OFFICE OF THE US TRADE REPRESENTATIVE

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2018 SPECIAL 301 PUBLIC HEARING

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THURSDAY
MARCH 8, 2018

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The 2018 Special 301 Public Hearing
convened in Rooms 1 & 2, 1724 F Street, NW, Washington, DC, at 10:00 a.m., Elizabeth Kendall, Chair, presiding.

PRESENT
ELIZABETH KENDALL, Chair
CARI BERDUT, U.S. Patent and Trademark Office
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
LISA DYER, U.S. Department of State
OMAR KARAWA, U.S. Department of Agriculture
STEVAN MITCHELL, U.S. Department of Commerce
MAUREEN PETTIS, U.S. Department of Labor
AURELIA SCHULTZ, U.S. Copyright Office
MICHAEL SHAPIRO, U.S. Patent and Trademark Office
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(10:00 a.m.)

CHAIR KENDALL: All right, let's begin. Good morning. My name is Elizabeth Kendall. I'm the acting assistant U.S. trade representative for Innovation and Intellectual Property.

This is the public hearing for our annual Special 301 Review. This review is a statutorily mandated exercise we undertake each year to develop an overall strategy to ensure adequate and effective intellectual property rights protection and equitable market access in foreign countries for U.S. persons that rely on protection of intellectual property rights such as copyrights and related rights, trademarks, patents, trade secrets and others.

Ensuring that U.S. owners of intellectual property have a fair and full opportunity to use and profit from their intellectual property is one of the trade priorities outlined in the President's recently
released trade agenda. This is the 30th Annual
Special 301 Review and the 9th public hearing
that USTR has hosted in connection with this
review.

For the record, I'd like to note today
is Thursday, March 8th, 2018. This hearing is
taking place at the Office of the U.S. Trade
Representative. We will make a transcript of
today's hearing available to the public on USTRs
website.

Today's hearing is scheduled to go
until approximately 3:00 p.m. and we will break
for one hour from 12:10 p.m. to 1:10 p.m. I
would appreciate everyone's cooperation in
keeping the hearing on track.

At this point, I'd like to invite my
colleagues on the panel to introduce themselves
starting with Labor.

MS. PETTIS: Good morning. I'm
Maureen Pettis and I work for the Bureau of
International Labor Affairs, Department of Labor.

MS. SCHULTZ: Good morning. I'm
Aurelia Schultz. I've from the U.S. Copyright Office.

MR. CHANG: Won Chang, Department of Treasury.

MS. DYER: I'm Lisa Dyer from the Departments of States Office of Intellectual Property Enforcement.

MR. CHANG: Good morning. My name is Sung Chang. I am at the U.S. Trade Representative's Office, Office of Intellectual Property.


MS. BERDUT: Good morning. Cari Berdut from the PAN and Trademark Office, Office of Policy and International Affairs.

MS. BLEIMUND: Hi. Emily Bleimund, Department of Health and Human Services Office of Global Affairs.

MR. KARAWA: Good morning. My name is
Omar Karawa from the Department of U.S. Admin of Agriculture.

CHAIR KENDALL: Thank you very much.

This is the Special 301 subcommittee of the Trade Policy Staff Committee, which is comprised of the agencies you've just heard of and the Department of Justice and a few others.

This subcommittee is chaired by USTR and we conduct the annual review. The review is based on public contributions, as well as the 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 insights and factual information you will share with us today.

The schedule of today's hearing is comprised of interested parties, foreign government officials, private sector stakeholders and stakeholders from civil society who responded to USTR's notice in the federal register published on December 27th and voluntarily
requested the opportunity to appear at this hearing.

As a reminder, the purpose of the hearing is to provide the Special 301 Committee with additional information that we can use in the deliberations that will result in the publication of the 2018 Special 301 Report to Congress on or about April 30th, 2018.

This year we've received public filings that address over 75 countries and many country-specific IP protection and enforcement concerns that may negatively affect our bilateral trading relationships. These filings are available to the public at www.regulations.gov.

Most of you may know that the Special 301 Report is the result of the congressionally mandated annual review of the State of Intellectual Property Rights Protection and Enforcement and trading partners around the world. The U.S. conducts this review through the Office of the Trade Representative pursuant to Section 182 of the Trade Act of 1974.
The provisions of this section are commonly referred to as the Special 301 Provisions of the Trade Act, which is where we get the name. Specifically, Section 182 of the Trade Act requires that the U.S. Trade Representative identify countries that deny adequate and effective protection of intellectual property rights or deny fair and equitable market access to U.S. persons who rely on intellectual property protection.

This statute explicitly 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 PFC designation, USTR created this 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 the Priority Watch List without change for at least a year.

The format of the hearing will be as follows: Each party has been allotted ten minutes. That is comprised of five minutes of prepared statements, leaving approximately five minutes for questions. We will be watching the clock and provide a time cue 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 general, please keep in mind of the purpose of the hearing, which is to provide information that the committee can use in satisfying the charge of the Special 301 Statute.

We will break for one hour as I mentioned from 12:10 to 1:10 p.m. So at this time, I would like to invite the Government of Bulgaria to start us off.

Welcome. Please introduce yourself
and begin your testimony.

MR. KONSTANTINOV: Very good morning to you all. Ivo Konstantinov, Embassy of the Republic of Bulgaria to the United States of America reporting to the Minister of Economy, the presiding agency on IP enforcement in the Republic of Bulgaria. The name is spelled I-V-O, first name. Last name K-O-N-S-T-A-N-T-I-N-O-V.

I'm here to present the measures taken in the past year by the Bulgarian government and the government bodies and agencies responsible for IPR enforcement. As we treat seriously and are concerned with the inclusion of our country for the fifth year in a row on the watch list in the section of Special 301 of the U.S. Commerce Act.

We realize the gravity and the importance of IPR enforcement. And our desire is to prove that we have taken sufficient measures to be taken out of that list as we strive to be preferred investment and trade partners to U.S. businesses and government.
There's several government agencies that jointly execute IPR enforcement in our country. They are the prosecutors of this Ministry of Culture, the Patent Office of the Republic of Bulgaria, the Customs Agency and the Ministry of Economy, our Department of Commerce together with the U.S. Embassy and country and respective government agencies here in Washington D.C.

Every year we receive a list of recommendations kindly provided by our U.S. friends and partners. And the past year, those were mainly concentrated in the four areas, which we have taken deliberate efforts to execute and apply according to the recommendations of our U.S. friends.

Mostly in the area of legal reforms. A specialized unit for computerized crime and intellectual property structure within the Ministry of Interior, structuring of IPR specialized prosecution office is not just in the capital city but in the providences and areas of
the country. And various measures to improve the
efficiency of the judicial in dealing with IPR
cases. Imposing this U.S. sanctions of criminals
in the field of IPR.

Those were the U.S. recommendations to
us last year and we've done a lot to apply and
take concrete tangible steps in following them.
Roughly a month ago, our parliament also adopted
the new penal code of the country, which now
incorporates very practical, deliberate
enforcement articles and procedures, particularly
on IPR where the penal code was more deficient
years ago in its old structure.

The prosecutor's office has filed a
total number of 125 orders against 130 accused
individuals. The total number of penalized
individuals in the area of IPR infringement in
the past year have been 139 including one
conditional imprisonment of an IPR infringement
individual, one probation.

One hundred and thirty-seven
individuals have been convicted for IPR related
crimes. Ninety-six of them by verdict decision enforced from the previous year, 65 conditional imprisonments, one effective deprivation of liberty as a form of detainment. And seventy probations and 540 fines at the prosecutor's office.

Ministry of Culture controls the observance of copyright and related rights acts and checks the inspections of transmission and re-transmission of T.V. programs, public performance of music at different sites, unauthorized use of computer programs and optical disk act.

One of the most important and sensitive areas is certainly the fighting of the software piracy where we've been alleged as a leading breaching hub for Southeastern Europe, particularly in the downloading of entertainment content or torrent trackers. And in 2017, a number of successful actions have been taken against software piracy and illicit download of entertainment content.
So fighting unregulated broadcasting, as well of television programs included fighting of unregulated public performance of musical works, combating the unauthorized use of protective works on the internet. And at least ten inspections were carried out. One mandatory injunction was issued to remove inconsistencies in violation of the law.

Torrent tracking operators cooperate now with law enforcement. With those that don't, some particular measures like constantly forcing them in migrating their sites to different service in order to bleed out and lose users is done by law enforcement on the ground.

So those are just some of the measures we've taken this past year. And we appeal to be taken out of the list, being confident that we have followed your friendly recommendations.

Thank you.

CHAIR KENDALL: Thank you very much for your testimony. The first question is from USTR.
MR. CHANG: Thank you again for your testimony. Bulgaria's written statement notes that there is a decline in piracy disseminated by internet providers in Bulgaria. And you've kindly in your testimony also mentioned 2017 improvements of software piracy and felony was the content.

Could you please tell us a bit more information about the basis of that statement in your written submission?

MR. KONSTANTINOV: Certainly. There's four factors that contributed to that one. Is that we have a stake ourselves now with local growing and local entertainment industry with Hollywood movies being produced in our country on a massive scale.

And Bulgarian software being developed already as a product and software service locally. Some of it is also the availability of content and affordability through the internationalization of Netflix, which was a significant move a year ago. And some is the
migration of the torrent tracking illicit
download of entertainment content to streaming
sites, which are outside of our country and
outside of our reach.

Those were the contributing factors
but there's a significant decline in the most
sensitive area where we are implicated usually,
which is the illicit download of entertainment
content and software. So the progress is really
visible.

CHAIR KENDALL: The next question will
be from ITA on behalf of the Department of
Justice.

MR. MITCHELL: Yes, we're particularly
interested in the information you were able to
provide on the efforts of the cybercrime sector
in the cross-border organized crime department of
the general government of Bulgaria -- of the
general directorate for combating organized
crime. My apologies. I hope you don't mind if I
refer to it as the CDBOP.

MR. KONSTANTINOV: Sure, sure. I get
what you mean. I know what you mean.

MR. MITCHELL: How will the government of Bulgaria ensure that the CDBOP has adequate resources for investigations of online piracy that then lead to effective prosecutions?

MR. KONSTANTINOV: The structure allows for it, as well as increased resources in budget, plus the constant regular training center provides for them. And the trainings are something new that developed the past two years. I will elaborate more in writing if I might to your question, which is excellent and thank you for it.

CHAIR KENDALL: Thank you. The next question is from the office -- The U.S. Copyright Office.

MS. SCHULTZ: I'm sorry. The 2017 Special 301 Report noted concerns with gaps in Bulgaria's law with respect to the exclusive rights granted to rights holders and copyright enforcement online. You mentioned the new criminal law amendments but could you please
describe any additional legislative steps that
the government of Bulgaria has taken in the past
year to address these concerns including any
bills or amendments that have been introduced and
their current status?

MR. KONSTANTINOV: We've described
quite a few of them, which time will not allow me
to list now. There's not just the penal code but
there's comprehensive package and reform in
legislation. Because obviously from the late
90s, the legislation indeed was obsolete to face
this, especially the new piracy practices. And I
will provide a list of those additionally.

MS. SCHULTZ: Thank you.

CHAIR KENDALL: Thank you very much
for your testimony and those are all the
questions we have today.

MR. KONSTANTINOV: Thank you to the
esteemed commission. Have a nice day.

CHAIR KENDALL: Thank you.

I'd like to invite the government of
Ukraine to come up and speak. And please state
your name for the record. Thanks.

MR. TITARCHUK: Good afternoon. My name is Mykhailo Titarchuk. I'm Deputy Minister of Economic Development and Trade of Ukraine.

On behalf of the government of Ukraine and Minister of Economic Development and Trade, I would like to inform you first of all, that it's really a serious issue, what I'm going to discuss now. And I would like to express my utmost respect to the Office of the United States Trade Representative and for other United States government institutions to all participants.

For the time being, the government of Ukraine approved action plan for the next three years. Whereas IPR is one of the priorities. So we're seriously considering about IPR in our country. So our work on IPR infringement issues has taken place on the following five areas.

First, reform of the system of the state administration is intellectual property rights sphere. Second, sanctioned intellectual property rights enforcement serves as IP
protection. Addressing parties in this field of copyright and related rights. Force legalization of software products in solid executive government bodies. And the last one is technical pending issues in the sphere of collecting management of property rights.

In terms of sanctioned intellectual property rights protection, our reform on judicial system and the framework of judicial system, a special IP court, will be established in Ukraine as recently in 2017 towards signs and special decree of creation IPR court by the President of Ukraine Poroshenko. So we're expecting this year and it's going to be 21 judges.

In terms of jobs lost and IP issues, so the government of Ukraine has already approved and submitted to the parliament a review for current session several jobs bills on IP issues. First is patent trolling, industrial designs and trademarks, Number 56.99.

Second is custom procedures regarding
IPR protection, 46.14. Then third one, geographical indication, 60.23. Fourth topographic of semiconductor products. Then innovations and utility mode, 75.38. Second one, copyright and related rights issue 75.39. And most important is on efficient management of property rights of rights-holders incorporate and related rights sphere 74.66.

So this third point is collective management issue. So for the time being, one of the biggest priorities for us, so in terms of this, the government job bill so it was prepared on the basis of recommendations of international experts enrolled into EU funded training projects transferring the protection and enforcement of intellectual property rights in Ukraine. As the government draft law in relation to function of limited number of organizations for providing with mandatory and extended collective management.

And also, it clearly differentiates the spheres, categories of property rights under
which the mandatory and extended collective management is provided. It will allow avoidance of current chaotic situation in the sphere of collective and royalty by Collective Management Organization for the use of copyright and the related rights objects.

So our task for 2018 is to introduce an automatic system of distribution of royalty based as a Ukrainian Agency of Copyright and Related Rights of the UACR. Also we are planning to transform the UACR into not state owned organization. The amount of collected royalty in 2017 by UACR was about $2.3 million and the other similar, it's 19 organizations for about $1.9 million.

Legalization of software products in executive government bodies, so our minister has developed and forwarded to the involved executive authorities for the approval of the Draft Resolution of the government ministers of Ukraine on improvement of software legalization inventory procedures in central executive authorities of
Ukraine, which the proposal for Microsoft Ukraine Company had been taken into account.

In March 2018, this Draft Resolution will be adopted by the government of Ukraine, which will improve software inventor procedures for determination existing needs in legalization and introduce more current mechanism of finance of legalization activities; both through information of separate budgets requested of which executive board and through budget program of mandating on software legalization in all executive bodies.

It will also permit to halt an inventory within several months with the purpose of determined real needs in software legalization.

The last one, IPR enforcement. So the activities of the National Police of Ukraine for 2017 secured 141 criminal proceedings in this field of copyright and related rights in one which 109 proceeding were initiated following the materials by the cyber police department.
Twenty-five persons were served with charges.
Twenty-eight criminal proceedings with charging
documents were forwarded to the court.

The amount of the compensated material
losses constitutes about $91,000. Due to
efficient cooperation with providers and rights
holders, representatives of cyber police
department terminated activity of internationally
recognized Internet third parties,
onlinecinemafs.to to find granting of the
European online cinemas. Also the activity of
Card Sharing Associates, ISEEHD.TV that render
its services on broadcasting of about 1,000 TV
channels was determined.

So also 2017, National Police of
Ukraine secured 214 criminal proceedings based on
criminal infringements related to IPR
infringements, among which 127 criminal persons
are related again to corporate related rights
infringements, 40 illegal distribution of this
disc for laser routing systems, 125 illegal use
of signs for goods and services and 22
infringements of industrial property rights.

Also, to represent the National Police of Ukraine carrying out activities aiming at fighting against illegal production storage, packaging and sale of falsified planned protection agents, toxic substances, agro-chemicals, pesticides, poisons with illegal use of marketing goods and services.

The activities will state fiscal service. About 9,700 cases of custom clearing suspension on suspicions of IPR infringements were orchestrated in 2017. The value on the infringement items was about $407,000.

The activities of the state service of Ukraine on medicines and drugs control. 2017 a state service issued 106 orders on interdiction or turnover of 426 types of supply quality falsified and registered medicines.

And recently the Council of Intellectual Property was established in February 2018 with the purpose of coordination interaction of the state and municipal authorities, law
enforcement, supervisory agencies, enterprise
organization and establishing IP sphere.

The main tasks of the Council are
strengthening IPR enforcement, fighting against
Internet piracy, bet controlling, software
legalization, developing legislation, interaction
with the High IPR court. Thank you very much.
Let me know if you have any questions. Thank
you.

CHAIR KENDALL: Thank you very much
for your testimony. The first question will come
from USTR.

MR. CHANG: Thank you for your
explanation of your work on collective management
organizations. What is the anticipated timing of
the next steps that you just talked about
including 2018 and beyond?

MR. TITARCHUK: As far as the last
ones?

MR. CHANG: Your work on CMO,
Collective Management Organizations
(simultaneous speaking.)
MR. TITARCHUK: Okay. Actually recently on the 1st of March was the first reading will pass in the department. We go to 244 votes and we're expecting actually to provide the final draft view for the second reading at the end of March. So I'm expecting the first or second week of April. So to put in the Hall of the Parliament for second reading. So if everything goes smoothly, we still have time to be approved until 26th of April.

CHAIR KENDALL: Thank you very much.

The next question is from the USPTO.

MS. BERDUT: Thank you. I have a question regarding the un-stayed support of cinematography law that was passed last year. Could you tell us more about that law and how it's been implemented?

MR. TITARCHUK: Okay. As you know, in 2017 that law was finally approved after a long debate. For the time being it was quite useful for our cyber police department as it allows them to use it more practically and especially once
your article was -- its fighting against anti-piracy.

For the time being, what I've seen also inside the cinemas, there is special software called camcorder, which allows any, immediately if there's something wrong inside. Plus, what we got from the state cinema agency that there is no evidence for the last year. And also what is good, there is association, which goes like Anti-piracy Cinema Association in Ukraine. And they also motivated people who was in place inside the cinemas if they see the evidence, to inform us and then after that, get benefits.

MS. BERDUT: Thank you.

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

MS. SCHULTZ: Good morning. Thank you for explaining so much about the software legalization process. In your view, what are the remaining challenges?
MR. TITARCHUK: Challenges everywhere. Because for the last year -- and actually you have to start from everything from the beginning. So the long journey starts from the first step. Actually, the priority is now to -- really to fix Collective Management Organization.

Second, legalization software, which is very important and I would like that my minister would show an example to other ministers. And the third challenge is I think we need to increase more law enforcement in terms of, you know, people who is trying not to respect intellectual property. So must be more cases and it seems the final stage for our reform is creating IPR court. This is very important.

Thank you.

CHAIR KENDALL: Thank you very much for your time. I'd now like to invite the representative for The App Association to come forward. And please state your name for the record.

MR. REED: Good morning. My name is
Morgan Reed and I'm the president of The App Association.

First of all, thank you all for this opportunity to testify. I'm happy to contribute our views on where the current state of play is with regards to trade. And also to focus a little bit on the intellectual property issues that we're all here to discuss.

Quick level set, we have more than 5,000 member companies around the world, most of whom are in the United States but are truly global. Many of our companies are as small as one person. But if there is one characteristic that plays throughout this, they're all global.

The smallest members amongst us are just as global as the large. The ability of platforms to put applications in the hands of people in literally every continent of the world has meant that global reach for small business is truly here today.

Our members drive about $143 billion app economy right now. More than $8 trillion
dollars of money flows through the mobile
ecosystem today through goods and purchases from
manufacturing to daily life. And they are also
critical to workplace productivity and health.

In that instance, a huge part of what
makes this possible is the fact that data can
flow freely and unfettered. And that people can
be fairly compensated for their work.

We look at our key areas in the trade
space as kind of a fairly straight forward flow
tree. We start with the problems we have in the
trade space around limiting cross border data
flows, data localization policies in countries
around the world, custom duties on digital
content, requirements to provide source code from
market entry, requirements for back doors and
encryption technique. And of course the thing
we're here to talk about, intellectual property
violations.

