Health and Human Services.

MS. SNYDER: Thank you. Keeping in mind the legislative mandate for the Special 301 Report, how do you suggest that the United States use the report to advance the administration's domestic and foreign policy goals related to pharmaceutical pricing and reimbursement?

MR. LOVE: One feature of the proposal by Secretary Azar domestically is to engage in international reference pricing for certain drugs on Part B of Medicare. For that to take place, you actually have to know what foreign prices are.

As has been noted in hearings this week, there's a real lack of transparency, not just in the United States but in other countries about what pricing is. You can't really implement Secretary Azar's proposal with any confidence if you don't know what U.S. prices are, if you don't

know the German price, the secret price in the U.K., etc.

So to that end, Italy has tabled a resolution in the WHO during the executive board that will be discussed in May. It was proposed as a draft resolution. I've shared it, of course, with your office and also with Karen and with everyone I thought would like it or not like it.

It's one of those rare areas where the things that I put forward, this actually seems to be consistent with the administration's position of pushing for more transparency on prices. That's one thing that I think would really be helpful.

I think also in the past, under the Obama administration, there was a lot of hostility to the idea that the WHO pushed countries to have soft norms on how much they fund medical research to the public sector, for example. I never really understood that, because I thought we were kind of carrying the load for the whole world in some sectors, and I thought

other countries would be encouraged to do more, and that would be an area I'd hope you'd revisit.

CHAIR LEE: Thank you. We have time for one more question. This one comes from the International Trade Administration at the Department of Commerce.

MS. SALZMAN: Thank you for your testimony. In KEI's view, are there foreign countries that lack adequate and effective protection and enforcement of intellectual property rights?

MR. LOVE: Yes.

MS. SALZMAN: What foreign countries should USTR identify?

MR. LOVE: I think there's, there are many countries where piracy of copyright materials, for example, is fairly common. There's a lot of misunderstanding about some of these issues. For example, I'm not aware of any compulsory licenses on patents ever been issued for drugs in China, for example, even though if you take a poll most people think they're doing

it every day.

But copyright, I think, is one area where there's been a real lack of enforcement. I think part of it is because some of the copyright or pricing models by the publishers in some of those countries aren't realistic given the income of some countries. So I think that I can't give you specifics, well, I could, probably, but I'd prefer not to without more verification. But I believe that's an issue.

And I think on the drug area, I mean, it's tough. I work on compulsory licenses. Almost no compulsory licenses are issued in any given year. It's not like people think it is. It's really unusual and it's really hard to get generic drugs into a country even through a barter club. I tried to get a cancer drug from India to Egypt for a patient who was facing a $900 a week price, and he made $300 a month. I was contacted by his family.

We couldn't get it shipped with DHL, we couldn't get -- I mean it was just an absolute

nightmare. So I think the problems on the pharmaceutical side are probably a bit overrated. I will say, though, that better enforcement of counterfeit products so they're safe and effective, which the U.S. government's been a leader on, is a good mission.

CHAIR LEE: Thank you very much for your testimony. Next we have MFJ International, LLC. Thank you. Please state your name and organization for the record and begin your testimony.

MS. JORGE: Thank you very much. My name is Mariana Jorge for MFJ International. I appreciate the opportunity to testify today. MFJ International is a consulting firm with a significant focus on increasing access to affordable drugs throughout the world. This testimony is not made on the behalf of any client.

IP provisions are important to provide incentives for the development of new drugs, but they cannot and should not be seen in isolation.

As is stated by the Federal Trade Commission, competition and patents stand out among the federal policies that influence innovation.

Both competition and patent policy can force the innovation but each one requires a proper balance with the other to do so. Error or systematic biases and how one policy's rules are interpreted and applied can harm the other policies' effectiveness.

Therefore, patents and intellectual property rights must be seen within the context of competition. The Special 301 review seeks to identify countries that denied adequate and effective protection of intellectual property rights.

While for some industries these can be pretty straightforward exercise, in the case of the pharmaceutical industry it is much more complex as the industry has two sides, the originator industry and the genetic biosimilar industry.

Therefore in this case it is even more

critical to strike the right balance between IP laws and regulations and competition policies so that both sides of the industry can thrive to ensure that patients have access to new drugs as well as to more affordable generic and biosimilars.

It is critical to have a careful assessment of what constitutes adequate and effective protection, which should not be interpreted as meaning that more protection is better as it would in fact undermine the necessary balance that must be struck to promote innovation.

Hence the identification of countries based on whether they are providing adequate and effective IP protection should be based on objective criteria that reflects the obligations undertaken by the countries in treaties like TRIPS, and bilateral original agreements.

However, it is deeply concerning that recent trade negotiations like the USMCA lack the necessary balance on intellectual property

provisions related to pharmaceuticals.

US trade policy has led to new and increasingly higher barriers to entry for genetic biosimilar products. This is not just about the market, other markets, but also for the U.S. market. The clearest example is the fact that the TRIPS agreement changed U.S. law by expanding the patent terms from 17 years from the day of granting of a patent to 20 years from its filing.

This single provision continues to cost billions of dollars to U.S. consumers in the generic biosimilar industry. Neither trade agreements or the Special 301 should delay or block the lines of generic or biosimilar products under the pretense of providing adequate and effective protection.

Moreover, if such protection undermines the U.S. generic biosimilar industry, it cannot possibly be considered to be providing adequate and effective protection as trade policy should not take sides to benefit one industry sector at the expense of the other.

Trade policy should not undermine, but be consistent with other government policies like health initiative that seek to make drugs more accessible. We know that this is a top priority of this administration. It is deeply concerning that U.S. trade policies are inconsistent, and in fact detrimental to other government policies that seek to increase access to affordable drugs.

For example, while the July 2018 Biosimilar Action Plan highlights the importance of striking a balance between encouraging and rewarding innovation in drug development and facilitating robust and timely market competition across the spectrum of pharmaceutical products from traditional small molecules to complex products to biologics, the Special 301 seems to focus only on how to broaden and expand the rights of originator pharmaceutical companies.

In our own opinion, this needs to change to endorse balanced provisions that allow both sides of the industry to thrive. That way, it will complete President Trump's goal of

increasing competition and lowering drug prices.

In conclusion, we believe that trade policy implemented through the Special 301 review and trade agreement should be adjusted to strike a balance and promote both innovation and access to affordable drugs. The protection of intellectual property right as it relates to pharmaceuticals must not be seen in isolation, but within the context of competition. Only then will such protection be adequate and effective.

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

MR. SUNG CHANG: Thank you. In your opinion and under the mandate that we have under the Special 301 statute, what is the most useful part of the Special 301 review process, anyway?

MS. JORGE: I think that one issue that is important is that the Special 301 cannot be looked at in isolation. It has to be connected with trade agreements. So when we say, oh, well, let's identify the countries that are not providing adequate and effective protection and

we look at what are the trade agreements, that should be the objective standard.

And if those trade agreements are only siding with one side of an industry, the whole process is undermined. It's not consistent with what the FTC says. Intellectual property is not an end in itself. It is hopefully the means for innovation but it has to be in balance with competition.

So, in terms of what you are asking, I don't think that we can take only the Special 301 and just look only at whether it's providing enough protection. We need to make sure where the balance is, and in my opinion that balance is off, and for a long time. It's also off with regard to the trade agreement.

CHAIR LEE: Thank you. The next question is from the Department of Health and Human Services.

