## UNITED STATES OF AMERICA

#### OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

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# 2017 SPECIAL 301 PUBLIC HEARING

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March 8, 2017 10:00 a.m.

Office of the U.S. Trade Representative 1724 F Street, N.W. Washington, DC 20508

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#### PROCEEDINGS

(10:06 a.m.)

MR. MEHTA: Good morning, everyone. I am

Probir Mehta, the Assistant U.S. Trade

Representative for Innovation and Intellectual

Property. I'd like to welcome everyone to this

morning's public hearing for the Special 301 Report.

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

Ensuring that U.S. owners of intellectual property have a full and fair opportunity to use and profit from their IP is one of the trade priorities outlined in the President's recently released Trade Agenda.

This is the 29th Annual Special 301 Review and the 8th public hearing that USTR has hosted in

1	connection with that review. So I would like to
2	note for the transcript and recording, today is
3	Wednesday, March 8, 2017. This hearing is taking
4	place at the Office of the United States Trade
5	Representative, or USTR, in Washington, D.C. We
6	will make a transcript of today's hearing available
7	to the public on USTR's website, <u>USTR.gov</u> .
8	Today's hearing is scheduled to go until
9	approximately 2:20 p.m. I would like to ask for
10	everyone's cooperation in this endeavor to keep the
11	hearing on track.
12	First, I would like to invite my
13	colleagues on the hearing panel, all of whom
14	represent U.S. government agencies that serve on the
15	Special 301 Committee, to introduce themselves. Why
16	don't we start at the end with Omar?
17	MR. KARAWA: Good morning. My name is
18	Omar Karawa from the Department of Agriculture.
19	MR. SMITH: Good morning. I am Michael
20	Smith from the United States Patent and Trademark
21	Office.
22	MR. MITCHELL: Stevan Mitchell,

International Trade Administration, Department of 1 2 Commerce. 3 MR. LAMBERTI: Good morning, everyone.

name is Matt Lamberti. I am with the U.S.

5 Department of Justice.

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- MS. PETERSON: I am Christine Peterson. I 6 7 am with the Office of the U.S. Trade Representative.
- MS. DYER: I'm Lisa Dyer with the 8 9 Department of State.
- 10 MS. PETTIS: I'm Maureen Pettis from the 11 Department of labor.
- 12 MR. CHANG: I am Won Chang, the Department 13 of Treasury.
- 14 MS. BLEIMUND: Good morning. Emily 15 Bleimund from the Department of Health and Human 16 Services.
- 17 MS. STRONG: Good morning. Maria Strong 18 with the United States Copyright Office.
- 19 MR. MEHTA: Thanks very much. The Special 301 Subcommittee of the Trade Policy Staff Committee is comprised of the agencies you just heard from and 22 is chaired by USTR. We conduct the annual Special

301 Review each year. This review is driven by stakeholder contributions and by the contributions of Washington-based agencies and our embassy-based personnel around the world. The Subcommittee is currently in the information gathering phase. behalf of these agencies here, we thank you for the views, insights, opinions, and factual information that you will share with us today. 

The schedule of today's hearing is comprised of interested parties, foreign government officials, private sector interests, and civil society, all of who have responded to USTR's notice in the Federal Register, published on December 28th, and voluntarily requesting the opportunity to appear at this public hearing.

As a reminder, the purpose of today's hearing is to provide the Special 301 Committee with additional information that we can use in the deliberations that will lead to the publication of the 2017 301 Report to Congress on or about April 30, 2017.

This year we have received public filings

that address over 75 countries and many

country-specific IP protection and enforcement

issues that may negatively affect our bilateral

trading relationships. Those filings are available

to the public at regulations.gov. The docket number

is [USTR-2016-0026].

So we recall the statutory authority for Special 301. The Special 301 report is the result of a congressionally mandated annual review of the state of intellectual property rights protection and enforcement in trading partners around the world, which the U.S. Trade Representative conducts pursuant to Section 182 of the Trade Act of 1974, as amended by the Omnibus Trade and Competitiveness Act of 1988 and the Uruguay Round Agreements Act. The provisions of Section 182 of the Trade Act of 1974 are commonly referred to as the Special 301 provisions of the Trade Act, hence the Special 301 Report.

Specifically, Section 182 of the Trade Act requires the United States Trade Representative to identify countries that deny adequate and effective

protection of intellectual property rights or deny 1 fair and equitable market access to U.S. persons who 2 3 rely on intellectual property protection. 4 statute requires USTR to determine which, if any, 5 countries should be identified as priority foreign 6 countries. Acts, policies, or practices that are 7 the basis of a country's identification as a priority foreign country can be subject to the 8 9 procedures set out in Sections 301 to 308 of the 10 Trade Act.

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In addition to the statutorily defined PFC or priority foreign country designation, USTR created the Priority Watch List and Watch List categories to assist the Administration in pursuing the goals of the Special 301 Review. USTR is also charged with developing Priority Watch List action plans where a country has been on the Priority Watch List without change for at least one year.

So with respect to the format of today's hearing, it will be as follows. Each presenter has been allotted 10 minutes. Each presenter will start with seven minutes of prepared statements, leaving

three minutes for panel questions. However, we will remain flexible within the 10-minute period, making adjustments as needed. We will be watching the clock and will interrupt with time cues when two minutes remain and when seven minutes is about to expire.

The panel will hold its questions until
the presenter concludes his or her statement. In
some cases, we have prepared questions based on
written filings. And in others, we will respond to
your testimony today. In general, please keep in
mind the purpose of this hearing, to provide
information that the Committee can use in satisfying
the charge of the Special 301 statute when conveying
your testimony and responding to any questions that
we may ask.

We will break today twice, once for about 20 minutes after the government testimonies and again for 20 minutes about halfway through the non-government testimonies.

Without further delay, I would like to invite the Government of Bulgaria to start us off.

1 MR. KONSTANTINOV: Good morning, esteemed I appreciate the opportunity to be here 2 3 today. For the record, my name is Ivo Konstantinov, 4 first name spelled I-v-o, second name, last name 5 K-o-n-s-t-a-n-t-i-n-o-v. I am representing the 6 Government of Bulgaria today in regards to the 7 inclusion of Bulgaria on the Watch List, which I will make the case makes us very concerned. 8

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We consistently participate at the hearings each year, appealing to the esteemed panel and the U.S. government to take us out and exclude us for an array of reason I am only going to briefly go through today.

As I said, we take the matter seriously.

There are four main areas that I want to highlight
this morning that we have improved and strengthened
in this area. There are two bills that have been
proposed for amendment in the national parliament
with the full and intent purpose of ensuring respect
of intellectual property rights, including measures
being taken against online piracy. It is the
penalty code, the amendments to the penalty code,

and the proposed amendments to the law amending and supplementing the copyright and related acts, both of which await passing and the votes, which is expected to go through without problem at the next Parliament. We have elections in roughly two weeks in our country by the 44th National Assembly in the Republic of Bulgaria.

Another important area is strengthening of the role of the specialized unit for computer crime and intellectual property at the Directorate General Combating Organized Crime. It is a special structure for enforcing IPR and investigating, including online piracy. It is part of the Interior Ministry and is the spearhead of the government efforts for criminal investigation and all the measures taken for IPR enforcement. Their capacity is increasing, particularly their cooperation with the local and divisional police precincts and structures of the Ministry of Interior.

Also something important that needs to be pinpointed in regards to strengthening the capacity of the judiciary in our country is the establishment

of specialized IPR prosecutorial units in the capital city of Sofia and other big cities, and the appointment of sufficient number of lawyers in them providing detailed guidance and training, as well as closely monitoring and analyzing of their work, which is very important for capacity building and IPR enforcement.

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Finally, I want to go through a few figures, which is the cherry of the law enforcement cake. This is most important results achieved. Ιn the past year, the newly instituted pretrial proceedings for crimes against IPR have issued 285 pretrial proceedings, of which 21 proceedings for violations of copyright and related rights and 264 proceedings for violations of industrial property rights. Prosecution statements brought to the court, including indictments, agreements, proposals, number of convicted persons in them is 106 statements against 112 accused persons, of which 4 prosecution statements against 4 accused persons for violation of copyright and related rights and 102 prosecution statements against 108 accused persons.

Most importantly are the convictions.

Last year, 99 convictions out of which 96 persons for violation of industrial property rights, and 3 persons have been convicted in Bulgaria by enacted judgment decisions for violations of copyright.

Penalties have been imposed as well:

provisional imprisonments 50, 45 probations, and 50

fines. That is just, in short, the achievements of

our government in IPR enforcement.