One way to understand IPR violations
for a small business is that unlike larger
businesses, IP violations can be end of life for
a small or a new company. We don't have the cash
flow to bear a large impact event with IP.

It also -- IP violations often are
concomitant with data loss, revenue loss, and
reputational damage. So IP is not just something
that happens and can be brushed under the carpet,
it's critical for the way that we do it.

We see these violations occur in
numbers of ways. First, we have piracy that
exists by replication of an application where the
digital rights management component is reviewed.
Content for an app will be repurposed elsewhere,
changing advertising keys to redirect add revenue
from a legitimate business or injecting malicious
code that collect users private information.

I want to take a moment and give an
illustration. One of the things everyone on this
panel has heard over the years in the IPR space
is this idea of well, you have the wrong business
model. So I'm going to tell you a story about
how a business model doesn't necessarily matter.

One of our members has an application
that was global in use. Small company, about
dfive people. It was a free application. Free
and supported. So you say, well it's free. It
should have no problem with piracy. Incorrect.

What we found from oversea piracy --
what happened to him from overseas piracy was
they took the content off the top of his
application. Put a new add network underneath
it. Laid it down, changed the name and put it
into the app store. So his literal free app was
competing with someone else who had added a new
ad network with his exact content.

And here's the double stinger.
Because a lot of his content was video, he was
still paying the streaming costs for the free
version of his app that was stolen with another
ad network. So not only was he not seeing the
revenue from advertising. He was paying the cost
for the stolen pirated app to exist. And so when
we talk about business models and IP, think of it
more largely than we have a business model
problem. No, we have a law enforcement problem.
We figure that the loss to app
developers from publishers runs between $3 and $4
billion a year due to the use of pirated apps.
And we do see where foreign regulators will use
regulations or fail to enforce protections that
facilitate IPR infringement.

Notably, we are concerned with
countries that do joint venture requirements or
foreign equity limitations, source code,
escrowing and market assets requirements that
really force our members to transfer intellectual
property. You get straight piracy on one hand
and then you have the other aspect of piracy,
which is -- not piracy where you have a
regulatory structure that really encourages our
members to divest themselves of their IP in order
to play in a market.

And so the Special 301 Report is
really critical to our members. And I think one
of the aspects that you should recall as you go
through this process is it is completely -- it is
completely relevant to the smallest and the
largest companies in the United States. And what we have shown from our studies is it is not regional in terms of its impact on the U.S. So we encourage your efforts to go forward and to think about the small business impact as well. Thank you.

CHAIR KENDALL: Thank you very much for your testimony. The first question will be from USTR.

MR. CHANG: Thank you very much for your participation in this year's 301 Review. I understand it's the first time that you've submitted comments to the review.

MR. REED: That is correct.

MR. CHANG: And participation of diverse stakeholders greatly improves the process. So thank you very much. In your written submission, you note that app developers and publishers lose an estimated $3 to $4 billion dollars annually due to more than 14 billion pirated apps.

Does the ATC have estimates or other
information about which foreign countries those
damages and pirated apps are coming from?

MR. REED: We do have some estimates
and you can see from our written testimony where
we talk about specific countries and where we've
seen the impact. The difficult part of it is
again, because if an application is side-loaded
into a mobile device, we have no idea on how much
usage there is. We have anecdotal evidence but
hard numbers are really hard to come by, mostly
through the way that the applications move
through the ecosystem.

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

MS. BERDUT: Thank you, Elizabeth. ATC
submission notes certain positive steps that the
government of India has undertaken to help
improve the protection and enforcement in
administration of IP rights in India. But we are
recommending PWL status because the country still
needs to create an adequate IPR system and
implement strong enforcement and that's a quote.

Could you please describe any specific challenges in India that continue to negatively affect your members?

MR. REED: I think that given the length of time we have here, that's preferable to give a written comment. But I would say that it's always a battle; everyone on this panel knows. You want to encourage the good acts that help this move forward. But without some pressure, it's very hard to keep those going.

I'd be happy to provide you a written response in longer term but I'm aware of our time.

CHAIR KENDALL: Thank you very much.

Our final question is from the U.S. Copyright Office.

MS. SCHULTZ: Good morning. Your submission notes that Algeria has inactive statutes to prevent piracy.

MR. REED: Yes.

MS. SCHULTZ: But it hasn't made any
new efforts to enforce this statute. Can you
tell us more about what kind of statutes these
are? And can you explain how the statutes would
work to prevent piracy? And which aspects of
enforcement of those statutes are lacking?

MR. REED: I am not our office's
Algeria expert but -- and I'm happy to have -- so
I'll be careful to make sure I don't say anything
that our Algeria expert will come at me in and
say I've got it wrong.

But in rough reality, it's that
Algeria appears to have statutes that should, if
they were enforced, actually do the kinds of
things we're discussing today. And so as
everyone in the Copyright Office is aware, it's
this de facto versus de jure problem. And my
understanding is from our person who's worked in
Algeria on these issues.

The de facto is so distant from the de
jure that it makes it very hard when we have
meetings with authorities in Algeria. They say
the laws are on the books. What's your problem?
And then the discussion is well, but we're not seeing any action. We're still seeing rampant piracy and our folks can see from IP addresses that there mobile applications are in use but they can't figure out how many.

So I will be happy to give you more specifics on the record if you'd like them but it's a de facto versus de jure situation with Algeria.

CHAIR KENDALL: Thank you once again for your testimony. Could the representatives from Alliance for Fair Trade with India come forward? And please state your name for the record.

MR. MURRY: Good morning. I'm Roger Murry and I am the Deputy Director of the Alliance for Fair Trade with India or AFTI.

We are a diverse group of organizations that support increase action to address the multitude of barriers to trade investment that U.S. companies face in India including those adversely impacted by India's
intellectual policies and practices.

AFTI was launched in 2013 to support increased action to address the barriers to trade and investment that U.S. companies are facing in India. Including the erosion of intellectual property rights and to serve as a mechanism for engaging with U.S. policy makers on these issues.

In light of this mandate, I'm here to request that USTR again place India on its Priority Watch List. As AFTI describes in detail in its written submission, India has not made sufficient reforms to protect IPR holders interest with respect to patents, copyrights, trade secrets and price controls. And continues to deny fair and equitable market access to U.S. entities who rely on IPR in myriad ways.

Before summarizing our concerns, it is important to note that the government of India took four noteworthy steps in 2017 to bolster patent and copyright protections.

First, it began a new national awareness campaign on the harms associated with
counterfeiting and piracy. It made notable progress to reduce longstanding delays on patent and trademark examinations by expediting the patent approval process and increasing examiner capacity.

Third, it announced revised guidelines to provide patent protections to computer-related inventions. And fourth, high courts in Delhi and Bombay provided content creators injunctive relief against pirated content. And the Department of Telecommunications helped carry out these orders.

Now we commend each of these actions but we want to state today very clearly that India must do much more. The government of India did not address critical and longstanding shortcomings to its IPR regime identified in the 2017 and prior Special 301 Reports. And took several new actions that created significant new intellectual property challenges.

Of note, we highlight five critical shortcomings. First, costly and time consuming
patent opposition hurdles for patent applicants
and long time lines for receiving patents.

Second, the lack of an affective
system for protecting data generated to obtain
marketing approval. Third, major hurdles to
patent protections for innovative medicines such
as measures in India law that had a legally
questionable additional criterion for the
patentability of medicines. And the possible use
of compulsory licensing and patent revocation.

Fourth, pressure to localize
manufacturing for industries as diverse as
information and communications technologies,
medical devices, solar energy equipment and
capital goods.

And fifth, price controls in the
fields of medical devices, pharmaceuticals, and
agricultural biotechnology that deny fair
equitable market access against U.S. products
with valuable intellectual property.

AFTI continues to track implementation
of the government of India's 2016 national
intellectual property rights policy. The government of India needs to act swiftly to translate those concepts in the policy that support IPR into concrete policy measures. But also must revise areas of policy that promote forced legalization, compulsory licenses or otherwise falls short of India's international obligations.

Finally, AFTI encourages USTR and other members of the subcommittee to engage with India throughout 2018 including through the Special 301 Process and the trade policy forum. AFTI continues to believe that together our governments can advance strong intellectual property rights that promote innovation trade and investment.

So in closing, I want to thank the subcommittee for its tireless work to improve intellectual property rights of Americans and I'm happy to answer any questions you might have.

CHAIR KENDALL: Thank you very much for your testimony. The first question will be
from USTR.

MR. CHANG: Thank you again. AFTI raises concerns with India's tracked national pharmaceutical policy, the NPP in 2017 including the areas of compulsory licensing and pricing policies. Can you please provide more details of the draft NPP including whether there are other concerns and when India will finalize this policy? Thank you.

MR. MURRY: I do not have any information today on when we expect India to finalize the policy. I think as it relates to compulsory licensing, the threat is often as economically impactful as the action. And the draft policy includes the threat of compulsory licensing. And that is a big signal to the industries, you know, in the United States of what's coming down the pipeline.

CHAIR KENDALL: Thank you. The next question will be from ITA.

MR. MITCHELL: Yes, this question concerns multilateral dynamics. After it's
called attention to India's intervening in international multilateral fora to advance the adoption of IP policies that run counter to robust protection and enforcement of IP. Could you describe what affects these actions have on how your members perceive India as a place to do business?

MR. MURRY: Well, I think our members -- our members operate and sell into multiple markets. So they engage with governments around the world including in Geneva and elsewhere. And it's really important that the United States work with governments from around the world to protect market access of products that are intellectual property. And so the signals that India sends both behind closed doors and publicly in those forums are immensely concerning and remain one of the critical issues that AFTI works on to educate both our U.S. representatives in Geneva and also representatives from other countries. And it's just immensely concerning to us.
CHAIR KENDALL: Thank you very much.

Our final question is from the Department of State.

MS. DYER: Thank you for appearing today. You mentioned the bright spot is an improvement in copyrights. Certainly Hollywood and Bollywood share a concern about piracy. We wondered if you had any updates on the anti-camcord-ing law. It's been waiting around for fifteen years before it's been passed. And I wonder if you have any updates and any insight into what's taking so long for this to move through the system.

MR. MURRY: Yes, I wish I did have an update. It's been one of the initial issues that AFTI has concentrated on since our founding. And since the initiation of the trade policy forum back in 2014.

It's been, you know, high on the list for our government as a way for both Hollywood and Bollywood to thrive together in the Indian market. And unfortunately we're not optimistic
that there will be progress in the short-term. But this is also an opportunity to look towards other ways to enforce and provide intellectual property rights and they are the actions of the high courts in Delhi and Bombay conjunctive relief.

It's just incredibly -- it's critical and somewhere that we think there's an opportunity for progress in 2018 as you all engage with your Indian counterparts.

MS. DYER: Thank you.

CHAIR KENDALL: Thank you once again for your participation.

MR. MURRY: Thanks for having me.

CHAIR KENDALL: Can the representatives from American Apparel and Footwear Association please step forward? And please state your name for the record.

MS. MITROPOULOS: Good morning. My name is Christina Mitropoulos and I'm a government relations representative at the American Apparel and Footwear Association.
AFA appreciates the opportunity to testify before the Special 301 Committee today. AFA is the National Trade Association representing apparel, footwear, travel goods and other zone products companies and their supplies, which compete in the global market.

We represent more than 1,000 world famous name brands, their management and shareholders. Our industry is nearly 4 million U.S. workers and its contribution of $384 billion dollars in annual U.S. retail sales.

Counterfeiting of our members brands remain a top concern. Footwear, apparel and other fashion items top virtually every list of top counterfeited products and seizures.

Our members competitiveness is highly dependent on the protection of the intellectual property embedded in their designs, their brands and their images. Stolen intellectual property costs our members billions of dollars in lost sales, damages their reputation and results in substantial legal expenses.
This morning, I would like to focus my testimony on three countries; China, Canada and Mexico. Last year, the U.S. chair placed China on its Priority Watch List. While our members report intellectual property improvements, China remains a source of pervasive counterfeiting. Actions to enforce intellectual property remain complex and expensive.

As we had previously mentioned, we believe the U.S. government should work with Chinese customs to prevent counterfeit goods from leaving China, especially in cases in which the legitimate versions of the product are not manufactured in China.

As the administration pursues its Section 301 investigation, we urge that it proceeds cautiously. While we agree that there are significant intellectual property concerns in China, we also stress that China remains an invaluable trading partner for our members and for our industry. For this reason, I want to be clear that we do not believe tariffs are a
solution to this issue.

China remains an important and growing market for U.S. exported and U.S. branded goods. For example, China remains a top market for U.S. exports of cotton and is a fast-growing market for U.S. branded goods that are made globally and sold in China. Many U.S. jobs are supported through these trade and investments links too.

Steps to address Chinese intellectual property practices must be taken to ensure that these supply chains and the U.S. jobs that support them are not interrupted by U.S. actions or Chinese retaliation.

Turning to Canada and Mexico. The USTR placed both countries on its 2017 watch list. Over the past year, our members report there is little clarity on the Canadian customs recordation system. And that it has not been effective since it launched.

One member reported its brand has registered with Customs but it has not actually seen any seizures. Members report that the Royal
Canadian mounted police is inactive related to trademark in counterfeiting matters.

Members report their local lawyers and investigators in Mexico have developed good relationships with regional police, Customs and the Mexican Institute of Industrial Property. Regional police have supported many raids for our members. Customs have increased working with members largely because of members trading efforts. However, corruption remains a concern when doing work in Mexico.

Additionally, members report parasite brands are prevalent. Parasite brands look and feel like a counterfeit but they do not directly call themselves by the brand name. In fact, the average consumer might be hard-pressed to notice the difference outside of the single distinction.

Moreover, members note the upcoming elections, we'll see changes at the head of Customs, the Office of the General Prosecutor and the Mexican Institute of Industrial Property, which they are worried could quickly reverse
course on progress.

While we recognize that there are significant intellectual property concerns in these countries, we also want to make it clear that we are supporters of NAFTA. During the past 24 years, our members have developed extensive supply chains that today account for millions of dollars of U.S. textile, apparel and footwear exports and imports to NAFTA countries. Directly and indirectly supporting millions of jobs in the United States and benefitting communities and consumers throughout the United States from Main to Miami to Monterey.

As we continue to engage in negotiations to modernize NAFTA, it is critical to strengthen the intellectual property provisions to address these issues.

We appreciate this opportunity to raise these concerns and we look forward to working with the USTR to address these issues. We consider this to be an ongoing process and we will provide you with updated information as our
members bring them to our attention.

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

CHAIR KENDALL: Thank you very much for your testimony. The first question is from USTR.

MR. CHANG: Thanks again for your testimony. Some countries have been identified for several years in the Special 301 Report for trademark or counterfeiting issues but may not necessarily be the largest or more important markets to your members. Are there any countries that you think should no longer be listed on the Special 301 Report for the issues that are most important to your members? Thanks.

MS. MITROPOULOS: So this year we identified both the successes and the challenges that our members have pointed out to us. And while we recognize that we didn't take a definitive stance on which countries should be listed, we wanted to leave that ultimate determination up to you.
But we wanted to highlight while there are successes in certain countries, those come with challenges. So we thought that, that was important to highlight.

CHAIR KENDALL: Thank you. The next question comes from the Department of Labor.

MS. PETTIS: Good morning. Your organization reports that there has been an increase in counterfeits in India, typically requiring extensive actions by the brands to resolve. Could you please describe in more detail the counterfeiting activity, trends and challenges facing the brand owners?

MS. MITROPOULOS: So a number of our members have worked in India and they're finding counterfeits not only in marketplaces but on ecommerce platforms in China. I'm happy to follow up with written comments on those specifics.

CHAIR KENDALL: Thank you. Our next question comes from Treasury.

MR. CHANG: For Turkey, AAFA reports
that changes in customs laws now make it
difficult and expensive to seize outbound goods,
forcing member brands to file motions before the
courts. Would you please explain in more detail
the changes in the customs law and the negative
effects on IP enforcement that resulted from this
in Turkey?

MS. MITROPOULOS: So I can -- I'm
happy to follow up with written comments on that.
One of our members identified that for us. I
don't know that much about it but I can certainly
follow up with you once I get more information
from that member.

MR. CHANG: Okay, thank you.

CHAIR KENDALL: Thank you. The next
question comes from ITA.

MR. MITCHELL: Thank you. Regarding
your observations concerning parasite brands,
have any of your members had partial success in
combating this problem? Do you see this as a
question of trade dress or something else?

MS. MITROPOULOS: So like I said,
parasite brands, it's a not a specific
counterfeiting issue per se. But a number of our
members have had successes in China, particularly
one brand brought an action in court and received
the largest judgment to date concerning parasite
brands. So that was definitely a success on
their part. And hopefully they'll continue to
succeed.

And as we noted in our comments, we
also have seen parasite brands popping up in
Mexico. So it remains to be seen what will
happen with that.

MR. MITCHELL: Thank you.

CHAIR KENDALL: Thank you very much
and thank you for your testimony.

MS. MITROPOULOS: Thank you.

CHAIR KENDALL: I invite the
representative for ACTION for Trade to come
forward. And please state your name for the
record.

MR. TEITELBAUM: Good morning. My
name is Joshua Teitelbaum. And thank you to the
Special 301 subcommittee for the opportunity to
testify on behalf of the American Creative
Technologies and Innovative Organizations Network
or ACTIONS for Trade.

ACTION for Trade is dedicated to
advancing a U.S. trade agenda that promotes
creativity and innovation. Our members include
business and trade associations involved in the
research, development and manufacturing patented
medicines. The development, production,
publication and distribution of creative works
like literary content. Recorded music, film,
television, and scientific technical and medical
journals and the development of technology of
software and hardware.

What ties the members of our coalition
together is the shared belief that our trading
partners should enact policies including strong
protections and enforcement measures for
intellectual property rights to fairly value
American creativity and innovation. And that
when they do, both the United States and its
trading partners see the returns to economic
prosperity and well-being.

The intellectual property-intensive
industries that ACTION represents support 58
million American jobs. That's nearly 40 percent
of the American workforce and they add jobs 7
percent faster than other industries. In other
words, we are a large and growing segment of the
American economy.

But in a global economy that is
increasingly defined by where creativity and
innovation happens, the Special 301 Report is an
important tool for ensuring it happens here. And
building on the commitment in the recently
published U.S. Trade Agenda that U.S. owners of
intellectual property have a full and fair
opportunity to use and profit from their IP
around the globe.

To further your investigation, ACTION
would like to highlight several areas of concern
where our trading partners intellectual property
rights are weak or insufficient.
First, several U.S. trading partners lack regulatory transparency and fail to record U.S. companies due process when enacting regulations affecting their IP. For example, bureaucratic backlogs in the patent approval processes in Canada and Korea undercut those nations commitments and free trade agreements, undermine incentives to innovate and result in significant delays in access to innovative lifestyle medicines.

Pricing controls in Canada and South Korea further weaken innovation by arbitrarily setting prices for patented medicines by reference to prices in less advanced economies or medicines of an older generation. In doing so, these countries aim to strip the global costs of innovative research and development and ultimately delay the introduction of new medicines into their own market. And compulsory licensing schemes in Malaysia allow local companies to make, use, sell, or import patented medicines without the consent of the patent
holder.

Second, intellectual property rights protection and enforcement efforts have not kept up with the technological developments in the distribution of pirated goods and services.

For example, China is a hub of the manufacture and distribution of illicit streaming devices. In addition, while China's largest search engine has taken strides to address takedown requests for infringing content, China places too high a burden on rights holder to prove infringement.

In Mexico, high levels of online piracy continue where the government has neither adopted policies, nor attempted action against a plethora of locally-operated infringing websites.

And Canada's Notice and Notice Enforcement Scheme blocks even takedown obligations for infringing creative works making it a global outlier in the protection of copyright online.