MS. SNYDER: Hi. Your submission gives a number of examples of policies and practices that you do not see as appropriate grounds for

listing a country in the Special 301 Report. Can you provide examples of specific policies and practices that would warrant listing a country in the report? What criteria would strike the appropriate balance that you reference in your submission?

MS. JORGE: One of the things we are talking about, this is about trade, right? This is about helping the U.S. industries to grow, to sell more, to export more. When we are focusing only on export more, one side of the industry where we are establishing barriers to entry to the other, that's a problem.

So in terms of actual policies, for instance, when it's only if one hand is looking for patent term extensions but none of the limitations or requirements that are to counterbalance. It's no balance.

There is, for instance, a focus on exclusivity but there is nothing about incentives to launch a pharmaceutical product. At the end of the day, what we are trying to do or what I think

we are supposed to do here, is to maximize U.S. exports. We are not doing that in pharmaceuticals, because it's like communicating. If you give too much protection on one industry you are actually establishing barriers to entry to the other.

And at the end of the day we're undermining one side of the industry, and in my opinion for the last 25 years we have been undermining one side of the industry.

For instance, on another policy we are talking about best mode. Best mode is in U.S. law and is critical so we are not reinventing the wheel every time. So after patent expiration, people, society can benefit from this.

Well, that is never focused on. We are only cherry-picking only the side of regulations that benefit only to the patent holder at the expense of everyone else. And the problem is, sometimes we might fail to just look at these as oh, well, it's all about foreign countries.

But this is not about foreign

countries. Everything is connected right now. I had a sentence from Gottlieb where it says, we need economies of the scale to be able to give the competition that we need in the domestic market to provide a biosimilar.

If we are locking access to U.S. biosimilar companies to other markets because we found a super-high levels of intellectual property and they cannot export it, we'll never reach economies of scale. We will not develop the biosimilar industry and we will hurt U.S. consumers as well as the budget and the deficit. It's all connected.

CHAIR LEE: Thank you very much for your testimony. Next we have National Association of Manufacturers. Thank you. Please state your name and organization for the record and begin your testimony.

MR. ONG: Sure. My name is Ryan Ong. I'm with the National Association of Manufacturers. Members of the Special 301 subcommittee, thank you for the opportunity to

testify today on behalf of the NAM and the more than 14,000 manufacturers, large and small, that we represent.

Innovation and intellectual property are the backbone for the manufacturing industry, which is the bedrock of the American economy. In 2015, value added from IP was nearly 40 percent of total U.S. gross domestic product, and according to the latest data, the United States was responsible for one-quarter of all research and development conducted globally. So yes, this matters.

American is a leader when it comes to innovation, but that also puts our businesses and ideas in the crosshairs of bad actors that would rather cheat than compete.

IP theft means that businesses on the verge of breakthroughs that can change lives and reshape industries can have their products stolen, their products undercut and their work decimated before they reach their full potential.

The NAM's Special 301 submission

identifies the need for a strategy and broad-based approach to address multiple cross-cutting challenges to manufacturing innovation. We also recommend seven countries for the priority watch list and an additional six countries for the watch list as a focus for this year's Special 301 Report. These targets include longstanding challenges such as China and India, as well as countries of growing concern such as Chile and Japan.

The NAM's written submission provides greater detail in these areas, but I'd like today to highlight three main threats facing manufacturers' intellectual property and innovation around the world, and the global context that makes this a critical opportunity for setting new precedence moving forward.

First, our competitors are increasingly using international organizations to weaken critical IP protections. Reports and policy guidance coming out of organizations like the World Health Organization erroneously claim

that IP is an inherent barrier to progress, overlooking the importance of innovation in finding powerful new solutions to global problems and ignoring the actual barriers in health, energy, and clean technologies and other areas that prevent innovative products from getting into the hands of those who need them most.

Second, foreign countries have expanded their use of unbounded compulsory licensing and other patent limitations, steps that harm innovation. Compulsory licensing has an important role in cases of emergency that comply fully with international rules and agreements, but too often this power is being used by competitors as a protectionist tool to promote or protect local manufacturing in the long-term damage to U.S. interests. This is a growing concern globally, but has been particularly problematic over the last year in Latin America.

Finally, rampant counterfeiting and piracy steals the successes of innovators large and small, and undercuts manufacturers across

industries. Manufacturers have long battled fake products sold in physical markets, but they face new challenges due to the explosion of fake products being sold online.

A 2017 estimate by the Commission of the Theft of Intellectual Property shows that counterfeit and pirated goods cost the U.S. economy between 29 and 41 billion dollars every year, and fake products can pose a direct risk to public health and the safety of consumers.

These are only three of the challenges facing innovative manufacturers, but there are plenty more challenges to innovation that put manufacturers and jobs at risk. That's why the United States has spent decades building a strong domestic legal framework to protect and enforce manufacturers' IP and why it has been a champion for stronger global enforcement of IP rights, but we must do more.

The Trump administration has shown a commitment to holding other countries accountable when they cheat, and rebalancing trade with our

foreign partners. We commend them for that commitment. We must strategically use all appropriate tools, including Special 301-related tools such as country classifications, out-of-cycle reviews and results-oriented action plans but also other tools such as full implementation of legislative authorities to enforce IP.

In addition, we must use this critical moment to set new precedence for IP protection. In bilateral and multilateral trade agreements, IP protection and enforcement should be an explicit priority. The U.S.-Mexico-Canada Agreement, for example, includes best-in-class intellectual property rules to protect the full range of U.S. manufacturing, inventions and innovations from foreign theft from its appropriation.

As Congress moves to consider USMCA and as the administration seeks new bilateral trade deals with the EU, UK, China, Japan and others, we have an unparalleled opportunity to

create fair and more enforceable systems that protect IP and promotes American innovation.

The NAM urges the agencies in this committee to seize this opportunity and create a fair and more enforceable trade network that promotes American innovation, that starts with protecting the IP that is so critical to the growth and success of manufacturers large and small. Thank you again for this opportunity. I'd be glad to take questions.

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

MR. SUNG CHANG: Thank you for your testimony. Your submission noted a trend in Latin America towards the issuance of compulsory licenses, or at least initial status in that direction, and these steps appear associated with price negotiations over patented drugs.

Have any of your members indicated that they will revisit entering these markets in view of these developments? What steps has the industry taken to communicate its concerns to the

countries in this region, and what types of responses have those governments provided?

MR. ONG: Sure. Happy to answer this question to provide follow up information after additional conversations.

But I will note for our innovative manufacturers, they look very, very carefully and closely at the business environment as they're considering trade, investment and integration into other markets.

And so the environment for protection of intellectual property has a direct impact on consideration for what they may do in that market.

As a broad, cross-cutting manufacturing association, we watch a variety of IP issues that impact a range of sectors. I will tell you from our broader membership that companies outside of the innovative pharmaceutical sector are also very closely watching events and actions in Latin America.

We highlighted a couple of specific

instances in our written submission that I won't go into now, in Chile and Colombia and other locations.

I do know from our own conversations with members as well as our constituent associations that there have been active and robust efforts to engage locale governments and local stakeholder groups, including business and other groups to communicate the level of concern and try to find appropriate paths and ways forward, and to be able to communicate the long term impact for those markets of taking and moving in a more anti-intellectual property direction. Those conversations are ongoing.