In conclusion, I would just like to mention that both the entertainment and software industries in our country are growing. The IT community in the industry constitutes now 15 percent of our national GDP, and we have our own stake as economy and country in this because our IT community produces now content and product itself that is a very important object of IPR breaches and infringement. We are ourselves interested in taking serious measures in this.

We have also seen improvement in what we call content availability. I just want to mention trivia which is not unimportant. It is that Netflix

1	became available all over Europe, including Eastern
2	Europe last year. We don't know why, and we hope
3	that the content of Amazon Prime will become
4	available in their video and entertainment contents
5	in our part of the world. Content availability and
6	product affordability is a very important part also
7	of the measures in addition to law enforcement, of
8	course, for IPR enforcement especially in the
9	entertainment and software industries.

As I said, this is very important for us.

A lot of the U.S. IT giants have their development
and production centers and code writing units in our
country, including VMware, Hewlett-Packard, and IBM.

To us, the stakes are very high, and we appeal to
the U.S. government to be taken out of the list
because we believe that we take the matter
seriously, and we have done quite a few measures,
taken quite a few measures to improve the situation
and the environment.

 $\label{eq:with_theory} \mbox{With this I will conclude my presentation}$  and thank you again for the attention.

MR. MEHTA: Thanks very much, sir. The

1	first question for you will come from the Department
2	of State.
3	MS. DYER: What has Bulgaria done to
4	increase its resources for IPR enforcement, law
5	enforcement? You partially addressed the training,
6	but for instance, those that are fighting online
7	piracy?
8	MR. KONSTANTINOV: The new thing we
9	share the measures each year, but the new thing is
10	particularly strengthening capacity outside of the
11	capital city through the training of prosecutorial
12	units in smaller counties and municipalities, and
13	the very close cooperation of the organized crime
14	Combat Organized Crime unit with the local police
15	precincts which has increased and improved
16	significantly throughout the past three years in
17	particular. That is what we are doing in terms of
18	capacity building outside of the capital city.
19	MS. DYER: Thank you.
20	MR. MEHTA: Our second question will come
21	from the U.S. Patent and Trademark Office.
22	MR. SMITH: In your submission, you
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mention that the Council of Ministers approved a

draft project to amend the Penal Code. And then in

your statement you also state that the project was

submitted to the National Assembly at the end of

2016. Can you explain how these amendments would

improve the enforcement as well as the process and

time frame for potential approval?

MR. KONSTANTINOV: It mostly relates to the shortening of the procedures and simplifying prosecution opportunities. But may I take additional time to answer in writing to this question, to be more precise, please.

MR. MEHTA: I think we have time for one last question. Department of Justice.

MR. LAMBERTI: Thank you very much. We are very pleased to see that the Government of Bulgaria, as you mentioned in your testimony, has established specialized IPR prosecutorial units in Sofia and other major cities. And the Department of Justice, the U.S. Department of Justice actually had a role in helping found the first one in Sofia, so we are very happy about that.

1	You mentioned in your testimony that,
2	quote/unquote, "The necessary resources were
3	allocated to improve the prosecution in IPR cases."
4	Can you give us more details on this, on these
5	specialized units? What other major cities other
6	than Sofia have the units? How many specialized
7	prosecutors are in each of the units? Are they
8	dedicated 100 percent to IPR cases, or do they have
9	other types of cases? And how many cases do they
10	have?
11	MR. KONSTANTINOV: That is an excellent
12	question. I would also like to take some time to
13	send precise written answers to that, but thank you
14	for the question. It is quite important.
15	MR. LAMBERTI: Thank you.
16	MR. MEHTA: Great. Thank you very much,
17	sir, for your testimony today.
18	MR. KONSTANTINOV: We appreciate it.
19	MR. MEHTA: Just two notes. I'd like to
20	first actually invite the Government of Ukraine to
21	come up. While my colleague is coming to the
22	presentation table, first there will be an
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opportunity for post-hearing briefs, for people to
file them. They are optional, so that is a way to
supplement your response. Second, my colleague
Paulina will be providing time cues throughout the
testimony, so please do remain alert to that. Thank
you.

Welcome, sir. Please begin your testimony.

MR. SHYMKIV: Good morning, dear Chairman, distinguished panel. My name is Dmytro Shymkiv. I am Deputy Head of Presidential Administration of Ukraine and also Secretary of National Reform Council. On behalf of Government of Ukraine, I would like to express my respect to the panel. The Government of Ukraine made the decision that it's important that the senior executive comes today to testify on the situation with IPR and the developments of IPR.

IPR is one of the top priorities for the Government of Ukraine and is one of the six priorities for the roadmap of U.S.-Ukraine cooperation. I would like to cover today the five

topics which comprise the area of IPR, areas that the Government of Ukraine address.

The first one is reform of the system of state administration in IP area. The second is strengthening IP protection through judiciary reform and legislation. The third is addressing internet piracy and law enforcement. The fourth is legalization of the software used by the executive government bodies. And the final one, it is the area of collective management rights.

So on the first one I would like to inform that IP protection is listed in the top priorities of the government which has been approved by the Parliament in 2016. According to this plan, in 2016 the Government of Ukraine has approved the concept of IP reform and Action Plan for its implementation. Under this plan, the former SIPSU will be liquidated, and the national IP office, which will unite all different institutions, will be established. The process is already in place.

The key elements of IP reform consists of three things. First, institutional change and

building the capacity within the Government of Ukraine related to the IP issue. The second is alignment with national IP legislation with EU standards on the EU-Ukraine Association agenda. The third is reorganization of system of collective management, which is one of the difficult areas which I will touch base at the end of my presentation.

The second area is related to judicial reform and legislation. What is very important and never happened before in Ukraine, the new law of judicial system and the start of the judges came in force on the 30th of September 2016. That sets the new structure for the courts in Ukraine and reassessment and recruitment of the judges. What is important is that by September 30 this year, 2017, intellectual property high court will be created in Ukraine, which will be a specialized court as a court of first instance which will specialize on IPR issues particular. That is stated in the law, and it is under full execution.

At the same time, the Government of

Ukraine has approved and submitted to the Parliament 1 several laws which are related to IPR issues. 2 3 are on patent control, industrial design, and 4 trademarks, on custom procedures regarding IPR 5 protections, on geographical indications, on 6 topographies and of semiconductor products, on 7 copyright and related rights. All these laws are related to IPR. It is taken seriously with the laws 8 being developed by the Ministry of Economy, reviewed 9 10 by Ministry of Justice, and are currently under revision of the appropriate committees in the 11 12 Parliament. 13 When we are talking about addressing internet piracy and law enforcement, the very 14 15 important law being passed by the Parliament on the 16 30th of September, it is a state support of 17 cinematography, and a significant part of this law 18 is related to IPR. This law was developed in

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representative from U.S. government, U.S. Embassy,

and other stakeholders in the Ukraine environment.

cooperation with American Chamber of Commerce,

European Business Association, engagement

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President of Ukraine vetoed it. And I want to explain exactly the position of the president in this, none of the elements which are related to IPR being vetoed. The president's veto explicitly provisions that are related to the cinematography, to support of the cinematography. The key concerns that the president expressed is how the budgetary support will take place, the percentage of support, etc.

The special group where I take myself as the lead, negotiating with the industry what the necessary corrections need to be made to the law, and the revision of this law will take place during April. IPR issues and IPR provisions of this law will not be reviewed, and they will remain as they are currently in the law, in the draft law. The elements of this law are very important because the provisions put a strong control on the infringement on the internet, and the pre-action protocol is precisely described in the law. It is a new provision about criminal prosecution on copyright piracy, camcording, and card sharing. All this is

in this law.

During 2016, Cyber Police Department in Ukraine was able with the cooperation of international bodies, law enforcement bodies, was able to shut down very top rated piracy sites which have been listed in the previous Special 301 Report, such as EX.ua, FS.to, Kickass.to. These are famous torrents that's been sharing illegal IPR contents, and they have been taken down.

On legalization of the software, in 2016
Ukraine doubled its spending on their software that
are procured by the central executive bodies
reaching \$3 million. In 2017 the budget -- sorry,
the allocation of the funds continue to grow and
will be around \$3.5 million to purchase additional
software by just state bodies. When we talk about
state-owned enterprises, SOEs, last year the amount
was also increasing, reaching \$6 million. The
biggest agencies that did the procurement is the
pension fund, Ministry of Economy reduced the piracy
rate from 67 to 35 percent within its institution,
and overall audit in 2016 indicated that the piracy

rate in the state institution reduced to the level of 37 percent.

In the area of collective management, probably the area of biggest concern and probably area of slow progress, the Ministry of Justice rejected the initial proposal of the reform in this area. This month, on March 3rd, World Intellectual Property Organization was working with Ukrainian authorities to develop a new draft of the law that will be submitted to the Parliament by the government and is currently under review. All stakeholders agreed to the structure of the law.