Finally, the creativity and innovation
Based sectors are particularly susceptible to acts, practices and policies that are designed to benefit local producers at the expense of manufacturers and employers and employees in the United States.

For example, China has several data localization policies that promote or enforce technology transfers to local competitors. These policies not only effectively prevent market access, but contribute to the theft of U.S. intellectual property.

Japan's new pharmaceutical pricing policies exhibit bias toward local companies as well due its strict qualifications on which companies can benefit from full price stability.

And the use of antitrust investigations by our Asian trading partners undermines U.S. rights holders are acquiring the transfer of U.S. patented technology to invest the companies. These investigations often lack due process protections and result in discriminatory and extraterritorial remedies.
ACTION for Trade looks forward to working with the Office of the United States Trade Representative and the other agencies at the subcommittee here as partners to address these issues in support of America's creators and innovators.

Thank you for your time and I'm now happy to answer any questions you may have.

CHAIR KENDALL: Thank you very much for your testimony. The first question will be from USTR.

MR. CHANG: Thank you and good morning. Your testimony notes that Mexico has the highest percentage of music pirate site users of any country and it's the second largest foreign market for illicit camcord-ing.

What do you think accounts for this?

I know you mentioned the lack of government action but in addition to that, what do you think accounts for this?

MR. TEITELBAUM: I think that there are changes in both technology and lack of policy
on the books in Mexico that allow these kinds of practices to continue. When it comes to policy for example, Mexico lacks strong secondary liability in its market. That would allow copyright holders to hold infringers on their content accountable for their practices online.

In addition, there are advances in technology that make practices such as camcording easier to carry out as opposed to in previous years when it may have been more practically difficult.

In addition, when it comes to advances in technology for things like stream ripping, there are advances in software that allow people who are interested in trying to simply download licensed music off of premium services. That allow them to then distribute those works either free or at reduced prices, undercutting the creativity and work of music creators and film and television creators.

CHAIR KENDALL: Thank you very much.
The next question comes from HHS.
MS. BLEIMUND: Good morning. In your members views, what action should Canada take to improve the process of developing new pharmaceutical pricing policies?

MR. TEITELBAUM: Thank you for that question. We have serious concerns about Canada's current proposals for the pricing for PMPRB.

That proposal would change the current reference pricing scheme for patented medicines that set maximum allowable prices including removing United States and Switzerland from the countries that are included in the reference pricing basket. And substituting for those countries of the less advanced economies with the stated goal of trying to bring down the price to the OECD median.

We would recommend that Canada implement pricing policies that are fair, reasonable and market based that include increased transparency and greater due process for stakeholders to submit comments as to which
countries would be appropriate for including in
the reference pricing scheme including the United
States.

We believe that the proposal that was
released in December did not include adequate
justification for the changes that they proposed.

CHAIR KENDALL: Thank you very much.
The final question comes from ITA.

MR. MITCHELL: Yes, you had mentioned
Canada and Notice and Notice, could you elaborate
a little bit as to how the current system has
affected action members. And also perhaps what
additional steps Canada might take to address
long line piracy.

MR. TEITELBAUM: Absolutely. Thank
you for the question. ACTION members include
members from the recording industry, the motion
picture association, the authors guild and the
Association of American Publishers whose creative
works are awarded from the legitimate
distribution in sales of their products online.

However, we find that digital piracy is rampant
and that in jurisdictions where there are strong protections for those copyrighter works including in the online digital space, we see a reduction in that digital piracy.

A Notice and Notice scheme without the obligation to take down request of infringing content allows that content to remain online even after the internet service provider or the infringer has been notified that the work is infringing on somebody's legitimate copyright.

So we believe it's important and imperative in order to reduce digital piracy that Canada implement at the very least a takedown obligation.

CHAIR KENDALL: Thank you very much for your testimony. I'd like to ask the representatives from the Biotechnology Innovation Organization to come forward. And please state your name for the record.

MS. BRAND: Good morning. I'm Melissa Brand, associate counsel and director for Intellectual Property Policy at the Biotechnology
Innovation Organization.

BIO is a nonprofit organization with a membership of over 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations. Our industry is responsible for creating over 1.6 American jobs and supports millions more. We research and develop products and improve health outcomes, increase agricultural productivity, produce cleaner energy and provide for a more sustainable economic future.

A defining feature of the biotechnology industry is the long and uncertain road from laboratory bench to market introduction. Biotechnology product development is fraught with risks and commonly requires rigorous regulatory review before product launch.

Strong and predictable IP protection is therefore critical for BIOs member to be able to attract the investment necessary to withstand these lengthy and challenging development periods. This is especially truth for BIO's
small and medium-sized enterprise members that
currently do not have products on the market and
therefore count IPs among their most valuable
assets. On behalf of BIO and our more than 1,000
members, I thank the committee for the
opportunity to testify today.

As detailed more fully in BIO's formal
Special 301 Report, certain U.S. trading partners
are implementing policies that will undermine the
IP rights of U.S. biotechnology companies abroad.
Today I will focus my time on the most pressing
of these concerns.

The issue in some compulsory licenses
by foreign governments is chief amongst our
concerns. BIO has asked that Malaysia be
designated as a priority foreign country because
of its September 2017 announcement that it will
issue a government use license, effectively a
compulsory license for a patented treatment for
Hepatitis C.

This patented treatment has been
available to patients in Malaysia for more than
two years. And the patent holder had previously announced that it would include Malaysia in its voluntary licensing program. A program that would satisfy the Malaysian government's procurement needs with affordable quality products.

Nonetheless in September, the Malaysian Ministry of Health abruptly issued its statement of intent to issue the unauthorized license providing little notice to the patent owner and no meaningful opportunity for the patent holder to provide input or address any concerns. The actions taken by the government of Malaysia are unprecedented.

Given the facts of this case, it appears that these actions are motivated by industrial policy, rather than a legitimate concern for access to medicines. While compulsory licensing may be permissible in certain limited circumstances, this is not such a circumstance. Nor should compulsory licenses be granted in processes lacking transparency and
We are concerned that if Malaysia's actions are left unchecked, others may follow this course of conduct and the spirit of the TRIPS Agreement will be further eroded. Other countries that have adopted or are considering adopting troubling compulsory licensing practices include China, Columbia, India, Indonesia, Russia, Thailand and Turkey. This problem cannot be overstated.

When U.S. biotech companies can no longer rely on IP protection abroad, the investment necessary to sustain the development of their innovations will be drastically curtailed. This is all the more pronounced for small and medium-sized enterprises.

The next concern I would like to highlight today is that of countries providing inadequate regulatory data protection or RDP. RDP is an important complement to patent protection, particularly for certain types of biotechnological products for which patent
protection may not fully protect the inventive contribution. However, countries like China, Argentina, Brazil, India, Mexico, Malaysia, Russia and Turkey provide either no RDP or inadequate RDP.

China presents a particular concern because although its law provides for some RDP and practice, use innovators have not received effective protection. China has proposed new RDP reforms but their implementation is yet to be seen.

Next I would like to emphasize BIOs ongoing concern regarding certain trading partners that have adopted unduly restrictive patentability criteria to discriminate against certain types of inventions. Such laws and regulations present unnecessarily challenges to the ability to bring new innovations to these countries. Specific details regards these regimes are set forth in our formal 301 submission.

Finally, we have observed countries
with strong economies and technological capacities implementing arbitrary and unjustified market access policies. Wealthy countries such as Canada, Japan and Korea are implementing pricing policies for patented medicines that arbitrarily undervalue these treatments and cures in favor of short-term budgetary gains. Not only are these countries disregarding their responsibility to promote public health innovation but these policies may have negative consequences for access purposes.

To conclude, I would like to thank the U.S. government for its continued efforts to see that our international partners respect our IP abroad. As acknowledged in our Special 301 Report, positive results have been achieved and we are grateful for such progress.

With that, I'm happy to answer any questions that the panel may have.

CHAIR KENDALL: Thank you very much for your testimony. The first question comes for USTR.
MR. CHANG: Thanks again. In the last part of your testimony, you did mention some positive developments. Some countries have been identified for several years in the Special 301 Report for patent and pharmaceutical issues but may not necessarily be the largest or most important markets to your members. Are there any countries that you think should no longer be listed in the Special 301 Report for the issues that are important to your members?

MS. BRAND: Thank you for the question. I think that we have noted in our report, the instances where countries have made particular improvements. I believe there are instances. For example, the Canadian courts recently issued a positive decision undermining the Promise Doctrine which had been a large problem for our industry.

I also believe there are other instances where countries such as Taiwan, I believe, are providing a patent linkage system now or have at least committed to do so. Sitting
here today, I admit that I do not know which
countries should be removed from the list. But I
do believe our report identifies which ones we
should continue to list. So we could follow up
with a specific list comparing those.

CHAIR KENDALL: Thank you very much.

The next question comes from HHS.

MS. BLEIMUND: Good morning. In your
submission, you site issues with Malaysia's
regulatory data protection regime as part of your
nomination to alleviate them as a priority
foreign country. Do the issues you raise reflect
recent changes to Malaysia's law or practice?
And can you provide some details about the
"onerous requirements" that you mention in your
submission?

MS. BRAND: I would best be suited to
follow up with specific details regarding whether
those are recent changes. I believe we put in
the report the identified concerns but additional
details I can provide in a supplemental
submission.
CHAIR KENDALL: Thank you very much.

The next question comes from PTO.

MS. BERDUT: Thank you. Regarding India, Footnote 18 of BIO's submission indicates recent revocations, oppositions and challenges to several biopharmaceutical products. Is Section 3D of India's patent act cited in these challenges? And is BIO aware of the patent status of these products in other countries?

MS. BRAND: I believe that 3D is likely cited. We can follow up and provide that information particularly. I believe that footnote discusses the -- not only the issue with 3D but the overall tenor against biopharmaceutical patents in India and the multiple challenges that are allowed both pre-grant and post-grant. And also the obstacles that are faced with 3D.

So I can follow up with additional details on whether 3D is cited in those decisions. And how those products are patented in others.
MS. BERDUT: Thank you.

MS. BRAND: Sure.

CHAIR KENDALL: Finally, USTR would like to ask one of the questions we asked other testifiers here, which is what policies do you think Canada or other countries you've identified should adopt for the problematic pricing policies that you note in your submission?

MS. BRAND: Sure. I believe that the representative from ACTION for Trade commented on some of the recommendations that we would likely make as well.

With respect to Canada, another concern that we have in their pricing policy is very onerous disclosure requirements. So not only are they onerous, but they raise a lot of concerns as to whether the data could actually be appropriately protected as confidential information.

So I think further review of those disclosure requirements would be necessary. I think more stakeholder input would be useful to
really convey the burdens that would be placed on our members.

The other thing I want to say quickly with respect to Japan and its pricing policies, we noted in our report that these will be particularly difficult for our small and medium-sized members. There are benefits or requirements essentially to conduct clinical trials in Japan or launch more products in Japan. And that's difficult for our smaller members as financial constraints amongst other things make that challenging.

So I think that eliminating those requirements that really favor a foreign economy that it's difficult for small members to meet, that would be a very beneficial step.

CHAIR KENDALL: Thank you very much for your testimony.

MS. BRAND: Thank you.

CHAIR KENDALL: I'd like to invite representatives from BSA Software Alliance to come forward. And please state your name for the
record.

MR. PROPP: Good morning. My name is Kenneth Propp. I am director for trade policy at BSA, which is the leading advocate for the global software industry. Thank you for the opportunity to testify.

Today it's clearer than ever that software is having a profound impact on the American economy. A recent report from software.org with BSA foundation documents that the software industry contributes more than 1.1 trillion to U.S. GDP, supports more than 10 million jobs with significant impact in all 50 states and invests more than $63 billion in research and development. And these beneficial effects from software are felt across all sectors of the U.S. economy.

American software can have a similar impact internationally but only if intellectual property rights are respected and enforced. And if market access barriers for U.S. companies are dismantled.
And these of course are the twin objectives in the Special 301 statute, identifying countries that deny adequate and effective protection of intellectual property rights or that deny fair and equitable market access to U.S. companies that rely upon IP protection.

The issues that I will highlight to you today relate to both components of the Special 301. And we believe that USTR and the other agencies can best help innovative American companies if it looks equally at both prongs of the statute. And we were gratified to see this approach reflected in the 2018 trade policy agenda, which identifies both breakdown of unfair trade barriers as a key objective. And also ensuring that U.S. owners of intellectual property of a full and fair opportunity to use and profit from their IP.

So first to market access barriers. Software companies today are spreading cloud computing sophisticated data analysis techniques
including through the use of artificial intelligence around the globe. But these technologies can be efficient, secure and competitive only if data may flow across borders for processing or storage.

But what we see around the world however is a continuing spread of national measures that prohibit or restrict cross border data flows. These can take the form of blanket prohibitions of transfer of data abroad or unreasonable conditions placed upon transfer of data. And in some cases, the restriction is simply a requirement that domestic data centers be used instead of foreign ones.

These barriers often come disguised as privacy or security measures. And to be sure privacy or security sometimes can be legitimate bases for national regulation of data flows. But too often the real motivation is protection as simply advantaging local industry.

In our submission to the subcommittee, we have called out restrictions on data flows
that have been adopted or proposed in countries as diverse as Brazil, China, India, Indonesia, Korea, Nigeria and Vietnam.

Vietnam has put their localization requirements into place. China's cyber security law requires that personal and other important information collected in China be held in that country. We are also following with concern, develops in the European union that could impede data flows from its territory.

Turning to intellectual property, protection and enforcement, we have two main concerns. The continued use of unlicensed software by government agencies, state enterprises and businesses. And inadequate enforcement against such unlicensed uses.

BSA periodically conducts global software surveys and our most recent one estimates that fully 39 percent of the software installed in PCs around the world is not properly licensed. And that's a proportion that has stayed stubbornly high in recent years.
In many countries, the percentage is substantially greater than that. We estimate that the commercial value of unlicensed software worldwide is in access of $52 billion dollars, a very large loss of revenue for companies.

Better enforcement against unlicensed software requires changes in laws in some countries. And in others, an increased willingness of authorities to enforce existing laws. China falls into the first category in our view, needing to amend its copyright and criminal codes to better address the widespread use of unlicensed software by enterprises in that country.

India is an example of the second. Its enforcement mechanisms through commercial courts are less effective than they need to be. And effective criminal enforcement mechanisms also need to be established. Our companies also depend on effective patent protection.

In conclusion, let me say that we have recommended that seven countries be placed on the
Priority Watch List and eight on the watch list. I'd be happy to answer your questions. Thank you.

CHAIR KENDALL: Thank you very much for your testimony. The first question comes from USTR.

MR. CHANG: Some countries have been identified for several years in the Special 301 Report for copyright or enforcement issues but may not necessarily be the largest or most important markets to your members. Are there any countries that you think should no longer be listed in the Special 301 Report for the issues that are important to your members?

MR. PROPP: I think our report singles out the countries that still require listing. We can reflect further on whether there are countries that should be removed from the list. And I can provide that information to the subcommittee.

CHAIR KENDALL: Thank you. Our next question comes from PTO.
MS. BERDUT: Thank you. In your nomination of China as a Priority Watch List country, you reference measures that preclude foreign entities from competing in China or competing on equal terms. Is your concern focused on MOCOM's technology import, export regulations or in a broader range of measures?

MR. PROPP: We have a broad range of concerns with China. It is not specifically focused on that particular regulation.

There is a constant stream of legislative and regulatory developments in China that pose a variety of different concerns to our members. The cyber security law alone raises concerns with respect to data localization, with respect to privacy and with respect to security — with the security review requirements. And that's just one law.

There are also secure and controllable requirements that have been issued in relation to government procurement. There are source code disclosure requirements. So these are quite a
few of the challenges in China.

    MS. BERDUT: Thank you.

    CHAIR KENDALL: Thank you very much.

The next question is from the U.S. Copyright Office.

    MS. SCHULTZ: Good morning. Could you elaborate further on your questions in EU related to IP and market access?

    MR. PROPP: With respect to the EU and IP, I would mention one in particular. And that is, there is a proposed revision in the copyright area of the proposed digital copyright directive.

    That has created uncertainty about the legality of text and data mining. It is an ongoing legislative process. The uncertainty was created by the commissions draft as the legislation has made its way through the parliament and now to the counsel. That issue continues to be dealt with.

    And the outcome is still not clear.

    But for the moment, there is no resolution of the question -- the important question whether text
and data mining will continue to be valid on a widespread commercial basis. Or instead would be limited to a subcategory of institutions such as research and educational institutions.

CHAIR KENDALL: Thank you very much.

The final question will be from USTR.

MR. CHANG: For India, there is a submission note of a positive development in July of 2017 related to amended patent examination guidelines for computer related inventions. While noting and I quote, "It will be important to monitor how this revision is implemented in practice."

Since July, have there been any indications from the patent offices as to how the guidelines are being implemented?

MR. PROPP: Thank you for the question. I am not aware of any. In principle, we are quite pleased with that development and we have not heard from our members that there are continuing issues with it. But I can certainly double check on that point.
CHAIR KENDALL: Thank you once again for your testimony. At this time, I'd like to ask the representatives from the China Chamber of International Commerce to come forward. And state your name for the record.

MR. JIAN: May I?

CHAIR KENDALL: Thank you very much.

MR. JIAN: Good morning. My name is Tan Jian with China Chamber of International Commerce, CCOIC. CCOIC is International Chamber of Commerce in China with around 87 members across various sectors.

We and other members experience and witness the great progress China has made in respect of protection of IP, particularly in recent years. China has established an IPR law system and implemented laws and regulations to protect IP rights of domestic and foreign rights holders. Result of that determination and with so effective and efficient law enforcement system, the Chinese government has made great efforts to strengthen the protection for trade
secrets, trademark, patents, cover art and other IP rights and to correct that country's piracy and other infringing acts. Most innovator in China also active in protecting their own IP rights and inferring not to infringe IP rights of others.

We know about the concern of the U.S. government about China's IPR protection but I have to say that most of the concerns are either coming change faced by many countries. All are being effectively resolved in China. And others are like other misunderstandings.

For example, there is a concern about the civil enforcement of IP rights in China. The truth is China has set up specialized intellectual property costs in Beijing, Shanghai, Guangzhou and another teams specialize in IP tribunals. Chinese courts do not hesitate to grant preliminary injunctions if statutory commissions are met.

They also facilitate obtaining evidence in the hand of opposing parties and
increase damages to fully reflect the value of
the IP. For instance, in 2016, Beijing IP court
ordered a defendant to pay 50 million RMB in
damages for property infringement.

In addition, foreign companies are
treated equally in China courts. Foreign
companies win rates average around 80 percent
right now. China is increasingly being selected
as the forum of choice for non-Chinese companies
to mitigate IP disputes. China is continuing its
efforts to improve the trial procedure of IPR
cases.

On February 27th this year, new
guidelines for this proposed were unveiled by
Chinese leadership. There are also concerns
about the protection of trade secrets. China
revised anti unfair competition law in November
of 2017. It granted the scope of protecting trade
secrets and increased the statutory damages.
While the amount of actual losses cannot be
determined, the forced damages up to RMB 3
million can be awarded by the court. Provisions
regarding preliminary injunction, property and the evidence preservation are fully applicable to disputes involving violation of trade secrets.

Trade secrets submitted to government agencies and the courts are kept confidential in accordance with the anti-unfair accommodation law and many other laws and the regulations. Concern also extends to counterfeiting and piracy in e-commerce market. Counterfeiting and piracy exists in China as it is a world factory.

The government of China has devoted numerous resources to crack down on counterfeiting and piracy through routine supervision and special campaigns and by the administrative law enforcement and the criminal trials.

A U.S. company named EVRIL, with only 25 employees has benefitted from 67 initiative raids, 20 Customs seizures and eight criminal raids in China. According to EVRIL, the problem most pressing onus had is not that the Chinese have a better system, but that the brand owners
do not know how to make that system work.