CHAIR LEE: Thank you. The next question is from the Department of Health and Human Services.

MS. SNYDER: In your submission, you assert that countries like South Africa and Indonesia are contributing to the problem of IP erosion in multilateral fora.

Can you provide more specific

information? How do you suggest using the special 301 Report to address your concerns related to what you describe as IP erosion in multilateral fora?

MR. ONG: Sure. And that's a good question because multi-lateral organizations, themselves, are not directly subject for the special 301 within scope. You know, these instances really pop into a variety of specific initiatives.

Sort of the largest area that we've seen some of these particular discussions as I mentioned before is at the World Health Organization where whether we talk about initiatives or language related to the U.N. high level panel and access to medicines, discussions on the WHO roadmap on access to medicines and vaccines, or broader discussions related to compulsory license and balance of IP versus other provisions, countries like India, South Africa, Brazil and others are frequently drivers for moving those conversations in a direction away

from traditional IP rules and criteria and sort of in that particular direction.

A couple of things that I would note. One, given sort of member state focus and member state driving on these issues that opens up opportunities within the scope of the 301 and bilateral conversations and action plans that take place to be able to raise these concerns and hopefully find more constructive conversations to take place within these organization, for the U.S. to work with other member states on an individual basis.

But the other element to this is awareness of the ways in which these conversations that may take place at say the World Health Organization directly impact regulatory regimes and regulatory frameworks in individual markets that may themselves be the subject of 301 investigation.

And so understanding how a discussion on IP and access to medicines at the WHO may then directly port into an influence, say, compulsory

licensing discussions in Latin America.

CHAIR LEE: Thank you for your testimony. Next, we have the National Academy of Legal Studies and Research Litigation Project. Thank you. Could you please state your name and organization and begin your testimony?

MR. SINGLA: Dayaar Singla for the NALSR Litigation Project.

Good afternoon members of the subcommittee. I'm an Indian exchange student at the Santa Clara University School of Law and I would like to thank Professor Gross and Dean Kloppenberg for this opportunity.

I speak here on behalf of the the NALSR Litigation Project. The NLP is an independent student joined group based out National Academy of Legal Studies and Resource University of Law, Hyderabad, one of India's premier national law universities.

I would -- before I begin -- and we are extremely grateful for the invite to present our views before the subcommittee. Before I

proceed further, I would like to note that the NLP, views of the NLP do not necessarily reflect those of NALSR or of those in NALSR.

I shall be submitting before you on two areas of concern. Firstly, I note that the Indian government over the last, over the course of last year has taken various steps as well as policies which are pro-IPR and on the basis of these I recommend the removal of India from the priority watch list.

Secondly, we submit the global trends regarding various governments mandating source code disclosure requirements.

In regard to India, as per the 2018, 301 report, it took note of concerns related to IP enforcement, protection mechanisms, online piracy, lack of camcording legislation and India's IPR stance in the global fora, we have submitted through our written statement, the positive steps that have been taken in regard to these issues.

Firstly, I bring to your kind

attention that the cover of protection under the IPR regime in India has increased over the last year. The Indian government has approved extension of the WIPO Internet Treaties.

It has made progress on amending the Cinematograph Act to curb camcording incidents. It has also made appointments to the intellectual property appellate board, which is now functional.

These were some of the issues that were raised in the 2018 301 report and have now been resolved. Secondly, various steps have been taken to increase the ease in securing intellectual property rights.

During the last year, the IP offices have been radically transformed through numerous initiatives. Thirdly, the government has taken various steps to encourage IP awareness amongst the youth, which shall help promote and build a stronger IPR culture.

Finally, over this weekend itself, the e-commerce policy was released. While we have

not had the opportunity to analyze it in detail, the policy proposes anti-counterfeiting measures to protect trademark owners, as well as anti-piracy measures.

As mentioned, significant efforts have been taken over the period of last year and in light of these submissions, we recommend the removal of the Indian government from the priority watch list.

Moving to the second issue, as has been consistently stated, the transfer of source code presents an untenable risk of theft and piracy, yet some governments implement source code disclosure requirements as a minimum requirement for legal market entry. These requirements therefore prove as major disincentives for international trade.

The broad policies of countries, of such countries can be placed on the spectrum from states which require mandatory source code disclosure requirements for entry in the market. Secondly the states which require source code

disclosure first off, they block you by the public sector.

Thirdly, states which prefer open source software over closed source software for the government procurements and finally, we have states which actively push for an international regime where source code disclosure is prohibited.

Russia, China and Nigeria fall under the first category. Regarding the Russian requirements, the practice of mandating source code disclosure when the government itself is not procuring such software is specifically contentious.

It is as it also becomes a threat to the various other countries, which might be using the software to protect or otherwise in the sensitive installations.

In the case of China, the new cybersecurity law, which has been implemented since 2017, has brought back the source code disclosure requirement. Another notification at

the WTO also hints towards the same. This law is also a move towards developing and applying national technical standards and thereby is counted to the obligations under the WTO agreement on technical barriers of trade.

The Nigerian government continues to have localization requirement across a broad range of IT applications.

The states of Brazil and Indonesia fall under the second category of mandating disclosure for government procurements. India and South Africa fall under the third category where there is a policy preference of open source software over closed source software when the question is of government sector procurement.

However, this preference is waved off when it is proven that the CSS is better than the OSS for the purposes required. Therefore it can be said that such of a requirement or preference does not offer any threat to IP right, intellectual property rights of these companies.

Finally there are various states which

fall under the fourth category, including the United States of America, Japan, Canada, Chile, Colombia, European Union and others who have worked towards creating global security environment in terms of source code disclosure and recommend these efforts.

In light of these submissions, we recommend that the steps may be taken on a case by case basis with regards to these countries to have a better international regime for tech companies as well as app developers.

Thank you. We look forward to understanding the USTR's 301 report in any manner possible and I'm happy to answer any questions that you may have.

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

MR. S. CHANG: Thank you for your testimony. You just told us several key IP reform improvements India has made in the past year. Could you also tell us the top three challenges that remain for India that it should

address in the coming year?

MR. SINGLA: With the challenges, I would like to state that various members have pointed to the data localization requirement, which has come under the new policy. Secondly, the e-commerce market place, which was released just this week, it also mentions source code, source code disclosure requirement, however, the source code disclosure requirement is very limited in nature.

It is basically in terms of AI applications, as it mentions that a lot of decisions will be made through artificial intelligence.

And when it comes to these they might lead to validation of consumer interest and therefore, there might be a requirement for the source code of -- for looking at the source code because as you've seen previously as well, artificial intelligence generally learns from the current conditions, which might not be perfect, and therefore there might be a requirement in

terms of fundamental rights violations or privacy rights violations for the same.

Data localization, your AI source code disclosure requirement, and thirdly I think the delays in the U.S. -- in getting access to back ends has been something that has been mentioned by various other organizations.

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

MS. FERRITER: Thank you. Could NALSAR comment on how it views long standing IP challenges in India that are cited in past special 301 reports?

These include, quote, those which make it difficult for innovators to receive and maintain patents in India, particularly for pharmaceuticals enforcement actions and policies that are insufficient to curb the problem, copyright policies that do not properly incentivize the creation and commercialization of content, and an outdated and insufficient trade

secret legal framework, end quote.