What is very important this year also are the payments that have been collected in the Ukrainian market by CMO also increased by 23 percent. Attention is made to establish new electronic system where the transparency for all copyright holders on the collections from the broadcasting institution be visible to all copyright holders and the proper work around the CMO is done. Still, we believe that the area of CMO should additional attention from us and further

1	improvement, all this being done during the last
2	year by Ukraine.
3	Let me remind you that Ukraine is
4	currently under severe attack by Russia both in the
5	security issues as well as economic issues.
6	Nevertheless, IPR remains and will remain top
7	priority for the Ukrainian government because we
8	believe that it is one of the cornerstone of
9	building contemporary society, contemporary country
10	in the partnership with the United States of
11	America.
12	Thank you.
13	MR. MEHTA: Thanks very much for your
14	testimony. For our first question, I'd like to look
15	to our Department of State.
16	MS. DYER: Thank you very much for your
17	statement. You have outlined a number of important
18	plans that Ukraine has laid out for the year. What
19	is the most important and concrete achievement that
20	Ukraine has achieved over the past year? Thank you.

for the question. I think the top, I think,

MR. SHYMKIV: I think that -- thank you

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1	achievement is the fact that the law, which has very
2	often been discussed in this hearing before,
3	actually went through Parliament. It went through
4	the first reading. It went through the second
5	reading. It is unfortunate that the provisions
6	which is related to the supports of the
7	cinematography contradicted the budget code of
8	Ukraine, but there is a strong support by the
9	president to actually have the law passed. The veto
10	doesn't mean rejection of the law. It needs to be
11	properly corrected in some provision. That is a
12	very important step because it sets the foundation.
13	When this law was passed, the EX.ua
14	announced they're shutting down their website
15	because they understood that it's inevitable. I
16	think this is important in overall history.
17	MS. DYER: Thank you.
18	MR. MEHTA: Thanks. For our second
19	question, if I can look to the Department of Labor.
20	MS. PETTIS: Good morning. In your
21	written testimony, you indicated that a draft
22	collective management law would be provided at a

1 WIPO regional workshop that recently took place.

2 | Can you provide an update on whether the Government

3 of Ukraine has released that draft law, and what is

4 the timeline for enacting a law that promotes

5 accountability, transparency, and fairness to

6 | foreign rights holders?

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approval.

MR. SHYMKIV: Thank you. The mission took place on the 3rd of March in 2017 in Kiev. This was by the World Intellectual Property Organization. There was joint -- the experts were working with the Ministry of Economy, the designated division that is currently forming the national IP office. worked with IFPA, with CISAC, with SCARP, IFPRO, and they actually drafted this law. This law is provisioned and will be submitted by the Ministry of Economy to the revision according to procedure of the cabinet of Ministers of Ukraine. That is required revision of Ministry of Justice and additional ministries and then voted by the cabinet. Normally, at average it takes approximately months. And then it will be submitted to the Parliament for

1	At the same time, the special working
2	group is working on the software and the pilots that
3	will enable us to develop a solution that will
4	enable us to implement a system that's the proper
5	tracking of their usage of copyright objects by the
6	different institutions. Thank you.
7	MR. MEHTA: Thanks very much. Department
8	of Agriculture.
9	MR. KARAWA: Thank you. U.S. agricultural
10	and pharmaceutical companies continue to alert us to
11	the wide availability of counterfeit seeds and
12	medical products. As you are aware, these products
13	could potentially be dangerous for Ukrainian
14	consumers. What are your plans in the year 2017 on
15	eliminating these contraband products from the
16	market?
17	MR. SHYMKIV: Thank you. The area of the
18	distribution of illegitimate or counterfeit
19	products, such as PhRMA, one of their area topics
20	was not by international companies that buy their
21	products in Ukraine but also local companies in

Ukraine. The discussion which is going on right now

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is about developing a solution where there is a possibility to identify the infringement for the consumers, because when we are talking about pharmacy today, when they receive their product through a distributor, it's very difficult. The contemporary tools that are used to print out the packaging, they actually look very, very much, it is very difficult to distinguish the packaging. The only way how there is a possibility to identify it through the special technology where the tracking of the license issued for the particular pharmaceutical products is done.

Cabinet of Ministers of Ukraine developed a special program that will focus on addressing pharmaceutical products distribution, which relates to the referential pricing, but also the originality of the products, which will enable actually the proper trackage across different pharmaceutical distribution channels. We are aware that this is one of the big issues because Ukraine very often being used as a hub for distribution further to other countries. The law enforcement role of the

1	Cyber Security Police, which we established a year
2	ago, has been focusing on this.
3	MR. KARAWA: Thank you.
4	MR. MEHTA: Department of Commerce.
5	MR. MITCHELL: Good morning. Stakeholders
6	have reported that in 2016 the Ministry of Economic
7	Development and Trade did not participate in the
8	discussion of legalization of government use of
9	software and that no representative or agency has
10	been given authority to take action on this issue.
11	My question is, is this true? But if it's not, what
12	do you suppose the reason is for this misperception?
13	MR. SHYMKIV: Excuse me, could you repeat
14	who, which event?
15	MR. MITCHELL: Sure. That the Ministry of
16	Economic Development and Trade did not participate
17	in the discussion of the legalization of government
18	use of software and that no one has been given
19	authority to take action on this issue.
20	MR. SHYMKIV: Yes, sir, that's not true.
21	Everything that I have been sharing with you and the
22	establishment of the national IP office been
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1	initiated by Ministry of Economy and Trade. The
2	legalization of the Ministry of Economy and Trade,
3	which been announced on the last year here by
4	Minister of Economy and Trade, been signed the
5	memorandum with Microsoft. As I mentioned in my
6	testimony, they reduced their piracy from 67 percent
7	to 35 percent. The Ministry of Economy and Trade is
8	actually the ones who are chairing all the meetings.
9	They are the ones in direct contact with the
10	American Chamber of Commerce and are the main
11	leaders on this one. Unfortunately, they couldn't
12	be present today because the hearing has been
13	shifted and the Deputy Minister of Economy and Trade
14	had a meeting, a discussion bilateral agreement with
15	Israel, and she is currently in Israel.
16	Thank you.
17	MR. MEHTA: Great. One last question from
18	USTR.
19	MS. PETERSON: Sure. You noted in your
20	testimony that EX.ua, one of the sites that has beer
21	featured in the notorious markets list for several
22	years now, has announced intentions to close. My

question is whether the Government of Ukraine is concerned that they may resume operations and whether the Government of Ukraine has given some thought to steps that can be taken to prevent those operations from resuming?

MR. SHYMKIV: Thank you very much. The EX.ua closed their operation so the users in Ukraine cannot access the content, excluding their personal files that they would like to use. Anybody in the Ukraine can attest to that. The challenge is that the owners of EX.ua decided to move their project somewhere else. They definitely understand that the law enforcement in Ukraine will be harsh with the new legislation approved.

We believe that they will be moving to some other countries for the hosting. But as well, they understand that the service, if it will be provided in Ukraine, will have restriction and serious action from Ukrainian government.

The one notorious distributor of illegal music, the social network VKontakte, is a top concern for Ukraine because it also participates in

1	the propaganda machine against Ukrainian citizens
2	and against the western world. So we strongly
3	believe that as we looking today at or previously
4	looked at such sites as distributing illegal
5	content, we also need to look at the social networks
6	that are distributing illegal content across the
7	world from Russia.
8	MR. MEHTA: Thank you very much for your
9	testimony today.
10	MR. SHYMKIV: Thank you.
11	MR. MEHTA: The time is now 10:40. We
12	will take a quick 15-minute break, and we will
13	reconvene here at 10:55.
14	For the folks standing in the back, we
15	have a number of open seats up here, too, so we
16	would encourage you to use them. Thank you.
17	(Off the record at 10:41 a.m.)
18	(On the record at 10:55 a.m.)
19	MR. MEHTA: Welcome back. At this point,
20	I would like to call the U.SIndia Business Council
21	to please approach.
22	DR. AGHI: Good morning.
	Free State Reporting, Inc. 1378 Cape St. Claire Road

Annapolis, MD 21409 (410) 974-0947

1	MR. MEHTA: Welcome, sir. Please
2	introduce yourself for the record and begin your
3	testimony.
4	DR. AGHI: My name is Mukesh Aghi. I am
5	the President of U.SIndia Business Council. Thank
6	you for giving me the opportunity to testify today.
7	USIBC is the premier business advocacy organization
8	representing more than 400 of the largest global
9	companies with U.S. business interest both in the
10	U.S. and India. The council mission is to serve as
11	the primary interlocutor between businesses and
12	government leaders, resulting in increased trade and
13	investment to strengthen ties between the two
14	nations.
15	The council believes there have been
16	important developments related to intellectual
17	property policy in the last 12 months. These
18	developments have paved the way for improvement in
19	India's IP environment. We are encouraged by these
20	general trends.
21	In 2016 we saw many concrete
22	government-to-government dialogues continue on a

variety of IPR issues, including the U.S.-India

Trade Policy Forum and the U.S.-India Strategic and

Commercial Dialogue. The level and frequency of

engagement between the U.S. and Indian governments

has continued to build and sustain from year 2015.