In addition, the private sector also takes actions, particularly operators of e-commerce platforms corroborating with right-holders, and the law enforcement department have taken a series of matters to effectively curb online counterfeit and piracy. Like the U.S. government, the Chinese government attach great importance to IP protection. Like U.S. companies, Chinese companies including 60 overseas members traded innovation. I believe those countries and the business cycles from both countries should cooperate, rather than criticize and blame each other to enhance the protection of IP in the two countries and in the world. Thank you.

CHAIR KENDALL: Thank you very much for your testimony. The first question comes from USTR.

MR. S. CHANG: U.S. parties report that patent infringement damage awards in China are very low relative to U.S. damages, and that I
some cases, the damages are not deterrent. How would you respond?

MR. JIAN: I will like to have my colleague, Mr. Qing Ren reply.

MR. REN: Yeah, as we, according to our knowledge, the Chinese government and the Chinese courts know about this concern from the other governments and foreign-rights holders. There is measures taken in this regard to address this issue.

If you have time to read the opinions recently issued in late February, it is again assured that the damages will be awarded to fully reflect the value of IP rights. So we are -- our observation is that this issue has been or are being effectively addressed. Thank you.

CHAIR KENDALL: Thank you very much.

The next question comes from USPTO.

MS. BERDUT: Thank you. China still does not generally treat sporting events as having sufficient creative content to qualify as a work eligible for copyright protection. Can
you comment on this gap in China's copyright protection regime?

MR. REN: You are talking about the protection of the sports program? Yeah. There are discussions in China in which way to protect sports program. There are some opinions to support that to protect a sports program under copyrighting law.

There are some other opinions to support to protect the program under anti-competition law or other laws and regulations. So any event, there are laws and regulations applicable to these areas, and the rights holders have a channel to protect their rights.

Probably, different countries have different --- I mean, specific laws to address these issues as NDD. What is important is whether they the rights and interest of the rights holders is protected. Thank you.

CHAIR KENDALL: Thank you very much.

The final question will be from the State Department.
MS. DYER: Thank you for appearing here today. An important step in enforcement in China is the transfer of an administration action to criminal authorities.

U.S. parties report that a major obstacle to such referrals is that the administration authorities lack investigative powers to provide such information and determine what information that would be sufficient to satisfy those criminal authorities. What are the prospects for adoption of a reasonable suspicion standard in the near future? Thank you.

MR. REN: Thank you for the question. The transferring of cases from other municipality authorities to criminal authorities indeed is an issue that attracts much attention from our foreign rights holders.

As far as we know, the government has taken a series of measures to enhance the connection between the two enforcement systems. In our written submission, we also describe a brief recent development in this area.
For example, the government of China established a platform to help the transferring of the cases from all of these authorities to criminal authorities. This platform has been not only started at the central government level, but also at the provincial level, even lower down to the level of the --- I mean, the county level.

So the conditions to initiate an investment probably is not the same as a criminal trial, but as soon as the conditions is met of a security organ, we will execute the criminal procedure. Thank you.

CHAIR KENDALL: Thank you very much, once again, for your testimony today. At this time, I'd like to invite representatives from the Computer and Communications Industry Association to come forward and please state your name for the record.

MS. STELLY: Good morning. My name is Rachael Stelly, and I serve as a Policy Counsel. Sorry. And I serve as a Policy Counsel for the Computer and Communications Industry Association.
Thank you for this opportunity to convey the views of CCIA in regard to the 2018 Special 301 Report.

I want to preface these remarks by noting it that I am stepping in at the last minute for our Vice President, Matt Schruers, who unfortunately is out with the flu. I will read his prepared written remarks. Any questions regarding this testimony or our written comments that I cannot answer will be addressed in our post-hearing submission.

CCIA is a trade association of internet and technology firms, many of whom export goods and services that are regulated by the domestic copyright laws of our trading partners or benefit from the commerce enabled by these goods and services. This statement focuses on four specific subjects addressed in CCIA's written submission.

First, the continued concern about the rise of snippet taxes in foreign markets.

Second, the need for USTR to require
comprehensive implementation of intermediary liability protections abroad, particularly where required by our Free Trade Agreements.

Third, the opportunity that the re-negotiation of the North American Free Trade Agreement presents to modernize the intellectual property chapter. And fourth, the forced transfer of intellectual property through discriminatory regulations directed at U.S. exporters.

First, regarding snippet taxes, these taxes and related regulatory initiatives are sometimes referred to as ancillary copyright, but are in fact regulations on the quotation of published online content. CCIA first raised concerns about ancillary copyright back in 2012, but unfortunately, previous administrations failed to resolve the issue.

Since then, the internet industry has witnessed the spread of these detrimental laws throughout European member states, including in Germany and Spain. France's newly-implemented
image indexing law also poses a similar threat insofar as it creates a right to be indexed, which is inconsistent with global norms.

Now, the European Commission is proposing a snippet tax to be imposed in all member states. Left unchecked, these taxes will impede market access for U.S. exporters throughout the EU. USTR has previously watch-listed countries for TRIPS and other international copyright law violations, and the European states should not get a pass.

Second, the Special 301 process should address non-compliance with international norms regarding online copyright intermediary liability protection. U.S. trading partners who have entered into Free Trade Agreements with the U.S. should honor these commitments.

As described in greater length in CCIA's written submission, Australia's 2003 FTA commitment to the U.S. to provide intermediary liability protects to service providers has not been fulfilled.
Of immediate concern is a recent legislative proposal that seeks to expand such protections to comply with the FTA, but only to a limited set of non-profit, education, and disability-focused organizations. This failure to expand protections to online services poses an immediate threat to U.S. exporters in the Australian market.

Third, the re-negotiation of the North American Free Trade Agreement provides a key opportunity to expand U.S. market access by updating the intellectual property chapter. For example, Mexico has yet to adopt an intermediary liability framework that reflects the international norm analogous to Section 512 of the DMCA.

This is an opportunity to get trade modernization right. A 21st Century trade agreement must reflect the digital age and recognize the protections that have allowed for the growth of the internet sector in the United States and around the world.
The intellectual property chapter in NAFTA should include protections for online intermediaries and include relevant limitations and exceptions reflected in U.S. copyright law.

Fourth, USTR should address forced transfer of intellectual property under Chinese law and proposed regulations. U.S. Cloud service providers are strong American exporters supporting tens of thousands of high-paying American jobs.

Draft proposals threaten to significantly disadvantage U.S. Cloud service providers in favor of domestic Chinese companies by requiring foreign Cloud service providers to turn over essentially all ownership and operations to a Chinese company. This includes valuable U.S. intellectual property, knowhow, and use of reputable brand names.

In conclusion, the Special 301 process should place greater emphasis upon discriminatory practices directed at U.S. exporters that create new rights for domestic industries by focusing on
balanced copyright international trade.

From the quotation right to
intermediary liability protections, these
provisions ensure that crucial business
activities of U.S. exporters can take place
within the scope of copyright law. When
countries fail to implement these norms or fail
to adhere to commitments made to protect them,
U.S. export opportunities can be lost.

A strong intellectual property system
is one that reflects the needs of all
participants in the content creation, discovery,
and distribution supply chains. Discriminatory
practices under the guise of intellectual
property that target U.S. exports should be
identified and discouraged by USTR and the 2018
Special 301 Report. Thank you, and I look
forward to your questions.

CHAIR KENDALL: Thank you very much
for your testimony, and our best wishes for your
colleague to get over the flu. The first
question is from USTR.
MR. S. CHANG: 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.

For example, you explicitly clarify that CCIA is not nominating Mexico for the watch list, but identify several concerns about Mexico's legal regime. How do you think this input should be reflected on the Special 301 Report? Are you equally concerned about all trading partners you mentioned?

MS. STELLY: Thank you for that question. It's true we did not specifically make recommendations in our comments, but I'm happy to further clarify that in our post-hearing submission. Thank you.

CHAIR KENDALL: Thank you. The next question is from USPTO.

MS. BERDUT: CCIA asserts in its submission that ancillary protection is a violation of international copyright obligations,
that's in page two of your submission, and calls
the recent EU proposal to grant such rights to
press publishers as nominal entitlements.

Does CCIA view all neighboring rights
under the EU framework as violation of
international copyright obligations?

MS. STELLY: Thank you for that
question, and I'm happy to provide further
clarification in the post-hearing comments.

CHAIR KENDALL: The next question
comes from the U.S. Copyright Office.

MS. SCHULTZ: Is the FTA compliance
concern with Australia, is that a relatively new
development for your members, and how has the FTA
been working to date? You mentioned that it has
been enforced for quite a few years.

MS. STELLY: Thank you for that
question. As explained in the written comments,
we have raised this in previous 301 and in TE
submissions.

However, it's an immediate concern
just based on the fact that the Australian
government has introduced a bill to try to comply
with the FTA and expand these safe harbor
protections, but unfortunately, if effectively
carves out online services in the way that it's
drafted, and I'm happy to provide more detail in
our post-hearing submission.

CHAIR KENDALL: Thank you very much.
The final question comes from ITA.

MR. MITCHELL: Yes. This is another
question we are posing on behalf of our law
enforcement colleagues. Are there markets that,
in your view, do a good job of balancing the
respective rights and obligations as content
providers and ISPs? What markets are they, and
why is that true?

MS. STELLY: I'm happy to expand more
on post-hearing comments, but I would say that we
would believe that the U.S. system is doing a
great job.

CHAIR KENDALL: Thank you very much
for your testimony today. At this point, I would
like to invite the representatives from the
Consortium for Common Food Names to come forward, and please state your name for the record.

MS. MORRIS: Hi, I'm Shawna Morris, Senior Director with the Consortium for Common Food Names. I am Shawna Morris, Senior Director with the Consortium for Common Food Names. Thank you.

The Consortium for Common Food Names appreciates the opportunity to highlight the persistent and serious problem of the EU's transgressions regard geographical indications. This issue continues to be highly problematic for the U.S. food and agriculture sector, and will require continued vigilance and action on the part of the U.S. government.

CCFN is a non-profit alliance that represents the interests of consumers, farmers, food producers and retailers. Our primary mission is to preserve the legitimate rights of producers and consumers worldwide to use generic names.

A year ago, we appeared before this
body and laid out some of our greatest concerns regarding a coming escalation of EU activities in this area, and in fact, in 2017, we saw EU GI efforts reach a fever pitch, which necessitated an unprecedented level of response from both our organization and the administration.

Last year, the EU forged ahead with its trade agreement agenda with many of our largest and most important trading partners. Mexico, Japan, China and the Mercosur nations.

We strongly believe the U.S. must also pursue trade deals with these types of key markets this year. Last year, as part of these agreements, the EU consistently sought to confiscate common food and beverage names to block competition in those markets.

Those efforts were largely being backed last year in Japan, although work remains to ensure the rights of prior users of key terms, preservation of cancellation rights and establishing a reasonable approach, though related labeling requirements remain.
We commend the administration for its considerable work to educate Japan on the importance of ensuring that the EU-Japan FTA will not negatively impact U.S. market access rights to the Japanese market, and that Japan upholds the principles enshrined in its own GI regulations.

In Mexico, China and the Mercosur region, we hope to see similar successful results from the intensive combined industry and government efforts that have been devoted to upholding the rule of law and U.S. market access rights there.

In Mexico in particular, we seek nothing less than what the Mexican government has touted as its goal for the NAFTA modernization negotiations: that existing market access rights be preserved and that any new commitments be incorporated to complement those existing preserved rights.

We remain committed to this outcome in the NAFTA process, and it's essential that Mexico
remain committed to it as well, including within its continuing negotiations with the EU.

As for the EU's GI strategy, it continues to expand beyond simply free trade deals. Indeed, this past year illustrated more clearly than ever that the EU is executing a global policy agenda across many key U.S. export markets, with the express goal of hamstringing competition from American and other companies.

An important point is that the EU is not just targeting a set scope of products. Rather, the list of products it attempts to protect is changing and expanding all the time. This was best illustrated by the EU's decision last year to abandon its commitment to uphold standards set through the Codex Alimentarius process by approving a GI for a term with an existing international standard.

We expect that the EU and any other U.S. trading partner would be quick to condemn the U.S. if the shoe were on the other foot. If this government sought to enshrine into legal
text requirements that barred competition from
other countries globally rather than pursuing the
market-opening approach, the EU and others would
be quick to criticize. It is therefore natural
that the U.S. and others should condemn and
combat the EU's tactics in the clearest manner.

And finally, in the area of GIs and
trademark filings, we continue to see entities
supported by European governments attempting to
misuse the U.S. trademark system to try to
inappropriately register certification marks here
for terms that have long been generic in the U.S.

The U.S. government must remain
vigilant to avoid that outcome and recognize such
applications for what they truly are: brazen
tries to clear the field of non-EU
competitors.

In fact, we strongly recommend that
further improvements are made to the PTO
trademark review process to more effectively
ensure that the U.S. system can safeguard common
names in the interest of trademark holders.
We greatly appreciate the strong and swift U.S. government responses over the past year to the EU's competition-restricting efforts on GIs. These actions have been critical to supporting U.S. farmers and food and beverage manufacturers.

In conclusion, we ask you to continue the core objectives outlined in the 2017 report, and to continue to enhance U.S. efforts to hold our trading partners to their commitments, and we will continue to work closely with government agencies to achieve these ends. Thank you.

CHAIR KENDALL: Thank you very much for your testimony. And the first question will come from USDA.

MR. KARAWA: Hello. I would also like to extend my thanks for your testimony. My question is, in your submission, you highlight the UK, United Kingdom, as an example of a country that has supported provision of GIs and highlight the example of UK's multiple GIs for types of cheddar, which makes clear that the user
or the users of the generic term cheddar is preserved. Could you elaborate on why you consider this to be an appropriate alternate path for the protection of GIs?

MS. MORRIS: Thank you. We think that

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MR. KARAWA: And the second part, could this approach be used in other countries? Thank you.

MS. MORRIS: Thank you. In response to your last question, yes, we certainly think that it's a very positive type of model that other countries and other sectors could and should be using.

The combination of a regional term together with a generic term and protection being extended only to the terms when used together in full is a model that we believe provides both protection in a legitimate sense for the GI applicant to allow them to establish their rightful protections while preserving the rights of generic users.
We certainly hope that as the UK-EU talks move forward regarding Brexit that this is an approach that the UK insists upon as it develops its own GI regulations.

CHAIR KENDALL: Thank you very much.

The next question comes from USTR.

MR. S. CHANG: CCFN raised concerns with the process in Mercosur countries that are conducting a public consultation and opposition process with respect to EU GIs that could potentially be protected through a free trade agreement between Mercosur countries and EU. In your view, what specifically is lacking in this process?

MS. MORRIS: Thank you. One of the key concerns we had with the Mercosur process was an extremely short time window for commentary. There were lists of upwards of 300 names published all at once, so we had comment periods that were typically 30 days or thereabouts that put a tremendous burden on those looking to defend their rights in those markets to be able
to provide sufficient evidence and comments in
the appropriate time frame.

We also, based on what we're hearing
from our colleagues on the ground in industries
in those countries remain deeply skeptical about
whether these EU GI registrations being conducted
via FTA process, whether in Mercosur or in other
countries, are in fact genuine, and were making
decisions based on the facts at hand rather than
the outcome that the EU would like to see.

CHAIR KENDALL: Thank you very much.

The next question is from ITA.

MR. MITCHELL: You had mentioned in
your testimony the EU-Mexico FTA. Could you
elaborate on what market access impacts that
agreement might have on U.S. producers that rely
on common food names?

MS. MORRIS: Thank you for that.

Mexico is one of the largest export markets for
U.S. food and beverage manufacturers in terms of
export products. For the dairy industry, for
instance, it's by far our number-one export
market, and by far, largest cheese export market.

So you have a lot of industries that have well-developed market presence in that country in addition to high hopes for continued expansion opportunities, given the rights that are in place via the NAFTA agreement.

The interest from our standpoint and my members' angle is simply in terms of trying to preserve both their existing sales avenues and those future opportunities that were accorded under the NAFTA agreement.

MR. MITCHELL: Thank you. And a similar question regarding Canada. What, if any, negative impact have U.S. producers seen as a result of the completed CETA negotiations between the EU and Canada?

MS. MORRIS: Thanks for that. We were quite dismayed, as our comments noted, that Canada chose to put in place new restrictions on the use of terms that had long been generic in Canada so that companies looking to export some of those products to Canada now are forced to
modify how they label their products in a way
that may suggest to consumers that the product is
something other than the genuine article, which
is not the case and has our companies concerned
about the impacts they'll see there.

I'd say more alarmingly, recently,
we've seen efforts by the Europeans to undermine
even what was in the CETA agreement itself
through submission of direct applications for
some of those terms covered by the FTA.

If those terms are ultimately approved
by Canada, they would erode even the
grandfathering and other allowance rights that
were established under that agreement, something
that we think would be absolutely a travesty to
layer more restrictions on top of what's been put
in place already.

CHAIR KENDALL: Thank you once again
for your testimony. At this time, I would like
to invite representatives from the Footwear
Distributors and Retailers of America to come
forward, and please state your name for the
record.

MR. PRIEST: Good morning. My name is Matt Priest, and I am President and CEO of the Footwear Distributors and Retailers of America. We were founded in 1944, and our members range from small, family-owned businesses to global brands that sell to consumers around the world. Today we support nearly 500 companies and brands.

Protecting intellectual property remains vitally important to our industry as our members continue to incorporate cutting-edge designs and technology into their products. FDRA members have noted seven general concerns globally, many of which USTR has noted in past Special 301 Reports.

Number one, the growth of e-commerce has dramatically increased choice for consumers and given U.S. footwear businesses new tools and channels to reach those consumers, but it has also created countless new opportunities for bad actors.

This is true even on U.S.-based online
markets. Birkenstock, an FDRA member, made headlines in 2016 and 2017 when it pulled all of its products from Amazon in both the U.S. and Europe citing concerns about rampant counterfeit sales on the platform.

To address these issues, we must ensure companies have greater resources to reduce the unauthorized sale of IP-protected products, and that there is increased cooperation and collaboration between government authorities, platforms and rights holders.

Number two, when Customs seizes counterfeit products and alerts the rights holders, many cases never go further than the seizure of the product because of a lack of information. Additional information processes for better information-sharing could help track the real importer, increase enforcement actions and reduce repeat counterfeit sellers and shippers.

Number three, infringers increasingly ship tags and labels separately and attach them
to the counterfeit product in the U.S. in order to avoid seizure by Customs. In many instances, Customs officials are either not willing or not trained to consider trade dress or design patent infringement as a basis for seizure.

Number four, often, penalties are inadequate to deter criminal enterprises from engaging in trademark counterfeiting operations, a theme we've heard today throughout. In many countries, the penalties imposed for trademark counterfeiting operations are so low that they only add to the cost of doing business.

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

Number six, in numerous countries, there are legal and procedural obstacles to
securing and enforcing trademark rights.

Judicial systems in developing nations, for example, may lack transparency and independence, making it difficult for rights holders to pursue claims.

And number seven, counterfeiters now commonly register domains that advertise and sell counterfeit goods. As noted, companies face significant trademark infringement and lose valuable internet traffic because of misleading and fraudulent domain names. It can be hard for companies to find redress because a number of foreign registries are not transparent and do little to assist aggrieved rights holders.

Now I'm going to reference a couple country-specific issues that we have, and there are even more extensive comments within our submission.

For China, strengthening IP protection in China remains imperative, because China has a dynamic market of consumers eager to buy U.S. brands. It serves as a key footwear production
hub and has integrated the use of technology and
e-commerce at incredible scope and pace.

China has made a number of significant
improvements in its protection and enforcement of
IP rights over the past year, but more needs to
be done, especially at the local and regional
level.