MR. SINGLA: Well I will not comment on the basis of NALSAR, but on the behalf of NALSAR litigation project. With regards to patents in terms of end price control, I would like to renew attention to policy of Ministry of Chemicals and Fertilizers through our related January 3, 2019, under which patented new drugs and orphaned drugs have been exempted from price control for a period of five years from the date of their commencement of commercial marketing.

This allows for another exception, which will make Indian market attractive to multinational pharmaceutical companies and encourage them to introduce new drugs into India. This also removes the localization requirement in regards to this.

Was there a second part of this question? With regards to the trade secret requirement, there are other, under the Indian civil procedure code there are other options available for the companies to litigate in India.

However, it is true that there is no trade secret, trade secret legislation, per se.

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

MR. LAMBERTI: Hi, thank you. Thank you for flying out from California for this and appreciate your testimony. Your submission and your testimony today describes a number of steps that India has taken to create a friendly domestic environment for IP-intensive industries.

However, other submissions and other testimony earlier today describes India as advocating for the erosion of intellectual rights in multilateral fora. Where do you see the disconnect, the inconsistency between the --

MR. SINGLA: What we do mention is that until 2018, the USTR has always been putting India on the priority watch list and that is of course because of various reasons that India, that the USTR has mentioned in its reports consistently.

What we are stating here is that India

has been, there has been a shift in terms of India's policy towards IPR and as can be seen through the various steps, it is continuously moving towards providing a market which is better, which enforces the intellectual properties rights protection in a better, in a better manner.

And therefore, we would appreciate that if India is moved from priority watch list, which also shows that the USTR is responding to the manner in which India is working towards its legislations as well as its policies in taking steps. And hopefully this will be a further incentive for the Indian state to continue working on this issue.

CHAIR LEE: Thank you for your testimony.

MR. SINGLA: Thank you.

CHAIR LEE: Next is the Pharmaceutical Research and Manufacturers of America. Thank you. Please state your name and organization for the record and begin your testimony.

MR. MOORE: Thank you very much. I'm Chris Moore with the Pharmaceutical Research and Manufacturers of America. And on behalf of bio-pharmaceutical innovators in the United States and the more than 800,000 women and men they employ across the country, PhRMA appreciates this opportunity to testify before the Special 301 committee.

The United States leads the world in medicines research and discovery. Intellectual property, including patents and regulatory data protection drives and sustains bio-pharmaceutical innovation. It enables access to today's medicines and promotes investment in tomorrow's new treatments and cures.

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 for patients who need them.

But today innovators face tremendous challenges in major overseas markets that

threaten medical advances and put American jobs and exports at risk.

Special 301 gives the administration a powerful tool to identify and address severe and pressing barriers abroad and to level the playing field.

Special 301 is not only about promoting adequate and effective intellectual property protection overseas, it's also about ensuring that our trading partners provide fair market access for American inventions and that they appropriately value new advances.

We urge the administration to use Special 301 to address damaging market access barriers in Japan, Canada and Korea that significant harm to U.S. exports often through practices that discriminate against American innovators.

New policies in Japan use biased criteria that would allow local companies to get a competitive advantage and would discourage the launch of competing products.

Proposed changes to Canada's pricing policies are aimed solely at patent medicines and would undervalue U.S. innovations. In Canada and Korea, American innovators also face a range of intellectual property challenges, including inadequate patent term restoration. For these reasons and others, we ask that Japan, Canada and Korea be named priority foreign countries.

PhRMA submission also identifies top intellectual property barriers and threats abroad that require urgent action. In many cases these threats are driven by or actively supported by multilateral organizations.

Last year for example, Malaysia issued a compulsory license for an innovative medicine, a move that was not designed to address an urgent public health challenge but rather to facilitate the local development of a competing combination product.

Final regulations Indonesia issued in late December without any public consultation, similarly, transformed compulsory licensing into

an industrial policy tool. Patent products that are not manufactured in Indonesia can be compulsory licensed.

Contrary to its own procedures, the Colombian government accepted a petition for review in December of 2017 that could result in a compulsory licensing of patents protecting an entire class of innovative medicines.

In Chile, an innovative medicine developed in the United States is already at risk of compulsory licensing and now Chilean lawmakers are considering legislation that would grant the health ministry extraordinary new powers to force compulsory license decisions on the vaguest of grounds.

For these reasons, we ask that Malaysia be named a priority foreign country and that Indonesia, Chile and Colombia be placed on the priority watch list. Unfortunately, PhRMA members are also facing growing intellectual property barriers and threats in advanced economies, including the European Union, Saudi

Arabia and the United Arab Emirates.

Despite its role in medical research, the EU is days away from action that would undermine innovation by allowing local companies to make copies of patented medicines during the period of supplemental protection for export or stockpiling.

PhRMA asks that Saudi Arabia be placed on the priority watch list and that the European Union and the UAE at least be included on the watch list.

We urge USTR to use all available tools and leverage to address these and other challenges outlined in our submission. We particularly urge USTR and other federal agencies to address market access and intellectual property barriers in countries that are current and prospective U.S. trade agreement partners, or that are beneficiaries of the USGS peak program.

These existing agreements and programs, as well as ongoing and pending negotiations provide immediate opportunities to

address pressing market access and intellectual property concerns and to enforce current rules.

Thank you for the opportunity to testify today. We look forward to answering any questions and to working with you to address the serious concerns described in our submission for the 2019 Special 301 report. Thank you.

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

MR. S. CHANG: Thank you. Your submission and your testimony argues that discriminatory pricing policies deny fair and equitable market access. Could you please explain the link further?

And also, are there examples where companies have not sold products or where companies have pulled out of specific markets due to such policies?

MR. MOORE: The discriminatory practices that are outlined in our submission are very concerning for our members. They appear to discriminate in certain cases between foreign and

domestic suppliers.

That is certainly the case in Japan, has been the case in Korea. They also discriminate between patented medicines and generic drugs. That is the case in Canada.

There's real concern that these controls will prevent products that are manufactured in the United States from having the same competitive opportunity to supply these markets as domestic products.

We think that is a serious market access barrier. The Special 301 statute requires USTR to include countries on the list that are preventing fair and equitable market access for U.S. persons who depend on intellectual property rights.

It also gives some guidance in terms of what would constitute a market access barrier including whether these are barriers that appear to violate international agreements, that appear to be discriminatory, non-tariff trade barriers. We think that's the case with respect to the

countries and the practices that we've highlighted.

MR. S. CHANG: Thank you for that answer. Going back to the last part of my question, if possible, could you please give us some concrete examples of where your member companies have pulled out of specific countries due to such pricing policies?

MR. MOORE: For our members, we're producing products that are different than other products might be. They're products that are required by patients for their health. And so the last thing that any of our members want to do is to pull out of a country.

We also face the challenge under trade rules and intellectual property rules globally that if we fail to supply a product that is protected by a patent in a country, that product can then be compulsory licensed for failure to work the patent.

And so that's a very serious concern as well. So our members are constantly striving

to be able to supply these products but given some of the new proposals that have been cited in our submission, the types of cuts that we're looking at, the discriminatory nature of those cuts, I think that's going to make it very, very difficult for a number of our members.

CHAIR LEE: Thank you. Next is a question from the Treasury Department.

MR. W. CHANG: Thanks for your testimony. Over the past two years since the issuance of India's national IP policy, how does PhRMA evaluate India's implementation of the policy? What recommendations do you have to the government of India for implementation of the policy going forward? Thanks.