USIBC has been tracking intellectual property rights development made by India in 2016. In my testimony today, I will highlight some positive developments in this sector and then list all the pending issues that remain. The council hopes that the following issues will serve as a potential agenda for further collaboration and discussion between the Government of India and the U.S. government.

The main achievement of the Government of India on the IP front has been the introduction of National IPR Policy. This document was released in May 2016, following calls for India to produce a coherent architecture for IPR in the country. The policy is intended to become part of the curriculum in major centers of learning. It includes a proposal to develop a national research institute

for IPR to educate the public further on the benefit of protecting intellectual property.

In order to focus on domestic innovation, the IPR policy means to create a safe environment in which inventors and entrepreneurs can focus their efforts on producing new and innovative product without the worry of infringement. Importantly, the policy intends to promote enforcement and adjudication of violations that are brought to light. Additionally, it aims to review existing laws surrounding IP. These laws can be updated or adjusted with consultation from stakeholders to be improved. In particular, we are encouraged by the reference to improving trade secret protection.

Following calls from stakeholders, the

Government of India consolidated copyright issues

under the umbrella of Department of Industrial

Policy and Promotion. This move will eliminate

regulatory slowdown and improve efficiency and a

welcome change.

In 2016 we saw the Government of India add 459 new technically competent patent examiners in

various fields of technology. On the trademark side, 100 more examiners were added on a contractual basis. Currently, 62 regular appointments are in the pipeline to help alleviate backlogs.

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In January 2017 the Ministry of Commerce and Industry announced the launch of an IPR enforcement toolkit for police and IPR awareness campaign for children. The Cell for IPR Promotion Management, CIPAM, and the Federation of Indian Chamber of Commerce jointly prepared the toolkit for This allows law enforcement officials to police. quickly identify acts of counterfeiting and piracy, in addition to prescribing the guidelines for search and seizure for IP crimes. IPR education remains a priority issue, and CIPAM has stated that in coordination with the International Trademark Association, they will launch an IPR awareness campaign aimed at students to educate at a young age the importance of respecting IPR and danger of piracy.

In 2016 the courts in India issued six injunctions in favor of patent holders on different

occasions. These injunctions were granted on behalf of major life sciences, medical equipment, and telecommunication manufacturing companies when blatant patent violations took place. Additionally, the Delhi High Court upheld the patents of a major American audio company against infringement from domestic entities. These legal actions are an optimistic sign if they continue to become a trend.

Moving onto the pending issues that remain on IPR, our member companies have noted that implementation of the National IPR Policy has been slow, leaving many of the concerns it aims to address unchanged. Additionally, USIBC believes that there are ways we can work together to continue to strengthen the IPR policy. Specifically, the IPR policy could be improved by providing specificity with respect to inter-ministerial coordination on implementation, budget allocation, and enforcement.

The Government of India has, as I mentioned earlier, enhanced capacity by increasing the number of patent examiners. But other areas of the policy should remain and require more attention.

Implementation of the plan offers an opportunity to
advance concrete strategic and practical
improvements of the IP regime and could serve as a
basis of improving India's role as a global

innovation leader.

The Government of India must ensure compulsory statutory licenses comply with the Berne Convention and the TRIPS Agreement. Compulsory licenses should be granted in exceptional circumstances as a last resort. They do not provide sustainable solutions to long-term challenges.

Decisions should be made on public health grounds through fair and transparent processes that involve stakeholder participation and consider all the facts and options.

In the biopharmaceutical sector, companies saw some infringement of patents in 2016. Such infringements were often detected in the marketplace, and therefore, much of the damage was already done by the time the patent holders were able to seek recourse. Due to this, the Indian government should produce stronger and clearer legal

provisions and clear enforcement-related infringement of IPR and better protecting patent rights and to create predictability in the market.

There have been several cases of the Indian Patent Office denying the grant of patents based on interpretations of Section 3(d) of the Patent Act. Often, this contrasts with a grant of patent for same innovations by major patent offices around the world. Specifically, it requires interpretation of Section 3(d) to allow for outcomes that are both predictable and consistent with the global frameworks.

The setback in the area of computer related inventions, CRI, was continued in 2016 and was made even worse when revised CRI guidelines were issued last year that contained troubling test requirements. The abrupt withdrawals of 2015 final guidelines and reissues of the revised CRI guidelines without explanation undermine the rulemaking process for IPR that should be followed. Following an established rulemaking process is important because it provides industry with

1	transparency and predictability, two essential
2	ingredients for massive economic growth. The
3	Government of India should reinstate the 2015 final
4	guidelines as soon as possible.

In conclusion, USIBC commends the

Government of India for the progress that has been
made over the last 12 months on IPR. At the same
time, I would like to note that significant issues
have to be addressed in this sector. USIBC looks
forward to deepening its engagement with the
Government of India and the U.S. government in
working towards a common goal of ensuring India's
continued progress in IPR.

Thank you.

MR. MEHTA: Thanks very much, Dr. Aghi. For the first question, I'd like to look to the Department of State.

MS. DYER: Last year your organization recommended that India remain on the Priority Watch List. In light of these developments that you've described, do you still make the same recommendation this year?

DR. AGHI: I think if you look positive
reinforcement, and my experience shows that that
tends to move the needle in the right direction.
The reason we have not made recommendations this
time is because we're getting more and more engaged
with the Government of India, and we feel that we
should come back to this hearing in six months' time
with a recommendation itself.

MS. DYER: Thank you.

MR. MEHTA: Thanks. For our second question, I'd like to look to the U.S. Patent and Trademark Office.

MR. SMITH: On page 3 of your submission, you note as a positive development in IPR that in the arena of biopharmaceutical patents, the Delhi Patent Office in 2016 granted a patent for a molecule to a major life sciences company. Do you view one patent granted in this field is a sufficient annual target for India? Do you have figures on the number of biopharmaceutical patent applications that were rejected by Indian Patent Offices or otherwise not introduced to India's

restrictive patent policies?

DR. AGHI: I don't have the numbers of the patent files. But is it sufficient? I think we are trying to encourage India to be more innovative from a global IPR protection process, so I would say that one is not enough, and I can't give the details of the numbers of patent files itself.

MR. MEHTA: Great, thanks. And for our final question, Department of Treasury.

MR. CHANG: Thank you. It's been about one year since the issuance of India's National IPR Policy. In this time, do you believe that it has resulted in substantive, meaningful progress for your membership? Can you explain?

DR. AGHI: I think we have made feedback to the Government of India on the IPR policy where we agree and where our members don't agree -- disagree. As far as the execution goes, I think they have hired a substantial number of people.

They are moving in the right direction. I would say let's look at it another six months from now as to how the few hundred people they've hired, how they

1 execute. So I would say that progress has been made, and I think there are some more things that 2 3 should be done to take this in the right direction. 4 MR. MEHTA: Thanks very much for your 5 testimony today. 6 DR. AGHI: Thank you. Thanks a lot. 7 MR. MEHTA: I'd like to now invite the Trademark Working Group to please approach. 8 9 Welcome, sir. Please introduce yourself for the 10 record and begin your testimony. 11 MR. KILMER: Yes, thank you. I'm Paul 12 Kilmer on behalf of the Trademark Working Group. 13 I'm a partner at the firm of Holland and Knight. 14 The Trademark Working Group would again 15 like to thank USTR for the opportunity to present 16 the views of its participants in relation to 17 adequate and effective protection of trademark 18 rights globally. Our Global Trademark Report Card 19 which we have submitted to USTR highlights certain 20 issues and nations of special attention. 21 Unfortunately, as always, I have to begin with 22 China.

The bulk of our comments from our
participants again relate to China, including
elimination of direct appeals by opposers from the
Chinese Trademark Office to the Trademark Review and
Adjudication Board; CTMO opposition examiners who
are unpredictable, opaque, and too narrowly focused
in their determinations of whether a likelihood of
confusion exists between potentially conflicting
marks; inflexibility in relation to descriptions of
goods and services, especially high technology goods
and services; unreasonably high standards for
establishing well-known mark status and limited
protection from marks declared well known; a glaring
lack of transparency in all phases of trademark
prosecution and opposition practice.