FDRA remains hopeful that the Chinese
government will, over time, become increasingly
aware of the value both to Chinese consumers and
to the Chinese economy of vigorously protecting
IP rights. Despite many improvements, China is
still the leading source of counterfeit goods,
including footwear.

In our written testimony, we highlight
three general areas for improvement. Reducing
counterfeit products, improving the legal
landscape, and strengthening online platforms.

For Russia, massive markets of
counterfeit goods, both physical and online,
continue to flourish in Russia, and enforcement
procedures are generally slow and inefficient.
Online piracy continues to plague the Russian market, and the government has not established an effective enforcement strategy to combat the growing array of pirate websites located in the country.

The situation is concerning because of the vast size of the Russian e-commerce market and the fact that sporting goods, clothing and footwear are the fastest-growing categories for consumers.

As Russia prepares for the 2018 World Cup, it is imperative that it addresses its significant counterfeit problems.

And lastly, Brazil. Government support for IP enforcement is minimal in Brazil, and there is a lack of IP expertise amongst judges and law enforcement, and the legal system is very inefficient. FDRA also remains concerned that a dangerous precedent may be set in Brazil as it considers new regulations for internet platforms.

The proposed law would only require a
platform to take down content after a judicial order, which would create substantial barriers for companies attempting to protect the integrity of their brands.

In addition, because of a complex customs or regulatory system, which includes high duties, imported consumer goods in Brazil are often more highly priced than in other markets. These high prices fuel the smuggling of counterfeit goods into the black market. FDRA members, which are amongst the most popular consumer brands in Brazil must often compete with a flourishing black market.

In addition, it's important to note the U.S. does not have a free trade agreement in place with any of the countries highlighted by FDRA in its written testimony to the committee.

As the U.S. works to strengthen IP protection and enforcement for American workers and American businesses, FDRA encourages the administration to enter into new bilateral or multi-lateral trade agreements that will benefit
U.S. footwear companies and consumers.

In conclusion, our dynamic industry stands on the cusp of innovations that will alter the way we produce and sell shoes and the way consumers purchase shoes and connect with our brands. Now more than ever, it's vitally important that the U.S. government takes actions to protect the innovations, designs, brands and images central to the success of the footwear industry.

We stand ready to work with USTR and the other committee members on this critical issue, because doing so protects American footwear jobs and benefits U.S. footwear consumers.

And with that, I appreciate the opportunity to testify and look forward to your questions.

CHAIR KENDALL: Thank you very much for that testimony. The first question will be from USTR.

MR. S. CHANG: Some countries haven't
identified for several years in the Special 301 Report for trademark enforcement issues, so it may not necessarily be the largest or most important markets to your members. Are there any countries that you think should no longer be listed in the Special 301 Report for the issues that are most important to your members?

MR. PRIEST: That's a question you've been asking throughout the day, and I've been starting to think about it as I prepared to come up here. You know what, it's interesting, because we are so focused on these large markets. Our brands are massively recognized. They're desired in markets.

One of the challenges I think that we have is because of the fact that we focus on markets like China and Brazil and Russia, where there's massive amounts of consumers who want access to our brands, and they want access to legitimate product.

That's where we've put our attention. I'll be happy to go back and kind of review
secondary markets and make any post-hearing
submissions that capture some of those countries
that we think might come off that list.

CHAIR KENDALL: Thank you very much.
The next question comes from DOJ and will be
asked by my colleague from ITA.

MR. MITCHELL: In your submission, as
the second of the seven global trends you've
identified, you state that when CBP seizes
counterfeit products, additional information and
processes for better information-sharing could
help track the real importer, increase
enforcement actions and reduce repeat counterfeit
sellers and shippers.

We're hoping you could elaborate a
little more on what such information-sharing
practices might look like.

MR. PRIEST: Yes, I think that it
ultimately comes down to establishing whether
it's working groups or procedures that bring
together stakeholders. And I think this is the
heart of that process, in all honesty.
But having maybe a broader discussion about what information-sharing could take place at the enforcement level, and providing, I think, education for those who are enforcing at the border within Customs.

Because oftentimes, as I indicated in my testimony, we're getting into an era where there's such small shipments, there's so much product coming across the border, it's virtually impossible to expect that we have the amount of resources as a government to enforce that effectively.

So, the more I think that we can be in constant contact, whether through the CEEs, the Centers for Expertise with Customs, or other interagency discussions, I think is important so that ultimately, we do the best we can to continue to allow the legitimate flow of goods into the U.S. marketplace while at the same time trying to educate and stem the tide of illegitimate product.

CHAIR KENDALL: Thank you very much.
The next question is from PTO.

MS. BERDUT: Thank you. In your submission, in your written submission but also in your testimony today, you indicated that China has made a number of significant improvements in their protection and enforcement of IP in the past year, but you didn't provide any specific examples or references.

So my question is, what specifically are you referring to, and does it provide a roadmap for the future?

MR. PRIEST: I think it does provide a roadmap for the future in, specifically I think, the establishment of IP courts. I think I view this as a maturation process.

I think that as the US, we have driven so many global brands throughout the world in such big ways that we take for granted the fact that it takes other countries, who have a strong desire as China does, to develop its own indigenous brands that are globally recognized, that it's a maturation process and an
evolutionary process to establish the appropriate legal protections and infrastructure to help provide appropriate protection for IP rights in China.

So, the more that they can work through the courts, the more that they can establish kind of uniform application of the law, so establishing appellate courts that help adjudicate some of the concerns, the more they can increase the fees that are associated so it's not just about the cost of doing business, but there's some real oomph and deterrent effect behind the fees that are applied, I think all of these things are kind of a roadmap.

But keeping them on the list I think is important to do, because it continues the dialogue that our government can have in a productive way but at the same time recognizing they have made progress. It is a maturation process.

And as long as they continue, the central government's continued focus on
developing its own global brands, they'll be incentivized to establish very robust intellectual property protections in China in the years to come.

CHAIR KENDALL: Thank you very much for your testimony. We appreciate it. This concludes the morning session. We will now break for one hour. Please return by 1:10 p.m. so that we can continue to proceed on time. Thanks again.

(Whereupon, the above-entitled matter went off the record at 12:08 p.m. and resumed at 1:10 p.m.)

CHAIR KENDALL: Okay, we're going to get started. We have here a representative from the International Intellectual Property Alliance. Could you state your name for the record?

MR. ROSENBAUM: My name is Kevin Rosenbaum with the International Intellectual Property Alliance, IIPA.

Thank you for the opportunity to present the views of the IIPA in this year's
Special 301 process. We applaud the U.S. government for making 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 dialogue.

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 2016 study, contribute over $1.2 trillion to the U.S. economy, provide five and a half million 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 and 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 cultural and creative output. The ultimate objective is to promote markets where the creative industries can bring even more products and services than they currently offer in an increasing variety of ways from a greater diversity of players before an ever-growing global audience.

Advancing that objective is a proven means to grow U.S. exports, create good American jobs and enhance U.S. global competitiveness.

With this broad vision in mind, IIPA has
participated in every Special 301 review since
the 1988 Trade Act created this process. Given
some of the other comments provided, it is worth
reviewing the specific statutory language and
purpose of the Special 301 review: namely, to
identify, 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 and enforcement
in order to accommodate the perceived interests
of business sectors that, by their own words,
depend on expanding the zone where copyright
protections do not apply. This is not what
Congress intended when it created the Special 301
process and is not consistent with the clear
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, and 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 2018 Special 301 Report. All these are listed in our hearing statement with capsule summaries on the nine countries we recommend for inclusion on the priority watch list: Argentina, Chile, China, India, Mexico, Russia, Taiwan, Ukraine and Vietnam.

Our submission highlights five legal reforms that our trading partners should focus on to adequately and effectively address all forms of piracy in a fast-changing technological environment. Most fundamentally, U.S. trading partners must both accede to and fully implement
the WIPO Internet Treaties, which set global minimum standards for copyright 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 requirement to confine all limitations and exceptions 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, in particular regarding duration of copyright protection. The U.S. government should also ensure that the numerous bilateral and multi-lateral 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
To this end, it is important that trade agreements keep pace with evolving global norms for copyright protection and enforcement and evolving technology, and that U.S. trade agencies make it a top priority in 2018 to address the troubling gaps and shortfalls in compliance with obligations taken on by U.S. trading partners in these agreements.

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

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 the global markets for copyright material.
Conversely, the entrenchment of infringing services, including those that profit from enabling others to infringe copyright, is a leading barrier impeding the full access of U.S. creators and producers into markets worldwide. This infringement threatens the viability of license platforms and it makes it much harder for creators and producers to earn a living from their craft.

We applaud the U.S. government for establishing an annual review of notorious markets, which has already made a significant contribution in combating systemic online copyright theft, and we urge you to redouble efforts to encouraging our trading partners to adopt legal frameworks that create incentives for legitimate network service providers to work with rights holders to advance the common goal of a safer, cleaner online marketplace.

Achieving that goal requires the active cooperation of all participants in the e-commerce ecosystem. Our trading partners should
be doing much more to foster and encourage such
cooperation and the development of best
practices.

Furthermore, where notorious online
marketplaces are hosted in one country but target
consumers in another or worldwide, the failure of
the host country to take effective action against
them pollutes the markets of its neighbors and
trading partners. Increasingly, responsible
governments are pushing back against this
offshoring of enforcement responsibility.

So long as less responsible states
fail to institute effective means to crack down
on pirate operations based within their borders
but readily accessible worldwide, this trend will
continue and deserves the close attention of the
U.S. government.

Finally, all efforts to address
copyright infringement will be unsuccessful if
legitimate products and services cannot be
brought into a market to meet consumer demand.
Whatever form they take, market access
restrictions that unfairly impede the entry of legitimate products make it easier for pirate operations to fill the void. U.S. officials should continue to strive to eliminate or face out-market access barriers.

The health and competitiveness of the U.S. economy depends on a thriving copyright sector that creates revenues, jobs and exports, but promoting and respecting intellectual property rights and opening markets to products and services that depend on copyright also helps our trading partners.

Special 301 remains a cornerstone of the U.S. effort to advance modern levels of protection for copyright, more effective policies and tools to enforce that protection and freer, more open markets. We look forward to our continued work with USTR and other U.S. agencies to advance these goals. Thank you very much, and I look forward to your questions.

CHAIR KENDALL: Thank you very much for your testimony. The first question comes
from USTR.

MR. S. CHANG: Some countries regularly named in the Special 301 Report for copyright and related rights issues but may not necessarily be the largest or most important markets to your members. Are there any countries that you think should no longer be listed in the Special 301 Report for copyright-related reasons?

MR. ROSENBAUM: Thanks for that question. Off the top of my head, I do not think that's the case. I'm happy to check further with our members and will provide supplemental feedback if necessary. Thanks.

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

MS. SCHULTZ: Good afternoon. What are the latest trends that you're seeing in online copyright infringement in China, and do you have any estimated trade losses from China due to copyright piracy or separately from market access barriers?
MR. ROSENBAUM: Thank you very much for that question. China is a market where we're seeing pretty much all forms conceivable in terms of online piracy. So for example, it listed streaming devices. China is a hub for that. Stream ripping services.

One particular problem that we highlight is the problem of apps, and the app ecosystem fuels all forms of piracy, including -- it listed streaming device piracy, because these apps essentially facilitate the access of copyrighted content. People download the apps to their either handheld device or their illicit streaming device.

So this is a significant problem and one obstacle to enforcement against these apps has been that China has tended to look at it through what we refer to as the server principle, where if the infringing content is located at a server remotely, which many of these apps, that's how they work. They circumvent protections and they access content on remote servers to the
user.

Certain Chinese courts have held that where the content is accessed remotely and it's not stored on a user's device, then they won't find infringement. So that's been an obstacle. There was a case in which they did not apply that principle in 2017, which we highlight in our submission.

So what we'd like to see is a judicial interpretation normalizing that standard or perhaps in the copyright law reform process, if it could be addressed that way. And as to the second part of the question, it's very difficult to come up with numbers on piracy.

I can look to see if there are available, if I can supplement our submission with that. We highlight the Frontier Economics study on piracy which uses a method which we think is actually on the very low side. But, you know, it's very tricky when you're talking about losses due to piracy. So happy to supplement if I am able to.
CHAIR KENDALL: Thank you very much.
The final question comes from ITA.

MR. MITCHELL: This is a fact-intensive question, so I'll take it slowly. For Taiwan, between January 2017 and today, have Taiwanese prosecutors filed any cases involving piratical websites that specifically target Taiwanese consumers where the server is located offshore but the acts of infringement are taking place in Taiwan? We're wondering if any of your member companies have filed or explored filing in such instances.

MR. ROSENBAUM: So is the question whether our members have brought such a case to the attention of the Taiwanese authorities?
Okay, I can look into that. I don't know the answer to that.

My understanding is that the legal framework that currently exists in Taiwan does not allow for that kind of enforcement. In other words, the Taiwan authorities say, well, when the infringing content is hosted overseas, we don't
have jurisdiction.

But I can certainly check, and if I find any examples of that, I will let you know.

MR. MITCHELL: That would be helpful, thank you.

MR. ROSENBAUM: Sure, thank you.

CHAIR KENDALL: Thank you very much for your testimony. At this point, I'd like to invite representatives from the Internet Association to come forward and state your name for the record.

MS. CARROLL: Hi, good afternoon. Members of the Special 301 subcommittee, thank you for holding this public hearing. My name is Melika Carroll, and I am Senior Vice President of Global Government Affairs for the Internet Association.

IA represents over 40 of the world's leading internet companies. U.S. internet platforms are a significant driver of the U.S. economy. The internet industry represented an estimated six percent of U.S. GDP in 2014,
totaling nearly $967 billion, and accounts for millions of American jobs.

Hundreds of thousands of U.S. small businesses now use the internet to reach customers around the world in ways impossible a generation ago. In fact, the internet has helped the United States unlock a massive trade surplus in digitally-delivered services worth $159 billion in 2014.

While enabling trade in many sectors, the internet industry itself is growing in a new sector. Our industry is becoming a major producer and exporter of original content, bringing films, music and other creative works to audience around the world.

Our member companies are now the new faces of the American content industry, winning Emmys and Oscars and providing digital distribution for streaming-only Grammy winners. Last year, IA members released more films than any other major U.S. studio. Our members spent at least $10.8 billion on content with plans to
invest substantially more over the next several years.

IA companies have a strong interest in working with all rights holders to ensure that goods aren't pirated. Netflix, YouTube, Spotify, Pandora and others help drive down theft by steering heavy users to subscription services.

Online services that allow consumers to legally access content have resulted in a 48 percent year-over-year increase in music-streaming revenues, up to $2.5 billion for the first half of 2017 according to RIAA.

From this perspective, IA members share a common interest with other rights holders in ensuring that our trading partners adopt strong and balanced IP systems. In the United States, we take for granted a balanced and well-functioning IP system that enables the operation and growth of the internet.

Unfortunately, one foundational foreign barrier faced by IA members comes from inadequate and unbalanced systems of copyright
and intermediary liability protections in other
countries.

While proper enforcement of
intellectual property rules abroad is essential
for our members, and we encourage USTR to take
action against illicit activities, it is just as
critical for USTR to highlight countries that
misuse copyright in a way that restricts U.S.
platforms and small businesses online.

While our full submission highlighted
numerous unbalanced intellectual property regimes
around the world today, I want to focus my
remarks on what we believe are the most
problematic laws and policies that continue to
undermine and threaten U.S. innovation and
economic growth, particularly in the European
Union and in China.

A range of legislative proposals, new
laws and regulations in both member states and at
the European Union represent a significant
departure by the EU from its shared approach with
the U.S. on the foundational principles of a free
and open internet.

For example, the proliferation of ancillary rights and neighboring right laws in Europe directly threaten U.S. internet platforms. Giving new legal entitlements for quotations or snippets enable countries to impose levies or other restrictions on the use of this information. This is a practice which runs afoul of Article 10-1 of the Berne Convention, raising potential enforcement questions of the WTO.

The European Commission is also proposing changes to the Copyright Directive that would drastically shift the landscape of copyright intermediary liability in Europe. The proposed changes would make platforms directly liable for content uploaded by users, proposals that if implemented would eviscerate protections set forth in U.S. law.

The proposals would also require a broad range of online services to monitor and filter content and provides for a potentially intrusive multi-stakeholder process regarding the
design and operation of content-recognition technologies.

In addition to unbalanced IP policies in Europe, U.S. internet services are dealing with different and problematic measures in China that are forcing cloud service providers to transfer high-value intellectual property related to specialized cloud services, software and hardware to Chinese companies as conditions of operating in country. This is happening while Chinese companies in the U.S. are able to fully own and control such datacenters and cloud-related services here.

So we encourage the USTR to raise strong concerns about the European and Chinese proposals, recognizing that these continue to significantly increase costs and restrict market access for U.S.-based services.

To conclude, it is our hope that this year's report will break new ground in support of the digital economy and recognize the harm unbalanced IP policies have on both internet
industry and the U.S. economy as a whole.

A modernized NAFTA provides an immediate opportunity for USTR to promote a strong and balanced copyright framework that benefits all U.S. stakeholders, and without these business-critical protections, internet services and the industries we enable face troubling legal risks, even when they follow U.S. law.

With that, thank you again for holding today's hearing and to give us the opportunity to testify, and I'm happy to answer any questions.

CHAIR KENDALL: Thank you very much for your testimony. The first question will be from USTR.

MR. S. CHANG: Thanks again. 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. How do you think your input should be reflected in the Special 301 Report? Are you equally concerned about all trading partners you mentioned?
MS. CARROLL: That's a very good question. Thank you. I'd be happy to work with our members and come back to you with a more precise proposal for that.

CHAIR KENDALL: Thank you very much.

The next question comes from the U.S. Copyright Office.

MS. SCHULTZ: Good afternoon. You mention in your public submission that India's intermediary liability framework was a significant risk to U.S. internet services, particularly because there isn't a clear copyright safe harbor framework. Could you tell us how India's ISP liability framework hurts your industry, and if there are additional market access barriers in India?

MS. CARROLL: Sure. I'd be happy to talk about that with our members and get back to you again with more details in our post-hearing submission on India.

CHAIR KENDALL: Thank you very much.

The next question comes from USPTO.
MR. SHAPIRO: Thank you. Is the FTA concerned with respect to Australia FTA? Is it a relatively new development for your members? If not, what has been the impact in previous years?

MS. CARROLL: Thank you for the question. I'd be happy to work with the companies to see how that has impacted their business in Australia and get back to you with a post-hearing submission.

CHAIR KENDALL: The next question comes from DOJ and is presented by ITA.

MR. MITCHELL: Your submission explains that ISP safe harbors have been critical to the growth of the internet and to online trade. Can you provide some examples of how a country's lack of ISP safe harbors from copyright liability affects your members' decisions to operate and/or invest in a particular market?

MS. CARROLL: Sure. That was a question we also discussed with you at the hearing last year. I think we could come back to you with some more precise information about
MR. MITCHELL: Thank you.

CHAIR KENDALL: And the final question is also from ITA.

MR. MITCHELL: You've noted that many of your members develop content and rely on copyright enforcement, but in your submission, you discuss exceptions and limitations in each specific marketplace, although some of those countries are well known for not protecting copyright. What accounts for this?

MS. CARROLL: Sorry, what accounts for?

MR. MITCHELL: For their treatment in your report that you've focused on exceptions and limitations instead of their lack of copyright enforcement in a traditional sense?

MS. CARROLL: Right. Again, I'd be happy to talk with the member companies and provide you some more information about how we perceive the difference in the two.

CHAIR KENDALL: Thank you very much.
for your testimony today. I'd like to invite representatives of Knowledge Ecology International to testify, and please state your name for the record.


First off, I just want to say that there are several things in the submissions by the companies that represent the pharmaceutical industry. They complain about measures all over the world that have to do with drug pricing. Not directly an IP issue, per se.