MR. MOORE: Well we have been in many discussions with the Indian government. It's always our goal to try to engage constructively with governments around opportunities to create the right environment for bio-pharmaceutical innovation in their countries.

And some of the challenges that our

industry continues to face in the Indian market make that very difficult. The inability to maintain and enforce patents that we have in that country because of challenges with the enforcement procedures, things like Session 3D make it very difficult for our companies to get patents in India.

We aren't able to secure regulatory data protection in India. It's very difficult to do clinical trials in India both for our member companies but also for Indian generic drug companies.

And so all of those things are issues that we have brought to the Indian government and we look forward to concrete steps to resolve those issues.

CHAIR LEE: Thank you very much for your testimony. Next is Public Citizen.

MR. MAYBARDUK: Thanks very much, members of the committee, good to see many of you again, and let me start by saying I appreciate that yours is a challenging and delicate job,

that this is a long day, and that you take some criticism. So I thank you for hearing from us.

Public Citizen is a nonprofit, consumer advocate --

CHAIR LEE: Sorry. Let me just interrupt for just a second. Could you state your name --

MR. MAYBARDUK: My name for the record. Yes.

CHAIR LEE: -- for the, for the record? Thank you.

MR. MAYBARDUK: Yes, sir. Peter Maybarduk. I'm the director of our Access to Medicines Program. We've been seeing each other here for many years. So Public Citizen is a nonprofit, consumer advocacy organization. We accept no money from any government and no money from any business. Our 500,000 members and supporters are U.S. consumers.

As the director of our Access to Medicines Program, I work with partners across the United States and around the world to make

medicines affordable and available through tools and policy and law and our submission that you have that draws on our experience providing technical assistance to public agencies particularly in developing countries on patent and other IP rules to protect access to medicines.

But it is worth saying that we are working more and more in the United States these days, given the pain that people living here are feeling from increasing medicine prices.

Of the latest Kaiser survey suggests that 24 percent of Americans either themselves or within their family are self-rationing their prescriptions.

They are failing to fill prescriptions precisely because of cost, because of the high price of pharmaceuticals in the United States, fully one-quarter of the U.S. population.

This is according to Harvard and Politico, drug pricing, the number one issue that Americans have for the U.S. Congress at the

moment.

You ask Democratic oriented voters, Republican identified voters, you find that both at the moment list drug pricing ahead of every other salient issue that Congress might address. They're really hoping for strong action to make medicines affordable here at home.

Now in this context we would note that the Trump administration, we've actually seen take some modest and positive steps towards lowering drug prices. However, when we analyze the good and bad of administration policy, the practice of blaming other countries for high prices here constitutes the ugly in the good, bad and ugly of those practices.

We're concerned that the Special 301 report from last year seemed to follow that aggressive approach, merely criticizing foreign practices that are designed simply to make medicines affordable. The report reflects, quote, the resolve of the administration to call out foreign countries, which we took to be some

very interesting language.

Well some context about this approach. There is no logical reason, let alone evidence to think that people in the United States will pay less for medicine if the U.S. government works to compel other countries to pay more.

That's crazy talk. That's not how business works. Companies are working to maximize revenue in every market, and they are not pricing to recover research and development cost, but rather to recoup revenue.

That's not just how all industries work. That's also what the U.S. government found in its own reports on the subject. HHS in 2016 had a report on prescription drug spending in innovation that identified the simple and obvious revenue maximization model.

One recent study found that prescription drug corporations receive 176 percent of global R&D costs from the excess profits they make charging high prices in the United States alone.

But what does make pharma pricing different from other sectors is that the patent-based industry operates without typical competitive constraints and in the USA without even government negotiating powers that check on price. So while there's an extent to which we pay for innovation and of course taxpayers put in $30 billion a year for the National Institutes of Health publicly funded by medical research and development, there's a greater extent to which we pay for monopoly, it's the monopoly conditions of the not quite markets for pharmaceuticals that make prices so high.

However, our country is beginning to seriously question and challenge this status quo. Many types of reform are active in Congress right now, are active with the administration. We'll probably see the limiting and banning this year of particular pharma industry abuses, thanks in part to the leadership of Republic Senator Chuck Grassley.

Even compulsory licensing, a hot topic

today, there are at least two bills in Congress favoring the use of compulsory licenses in the United States. One already has the support of full half the members of the House Democratic Caucus, half. So these are not marginal issues in our own country any longer. There are bills to reduce exclusivity periods and serious efforts to patent reform.

I see that I only have a minute, so I'll have to move rather quickly but it's worth noting that again, here in the United States, Baltimore City has requested compulsory licenses as a remedy for the opioid addiction crisis for treatments for naloxone. Louisiana has explored this for Hepatitis C, the same drug that's being criticized for Malaysia's action effectively do the same thing that Louisiana's looking to do. The interest of U.S. elected leaders should lead to a softening of U.S. pressure against similar policies abroad.

Now it is worth addressing the mandate, the Trade Act of 1974 briefly. You

asked about discrimination. Our understanding with the prior speaker, if pricing policies neither discriminate against American firms, in particular, nor violate an international agreement, it is inappropriate to include them in Special 301. Patented, distinguishing between a patented and a generic product is not discrimination, as regards trade practice. It's policy. It's smart policy.

Current administration will leave office eventually and it looks as those at least some subsequent governments will see these issues quite differently if we follow the track of U.S. politics today on drug pricing, we think that we should exercise some caution in our approach regarding such globally explosive issue and how we target our trading partners and how far we stray from our own values at home, not least given that many people's lives are at stake.

Balance of our comments you can find in our submission and I will answer your questions.

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

MR. S. CHANG: Thank you for your testimony. With respect to the Malaysia compulsory licensing issues, how does Public Citizen respond to stakeholders' comments that the Malaysian government's actions undermine the current research and development model for innovative medicines?

MR. MAYBARDUK: Well again, we're looking at doing the same thing in the United States today, as a first matter. But also Gilead in that case -- and this is detailed in our comments -- Gilead in that case had licensed its product, which is a Hepatitis C cure, a very expensive Hepatitis C cure that is critically important for the 500,000 Malaysians that are living with Hepatitis C today, had licensed that product for generic competition in many countries but not in Malaysia.

Malaysia sought to expand essentially the competitive territory for that product by

pursing government use license, and it was through pursuit of the government use of those patents that Gilead subsequently decided to, as I understand it, extend its, extend the licenses to Malaysia as a territory. So this is Malaysia working to induce more procompetitive behavior from the patent holders successfully in a way that can help them actually end the Hepatitis C epidemic.

CHAIR LEE: Okay. Next is a question from the Department of Health and Human Services.

MS. SNYDER: Your submission suggests that the Special 301 report should not criticize countries for a lack of transparency or due process unless such criticism clearly articulates the alleged violation of a TRIPS standard. Is TRIPS the only standard that should apply, or would you consider them to fall within the market access prong of the report's legislative mandate if the policies cause disproportionate harm to foreign companies?

MR. MAYBARDUK: Well I think that the

standards -- so the trade act states for IP provision, that violate provisions of international law or international grievance which both the U.S. and foreign country are parties, so a trade agreement standard would also apply, a NAFTA standard would seemingly also apply. Or constitute discriminatory, non-tariff trade barriers.