Amongst the issues highlighted in this year's report, the absence of relative grounds that is likelihood of confusion, refusals. A disturbing trend highlighted in this year's report is the increasing number of nations that do not examine and reject trademark applications on relative grounds that is likelihood of confusion with previously

registered marks.

The European Union and most of its member states are unfortunately falling into that trend amongst other countries. Considering the high cost of opposition proceedings, along with the prospect for public confusion if similar marks are registered and used for related goods or services, it is a disservice to both trademark owners and the public that trademark offices do not fill the function of issuing relative grounds refusals. From our membership, we have learned that the failure to examine and refuse applications on relative grounds costs American trademark owners many millions of dollars a year prosecuting unnecessary opposition and cancellation proceedings.

Default judgments: Many millions of dollars are also spent each year by American companies to prosecute opposition and cancellation proceedings as well as court actions that are not defended but nevertheless continue to decisions on the merits. Jurisdictions that do not enter judgment by default include Brazil, China, the

European Union and many of its member states, Japan,
and South Korea.

Oppositions: The absence of effective opposition proceedings allows trademark pirates to steal valuable brands, especially those owned by American and other foreign companies. A number of nations such as Angola, Belarus, Kazakhstan, and Panama do not have opposition proceedings, while others such as Ukraine and Vietnam provide opposition proceedings in name only.

The slows: In our last three submissions, we called attention to nations such as India and Brazil that failed to adjudicate trademark oppositions and cancellations within a reasonable period of time. These nations continue to deny trademark owners effective protection against infringing marks and also fail to adjudicate proceedings brought against American companies within a reasonable period of time.

For example, a non-use cancellation proceeding has been pending in India against an American company's registered mark since 2007. In

1	the interim, the company that brought the action has
2	changed its name and trademark, and the American
3	company has submitted unrefuted evidence of use of
4	its mark. Nevertheless, I have been advised that it
5	will be another $1\frac{1}{2}$ to 2 years before this $10$ -year
6	old action is addressed by the Indian Trademark
7	Office. Meanwhile, a cloud hangs over the American
8	company's trademark registration.

Certification marks: Despite USTR
highlighting this issue in its last three Special
301 Reports, many nations from Afghanistan to Yemen
still do not protect certification marks.

Multi-class applications: There are at least 38 nations that require single class trademark applications. This requirement in nations such as Argentina, Brazil, Mexico, Pakistan, and South Africa leads to additional costs both in terms of initial filings and in relation to maintenance of multiple registrations rather than one single-class, multiple-class registration.

Formalities and recordations: Many nations continue to require formalities that are

1	overly burdensome to trademark owners. For example,
2	Argentina, China, Panama, the Philippines, and Saudi
3	Arabia all maintain burdensome legalization
4	requirements. Other nations such as Brazil,
5	Indonesia, Mexico, Nigeria, Pakistan, and South
6	Korea continue to require recordation of license
7	agreements. Such requirements are unduly burdensome

and set a trap to the unwary.

Stealth Paris Convention: There continue to be a number of nations such as China, Egypt, Indonesia, and the United Arab Emirates in which newly filed applications may not be effectively located for purposes of trademark clearance searches during the six-month priority period afforded by the Paris Convention. Such nations either should be required to reveal the details of newly filed applications promptly, or Paris Convention-based applications arising from such nations should be denied priority for filing date purposes.

Consents to registration: There remain a number of nations, such as Argentina, Brazil, China, Colombia, Japan, Mexico, and Thailand, that give

1	little or no weight to consents to registration,
2	even though such consents are provided by trademark
3	owners who generally have a better appreciation for
4	real-world marketplace conditions than do trademark
5	office officials.
6	All of these practices and others noted in
7	our Global Trademark Report Card pose obstacles to
8	effective and adequate protection of trademark
9	rights abroad.
10	Thank you.
11	MR. MEHTA: Thanks very much, Mr. Kilmer.
12	For the first question, I would like to look to
13	USTR.
14	MS. PETERSON: In the Trademark Working
15	Group's Trademark Report Card, Global Report Card,
16	you noted that Mexico's trademark system is outdated
17	in several areas, including with respect to
18	requiring recording of licensing agreements and the
19	ability to file only single-class trademark
20	applications.
21	MR. KILMER: Right.
22	MS. PETERSON: We are aware that Mexico

1	recently passed trademark opposition procedures. Do
2	you see any other positive signs of trademark law
3	reform in Mexico?
4	MR. KILMER: I really don't at this time.

At least we haven't been informed of any. The opposition practice also we're still trying to get some appreciation for. It struck us initially as a rather Byzantine and odd procedure. And as I say, we're still studying it in the real world to see how it will operate within the Mexican Trademark Office, and I think that jury is still out as well. But otherwise I have not been advised of any developments especially in relation to things like multi-class applications and also recordation of licenses, which is a tremendous burden on American companies there.

MR. MEHTA: Thanks very much. For the second question, if we can have the Department of Agriculture.

MR. KARAWA: Of the many concerns that the Trademark Working Group has identified as to China, which is presently the greatest concern and which

concern could you identify as potentially being resolved most easily?

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MR. KILMER: I think the greatest concern that I've heard expressed from our membership relates to the CTMO, the China Trademark Office, and really in two respects. The first respect goes to the opposition examiners at the CTMO. Opposition examiners serve as administrative law judges effectively. We understand their training is very limited and that they are under a great deal of pressure from very large dockets to issue what I would call very perfunctory decisions. By that I mean they tend to look only as to whether the two trademarks at issue are basically identical and whether they are registered or sought to be registered in the same subclass; in other words there is a classification system, and under that there are multiple, multiple, multiple subclasses. So their focus is extremely narrow.

As a result of that, what is beginning to happen is we're seeing a lot of adverse decisions against American companies in opposition proceedings

at the trademark office level. Then they go up to the Trademark Review and Adjudication Board, and we get much better decisions from them. They seem to be much better advised as to the nature of trademark rights in the breadth and extent of them. They also give broader protection to well-known marks.

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I'll tell you what I'm seeing in some instances as a result of that is that U.S. and other companies from Europe and so forth are jumping over the trademark office opposition proceedings and allowing infringing trademarks to register, and then mounting their initial attack before the trap, which used to be an appellate board but now also basically hears these types of cases de novo. It's really kind of a silly and wasteful process when you are jumping over the initial trial court effectively and going to the court of appeals immediately. happening with some regularity in China now. doing a disservice to the Chinese trademark system, and I would think it is something that China would want to take cognizance of and also try to correct.

The other thing that we are noticing in

the China Trademark Office is this very kind of 1 narrowly focused examination procedure which kind of 2 parallels their opposition proceedings. 3 That is 4 trying to explain to the Chinese Trademark Office 5 the nature of new, especially high technology goods 6 and services, and trying to get them to properly 7 classify them. They really want you to pigeonhole whatever you file with them in their description of 8 9 goods and services, whether it makes any sense or 10 not. It just strikes me they need some additional 11 flexibility there.

And I think the whole issue of transparency. This is something we've raised numerous times before. There are no effective ways to find out where your application stands or where your trademark opposition stands or even your appeal to the trap. This is something we don't find in most advanced nations, and it seems like a fairly easy thing that they could work on.

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And, of course, default judgments as I mentioned is the other one, and they are not alone. There are many, many nations that don't recognize

1	judgment by default. But I can't tell you how many
2	instances I've had in my personal practice where a
3	Chinese trademark pirate filed for my client's mark,
4	filed it off by one subclass, managing to get it by
5	the examination process. We opposed and the pirate
6	failed to defend, but the CTMO nevertheless went
7	ahead, rendered its own judgment on the merits
8	without the pirate defending.
9	MR. MEHTA: Thanks very much.
10	MR. KILMER: How I do go on.
11	MR. MEHTA: Your time has unfortunately
12	elapsed. Thanks very much for your testimony.
13	I'd like to next invite Public Citizen to
14	please approach. Welcome, sir. Please introduce
15	yourself and begin your testimony.
16	MR. MAYBARDUK: Thank you. My name is
17	Peter Maybarduk. I am the Access to Medicines Group

Peter Maybarduk. I am the Access to Medicines Group
Director at Public Citizen. Public Citizen is
consumer advocacy organization based here in
Washington, D.C. We have 400,000 members and
supporters and a 45-year history representing the
public interest before Congress, the agencies, and

the courts.

I have provided copies, printed copies of our testimony for the members of the panel for your reference while I speak today. It is good to see some old colleagues, even dare I say friends, and even though being here this morning and annually is not really an occasion for joy for us for reasons that I will discuss.