I just want to remind the committee that President Trump got elected on a promise to negotiate drug prices and to cut $300 billion out of the Medicare budget, which is not even $300 billion, so it was a pretty aggressive cut he proposed.

And he's not going to be able to deliver on a fraction of those promises unless he
employs some of the mechanisms that drug companies are complaining about.

So you don't want to be throwing down policy mandates in areas that are going to constrain his ability to deliver the promises he made to his own voters to protect them from high drug prices in the United States.

I'm going to talk now on compulsory license, and I'm going to read from a text I prepared, which I can share if you want. PhRMA and other groups lobbying on behalf of big drug companies frequently target the use of compulsory license as a, quote, harmful IP-related trade barrier, quote. KEI sees compulsory license as important and very much under-utilized as a tool to address excessive pricing and restrictive licensing practices.

I'll take a minute to provide some context for this proceeding. First, the United States has at least 15 separate statutes that can be used to permit non-voluntary use of patents, not accounting for various exceptions to patent
rights for research and usage by medical professionals.

Second, the United States is by far, and I mean by far, the most frequent user of compulsory licenses. USTR itself overturned an injunction on the importation of iPhones and iPads that infringe on patents owned by Samsung on August 3, 2013.

Under the Supreme Court eBay doctrine regarding the enforcement of injunctions, courts routinely permit infringement of patents when royalties are paid to the patent holder.

For another example involving Apple, in 2017, Apple successfully asked a judge for permission to use, without a voluntary license, the subject of an ongoing royalty, U.S. patent number, 5,781,752, titled table-based data speculation circuit for parallel processing computer.

The compulsory licenses under the eBay doctrine are fairly common, about one a month for a while, but less frequently as parties tend to
grant voluntary licenses when it's perceived to be hard to enforce an injunction, and these compulsory licenses cover a wide range of technologies.

In the area of medical technologies, the most common compulsory license ordered by the courts are for medical devices and diagnostics, of which there are many, on everything from contact lenses to artificial heart valves to diagnostic technologies. Often, the companies requesting such compulsory licenses are innovators themselves.

For example, in 2008, Abbott used the eBay doctrine to obtain a compulsory license on HCV genotyping testing patents. Similar compulsory licensing efforts were successful, and several high-income countries including Germany was requesting a compulsory license, and in Austria, Australia, and the UK, to mention a few other countries.

The United States also has used the threat of compulsory license to force more
liberal licensing or price discounts in cases where the federal government was the funder of research, including the patents on reverse genetics used in the manufacture of vaccines for the avian flu, stem cell patents held by Wirth, the Abbott patents on ritonavir, which is an HIV drug, and the Fabre patents now held by Sanofi to mention a few cases under the Bayh-Dole Act.

In 2016, 51 members of Congress asked the federal government to make more frequent use of this Act. Recently, 18 members of Congress asked the federal government to use 28 USC 1498 to grant compulsory license on patents for hepatitis C virus drugs.

And the Senate Armed Services committee in 2017 adopted a directive to the Department of Defense to use compulsory licenses when prices on Army-funded drugs like Xtandi, a prostate cancer drug, are more expensive in the United States than other high-income countries.

Many persons, including President Trump, have called for changes in the law to
allow Medicare to negotiate drug prices. If Medicare negotiates drug prices, it will involve a threat by the United States to withhold reimbursement, narrow formularies or increase copayments. All these measures hurt patients.

We want the Congress to give the government more robust authority to use compulsory licensing in order to protect patients, effectively putting a monopoly at risk rather than the patient when there are disputes over prices.

Finally, we are planning to ask Trump, the Trump administration, to use, under existing statutes, either or both 35 USC 203 or 28 USC 1498, again, monopolies on at least three drugs this calendar year. In every case, there are significant abuses of patent rights and negative consequence for patients.

We also call your attention to the fact that there are emerging very big patent thickets for two new important technologies: CRISPR gene-editing tools, and CAR2 treatment.
And we think that at some point, the government
is going to have to use compulsory licenses to
force more liberal license in these areas or
suffer the consequences of not doing so.

I have an annex here about the
statutes here that I mentioned. I can stop right
here. Thank you.

CHAIR KENDALL: Thank you very much
for your testimony. The first question is from
USTR.

MR. S. CHANG: Your public submission
comments on the Special 301 process notes that
USTR should, quote, retrain its focus, end quote,
and use a process to, quote, develop and outline
the policies and norms that it wants to promote,
end quote.

Do you have any specific suggestions
for individual countries nominated for or
previously included in the Special 301 Report?
Thank you.

MR. LOVE: Yes, I think from our point
of view, the fact that trade policy is focused on
patents and drug pricing exclusively to promote innovation overlooks the important role of the National Institutes of Health and other government agencies for funding, or the same thing in other countries.

Secretary Azar, when he was confirmed, as you may have noticed, he made reference to the fact that he was gratified when the European Union had increased their funding of biomedical research, and he thought that was one of the things that helped sort of re-address the imbalance between the U.S. as the primary supplier of public goods in the medical research area for the whole world.

There's just no country that does anything remotely close to what the United States does in terms of public sector research, and most of the scientific advances in diseases are really due to what's being paid for by taxpayers here.

We don't really do anything about other countries like Switzerland and other countries, for example, that do next to nothing
in terms of funding public sector research.

The WHO negotiations have, on this issue, have often gotten a very negative impact from USTR because it's perceived as some kind of threat to patent rights, but it shouldn't be seen that way. It should be seen as a complement to the incentives you get from patents.

So we think that by solely focusing on the incentives for private companies and ignoring what happens in the public sector, that you have a bias towards the private sector which doesn't reflect what domestic policy is to the United States.

CHAIR KENDALL: Thank you very much. Following up on that answer, we have a question from HHS.

MS. BLEIMUND: Hi. Thanks for your testimony. In your submission, you asked the committee to, quote, look at the trade-related aspects of funding the research that enters the public domain and advances science. Can you elaborate further on this statement and how it
relates to the work of the Special 301 Report?

MR. LOVE: Well, just yesterday I was taking a look at a drug that costs over $300,000 in the United States, and I was looking at the patent landscape, and I noticed that there was patents from a university in Australia and from a university and a government-funded research center in Belgium, for example, on this particular drug.

When the United States funds the research on a drug, like Spinraza, for example, which is for a rare disease, U.S. government retains a royalty-free right on the patents, and it has these marching rights on that. But that doesn't really extend to research that's funded in Canada or in Belgium or Australia or other countries.

We thought a reciprocal agreement where we would have access to the patents that were funded in those institutions, and they would have access to the patents that we were funded, in some level, at least a protocol where you
could actually at least request the use, if you
felt there was a compelling public health reason
to do it for, that's an area that we have raised
several times in the past with HHS in the past to
sort of look at this issue. And that's one
trade-related aspect.

Another issue is the U.S. gives grants
to researchers around the world, but some
countries, when they have government-funded
research programs, would not make the grants
available to American residents. And I think
that you might ask yourself why you're being so
open and they're not.

Another thing is that the NIH puts
conditions. It requires if you get a government
grant to put your research into a publically
accessible archive, so all scientists around the
world, whether they're in China, Germany, the
United States or Switzerland, they can get access
to that. And those policies are not universal
around the world.

So I think that in addition to having
the data in archives, I think you might also look
toward, in some cases, the permission to do
machine-generated translations of research in
foreign languages so American researchers could
benefit from it.

CHAIR KENDALL: Thank you very much.

The final question comes from USTR.

MR. S. CHANG: Your submission
suggests that USTR address what you refer to as
the global crisis in orphan works. In your view,
what might such an examination include, and would
it align with the statutory framework?

MR. LOVE: One of the problems with
the orphan works is the extension of the
copyright year from life plus 50 years -- which
is already, in our opinion, too long -- to life
plus 70 years, and we know that often the
companies lobby the USTR to have other countries
do that. There's things that can be done to
mitigate those effects.

One would be to at least permit
registration on works that have long maturities.
And the U.S. actually does that to some extent. We have, even for any copyrighted work, you can limit the remedies that are available on an infringement case. So they're different if you register the work than if you have not registered the work. So I think that those fit within the existing thing.

The other thing that the Library of Congress has recommended is to use limitations on liability for works where you can't identify the owner. And the Library of Congress recommended that because it wasn't constrained by the three-step test, which was considered restrictive by the Library of Congress at that time.

For that to work, you have to have the flexibility in setting damages for infringement that exist in the WTO agreement but has been threatened by some of the bilateral agreements that USTR has proposed.

CHAIR KENDALL: Thank you very much for your testimony. At this time, I'd like to call the representatives from the National
Association of Manufacturers to testify, and
please state your name for the record.

MR. ONG: Members of the Special 301
Subcommittee, thank you for the opportunity to
testify today. My name is Ryan Ong. I'm
Director of International Business Policy at the
National Association of Manufacturers, or the
NAM.

We are the nation's largest industrial
association and serve as the voice for more than
12 million women and men that make things in
America. Manufacturing contributed a record
$2.25 trillion to the U.S. economy in 2016, and
remains a critical engine to grow the U.S.
economy, create high-paying jobs and provide
opportunity and prosperity for Americans.

Innovation and intellectual property
are crucial to that success and the foundation of
a globally competitive manufacturing base. The
United States has long been a champion for
innovation and IP protection around the world.

These strong protections are critical
for manufacturers of all sizes, but particularly for our small- and medium-sized manufacturers, 90 percent of our membership, for whom the cost and complexity of defending their IP rights around the world can be prohibitively high.

Unsurprisingly, manufacturers face challenges in foreign markets, from governments that flout international rules and restrict effective protection and enforcement for U.S. IP through their policies and activities.

The NAM's formal Special 301 submission discusses many of these markets, including formal recommendations for ten priority countries, such as China and Canada, and information on challenges in nearly 40 others, ranging from Algeria and Korea to Turkey and Argentina.

Our formal submission also flags a series of cross-cutting issues, such as global counterfeiting, increased restrictions on legitimate trademark use, and insufficient protection of business-confidential data in
But I want to use my time today to highlight three specific cross-cutting issues and challenges that our members face. First, we're seeing increasing attempts to weaken the global IP framework through activities and initiatives in international organizations and forums.

These are forums and organizations that play a critical role in supporting U.S. foreign policy and U.S. economic growth. But we see an increasing number of efforts that falsely claim that IP is the barrier and an inherent obstacle to policy goals such as health, environmental protection and development.

These dangerous approaches not only ignore the role of innovation in solving these challenges, but also prevent frank discussions about the full range of barriers that block access to important products and technologies, making it both politically and technically harder -- not easier -- to find solutions that involve all stakeholders.
The January World Health Organization executive board meetings were a perfect illustration of this challenge. The meeting agenda included a series of reports and plans designed to weaken global IP protections. Front and center were efforts to institutionalize troublesome recommendations from the strongly biased and deeply flawed 2016 U.N. High-Level Panel on Access to Medicines.

This panel's report, which was criticized by the U.S. government under the previous administration and avoided by the Secretary General that launched it, has been resurrected by supporters and pushed onto the agenda in a variety of international forums such as the U.N. Human Rights Council, the WTO, WIPO and the OECD.

These efforts are troubling enough on their own, but are also affecting national-level policies in critical U.S. export markets, such as Chile, Colombia and Thailand in ways that harm U.S. innovation and high-paying jobs.
Now, thanks to strong efforts by HHS and the interagency team, the United States took a strong, robust negotiating line in January and was able to fend off some of the more troubling proposals, but we still face this growing challenge.

The United States must be strong and strategic to continue to push back against these efforts and your agencies have a critical role to play, working through a tightly coordinated interagency coordination process and with other like-minded countries, to be able to push back robust and harmful activities.

Second, innovative manufacturers are facing new threats from countries seeking to undermine patent protection that supports strong U.S. exports of innovative products. These attempts can come in a variety of forms, which we lay out in detail in our more detailed submission, but would be happy to answer more detailed questions at any point in time.

But we see a range of high-profile
examples popping up in markets from Malaysia to Canada, from Colombia to Turkey, from Russia to Japan.

And while these policies, including compulsory licenses, can be legitimate government tools when used correctly, they cannot be an excuse for protectionism or as a cover to promote local companies at the expense of U.S. manufacturing, and they must be developed and implemented transparently based on open stakeholder consultation.

Third, trade secrets are becoming increasingly critical for manufacturers of all shapes and sizes, and the United States' strength in trade secrets protection with the 2016 passage of the Defend Trade Secrets Acts, which the NAM strongly supported, and a few other countries and regions have promoted reform to their trade secrets legal regimes, such as the European Union, Japan and Taiwan, but many others have not.

And although the headlines in this
space are often dominated by places like China, India and Russia, countries around the world fail to protect trade secrets effectively with their laws, policies and enforcement actions.

And that brings me to my last and final point, which I'll be happy to elaborate further on in questions. The NAM urges the U.S. government to make a strategic use of all available options to promote and protect innovative manufacturing.

These must include a variety of tools from strong, enforceable IP protections in current and future trade negotiations, use of robust enforcement tools in organizations like the WTO, robust use of domestic tools, including those provided by the Trade Facilitation and Trade Enforcement Act, and a pro-IP message in international fora. All of these tools are critical.

With that, let me thank you for the opportunity to testify here today. I look forward to hearing from you and your agencies
with particular questions and following up with
more detail in follow-up questions.

CHAIR KENDALL: Thank you very much.

The first question is from USTR.

MR. S. CHANG: Are there any countries
that have been listed in previous Special 301
Reports with issues of concern to your members
that you would no longer recommend we include,
if, for example, the market is not of the same
size or importance as other markets that you
nominate?

MR. ONG: I appreciate it. In looking
at our submission, our list of countries where we
have issues of concern, I think, has continued to
grow. We look each year, in consultation with
our members, to understand and to document the
current situation that our members are facing.
And throughout our submission, we have noted some
areas of improvement. In markets like China and
India, there are specific things to be able to
point to.

That being said, our overall
assessment of these markets and of other markets continues to encourage us to request placement for those countries, for example, on the priority watch list, as well as other countries and their classification based on the challenges that our manufacturers are facing now. I'd be happy to follow up with more detail on that if it would be helpful.

CHAIR KENDALL: Thank you very much.

The next question is from Treasury.

MR. W. CHANG: Hi. The Federation of Indian Chamber of Commerce and Industry noted as part of it 2018 Special 301 submission that foreign investment has risen to unprecedented levels in total FDI between U.S. and India at $37 billion in 2016. How do you explain this growth given the IP deficiencies that you have described.

MR. ONG: Sure. That's an excellent question. And in our work on India, in the IP and the non-IP context, we speak significantly about the importance and the robust and
increasing interest from many of our cross-
manufacturing members in that market.

I think the point to come to is that
investment in India remains constrained in number
of IP-intensive industries because of the
challenges that they face in this market. And of
course, those investment numbers include both IP-
intensive and non-IP-intensive industries.

Many of our IP-intensive and
innovative manufacturers are interested in the
potential that the India market can bring, but
practically and operationally, the significant IP
challenges they can even face in that market
restrain their ability to be able to invest and
sell robustly.

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

MS. DYER: Thank you for your time.
To follow on with respect to India, give me the
sense of priorities. You listed many different
issues that you enumerated. Is there a
hierarchical list in the way that it's listed
within your submission, or can you offer us some priorities? Thank you.

MR. ONG: Sure. So, the breadth of our membership means that we have members who care about a diversity of intellectual property issues in India, and many companies look at the market based on their operations in multiple spaces.

Certainly the challenge with India on the patents base remain first and foremost for many of our members. Those are the areas in which I think we've seen the most challenging areas for progress.

Those are the areas in which many of the core and most fundamental issues, including patentability criteria, including Section 3D of the Indian Patent Act, and many others, remain largely unchanged and in which the size of the market is significant enough that there would be both interest in helping to remove those barriers and increasing frustration about the lack of progress, and in some cases backward movements in
those areas.

MS. DYER: Thank you.

CHAIR KENDALL: Thank you very much for your testimony. At this time, we'd like to call representatives from the Pharmaceutical Research and Manufacturers of America to come forward, and please state your name for the record.

MR. MOORE: Hi. My name is Chris Moore. I'm with the Pharmaceutical Research and Manufacturers of America, and on behalf of biopharmaceutical innovators in the United States and the more than 800,000 women and men the employ across the country, PhRMA appreciates this opportunity to testify before the Special 301 committee.

The United States is the global leader in medicines research. Intellectual property including patents and regulatory data protection, drives and sustains biopharmaceutical innovation. It enables access to today's medicines and promotes investment in tomorrow's treatments and
cures.

Where markets are open and intellectual property is protected, PhRMA members have the predictability and certainty necessary to research, develop and deliver new medicines for patients who need them. But today's hearing comes at a time when innovators face unprecedented 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. It's also about ensuring our trading partners provide fair access to their markets and appropriately value new advances.

We urge the administration to use Special 301 to address discriminatory pricing policies in Canada, Korea and Japan that would benefit drug companies in those countries at the
expense of medicines developed in the United States.

Proposed changes to Canada's pricing policies are aimed solely at patented medicines and would discourage the launch of competing products. New pricing policies in Korea and Japan use biased criteria designed to allow local companies to get a price advantage. In Canada and Korea, American innovators also face a range of intellectual property challenges, including inadequate patent term restoration.

For these reasons, we ask that Canada and Korea be named priority foreign countries, and that Japan be placed on the priority watch list. Equally troubling are industrial policies that discriminate against U.S.-manufactured goods. Turkey has decided to remove products from its national reimbursement list that are not produced in Turkey.

On the very day we submitted our Special 301 comments, Turkey de-listed the first wave of 44 products, and further waves of de-
listing are expected throughout 2018. We urge that Turkey be placed on the priority watch list and that USTR conduct an out-of-cycle review.

Part of the submission also identifies top intellectual property barriers and threats abroad that require urgent action. Last year, for example, Malaysia announced a compulsory license for an innovative medicine, a move that appears designed to facilitate the local development of a competing combination product.

Contrary to its own procedures, the Colombian government accepted a petition for review in December that could result in compulsory licensing of patents protecting an entire class of innovative medicines. Saudi Arabia has knowingly facilitated the infringement of breakthrough treatments by approving the marketing of competing products during the period of patent or regulatory data protection.

We ask that Malaysia be named a priority foreign country, and that Colombia and Saudi Arabia be placed on the priority watch
PhRMA members are facing growing intellectual property barriers and threats in the European Union, The United Arab Emirates and a range of multi-lateral forums. Despite its global leadership in medical research, the European Union is considering a plan that would undermine innovation by allowing local companies to make and export copies of patented medicines during the period of supplemental protection.

The United Arab Emirates is a member of the Gulf Cooperation Council Patent Office but is now demanding that patent applications be filed with the UAE Patent Office, putting the status of GCC patents and pending patent applications in doubt.

This demand appears to apply only to biopharmaceutical patent applications, raising questions about the UAE's compliance with its WTO obligations.

PhRMA asks that the European Union and the UAE be included on the watch list, and urges
USTR to address these and other challenges outlined in our submission using all available tools. We particularly urge USTR and other federal agencies to address market access and intellectual property challenges in countries like Australia, Canada, Colombia and Korea that are U.S. trade agreement partners.

Ongoing NAFTA and KORUS negotiations provide an immediate opportunity to address pressing concerns and to enforce existing rules.

Thank you for the opportunity to testify today. We look forward to answering your questions and to working with you to address the concerns described in our submission.

CHAIR KENDALL: Thank you very much for your testimony.

The first question is from USTR.

MR. S. CHANG: Are there any countries that have been listed in previous Special 301 reports for issues of concern to your members that you would no longer recommend we include?

For example, the market is not of the
same size or importance as other markets that you help.

MR. MOORE: Thank you very much for the question. Like other organizations, we seek each year to respond to your request for comments for the Special 301 report in a way that prioritizes what we believe at the time to be the most serious threats that our industry is facing in certain countries around the world.