So I think our standard there, again, you know, it's not, it's not discrimination to distinguish between patented or generic products. It's good policy. You should distinguish them in price and cost. It's also not entirely clear to me whether it's merely a matter of foreign firms versus domestic, though it'd be interesting to converse on that. As opposed to American firms in particular.

But I think we have to look at where, you know, where there's an overlay of coincidence. If the distinction that's being drawn is the patent, that's not discrimination. That is a, that is policy. Sorry, does that

answer your question?

MS. SNYDER: I think that gets to most of it.

CHAIR LEE: Thank you. We have a final question from the State Department.

MR. HENRY: This question relates to your comments regarding pricing. Your submission mentioned that, quote, there's no evidence to suggest that high prices for innovated medicines are rooted in high research and development costs that the rest of the world does not sufficiently support, end quote.

However, the study cited in your submission in support of this statement, instead seems to suggest that higher prices paid by U.S. patents, taxpayers and businesses subsidize pharmaceutical R&D for the rest of the world. Could you clarify how Public Citizen views this?

MR. MAYBARDUK: Americans pay outrageous prices for pharmaceuticals, higher than just about every country in the world. However, most other countries pay prices that are

far too high also. So the premium pricing that people living in the United States are paying is going to the industry but is not necessarily going directly to R&D costs because prices aren't coming from R&D costs.

Prices are coming from revenue maximization under conditions where you have a monopoly on an essential product. The government isn't sitting down to negotiate with you, and there are no disciplines on price. You charge whatever you can. They're not tied to R&D costs. It's not to say that R&D is not expensive, and we fully support a broad range of policies to drive R&D toward the medical needs that people have but there isn't a direct nexus between what the price of a product is and what the investment that went into that, went into that product may be.

And if we try and change pricing aboard, it will have zero effect on pricing for Americans because we'll still see revenue maximization in all markets.

CHAIR LEE: Thank you for your

testimony.

MR. MAYBARDUK: Thank you. If I may just really briefly, I understand that one of the questions today has been what would we like to see U.S. charge, or what do we see as sort of the appropriate range of the report. And I think it is worth just saying really briefly that there are criminal defenses defined under TRIPS, both in trademark counterfeit and copyright piracy.

CHAIR LEE: So we do have the opportunity for a post comment, or sorry, post hearing submissions from people who testified, so that maybe something an area that you pursue for any sort of post hearing filings.

MR. MAYBARDUK: Very good.

CHAIR LEE: Thank you. Next is the Trademark Working Group.

MR. KILMER: Good afternoon. I'm Paul Kilmer appearing on behalf of the Trademark Working Group. Thank you for the opportunity again to address trademark issues that affect U.S. brand owners.

What we did this year as we did in past years is ask our members what trademark laws and practices abroad cost you the most time and money. And the list starts with, as it did last year, China in general. One issue that came to the top this year are trademark squatters and pirates who are now becoming, not only more prevalent in China but also starting to practice their trade in the United States and in other foreign countries.

Another concern was that China is considering eliminating relative grounds refusals in trademark examination. This is an issue we face in other countries and what it does is force brand owners to bring more oppositions and invalidation proceedings than if the trademark offices would do relative grounds in what we call likelihood of confusion, examination, during the examination phase.

The absence of default judgments is also costing American companies a lot of money in China. Many of the serial trademark pirates and

squatters will file applications and then not bother to defend oppositions or invalidation proceedings, and yet the U.S. company must submit evidence and arguments and spend a good deal of money in cases where the applicant, many times a pirate or squatter doesn't bother to show up and defend their application.

The failure to give due weight to witness declarations by U.S. companies, in other words, affidavits, the Chinese trademark office as well as the TRAB gives no weight to such declarations even if the contents of the declaration is not challenged in a proceeding.

The elimination of direct appeals to the TRAB from the CTMO, another issue we've raised in the past, which is costing U.S. brand owners a lot of money because what that means is the mark they have challenged becomes registered. It is entitled to all the presumptions of registration. And then the trademark owner is forced to bring a brand-new proceeding, rather than an appeal. And this costs a great deal more

time and money.

China also has still a great many burdensome formalities in the Beijing IP court, as well as in other contentious proceedings. They remain very inflexible in terms of accepting goods and service descriptions, especially in high technology and new technology fields, which we're trying to address somewhat in the TM5 process, but it is slow in coming.

The failure to allow amendment of applications challenged in contentious proceedings, in oppositions and invalidation proceedings is causing a lot of problems with brand owners in situation in which they might be able to otherwise settle the case. If you allow amendment during contentious proceedings sometimes the parties can decide, well, my goods really don't compete with your goods. Or my mark really isn't that similar to yours. They enter into an agreement and yet the trademark office will not allow you to amend your goods and services in the challenged application during the

course of those contentious proceedings.

India is another nation that does come up quite a bit in our discussions with participants. The inability to obtain quick seizures of counterfeit goods under Section 115 of the Indian Trademark Act is particularly troublesome and is causing brand owners to not be able to seriously control counterfeiting in India in some situations.

Also the pendency of thousands of oppositions, rectification proceedings and cancellation proceedings brought more than three years ago continues to be a serious issue. License recordation and registered user requirements is another issue that comes up constantly. The absence of certification mark registration in countries ranging from Algeria to Yemen is another issue that our members bring up regularly.

Failure of countries to accept letters of consent and coexistence agreements is another major issue. Failure by some countries, in fact

many countries to accept multiclass trademark applications continues to be a problem. There are more than 35 such nations listed in our report. There are many more issues listed in our submission, including failure to recognize letters of protest. Nations that do not recognize the doctrine of excusable nonuse to maintain trademark registrations and many more.

Thank you for your time. I would enjoy hearing your questions.

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

MR. S. CHANG: Thank you. Your submission highlights certain trademark laws or practices in Central Asia, which may merit special attention. Is there a particular law or practice which your members consistently highlight as particularly problematic in the region as a whole?

MR. KILMER: There are many nations in Central Asia that still don't have opposition proceedings, where you file a trademark

application, you're not really allowed to -- someone else files a trademark application. You're not really allowed to contest it until it's registered. And many of our members have commented that, you know, they have to wait, allow registration and again all the presumptions that flow from registration before they can take effective action.

I'd say that's probably the number one issue in those nations.

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

MS. FERRITER: Thank you. Have you seen any Middle East and North Africa regional or individual improvements or deteriorations in trademark processes since last year? If you could fix one thing in the MENA region or one issue in a specific MENA country, what would it be? And what is the one complaint you hear most regarding trademark processes in the MENA region?

MR. KILMER: Yeah. I mean the

legalization requirement is one that affects many nations in the MENA area. Some even have what they call super legalization. After you go through the whole process of legalizing documents in the United States, then you need to go to that nation and within the nation, legalize again. It is -- it's something we don't find outside of that region at all.

Another thing that affects our members profoundly is the cost involved in registering marks in many of those countries. Some of the fees charged to file trademark applications are extremely high and remain extremely high. So we do hear a good deal about that as well.

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

MS. PETTIS: Thank you for your testimony. Your submission mentions that serial trademark pirates or squatters in China are a growing and costly problem for your stakeholders. Could you further elaborate on the process being

experimented by the Chinese -- the China Trademark Office to address this issue, and your view on the potential effectiveness of this process?

MR. KILMER: The China Trademark Office has begun to implement what they call a blacklist. And one can make a filing with the China Trademark Office, pointing out a particular person or company that has engaged in the practice of large-scale trademark squatting. The CTMO is at this point in time, anyway, as far as I know, informally making a list of some of those individuals and companies.