Our testimony provides principles, and

I'll talk a little bit about those that we believe
should guide the 301 process to mitigate the
substantial harm that we think it does to global
public health and other public interest, as well as
comments on the particularities of many countries'
intellectual property policies which we can discuss,
but I can't pledge to have it all in my head for
purposes of our brief 10 minutes. We can make that
effort if you have specific questions. Certainly,
we will provide follow-up for any country disputes
or questions that are of interest, and we're
available to the Committee to talk throughout your
process, provide our analysis of how policies

comport with TRIPS or other obligations.

on the public interest aspects and flexibilities in intellectual property regimes. Rules are not there, of course, simply to provide maximum protection to right holders. They also include many limitations which are there to protect public interest, from health technology access, access to educational materials, technology transfer, and so on, values that are articulated in the TRIPS Agreement and every meaningful, accorded document related to intellectual property globally.

The United States, of course, uses its

flexibilities under these regimes quite a bit,

including in the area of issuing compulsory

licenses, whether through the courts or the

Department of Defense on military technologies and

other areas. We think those are very important

considerations when thinking about whether and how

we're going to sanction or penalize or list or

potentially seek to intimidate a country that is

availing itself of the same rights and trying to

defend its public interest in the same way that the United States does at home.

As many of you know, we have spoken before but it bears repeating, access to medicines globally depends in no small part on the availability of generic competition to reduce prices and ensure prices continue to fall over time. At the turn of the millennium, of course, we were witnessing the death of many millions of people from HIV and AIDS for lack of access to technologies that had been developed, catalyzed in no small part by public funding but were priced at \$12,000 per person per year and above.

It is because of the advent of generic competition and robust public interest policies in IP that we were able to achieve essentially the development of the Global Fund and PEPFAR that essentially poor people's lives became costefficient to save in view of international donors, and we have reached a point today where there are 17 million people, I think is the latest figure, on life-saving treatment in low- and middle-income

countries.

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This is only possible because of the use of exceptions and flexibilities and not simply viewing the world as one in which monopoly control over pharmaceuticals should always reign paramount. And it matters quite a bit today in the context of biosimilars and cancer drugs, the majority of which come on the market priced at more than \$100,000 per person per year. In my work providing technical assistance in developing countries, I have seen the difficult choices that health agencies have to make sometimes, and procurers and hospitals have to make where they can sort of look in the hallway and know that there is a line of people waiting for a particular drug. They can't necessarily afford it if they are going to sustain other wings of the hospital, if they are going to buy drugs for other conditions, provide enough beds for patients, and so The cost constraints are very real.

Now, of course, the standard counter argument to this, and of course we'll hear more from Doctors Without Borders and KEI and others today,

1 the standard counter is, well, but we have to pay
2 for research and development.

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Now, several points here: One, the public pays into research and development, \$30 billion annually through contributions to the National Institutes of Health to fund the invention of many new medical treatments. Two, of course, the mere principle that we have to pay for R&D somehow does not mean that ever greater monopoly protection would be beneficial, and there is not a lot of precise calculus out there what is the appropriate balance to strike. But, three, and I think this is an important point, including for our own battles with drug prices in the United States today, prices are not derived from R&D costs. There is occasionally the argument made that if we drive up other countries' prices or compel them to pay more into the system that we'll get lower prices. I would actually probably like to think that's true, but I don't think there is much reason to believe that it is true.

Pharmaceutical companies, of course, are

profit-maximizing entities, and they are going to price according to what they can make from a given If you look at the Wyden-Grassley testimony that came out in the Senate last year, you see how Gilead made its calculus for the prices of the hep C drugs, and it has to do with at what point payers will stop paying and Congress will get so outraged that it will have negative consequences for the pharmaceutical company.

We don't expect companies in any other sector to set prices according to R&D costs, so why would we think that's the case here? Companies are going to make the money that they can, and I am not even here to fault them for that. That's the structure. That's how we've set up our markets. But it is incumbent upon us to set appropriate public policy parameters so that we can save people's lives and not sacrifice them to the interest of shareholders.

So I think that is a very important consideration when thinking about whether simply castigating other countries for their IP policies is

going to benefit or come back around to benefit

Americans, including the area of drug prices. There
is no reason to think it wouldn't keep driving

prices up in that context.

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I guess I'll also say this: experience working in developing countries, what I often see is we get the sort of story and hear that there are countries that are trying to get over on the United States. I see another side of it frequently, which is I work with people, courageous people in governments and health agencies who are trying to advance policy, who are trying to get a compulsory license, for example, on an expensive AIDS drug or cancer drug that would significantly improve the efficiencies of their health care system. What they confront is opposition from their trade administration that is concerned about pressure from Washington, and they face different obstacles trying to get a policy like that through, sometimes intimidation.

I witnessed just a few months ago on the floor of the congress of Peru where functionaries of

the Ministry of Health presented a report that had been buried by their government, their best reporting according to their expertise of how they thought they could save people's lives and reduce costs in AIDS treatment. And they had been prohibited from publishing this report. They got a last minute permission, presented it, contradicting the findings of the Trade Ministry but representing best findings in the Ministry of Health. The next day that official was sacked. So there's considerable pressure against countries pursuing what they believe to be their best estimation and their country's best interests.

I find these people to be quite brave to stand up in that context, and it's the sort of thing that makes me concerned for what we do here representing U.S. government agencies. My father was a Foreign Service Officer. I understand the constraints. I want to stand for the best of our country. That is why I do this work. I imagine that is why many of you do this work. I think when writing up this report, we have to be able to, when

going to the principles, now think about distinguishing between things that are criminal activity, like a counterfeiting enterprise, and a country that's simply trying to do the best by its people in other areas.

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Right now, I think we could critique the 301 Report by saying that it does not adequately draw that distinction, and you have the conflation of legitimate public policy interests with criminal activity. Our principles are designed to give you sort of a menu of options. We understand that we're not going to agree on all of them. But I hope that it articulates to a degree what concerns the public interest community about the 301 Report, and then we can start to have a conversation about how we can make meaningful the U.S. commitments that are often listed in the report. We're not going to interfere with a country's rights to promote and protect public health in compulsory licensing. If every time a country considers a compulsory license they wind up one way or another in the Report, we don't have a way to give much credence to that United

States commitment. So we would like to see more specificity on those fronts, and we would like to see some indication on what a country can actually do to get off the list in this case.

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I know that I'm almost out of time, so I don't think I'll be able to go through the principles or country controversies as we might I note there was a question from HHS last like. year, which I think we have addressed in here about one of our comments on ancillary policies and pharmaceutical pricing policies, and I'd draw your attention to that in the testimony. And I should probably just turn it over for questions. But we are, of course, very happy to delve into the specifics of this Report as much as useful to aid your process. It is, of course, a question for us every year, and then we come and we do our best to answer, but we do question whether it is appropriate to push a process where we have to come and answer questions that countries really shouldn't have to answer because it's their business how they best promote the public interest under their existing

1 trade obligations. Thanks. 2 3 Thanks, Mr. Maybarduk. MR. MEHTA: We are 4 almost out of time, but I think we have time for 5 just one question. If I can ask the Department of Commerce for that one? 6 7 MR. MITCHELL: Thank you. This question begins with Canada but is actually a broader process 8 9 sort of question. With respect to Canada, in the 10 past, the Special 301 Report has identified the lack 11 of a right of appeal in Canada's administrative 12 process for reviewing regulatory approval of 13 pharmaceutical products. Other countries were 14 sufficiently concerned about that gap to negotiate 15 it, including the EU which in the CETA negotiated an 16 obligation to provide symmetrical rights of appeal. 17 And so my question is what channels does 18 Public Citizen think that the U.S. government should 19 take in addressing IP-related trade issues such as 20 the lack of right of appeal? 21 MR. MAYBARDUK: Well, I'm not deep on that 22 issue, but I see we do reference it. I'll have to

probably get back to you on the particulars. 1 note that right of appeal in a regulatory context 2 3 would be one of these ancillary policies that we're 4 talking about. It's not strictly speaking IP. It's 5 a policy that affects a product that is protected by 6 In that context we think it's only appropriate IP. 7 and only permissible under the statute, as I understand the Trade Act, to address that in the 8 301 Report, if there is a specific allegation of 9 10 discrimination or violation of a trade agreement. 11 And I'm not aware of that. I'm not aware of such an 12 allegation in that particular context. 13 MR. MEHTA: Thanks. One last question, 14 HHS. 15 MS. BLEIMUND: Thanks for your testimony 16 today. I just have a quick question about 17 In your submission, you note that Indonesia. 18 Indonesia followed its national rules when it 19 granted a government use license on a number of 20 drugs several years ago. We've had public comments

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from Indonesia submitted in connection with Special

301 in the past that indicated that it did not

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1	follow its national procedures in that process. I
2	was just wondering if you have any comment on that
3	discrepancy.