Sometimes that results in listing every year the same types of countries, unfortunately. But, we don't think it's just the size of the market that is always the deciding factor here.

Sometimes we're seeing cases where we have a significant impact on our industry and it could be in a market that might be smaller overall.

The action that that market is taking might set a very dangerous precedent globally. And so, there are a number of factors that go into our decisions in terms of what countries to
present to you.

CHAIR KENDALL: Thank you very much.

The next question is from HSS.

MS. BLEIMUND: Your submission argues that discriminatory pricing policies deny fair and equitable market access.

Could you please explain the link further? Are there examples where companies have not sold products or where companies have pulled out of specific markets due to such policies?

MR. MOORE: We have, as an industry, are facing market access concerns in a number of different countries around the world.

It is relatively -- has been relatively rare, but, unfortunately, an increasing trend to see countries that are not produced -- I'm sorry, products that are not produced locally, unable to enter certain markets.

That has been the case with Algeria, it's now the case with Turkey, as I mentioned.

But, we also see a very concerning
trend to advantage local companies in different markets through discriminatory policies that enable companies to get a price advantage.

If, for example, they are launching products first in that market, they are conducting a certain number of clinical trials in that market, if they're producing in that market, if they're doing joint ventures and sharing research and development with a local company, we think all of those things constitute very serious market access challenges and non-tariff barriers that are important to address through the 301 process.

CHAIR KENDALL: Thank you very much. The next question will be asked by ITA.

MR. MITCHELL: How does Malaysia's use -- I'm sorry. How does Malaysia's use of compulsory license compare to other countries that have issued compulsory licenses in the past?

MR. MOORE: Well, thank you very much for the question.
As stated in our submission, we believe that compulsory licensing is and should be an extraordinary measure that is used in emergencies and as a last resort.

Malaysia has announced a compulsory license for an innovative medicine that we believe is unwarranted. It took that action despite the offer of a voluntary license by the innovative company involved.

And, it appears to have done this really to facilitate the local development of a competing product.

And, there appears to be an effort under way to export the Malaysia example to countries abroad.

And so, we believe those things in combination warrant the recommendation that we have made for Malaysia in our Special 301 submission in addition to the other challenges that we see in that market.

CHAIR KENDALL: Thank you very much.

The final question will be from U.S.
MR. S. CHANG: This year, PhRMA is requesting that three countries be designated as primary core countries.

How does PhRMA distinguish between these countries and those it has nominated for the priority watch list?

MR. MOORE: Thank you.

We clearly are looking at what we believe to be the most onerous and egregious practices that we see in different countries around the world.

We also are looking at the impact on our industry and our business, not only in those markets, but also in other markets around the world.

And, we are also looking at the extent of some of those challenges. So, for example, in each of those three markets, we are highlighting certain primary concerns for the industry but they also go hand in hand with many other challenges, some of which have been very
longstanding.

We're, of course, also looking at those countries and their practices against the criteria that are set out in the statute for priority foreign countries. And, we believe that each of these countries meets those criteria.

CHAIR KENDALL: Thank you very much and thank you for your testimony.

At this point, I'd like to invite the representatives from Public Citizen to testify.

And, please state your name for the record.

MS. KILIC: Hi, it's Burcu Kilic from Public Citizen. Thank you very much.

Thanks for providing me the opportunity to testify here today on behalf of Public Citizen and it's more than 400 members and supporters.

Public Citizen is national nonprofit customer advocacy organization with a 45-year history of representing customers interests in Congress, Executive Branch and the courts.
Public Citizen's Access to Medicines Program works with partners worldwide to improve health outcomes through use of pharmaceutical cost lowering measures including generic competition.

We submitted our written comments for this review last month. My testimony will draw upon those comments and our experiences working on the ground with government agencies, civil society organizations, academics and patient groups.

I will follow the same methodology as our written comments. My oral testimony, however, will focus on two countries, Malaysia and Colombia.

But, before that, I would like to note some commitments which are articulated in past Special 301 reports such as the United States respects and trading partners try to predict public health and, in particular, to promote access to medicines for all.

And, the United States respects its
trading partners' rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement.

We support these commitments which echo the World Trade Organization's Doha declaration on TRIPS Agreement and public health.

In compliance with these commitments, we would like to address specific practices that can and should be improved.

We suggest the following principles to support this modest reform.

The Special 301 report should omit any reference, whether express or implied, to any country's TRIPS compliant or FDA compliant policies that advance the public interest.

The Special 301 report should only address intellectual property, not ancillary public policies such as pharmaceutical pricing unless those policies are specifically alleged to be discriminatory.

The Special 301 report should not list countries for adopting U.S. policy preferences --
for not adopting U.S. policy preferences if those
countries have no bilateral or international
obligation to adopt the same.

    We distinguish between TRIPS and FDA
standards and we want you to do the same.

    We observed that some countries are
criticized for not adopting measures such as data
exclusivity, patent linkage or biologics
exclusivity, even if that country doesn't have a
trade agreement with the United States expressly
and specifically requiring so.

    Last, but not least, criticism in the
Special 301 report should be accompanied by
express and clearly articulated criteria.

    Applying these principles to our
analysis, I'd like to share some of our
observations and comments.

    I'm going to start with Malaysia as it
is one of the countries I've been working on
since 2011.

    Malaysia hasn't been on the Special
301 list since 2012. This year, PhRMA and BIO
asked you to treat Malaysia as priority foreign country for its decision to expropriate patent rights of general sciences which is called biopharma at disregard of patent rights.

Having read both PhRMA and BIO's submissions and heard their testimony today, I would like to do some fact checking.

As of 2015, it is estimated that around 143 million people are infected with Hepatitis C. Hepatitis C infects and damages the liver, and that's the largest organ in our bodies.

The virus usually spreads through a contact with infected blood. It is most commonly transmitted through sharing of needles by injection drug users.

Healthcare workers are also at risk through needle sticks and as are babies born to mothers with Hepatitis C.

But, also, you're at a higher risk if you get a blood transfusion, an organ transplant before 1992.
Most people that were infected with Hepatitis C don't have any symptoms for years. For most patients, it's a chronic illness which means that it doesn't go away. And, for many, it leads to cirrhosis or liver cancer.

An estimated 3.5 million people in the United States are living with chronic Hepatitis C infection. And, most don't feel ill or know they're infected according to the Centers for Disease Control and Prevention.

More than 500,000 people have been suffering from Hepatitis C in Malaysia. Sofosbuvir Sovaldi when used with another drug can virtually cure most of the cases of Hepatitis C in 12 months -- 12 weeks.

The list price of Sovaldi set by the patent holder, Gilead Sciences in the U.S. is $84,000; and, in Malaysia, this is $71,000.

The median household income in Malaysia is only $4,500. So, the price is about 16 times higher than a family's total income.

Apart from the price, the
patentability of the drug is questionable despite its medical benefits and the image is based on old science and it's disclosed in other patent applications.

In 2004, Gilead signed a nonexclusive licensing agreement with seven India based companies covering 91 lower and middle income countries, but Malaysia was excluded from the licenses.

The Malaysian government engaged in negotiations with Gilead for two years to be included in the licenses and reduce the price, but the negotiations failed because Gilead didn't offer a price lower than $12,000.

A year later, in September 2017, after consultations with the relevant stakeholders, Malaysian government authorized government use of Sofosbuvir Sovaldi and just before the government authorization, in August 12, 2017, Gilead announced that on Twitter that the scope of licenses is extended to cover Malaysia. There was no official announcement or notification to
the Malaysian government.

This was a very strategic and timely
tweet which aimed to anticipate Malaysian's
government decision on government use. By doing
so, Gilead hoped to avoid its reputational damage
and wiggle its way out.

I see that my time is up, so I'm going
to stop here in the interest of time. I mean, we
have a very comprehensive submission, I recommend
you to read that. And, we will also submit our
comments on Malaysia and Colombia as a post-
hearing submission.

CHAIR KENDALL: Thank you very much
for your testimony.

The first question is from HHS.

MS. BLEIMUND: Thank you.

You may have already answered part of
this, but you asserted that health advocates in
Malaysia found that a voluntary license would not
be as effective as the Malaysia own imports plan
at reducing price and expanding access.

Can you provide any more detail on
this? We looked at the WTO report that was cited, but it doesn't appear to address this issue with respect to Malaysia.

MS. KILIC: Yes, sure.

Just to add on what I said about the voluntary license, so the Malaysia government negotiated the prices for two years which the negotiations failed. And then they decided to go with the government use.

And, the government use only applies for the noncommercial public use. So, it's not like commercial, it's not for the local industry. It's only for the sale in the public hospitals.

And, they were just about to issue the government use and Gilead tweeted and said that, oh, we expanded the scope of the voluntary licenses, now it covers Malaysia.

But, it was just one tweet, that wasn't an official announcement. And the governments do not act on tweets. So, the government cabinet, they went on their decision to issue government use licenses for the public
1 hospitals.

2 Now, the price is like, let me check this here, so the price is, yes, 1000 Ringgit. Like there are -- the ability to seek treatment is available in Malaysia for -- in public hospital and clinics. It's the 1000 Ringgit which is equal to $250.

3 And, Indonesia is part of the Gilead licenses and, according to license conditions, the price for Indonesia is like almost $300 per month. So, this is a treatment for 12 weeks which is like more than like three months. So, the price is still higher, the price which is offered by Gilead just before the government use licenses on Twitter is still higher than the price that the Malaysians are like providing this drug to Malaysian patients.

4 CHAIR KENDALL: Thank you very much.

5 The next question is from Department of State.

6 MS. DYER: Thank you for being here today.
What is Public Citizens' view of the observation that certain countries may have failed to address obstacles to healthcare access such as import taxes, lack of moral law and underdeveloped supply chains, the resolution of which would likely bring tangible health related benefits without undermining incentives for application?

Thank you.

MS. KILIC: Public Citizen has a very clear position on Special 301 lists and Special 301 report.

We believe that that report should only address the intellectual property issues, not the ancillary policies like the public health policies.

So, but we will be able to -- if you are asking about our position, we can submit a position about this as a post-hearing comment. But, we strongly believe that we should be discussing intellectual property issues here. That's the scope of the Special 301 list.
MS. DYER: Thank you.

CHAIR KENDALL: And, the final question is from USTR.

MR. S. CHANG: Thank you.

In other public submissions for this hearing, we have heard that, for example, most biotechnology companies do not have products on the market and rely heavily on the strength and scope of intellectual property rights to generate the investments needed to commercialize their technologies.

How is your response to concern that weakening IP protection enforcement could prevent small and medium sized companies from bringing products to market?

MS. KILIC: I'm not clear what you mean by weakening intellectual property protection because like all the countries like which are members of WHO have the same standards as TRIPS standards.

So, and there's nothing like weakening of intellectual property, instead like there is
strengthening, there is like all these efforts to strengthen the intellectual property policies.

And, when we talk about innovation, I wrote my PhD on pharmaceutical innovation and I can give you -- I can talk about this for like five hours.

But, when we talk about SMEs, SMEs are very particular, you know, and they have like the special circumstances apply to SMEs and we need to -- we also need to distinguish which SMEs are we talking about. Are we talking about SMEs in the United States or are we talking about SMEs in other countries?

So, it is important to distinguish between the SME and usually, biotechnology industries using this line now, we are a bunch of SMEs, the other biotechnological innovation starts in the SMEs.

But, then, you know, those spinoff companies usually like get acquired by the big pharmaceutical companies and the companies, the big pharmaceutical companies which we call
corporations sell those drugs in the market, not the SMEs.

CHAIR KENDALL: Thank you very much for your testimony.

At this point, I'd like to call representatives of the Trademark Working Group to the table.

And a reminder to state your name for the record.

MR. KILMER: Good afternoon, Paul Kilmer on behalf of the Trademark Working Group.

This year, the Trademark Working Group asked that its participants identify those foreign trademark laws and practices that cost them the most time and money.

The most costly trademark matters identified by our participants are, number one, the absence of relative grounds or likelihood of confusion examination by foreign trademark offices.

The absence of relative ground refusals in jurisdictions such as the European
Union and its member states is leading to thousands of registrations for virtually identical marks for overlapping or highly related goods and services.

This fact has forced U.S. companies to bring millions of dollars' worth of what should be unnecessary opposition proceedings every year.

Number two, the absence of default judgments in opposition and invalidation proceedings in China, Europe, Brazil, Chile, Japan and South Korea. The unavailability of default judgments forces U.S. companies to reduce evidence and detailed arguments against applicants and registrants who have expressed no interest in defending their trademark filings.

Number three, requirements for recordation of licensed users in nations such as Brazil, India, Nigeria, Pakistan and Thailand. Such requirements are cumbersome and unnecessary and represent a trap for the unwary which may lead to forfeiture of trademark rights.

Number four, legalization requirements
in nations such as Argentina, China, Egypt, Mexico and Russia continue to unnecessarily increase the costs and impede the ability of U.S. trademark owners to register and otherwise protect their rights.

Number five, the lack of acceptance of letters of consent or coexistence agreements to allow for registration of similar marks in nations such as Argentina, Brazil, China, Japan, Mexico and Thailand creates an unnecessary bar to registration.

The U.S. Patent and Trademark office has long recognized that commercial enterprises are generally in a better position than governments to assess whether the concurrent use of their respective marks will create consumer confusion.

Number six, China in general. The bulk of comments received by our group relate to issues encountered by foreign trademark owners in China.

These issues include elimination of
direct appeals from the China Trademark Office to the Trademark Review and Adjudication Board by unsuccessful opposers, most of whom are foreign companies.

This situation is exacerbated by continued poor decision making by China Trademark Office opposition examiners.

The Chinese system also continues to suffer from a disregard for affidavits and witness declarations in inter partes proceedings.

There are also unreasonably high standards for establishing well known mark status and narrow protection for marks declared well known.

A glaring lack of transparency invades all phases of trademark prosecution, opposition and invalidation practice in China.

Number seven, oppositions, the absence of effective opposition proceedings in a number of nations such as Russia, Ukraine, Indonesia and Panama allows trademark pirates to steal valuable brands, especially those of foreign trademark
owners.

Number eight, the slows, nations such as India, Brazil, the Philippines and Malaysia are notorious in slow and adjudicating trademark oppositions and cancellations.

India is adjudicating only more recently filed proceedings in a timely manner.

Infringers take advantage of such nonfunctioning systems to substantially delay registration of foreign trademarks.

Number nine, certification marks, despite USTR highlighting this area in its last four Special 301 reports, many nations ranging from Algeria to Yemen still do not afford protection to certification marks.

Number ten, the multi-class applications, more than 35 nations including Brazil, Mexico, the Philippines, South Africa and Thailand still require single class trademark applications.

Such systems lead to additional cost, both in terms of initial filings and in relation
to docketing and maintenance of multiple
registration.

South Paris convention applications,
there still continue to be several nations in
which newly filed applications may not be
effectively located during the six month Paris
Convention priority period.

These include Cyprus, Guiana,
Indonesia and sometimes China, although indexing
in China has begun to pick up in recent years.

Finally, a number of nations do not
have letter of protest procedures available to
object to applications under examination.

These nations include Australia,
Brazil, China Colombia, South Africa and
Thailand.

Have letter of protest procedures
would prevent infringing and otherwise
objectionable marks for being advertised for
purposes of opposition, thus reducing the cost of
objecting to inappropriate filings.

Thank you.
CHAIR KENDALL: Thank you very much for your testimony.

The first question is from USTR.

MR. S. CHANG: Among the many issues you listed in your submission, which should the government of India prioritize for a near term fix?

MR. KILMER: I think the most important one is to catch up on very ancient cancellation and opposition proceedings.

I have a couple of proceedings pending for clients of mine that go back 12 to 14 years. And, I think if they could begin the process of eliminating that tremendous backlog of old opposition and cancellation proceedings, it would go a long way toward satisfying a lot of the issues that have been raised in relation to India.

CHAIR KENDALL: Thank you.

The next question is from USPTL.

MR. BERDUT: Thank you.

You noted that two of the most costly
issues for trademark owners are the mandatory recordation of licenses or registered user requirements and the lack of default judgments.

MR. KILMER: Yes.

MR. BERDUT: In countries where license recordal is not mandatory, can you provide examples where non-recordable can hinder a company's ability to enforce its marks?

Another question, similarly, in jurisdictions without default judgments, do you encounter instances where companies have had to waste resources defending against frivolous oppositions?

MR. KILMER: Yes, in relation to recordal of licensed user, there have been instances where companies have actually lost their trademark rights entirely by failing to abide by licensed user requirements.

And, I personally experienced that with a couple of clients of mine. So, it can be more than a little detrimental to fail to record licensed users in certain nations.
And, we detail in our full report those nations that have the most egregious, if you will, requirements for licensed users.

In terms of default judgment, I don't -- I'm really not familiar with any instances in which U.S. companies have been adversely affected by nations that impose default judgments. Is that the nature of your inquiry?

MR. S. CHANG: Yes, sir.

MR. KILMER: Okay. I'm really not familiar with that. I think most American companies are prepared to encounter the U.S. legal system. And, I think they're greatly relieved when they go overseas and they don't have discovery and they don't have motions practice and they don't have live witnesses and everything is done on written submissions in the form of affidavits and so forth.

So, I think they actually find, quite frankly, many foreign opposition cancellation litigation procedures a lot less costly and time consuming than what we have in the United States.
and are in an odd way grateful to be able to take advantage of those systems.

CHAIR KENDALL: Thank you very much.

The next question is from Department of State.

MR. KILMER: Sorry, don't want to leave too soon.

MS. DYER: Thank you for being here.

Your written submission touches a little bit upon on the European Union including that the standard for proving acquired distinctiveness for configuration marks appears to be higher than many other jurisdictions.

Can you elaborate more on your assessment of the EU and what reforms you would recommend seeing take place there?

MR. KILMER: Yes, I mean, definitely evidence of proof of what we would call secondary meaning consumer recognition of design marks and logos and as well as all kinds of trade dresses, a much higher standard to meet in the EU than it is here.
They also have design legislation
which I think is confusing still to a lot of
American companies as to what is protected under
European design legislation versus what is
protected by trademark rights.

And, I would like to see a little more
clarification in that area as well.

But, as I stated in my comments, I
mean the major issue with the European Union is
the absence of likelihood of confusion analysis,
relative rights examination in the trademark
examination process.

That is just allowing hundreds of
marks, if not thousands of marks to get through
the European system every year that are almost
identical to U.S. trademark owners' rights in
Europe.

And, they just go through this system
and then the U.S. trademark owner has to first
catch them, find out they are there and then
spend the time and money to oppose them. And,
most of those cases, again, are not defended and
the European Union doesn't have default judgments.

So, we have to end up going through the entire process for our clients, thousands and thousands of dollars are spent and the other side doesn't even bother to defend. At the end of the day, yes, you win, but at what cost?

CHAIR KENDALL: Thank you very much for your testimony.

At this time, I'd like to call the representative for the Union for Affordable Cancer Treatment to testify.

And, please state your name for the record.

MS. RESS: Manon Ress for the Union for Affordable Cancer Treatment. Good afternoon, I put my glasses, I have to make a choice between seeing my notes or you, I'm at that point.

CHAIR KENDALL: Choose your notes.

MS. RESS: I'm speaking today on behalf of the Union for Affordable Cancer Treatment which filed a comments in this docket.
The Union for Affordable Cancer Treatment, as the name indicates, created in 2014 is concerned about the ever increasing cost of cancer indication in the U.S. and globally and we are committed to universal access to new technologies at affordable prices.

Based on the process that brings us here again as well as comments provided by industry representatives, the staff of USTR will, I quote, call out foreign countries and expose the laws, policies and practices that fail to provide adequate and effective IP protection and enforcement, end of quote.

USTR says one of the, I quote again, top trade priorities for the Trump Administration is to use all possible sources of leverage, end quote.