Unfortunately what tends to happen is the squatter changes its stripes. It forms a new company under a different name and then continues the practice under that name or under the name of a different individual. So it's still is something that our members are very concerned about and is still seeing more of them than we would like to see. Although certainly the Chinese government has taken some steps to try to

curb the practice.

CHAIR LEE: All right. The next question will be from the U.S. Patent and Trademark Office.

MS. FERRITER: Thank you. Your submission mentions that serial trademark pirates or squatters -- or sorry. Sorry. I was not paying attention.

MR. KILMER: No, no, not a problem. I can answer it again. I'll try to answer it in a different way.

MS. FERRITER: No, no. I have lots of questions to ask. Could you elaborate on the types of formalities required of trademark owners in the Gulf region, including Kuwait, Saudi Arabia, and the UAE? How much of the burden do these formalities place on the Trademark Working Group participants?

MR. KILMER: Right. There are quite a number, and we covered the legalization already, but the requirement of recording registered users is another one. Most of the

countries in that region, if you have licensed users, they require you to record those licensed users with the government before you really get the full benefit of your trademark rights.

Some nations actually will deny you the ability to protect your trademark if you don't record your license. Some will actually keep you from enforcing your license against your licensees. So it's a very tricky thing. A lot of U.S. companies frankly are not aware of some of those requirements or the impact, if they fail to record their license agreements.

CHAIR LEE: Thank you very much for your testimony.

MR. KILMER: Thank you.

CHAIR LEE: Next is the U.S. Chamber of Commerce. Thank you. Please state your name and organization for the record and begin your testimony.

MS. SZYMANSKI: Sure. My name is Ellen Szymanski. I'm the executive director at the Global Innovation Policy Center at the U.S.

Chamber of Commerce. First, thank you for the opportunity to testify today.

The countries included in our submission we based on geopolitical importance, market size, and maybe there might be a particular IP issue that we wanted to highlight. And we hope we've provided enough information on those countries, but I'm sure you have questions or clarifications, and of course we'll be very responsive in responding to those questions today, but also after the hearing.

In addition to the countries that we highlighted by name, we've also supplemented our submission by our U.S. Chamber International IP Index. And it's a scorecard that looks at the -- 50 economies around the world, which is about 90 percent of GDP, and takes a look at their IP system, so hopefully that can be informative to you.

Our research from the index shows a lot of socioeconomic benefits that accrue from a high IP standard. And just to highlight a few,

if you have a high standard IP system, you're 53 percent more likely to experience increased R&D investment in your economy, 55 percent more likely to adopt new technology, and 30 percent more likely to get your innovations funded.

In today's knowledge-based economy, IP is critical. Some of the countries -- some of our country's largest trading partners have taken small steps in the right direction. And I'd like to point to India for example. It's introduced reforms to align its IP environment with the international system, and it's addressing its patent backlog.

Recognizing this potential, we partnered with the U.S.-India Business Council and the India Federation of Indian Chambers of Commerce and Industry to launch the first ever Track 1.5, U.S.-India IP dialog. And we thank the U.S. PTO and the rest of the U.S. government for their support in that initiative.

Despite positive developments we've seen around the world, the challenges for IP

owners abroad remain. Lack of enforcement to protect copyright holders, misapplication of competition policy, price controls, compulsory licenses, undermining the IP protection through multilateral organizations is examples of some of those issues.

For example, the Chilean congress is considering a bill that would amend the grounds for compulsory licensing, setting a troubling precedent. All of this is -- all of these types of undermining of the IP system end up favoring domestic commercial interests at the expense of innovators, creators, and consumers around the world.

But I'd like to end on a positive note. The USMCA and the forthcoming FTAs provide an opportunity to strengthen IP protection. To illustrate the strengths of the IP chapter of the new NAFTA, GIPC benchmarked it against the IP standards in our index. The research revealed that the original NAFTA scored a mere 48 percent on our index, but USMCA will score 80 percent.

We commend the negotiation team on the completion of USMCA, and we're working hard to educate members of Congress on the benefits of the agreement. Thank you very much.

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

MR. S. CHANG: Thank you. Your submission states that several developing countries, quote, continue to take steps in the wrong direction, end quote, including Malaysia. What specific problematic steps has Malaysia taken, and with respect to the Malaysian compulsory licensing issue included in your submission, what are your views and what steps should Malaysia take to resolve them?

MS. SZYMANSKI: That is the main issue on Malaysia. I think our submission goes into a number of other areas. But certainly the compulsory license in Malaysia is very troubling. So I think that, you know, there's been a number of questions on Malaysia and on compulsory licensing themselves, and on price controls and

many of those types of steps that are undermining the IP system.

I want to make one additional point beyond I think what some of my colleagues have made. If you look at what happened in Europe as an example of what happened when they started price controls. Before price controls in Europe, they invested 24 percent more in R&D investment and IP. After price controls, they invest 40 percent less.

So we need to protect intellectual property here in the United States and abroad because we have to create that pipeline and secure that pipeline of new medicines so we can address some of the challenges in our health care system.

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

MS. FERRITER: Thank you. IIPA submission characterizes South Africa's recent policy actions on intellectual property reform as

potentially undermining the modern marketplace by failing to establish a clear, legal framework. While at the same time, South Africa's score on the U.S. Chamber's IP Index improved marginally. Why is that?

MS. SZYMANSKI: We absolutely agree with the assessment from IIPA, first of all, and our submission does go through the IP policy and some of the troubling aspects of it. And we've spent a lot of time in South Africa talking to the government about that. So I wanted to say we definitely agree with that statement.

As far as the index goes, we added a number of criteria in the index, and South Africa did well on some of those indicators. The index is ranked on 45 indicators that are all measured equally. They all have the same points in the index. So as a result you might have something that's very troubling, but it's only going to reduce a country's score marginally. And the same for, they may have taken a huge step in let's say the areas of trademark, but that's only

going to increase their score marginally.

So we -- so that's why sometimes, you know, there might be great uproar on a policy in a particular country, but it's really only a marginal difference on our index.

CHAIR LEE: Okay. Thank you. The next question is from the International Trade Administration of the Commerce Department.

MS. SALZMAN: Thank you. In your submission you stated that Japan's new health technology assessment system is cause for alarm because, and I quote, since it has the potential to significantly undervalue the principle of fair value for innovation, end quote. And that's from Page 64. Could you please elaborate on this new system and how it would impair the efficacy of Japan's system?

MS. SZYMANSKI: Sure. I probably don't know the system as well as some of my colleagues, so I would like to take the opportunity to give you additional information after the hearing.

But what I would say relating to Japan's system and many others, we have to understand that innovation is not an aha moment and then we have a new product. There's a lot of investment that goes into it, high risk investment. And the other thing that concerns me internationally but in the United States as well is that investment in new medicines is not a guarantee.

It's not a guarantee that that investment will go into medicines, and it's not a guarantee that that investment will go into your invention. You have to create a stable and predictable IP system that's going to attract it. And so there are a number of highly developed countries that we find are implementing policies that are really going to have an effect on the innovative pipeline of medicines, so Japan, Canada and a number of others.

CHAIR LEE: Thank you. And we have time for one more question from the Department of Agriculture.