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MR. MAYBARDUK: I believe I recall that day, and it was quite shocking to us. We can only feel that there must have been some internal politics or miscommunication. We worked a bit on It is several years ago now. But it's a that case. presidential decree authorizing government use for patents on seven HIV/AIDS and a hepatitis B It's permissible under TRIPS. medicine. There is individual consideration of royalties, I believe, in that case. Again, I'd have to look back at the particulars, but I do recall the controversy, and I can say with confidence that our understanding was they followed perfectly well their national rules and the international rules. We can review the record to see what the particular dispute was.

MR. MEHTA: Thanks very much,

20 Mr. Maybarduk, for your testimony today.

I'd like to next invite the Program on Information Justice and Intellectual Property to

1	approach. And just again another reminder that we
2	will have opportunities for the submission of
3	post-hearing comments should any of the presenters
4	wish to supplement their testimony. Thank you.
5	Sir, you can just give it to us and begin
6	your testimony, yeah, thanks.
7	MR. PALMEDO: Take one and pass them down.
8	MR. MEHTA: Great, we'll do it, thank you.
9	Please introduce yourself and begin your testimony.
10	Thank you.
11	MR. PALMEDO: Thanks for the opportunity
12	to testify at this hearing. My name is Mike
13	Palmedo. I work for the American University,
14	Washington College of Law's Program on Information
15	Justice and Intellectual Property, or PIJIP for
16	short. We're an academic research program that
17	promotes the public interest in IP policy. My
18	recent research at PIJIP has involved the comparisor
19	of copyright limitations in different countries and
20	the examination of outcomes associated with
21	different copyright limitation structures.
22	My testimony has four key points: U.S.

firms that rely on copyright limitations benefit when foreign nations adopt open, flexible general exceptions such as fair use. Copyright industries still earn money in these countries when they do so. The Special 301 Committee should include analysis of copyright limitations when evaluating whether a country provides adequate and effective protection of IP. And the 2017 Special 301 Report should highlight countries that are moving to adopt more flexible copyright practices at its best practices section.

So I feel the U.S. balances interests of those who own IP and those who use it. In the field of copyright, this involves protection against infringement and, when appropriate, limitations allowing unauthorized reproduction and use. The best copyright limitations allow firms in certain sectors, like information, research, and communications technology, to use works as needed, including in certain uses without authorization that don't affect the commercialization of the work and flexible limitations which allow greater

interpretation of new technologies.

U.S. firms that rely on copyright

limitations have done well when foreign countries

have adopted open limitations in their laws. The

most direct example is where countries have adopted

fair use exceptions similar to those found here.

Between 2006 and 2007, that was three countries:

Singapore, Israel, and Taiwan.

Industry level data from the BEA shows that foreign affiliates of U.S. information sector firms in these countries prospered since the adoption of fair use there. Firms in the information sector here are those industries with NAICS codes beginning with 51, including high tech industries such as data processing, post-dated software development, as well as traditional copyright industry such as publishers and most picture and sound recording industries.

If you look at the handout, Year 1 is total sales of foreign affiliates of U.S. firms in the sector. You see that sales had been growing before the adoption of fair use, but after it, the

total sales grew faster in Singapore and Taiwan

while the rate of growth remained constant in

Israel. Affiliate sales in Israel and Taiwan remain

a small percentage of worldwide affiliate sales, but

Singapore's share of world affiliate sales rose from

5.7 to 8.2 percent after fair use, and that's a tiny

country with a population of 5 million.

Additionally, the ratio of total sales in this sector from Singapore, Israel, and Taiwan, the total sales by affiliates based in Europe has increased from .09 to .16. This shows that the overall growth of affiliate sales in these countries outpaced the growth of affiliate sales in the set of countries that do not have fair use.

Moving to a different sector, it's a similar story. In the handout, Figure 2 is total sales from foreign affiliates of U.S. firms in the scientific, technological services sector. These are industries under the NAICS code 54, and they include research and development services and computer systems and development among others.

Total sales in Singapore, Israel, and Taiwan are

presented in Figure 2 here. They increase significantly after the introduction of fair use in Singapore and Israel and remain constant in Taiwan.

Once again, the ratio of affiliate sales of these three countries to affiliate sales in Europe rose from .04 to .19 since fair use was introduced. This shows that sales of the fair use group are growing faster than sales in countries with less open copyright exceptions.

I could go through more of these, but the time, I'm just going to say here that the BEA's industry level data on other indicators, such as total assets held by foreign affiliates or value-added by them, tells a similar story. Since the introduction of fair use, these countries' U.S. parent firms have been building up their affiliates, and the returns are growing. This is true both in an absolute sense and in relation to affiliate growth in countries with more restrictive rules of copyright exceptions.

The next point is that U.S. firms still receive payments for the use of IP in these

countries. The BEA data does not show a decline in payments for the use of American IP from Singapore,
Israel, and Taiwan. Tables 3 and 4 show the status aggregated by two types of IP goods. Figure 3 shows data on payments for movies and TV programming from 1999 to 2015. There is an increase after the introduction to fair use in Singapore and Taiwan and remains flat in Israel.

BEA only has data from 2006 forward for the payments for use of IP in books and music. This is Figure 4. It shows that there has been an increase in payments on IPR from all three countries after the introduction of fair use, which brings me to really the main point.

I would like to make two suggestions to the Committee regarding fair use and Special 301.

First, the Special 301 Committee should include analysis of copyright limitations when evaluating whether a country provides adequate and effective protection. The inclusion of strong copyright limitations is a necessary component to an adequate and effective IP system consistent with evolving

U.S. trade policy.

The trade negotiated objectives stated in the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 require negotiators to seek levels of IP that, quote, "reflect a standard of protection similar to that found in United States law." Since USTR has promoted the adoption of flexible copyright limitations elsewhere, including on the TPP, it seems fitting that the Special 301 Committee would include consideration of copyright limitations in its annual review of IP laws.

Finally, the 2017 Special 301 Report should highlight countries that are moving to adopt more flexible copyright practices in its best practices section. Trading partners such as Australia, Hong Kong, Nigeria, and South Africa, among others, are currently debating whether to implement fair use in their copyright law.

Inclusion of fair use as a best practice would encourage them to do so, which would benefit U.S. firms and foreign firms alike.

Thank you.

1	MR. MEHTA: Thanks very much. For our
2	first question, if I could look to the Department of
3	Labor.
4	MS. PETTIS: Your statement requesting to
5	appear here states that U.S. firms can be harmed by
6	legal changes that have pulled back on copyright
7	limitations. This is your first bullet on page 1.
8	Can you provide examples of specific harms to U.S.
9	IP-intensive stakeholders caused by these legal
10	changes in specific countries?
11	MR. PALMEDO: The first example that comes
12	to mind would be France and Spain's moves to have a
13	snippet tax on search engine results. I believe
14	both of those countries ended up finding out that it
15	didn't work so well for them, so they ended up
16	pulling it back. But that is one instance where
17	Google in particular had to pull out of those
18	countries. I can provide more information on this
19	question in writing after this hearing.
20	MS. PETTIS: Okay.
21	MR. MEHTA: Thanks. Second question, U.S.
22	Copyright Office.
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MS. STRONG: Thank you. Your statement indicated that your testimony was drawing from recent research comparing copyright limitations in different countries done at PIJIP. Your letter also noted, as you just said now, that current debates are focusing on fair use principles in countries like Australia, Hong Kong, Nigeria, and South Africa.

We recall that in last year's Special 301 proceeding, PIJIP reported that I believe it was the American University College of Law was also in the process of drafting a survey of copyright experts and had hoped to gather information on up to 50 countries. Do you have any update on that endeavor that you might be able to share with this Committee?

MR. PALMEDO: Yes. Actually, I cut that out of this because I had to make it seven minutes or less. We are currently getting the survey results back. We sent them out towards the end of last year, and we've gotten about 20 to date, and there has been a back and forth. We're sending these out to law professors in different countries.

I believe there is 129 specific questions, and we
ask for changes about different copyright
limitations from 1970 to present, so there is a fair

amount of back and forth.

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We hope to present some raw results at the end of April, at the Creative Commons meeting in Toronto. We would love to keep you up to date. Our hope is that we can use that to do more precise econometric work. I talked today about countries that had adopted fair use very much like what we have in the U.S. But it is a more interesting question, I think, that as countries' limitations become more robust and the copyright systems become more open, can you see benefits, whether or not laws go from like zero to one on an indicator of is it like our law. So that's actually going to be the bulk of my work for the next half year or so is crunching all of the survey data, and I'd love to share it with you. I won't have much by the 14th, though.