In order to ensure that U.S., and I'm quoting again, that U.S. owners of IP have a full and fair opportunity to use and profit from their IP around the globe, end quote.
What's wrong with this? The Administration aggressive efforts to defend Americans from all foreign IP related trade barriers, end quote, means in plain language, in cancer patients language, in regards to new drugs, vaccine and diagnostic technology higher prices.

Higher prices means several things for patients which is another word for people. People who are injured or have a disease or a condition that requires a treatment that involves a new drug.

Higher prices mean that many people and, indeed, most people who need a new drug won't have access. And those how do, may face financial hardship, a financial disaster crisis coming on top of another medical crisis.

That's what PhRMA wants from you, they want you to use all possible sources of leverage to make drug prices higher. They want you to create a political landscape with countries like Colombia, Chile, Peru, Thailand, Brazil,
Malaysia, Indonesia, South Africa, India and even the Netherlands do not use lawful compulsory licenses to address excessive pricing on new drugs.

You are supposed to be the defenders of the unfettered monopolies on life saving technologies.

If you succeed, people will die and people will suffer and healthcare budget will waste cost scarce resources on overpriced medicine.

So, UACT, of course, is opposed to this approach. UACT does not want USTR to put patents before patients or drug companies before people.

UACT is also committed to innovation. We need it. And we know that this depends upon access to knowledge and both public and private sector investment in R&D.

Because UACT favors both innovation and access, we support efforts in the U.S. commerce and around the world to reform a system
of financing medical innovation.

We want government, including the United States, to progressive delink the incentive to invest in R&D from the prices of product that we have to pay.

We also want the global negotiation on innovation to stop focusing solely on product sector incentive like patent monopolies.

Including global norms in R&D funding, government need to embrace more inclusive approaches that recognize the value and importance of public sector investment in biomedical R&D as in the U.S.

The United States is a world leader in public sector funding of R&D through such agencies as the NIH, BARDA, the National Science Foundation, Department of Defense that runs a fair on energy.

USTR should be encouraging other government to step up their public sector funding on biomedical R&D including, most importantly, the elements that become public goods advancing
medical science.

UACT is concerned about people living in foreign countries including the billions of persons, the majority of the world population, in fact, living in developing countries.

Many Americans have little idea, if any, what high drug prices mean for a country with a per capita income that is one-fifth or one-tenth of the United States of America.

In 2016, the United States, had a per capita income of over $56,000 a year. Malaysia, has a per capita income of $9,860, just 17 percent of the U.S.

Colombia's per capita income was $6,310, 11 percent of the U.S.

India has a per capita income of $1,607, less than 3 percent of the U.S.

And for the bottom 80 percent of the population in these countries, things are much, much worse.

If you target this country over drug prices, you are getting -- you are going to kill
poor people, more poor people.

    But concerns of people living outside
the United States is not our only concern. I
live right here, I'm a cancer patient. I'm alive
because of an effective new drug that is still
expensive.

    Every three weeks since 2010, it's
about $20,000. I'm in touch with other cancer
patients who can't afford this. We are all
living in fear we will lose our insurance and be
forced to pay the 20 or 30 percent of the cost of
drugs that can cost more than $150,000 per year
or be denied coverage because a drug is off-label
or off formulary or because of other real
barriers to reimbursement and access.

    But we all know the United States
itself needs to curb excessive prices on drugs.
If you force every other country to abandon the
means of doing so, you lock the United States
into an expensive and unsustainable system that
we can't afford and which is hurting us more than
many here will admit.
Thank you.

CHAIR KENDALL: Thank you very much for your testimony.

The first question is from HHS.

MS. BLEIMUND: You have raised a number of important concerns about the impact and barriers to access to medicines can have on patients in the United States and abroad.

However, cancer treatment is also an area where recent innovations have generated enormous benefits for patients.

Do you have any concerns about how a lack of adequate and effective intellectual property protection in certain countries might impact incentives for future innovations in cancer treatments?

MS. RESS: Well, of course, I would like to ask the members of UACT to answer in writing to your very interesting question.

My first instinct is always, as you know, to tell you that innovation is probably even more important to patients than to many
representatives of the industry here because it's a question of life and death. So, it's not just money.

And, I do think that we believe that innovation is costly and patients recognize that they have to pay for innovation, we just don't like the rationing which is due to the financing is based on the monopoly and we think there must be other ways.

You all are very creative and intelligent people here. Is there any other way to finance something that you make it scarce and almost inaccessible for most people in the world?

CHAIR KENDALL: Thank you.

I think the answer to your question, if I had it, I would probably have a different job in the U.S. government.

(Laughter.)

CHAIR KENDALL: And which gets to this question from USTR which is, do you believe that U.S. trade policy should reflect current U.S. IP law and policy?
MS. RESS: Well, I would say that we are, at UACT, and I think most people I work with we are all opposed to counterfeit, we are all opposed to piracy and infringement.

We do think that when it comes to patent and medicine, life-saving medicine, there should be a different way to look at it from your point of view.

And, that's why I'm here today, again, is to remind you that this is about life and death for many people and maybe people in your families, too.

So, it's not as a trademark, I'm all for the trademark in Europe also and in the U.S. But they're a higher norm in Europe from what I understand.

And, even for punishing single piracy, but I would say, when it comes to access to medicine, there must be a better way to deal with issue than to prevent --- lower the cost and increasing access.

CHAIR KENDALL: Thank you very much.
And, the next question is from the State Department.

MS. DYER: Your written testimony and your testimony today talked a lot about drug pricing. I wanted to follow on with a similar question previously asked.

What is your organization's assessment of the observation of certain countries may have failed to address other obstacles to healthcare access such as import taxes, lack of rule of law and underdeveloped supply chains, the resolution of which could bring tangible healthcare benefits without undermining incentives for innovation?

MS. RESS: Well, thank you for your question. I'm not an IP lawyer, but I do understand it is about IP mostly.

But, I will say when I see the kind of money that some countries have to spend on access to medicine, it's a wonder that they can spend any money on anything else.

And, actually, in the U.S., we have a lot of schemes to, in a way, try to lower the
price of medicine.

Therefore, we can afford to have hospital and nurses and doctors and medical school.

And, I do think that there's a problem with the focus on making the budget of this country totally bankrupt so they don't have any more resources to spend on anything else if they want to save a few people with prostate cancer or lung cancer.

And, some of the countries that are doing these things like Japan or Korea are being targeted in the 301 report when, in fact, they're doing what either we should do or we are actually doing.

CHAIR KENDALL: Thank you very much and thank you for your testimony.

At this time, I'd like to call representatives from the U.S. Chamber of Commerce to testify.

And, please state your name for the record.
MS. SZYMANSKI: Good afternoon. I have a little bit of cold, so excuse my scratchy voice.

My name is Ellen Szymanski, I'm Senior Director of International IP at the U.S. Chamber of Commerce Global Innovation Policy Center.

Thank you for the opportunity to testify and thank you to the U.S. government for all your efforts to promote the protection of intellectual property worldwide.

Our submission seeks to highlight both systemic and country specific challenges. The countries we included this year were selected based on market size, geopolitical significance and specific IP issues.

This year, the Chamber released its International IP Index on February 8th. The index is an empirical assessment of the IP systems in 50 developmentally and geographically diverse economies around the world and it represents that 90 percent of GDP.

We used over 4,000 data points to
finalize these results.

The 2018 index reveals a number of trends in global IP protection over the last year. The U.S., UK and European economies, for example, remain atop the global IP rankings.

Throughout 2017, courts across the EU, UK and Australia utilized recent legislative changes to bolster the protection of creative content online.

India undertook important steps to recognize patentability computer related inventions and sustained efforts roll out IP awareness programs and workshops to implement the tenants of its 2016 National IPR policy.

Many other countries are building stronger foundations for IP, including Indonesia, Thailand and Vietnam through enforcement and awareness campaigns, et cetera.

A number of countries, including Malaysia and Saudi Arabia introduced policies to enable innovators and creators to utilize IP as an economic commercial asset to encourage
legitimate technology transfer.

Obstacles to securing effective patent protection for innovative products emerged in a number of key global markets as well in the EU, Australia and Saudi Arabia.

Both Malaysia and Colombia use government use license and regulatory proposals respectively to circumvent patent protection for innovative biopharmaceutical products to drive down prices.

South Africa published a draft IP policy which includes proposals to weaken patent protection.

Despite the Supreme Court rulings overturning the promise doctrine and strong federal circuit court decisions on digital rights management, the Canadian government's commitment to IP led innovation continues to be called into question, though its action -- through its action on free trade negotiations, proposal to change pricing policies that strip away the fair market value for innovation.
The IP Index illustrates how countries that invest more in robust IP systems are more likely to receive numerous economic benefits.

For example, countries that do well in the index are 45 percent more likely to have their innovation funded, 60 percent more receptive to entrepreneurship. They are producing 75 percent more output in creative and innovative sectors and they're 25 percent better at utilizing new technology.

This speaks to the core principle that is fundamental to a well-functioning innovative and creative sector, and that's the ability to receive fair value for your inventions.

We hope that the index serves as tool for all government who hope to become knowledge based economies through stronger IP frameworks.

Unfortunately, we're also seeing emerging global trends of degradation of IP rights in some of our most developed economies. These trends track beyond the ongoing experiences of our member companies in the world's key
markets.

This includes online IP theft, counterfeits, illicit streaming devices, challenges relating to fair pricing for innovation, demands for creative designs and consumer products and inadequate protection of trade secrets and economic espionage.

Trade secrets, for example, has become an increasingly valuable asset, but also an increasingly vulnerable asset.

While we take note of many of these big challenges, there have been some positive steps as well.

Furthermore, our Special 301 submission takes a deeper dive into opportunities and challenges in Australia, Brazil, Canada, China, Colombia, the European Union, India, Indonesia, Malaysia, Russia, South Africa and Turkey, it's 110 pages, so thank you for taking your time with it.

On China, we know the Administration energies have focused on the Section 301
investigation into China's technology transfer IP and innovation policies.

We believe these issues identified by the Administration are longstanding and have undermined the value held by American companies.

The Chamber is committed to working with the Administration to find a measured solution that protects American jobs and global competitiveness and the bilateral economic relationship.

Thank you very much.

CHAIR KENDALL: Thank you very much for your testimony.

The first question is from USTR.

MR. S. CHANG: Thank you again.

You just mentioned some positive developments in your statement as well, but are there any countries that have been listed in previous Special 301 reports for issues of concern to your members that you would no longer recommend we include if, for example, the problem is not of the same size or importance of the
markets that are developing?

MS. SZYMANSKI: That is a great question and I don't remember off hand every country that we covered last year. So, if I could answer that afterwards, I'd be happy to do that in a written submission.

CHAIR KENDALL: Thank you very much.

The next question is from the U.S. Copyright Office.

MS. SCHULTZ: Good afternoon.

For Australia, could you provide more details on why you believe that expanding their copyright safe harbor to all online providers would undermine its copyright system?

MS. SZYMANSKI: Sure. So, safe harbors is an important part of creating an effective copyright protection system.

But, if it's misused, if it's misapplied, if it's expanded, then it's no longer a safe harbor, it's more like a safe ocean.

And, we have to create a digital environment that is safe for consumers and also
allows the creative arts to make a living wage of their work.

If we aren't protecting content, then what we're doing is we're creating a system where only hobbyists, the independently wealthy or maybe artists who have some backing by charitable works is able to make a living wage and that's what we don't want.

There's a tremendous international content market that's not being developed and we would encourage countries around the world to develop proper safe harbor provisions as well as increased copyright protection in order to develop those industries.

CHAIR KENDALL: Thank you very much.

The next question is from HHS.

MS. BLEIMUND: Thank you.

You state that INVIMA's process to notify pharmaceutical patent holders when their patents could be infringed is difficult to utilize due to, quote, key gaps in Colombia's civil administrative framework.
Could you elaborate on those key gaps and how they impair the effectiveness of Colombia's system?

MS. SZYMANSKI: Well, I do know that we had a team meeting with the Colombia Minister today and I'm not as familiar with that detail on Columbia. But I do know it's in our submission. I'd be happy to follow up with more detail information.

CHAIR KENDALL: Thank you very much, we appreciate your testimony.

I'd now like to call representatives from U.S.-India Strategic Partnership Forum to testify.

And, please state your name for the record.

MR. VARMA: Good afternoon, Gaurav Varma, Chief Operating Officer of the U.S.-India Strategic Partnership Forum.

Thank you to the committee for giving us this opportunity.

USISPF, or The Forum, is a nonprofit
organization that was launched last year. The Forum has 30 Board members as their executives, including a dozen Fortune 500 CEOs, three former U.S. Ambassadors to India, a former Secretary of Defense and other senior executives.

The Forum represents 200-plus member countries from various sectors including IT, finance, defense, retail, healthcare, energy, manufacturing and food and agriculture.

It's important to note that the U.S. industries intellectual property experience in India differs by sector. For many of our Forum members, the IP experience in India has been positive and they have not faced serious IP issues.

In 2017, we saw several key takeaways with regards to India's IP environment.

In my testimony today, I will highlight some positive developments first.

Over the past year, the Cell for IPR Promotion and Management conducted several programs for enforcement officials and judges.
CIPAM also launched an IPR awareness campaign for children and an IPR enforcement kit in conjunction with the Federation of Indian Chambers of Commerce.

In 2017, India also merged -- India also announced a merger of the Intellectual Property Appellate Board and the Copyright Board. This was significant as the Copyright Board had previously not been functional.

The IPAB has appointed one chairman and we hope that royalty hearings will ensue so that the pending cases can be addressed.

Moreover, the Copyright's Office now has now published details on copyright cases on its website, increasing efficiency and transparency.

To tackle online privacy issues, CIPAM in collaboration with the National Internet Exchange of India identified 80 infringing websites last year.

The Forum commends the states of Maharashtra, Karnataka, Madhya Pradesh, Andhra
Pradesh, and Tamil Nadu who have established IP commercial codes. India's patent administration is improving with the complete digitization of its patent office in a move that is expected to increase efficiency and improve the patent review process.

On the regulatory side, our members have welcomed the revised patent examination guidelines for computer related inventions, removing the requirement that patents for software could only be claimed in conjunction with novel hardware.

India has also extended the startup IP scheme to foreign startups which will provide a fast-track mechanism for the grant of patent.

To further streamline the trademark process trademark rules, 2017 we implemented in March which will review the number of forms from 74 to eight consolidated forms for a trademark application.

These efforts that I just mentioned are greatly improving India's IPR environment and
the Forum applauds the work that India has done over the past year on IP protection.

That said, there are some ongoing sector specific IP issues and developments facing foreign members that we would like to bring to your attention.

In the media and entertainment sector, the Indian film industry earns $2 billion from legitimate sources such as screening at theaters, home videos and TV rights.

However, it loses nearly $700 million due to piracy which equates to 35 percent of the legitimate revenue.

Our member companies in the entertainment sector have observed that many piracy websites located outside India are supported by online advertisements that are targeted towards Indian consumers.

We would like to recommend the creation of a National Copyright Enforcement Task Force. This Task Force would reside within the IPR Cell and its aim should be to enforce
copyright laws.

    The Forum further recommends that DIPP
and the Copyright Board be fully empowered to
address all copyright issues. In this regard,
other regulatory boards should eliminate
regulations that conflict with the Copyrights Act
granting of exclusive rights.

    The Forum also recommends that India
should discourage advertising they place on --
that place ads on piracy websites.

    Those ads give piracy sites the
revenue they need to continue their unlawful
actions.

    Biopharma infringements remain a
concern. These infringements are often detected
too late after the damage is done.

    Moreover, lack of patent linkage in
the pharmaceutical industry provides leeway to
infringers.

    Our pharmaceutical members have voiced
their concern regarding the federal stricter
price controls for patented drugs. Forum members
have also noted and NPP uses the language of compulsory license to control prices for patented drugs which is against the principles of patent law and possibly not TRIPS compliant.

We have expressed our concerns on CL. Based on these issues in the life sciences sector, the Forum recommends the government of India maintain a centralized list of patented drug manufacturers requiring the company to seek license to manufacture a drug to report whether the drug is patented or not.

We have noted in our submission at paragraph 19 of the drug price control order. It was inherently designed for certain emergency situations and for a limited period.

The reference to use paragraph 19 as a continuous process for price ceiling controls should be considered in operation of the legal mandate of DCPO.

The Forum also recommends creation of a committee or a task force of government of India industry and other stakeholders to drive
and incentivize innovation and further the cause of reform involved IPR regime.

In the food and agriculture sector, we have seen serious problems with the biotech regulatory policies since 2010 which have stalled the introduction of innovative products by technology developers.

The Forum strongly recommends that the government of India should desist from introducing compulsory license of patented technologies or importing artificial price ceilings which would further discourage investment and innovation in new technologies.

In my closing remarks, it is evident that government of India has taken several important steps to better the IPR regime. But, some industry concerns remain unaddressed.

The Forum believes that the IP environment must be strengthened in order to create a safe environment that will encourage innovation, entrepreneurship without concerns of infringement.
The Forum encourages both governments to initiate a bilateral IP dialogue to signify the importance of IP.

Thank you.

CHAIR KENDALL: Thank you very much for your testimony.

The first question will be from the USTR.

MR. S. CHANG: You note a number of improvements to India's IP regime over the past year. While many of these improvements have been noted, there are other industry associations in your submissions.

A common refrain is that fundamental deficiencies affecting virtually every IP discipline including patents, regulatory data protection, trade secrets, trademarks, copyrights and enforcement remained unaddressed.

Have you seen government of India actions that address fundamental issues in any of these areas that warrant stronger consideration by the U.S. government?
MR. VARMA: I think we are seeing progress. I don't think we are there as yet. A lot more needs to be done and but we are seeing a positive direction of movement from the government of India side.

CHAIR KENDALL: Thank you very much. The next question is from the U.S. PTO.

MR. SHAPIRO: So, among the Forum's pending recommendations to the government of India includes a call to improve the transparency in the marketing approval process for pharmaceutical products.

Could you please describe the scope of the current problem and the Forum's proposed solutions for India's system? Thanks.

MR. VARMA: Great question. Can I get back to you with a written submission?

MR. SHAPIRO: Absolutely.

MR. VARMA: Thank you.

CHAIR KENDALL: Thank you.

The next question is from the U.S.
Copyright Office.

MS. SCHULTZ: You mentioned a lack of coordination and interagency policies that leads to adjudication for copyrights.

What do you mean by this and what suggestions do you have for both of those issues?

MR. VARMA: I think overall, we are seeing a lack of coordination between different departments of government of India. And, that's one of the few things that we have recommended is that the powers lie within a certain agency which is the Department of Policy -- Investment Policy Promotion, DIPP.

And, that will take care of the lack of coordination over there.

CHAIR KENDALL: Thank you very much. I appreciate it.

On behalf of the Special 301 Committee, I'd like to thank all of you for taking the time out of your day to have this exchange with us. We appreciate everyone's comprehensive research, thought, problem solving
ideas and efforts that went into both the written submissions and the testimony here today.

The Special 301 docket will reopen this afternoon and remain open until midnight on March 14. Those hearing briefs by interested parties that testified today are optional.

Please follow the instructions on the agenda in the original Federal Register Notice which is also on regulations.gov.

A transcript and a video of today's hearing will be available at ustr.gov. We will do our best to get that posted within the next two weeks.

Thank you very much to my colleagues on the panel as well as all of those who testified for your time and attention and a special thanks to the personnel at USTR who took care of today's logistics and setup.

Ladies and gentlemen, the Special 301 Hearing of 2018 is now adjourned.

(Whereupon, the above-entitled matter went off the record at 3:01 p.m.)
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CERTIFICATE

This is to certify that the foregoing transcript

In the matter of: 2018 Special 301 Public Hearing

Before: US Trade Representative

Date: 03-08-18

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.

[Signature]
Court Reporter