MR. KARAWA: Thank you for your submission and your comments so far. In your submission you highlight the link between IP intensive industries and job creation. Do you find that this argument helps when talking to foreign governments about the importance of strong IP policies?

MS. SZYMANSKI: Yes, I do. In our IP index, we look at socioeconomic indicators, such as job creation, and we actually have 29 of them. And so when we go to governments and we talk to them about why it's important to have an IP system, it has to be a benefit to them. It has to be a benefit to their economy. And when we're able to show the statistical correlation between a high IP standard and job creation or, as I mentioned, getting innovation funding, or, you know, attracting foreign investment, that's a much better argument. It's much more persuasive.

CHAIR LEE: Thank you very much for your testimony. Next and last, we have the U.S.-India Strategic Partnership Forum. Thank

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

MR. BJORKMAN: Good afternoon. I'm Neil Bjorkman. I'm with the U.S.-India Strategic Partnership Forum. I have the privilege of going last, so I'll try to be brief, and I'll try to not rely too much on my notes.

Briefly, we are an organization that is dedicated to deepening strategic and economic ties with India. We were founded by John Chambers and a number of prominent CEOs, including the CEOs of Pepsi, MasterCard, Medtronic, Adobe and others. And the first point I'll make is that despite trade tensions with India, which are quite longstanding, U.S. companies are in it for the long term when it comes to India.

They've been in India for over 100 years. They do a lot of research and development. They work very closely with the government of India and consider themselves good corporate citizens. Point number two, and this

is something I think that's been echoed by almost everyone, which is that innovation is really the key to economic success.

You know, the old saying, adapt or die. Right? And it's imperative for governments around the world to protect those innovators. So we very much appreciate the 301 process, as it is a form of leverage and it does help American companies protect their intellectual property abroad. My third point is more of a quick observation about the good and maybe the not so good in terms of India's recent actions in the IP space.

I think on the good side we're seeing India raise awareness about the importance of IP. So CIPAM, which is the Cell for IPR Promotion under DIPP educated 100,000 students. There were trainings that took place for over 58 officials at the Ministry of Micro, Small and Medium Enterprises, which I affectionately call MSME.

Also we've seen -- we've done some of our own work on the ground. We actually on the

14th of December hosted a roundtable discussion on piracy prevention, new media, and new challenges in partnership with CIPAM and DIPP. And the roundtable brought together diverse stakeholders from both the public and private sectors to talk about global best practices.

As others have mentioned, we've seen the patent process overall improve, so the number of patents granted increased by 14 percent. The overall number of claims pending examination dropped from over 200,000 to 130,000 this year. We saw the claims that were actually processed and filed increased by -- or sorry -- patent examinations increase by 51 percent.

In terms of problem areas, patent infringement is still a big problem, and often infringement is not detected until the violating product hits the marketplace, which is far too late. We also see that Indian law still allows third-party manufacturers to commercialize copies of an innovator's product even if those copies violate the patent.

Also and finally the national pharma policy in 2017 allows for the use of CL, compulsory licenses. There's also the ability to control prices on patented products. And the final point I'll make is simply that the U.S. government of course has to balance what's happening in the trade sphere with what's happening in the strategic sphere. So as much as we're siloed here today with a trade discussion, ultimately the President of the United States would have to weigh in on what to do, or, you know, if something were to come out of a 301, what to do about it.

Of course, on the strategic side, the relationship is extremely strong. India is our major defense partner and we do more military exercise with India than with any other country, and of course it acts as a balancing check against other actors in a very unstable region. Thank you.

Oh, my apologies. My final point is our recommendation would be to have the

governments convene an IP dialog, and we would be happy to facilitate any private sector participation in that dialog. Thanks.

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

MR. S. CHANG: Thank you for your testimony. You commend India for its implementation of the national IP policy. What areas should India prioritize for future implementation of that policy?

MR. BJORKMAN: Well I think broadly speaking, it's increased enforcement, increased awareness building, increased training. I think that's -- some of those are easier said than done. They require time, effort, and money.

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

MR. LAMBERTI: Good afternoon. USISPF cites the creation of India's commercial courts as a positive step towards improving India's intellectual property regime. Could you please describe the experiences of members of the forum

with IP cases, specific IP cases in India's commercial courts? And could you also describe the types of cases heard by these courts? Is it a broad range of IP cases including patents, trademarks, copyrights, and trade secrets?

MR. BJORKMAN: Thank you. I did not have the pen for that discussion, so for that part of our submission if I could perhaps provide something in writing at a later time, I'd appreciate that.

MR. LAMBERTI: That's fine. Thank you.

MR. BJORKMAN: Thank you.

CHAIR LEE: Thank you. Next is a question from the U.S. Copyright Office.

MR. GREENBERG: Your submission notes that the Indian film industry earns about $2 billion a year but loses $700 million a year due to piracy. How much does piracy in India cost U.S. stakeholders, and what efforts should the government of India take aside from just a camcording prohibition and amending the copyright

law to ensure adequate protection against circumvention of technological protection measures?

MR. BJORKMAN: I'm not sure about the specific number as it relates to the United States. Certainly there are large U.S. companies that have a big footprint in India in the media space. 21st Century Fox comes to mind right away. And on the second one, if I could get back to you, I'd appreciate that.

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

MS. FERRITER: Thank you. India has enacted dedicated IP crime units in -- and I'm sorry if I'm mispronouncing these names -- Telangana and Maharashtra, and there are plans to expand that program.

What experience have your members had in working with these units? And in addition, what areas would you suggest for capacity building and training to improve their resources

to assist right holders in enforcing their IP rights?

MR. BJORKMAN: So I'm not exactly sure on what the relationship is right now with our members and those specific units. But I'd be happy to get back to you.

CHAIR LEE: Great. Thank you. We have time for one last question, and it comes from the International Trade Administration of the Commerce Department.

MS. SALZMAN: Thank you. USISPF submission notes several recent improvements in India's patent regime over the past year, including the digitized Indian patent office, the draft amended patent rules and streamlined pre-grant patent opposition review procedures. Which patent reform has been most meaningful for USISPF members?

MR. BJORKMAN: Again, I'm going to have to have an internal discussion to try to figure that out. Thank you.

CHAIR LEE: Thank you very much for

your testimony.

MR. BJORKMAN: Appreciate it.

CHAIR LEE: All right. On behalf of the Special 301 Subcommittee, thank you all for taking time out of your day to have this exchange with us. We appreciate the comprehensive research, the thought, and the problem-solving efforts that went into the written submissions and oral testimonies that we heard today.

As mentioned before, post-hearing briefs by interested parties that testified today are optional, and if you are interested, please follow the instructions on the agenda or in the original Federal Register notice at Regulations.gov with the Docket Number USTR-2018-0037. The Special 301 docket will reopen this afternoon and will remain open until 11:59 p.m. Eastern Time on March 5th.

In addition, a transcript and the video of today's hearing will be available free of charge at USTR's website at www.ustr.gov. We will do our best to get that posted within the

next two weeks. So thanks again, everyone, including my colleagues on the panel and those who testified today, for your contributions, your time, and your attention.

Finally, a special thanks to the personnel at USTR who took -- took care of today's logistics and setup. Ladies and gentlemen, the 2019 Special 301 hearing is now adjourned.

(Whereupon, the above-entitled matter went off the record at 3:27 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: 2019 Special 301 Public Hearing

Before: USTR

Date: 02-27-19

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