MR. MEHTA: Thanks very much, Mr. Palmedo.

I would next like to invite the

Pharmaceutical Research and Manufacturers

Association of America. Welcome, sir. Please
introduce yourself and begin your testimony.

MR. MOORE: Thank you very much. My name is Chris Moore. I am with the Pharmaceutical Research and Manufacturers of America, or PhRMA. PhRMA represents the innovative biopharmaceutical sector in the United States. On behalf of those biopharmaceutical innovators and the more than 850,000 women and men they employ across the country, PhRMA appreciates the opportunity to testify before the Special 301 Subcommittee.

The United States is the global leader in medicines research, introducing nearly 550 new therapies since 2000 and investing in many of the more than 7,000 new treatments currently in development worldwide. Intellectual property protections, including patents and regulatory data protection, drive and sustain biopharmaceutical innovation. They enable access to today's medicines and promote investments in tomorrow's treatments and cures.

1	Where markets are open and intellectual
2	property is protected and enforced,
3	biopharmaceutical innovators have the predictability
4	and certainty they need to research, develop, and
5	deliver new medicines to patients who need them.
6	Innovation saves lives and helps reduce overall
7	health care costs. New medicines have cut heart
8	disease deaths by 38 percent and AIDS deaths by
9	87 percent. They account for more than 80 percent
10	of increased life expectancy of cancer patients.
11	There is much more to come. PhRMA members
12	are developing more than 1,200 new medicines for
13	infectious diseases, including viral, bacterial, and
14	fungal infections, smallpox, and drug-resistant
15	malaria. Advances in genomics are propelling the
16	discovery of new medicines. Made using living
17	organisms, biologic medicines are revolutionizing
18	the treatment of cancer, autoimmune disorders, and
19	other chronic conditions.
20	PhRMA members are working to overcome
21	systemic challenges that can prevent the poorest
22	from accessing medicines. They are leading more

1	than 340 initiatives with more than 600 partners
2	towards sustainable solutions that improve health
3	for all. Last month more than 20 biopharmaceutical
4	companies joined the World Bank and the Union for
5	International Cancer Control to launch Access
6	Accelerated, a first-of-its-kind global initiative
7	to address cancer in low- and middle-income
8	countries.

But around the world, some of America's leading trading partners maintain or are considering laws, policies, and practices that deny or would deny adequate and effective intellectual property protection and fair and equitable market access.

PhRMA's submission highlights six top barriers and threats that are preventing biopharmaceutical innovators from securing patents, maintaining and effectively enforcing patents and protection regulatory data. All require urgent action.

Restrictive patentability criteria in

Argentina, India, Indonesia, and other countries

prevent innovators and generics alike from

introducing new forms and new uses of medicines that

can promote adherence and lower overall health care costs. Canada's Promise Doctrine imposes a heightened and unworkable patentability standard. It confounds the time-tested process by which innovators transform promising molecules into valuable new medicines. Based on the jurisprudence developed by Canadian courts, 25 patents on innovative medicines have already been invalidated.

9 Patents on many other products are at risk.

PhRMA members are seeing progress in

Taiwan toward a mechanism that would provide for the early resolution of patent disputes, but weak patent enforcement remains a serious problem in China,

India, and other countries. Contrary to its trade agreement obligations, Australia does not provide patent holders with advance notice that a potentially infringing product has applied for marketing approval during the patent term. Recent actions by the Australian government to seek marketsize damages from innovators that pursue unsuccessful patent claims are discoursing patent enforcement.

Many U.S. trading partners, including
Algeria, Turkey, and Peru, do not sufficiently
protect regulatory test data. Regulatory data
protection is particularly critical for biologics
which may not be adequately protected by patents
alone. High tariffs and approval delays deny fair
and equitable market access for medicines invented,
developed, and manufactured in the United States. A
growing share of global trade in medicines now
occurs outside the WTO's zero-for-zero initiative.

After additional duties and assessments are factored in, effective tariffs on medicines in India can be as high as 20 percent. Federal and state taxes in Brazil can add 34 percent to the price of medicines, among the highest tax burdens on medicines in the world.

Because of lengthy regulatory delays,

getting approval to make a new medicine available in

China takes much longer than international practice.

Patients are forced to wait for the treatments they

need. These challenges are compounded by a growing

array of localization barriers from mandatory

1	technology transfer requirements in Indonesia, to
2	discriminatory import barriers and procurement
3	practices in Algeria and Russia.

Contrary to global trade rules, recent legislation in Indonesia appears to require innovators to manufacture all patented products and use all patented processes in Indonesia.

PhRMA urges USTR to prioritize these countries and concerns in the 2017 Special 301 Report and to use all available tools to resolve them. Meaningful out-of-cycle reviews are needed to assess progress and results in Canada, Colombia, and India. We particularly encourage USTR and other federal agencies to address longstanding intellectual property and market access barriers in countries that are U.S. trade agreement partners.

These agreements generally require intellectual property frameworks that protect regulatory test data and enable inventors to resolve patent disputes prior to the marketing of potentially infringing products. However, many U.S. trade agreement partners fail to adequately comply

1	with some or all of these obligations. We urge
2	federal agencies to systematically review compliance
3	and take steps necessary to ensure agreed rules are
4	followed.

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

MR. MEHTA: Thanks very much, Mr. Moore.

The first question, I'd look to USTR?

MS. PETERSON: In regards to India, on page 52 of the PhRMA submission, you note that in 2016, 12 products have faced issues due to the application of Section 3(d) of India's patent law, infringement caused by state-level manufacturing approvals, and the threat of compulsory licenses. Can you please describe how many incidents in each of these three categories occurred last year since the past 2016 Review?

MR. MOORE: Sure. We do keep track of denials related to Section 3(d) and are happy to provide a list of those to you. It is quite a long

list and continues to grow. We can provide that
full list for you that will include any of the
denials that took place last year.

I would just point out that in the case of those denials, one of them involved a generic pharmaceutical company based in India that was trying to patent a combination product for the treatment of HIV. This is a challenge that is not only affecting innovators but generic companies, not only affecting businesses based in the United States but also the ability of India's own industry to move into more innovative lines of business.

I believe you also were asking about a couple of other things?

MS. PETERSON: Infringement caused by state-level manufacturing approvals and the threat of compulsory licenses.

MR. MOORE: With respect to state-level approvals, one of the challenges that we found is that because there are differences between the states, and between the states and the federal system, there actually are products that are being

1	approved for marketing by the states during the
2	patent term, and so this has been a challenge for
3	us. Our members are not receiving any kind of
4	notice or ability to know when potentially
5	infringing products are in the marketing approval
6	process or have applied for marketing approval. And
7	so making progress toward an effective early
8	resolution mechanism in India would be very
9	valuable.
10	MR. MEHTA: Thanks. One more question, I
11	could look to HHS, please.
12	MS. BLEIMUND: Thank you. I have a
13	question about the concerns PhRMA has raised about
14	the market-size damages issue in Australia. Could
15	you explain how this type of measure differs from
16	other safeguard type measures in other countries?
17	MR. MOORE: As far as we know, the
18	practice that is being pursued in Australia is
19	unique to that country. As we have described in our
20	submission, we believe that Australia is
21	discouraging the enforcement of patents by
22	intervening in cases where the innovator's product

or patent was ruled invalid or not infringed and seeking damages in addition to those that would be due to the generic competitor.

The level of damages equates to damages that you might expect to find in cases of bad faith enforcement and certainly is having a chilling effect on the ability of innovators to effectively enforce their patents in Australia.

MR. MEHTA: Thanks, Mr. Moore, and that concludes your testimony. We are out of time.

For our next presenter, if I can look to Doctors Without Borders, please. Welcome. Please state your name for the record and begin your testimony.

MS. RUIS SANJUAN: Good afternoon. My name is Judit Ruis, and I work for Doctors Without Borders at the New York office. I would like to dedicate this testimony to Tobeka Daki and the millions of women around the world and here in the United States that need access to affordable medicines. Tobeka died last year in South Africa because of the high prices demanded by

pharmaceutical companies on existing cancer treatments.

Doctors Without Borders/Medecins Sans

Frontieres is an independent international medical humanitarian organization that delivers medical care to patients in nearly 70 countries. We provide medical care to victims of armed conflict, epidemics, natural and man-made disasters, and to others who lack health care due to social or geographical marginalization. Our work often focuses on the medical needs of populations living in developing countries whose needs have historically been neglected. But increasingly we are also being asked to respond to the unmet health needs of patients living in countries considered high-income economies.

Through our work, MSF witnessed the everyday impact on people of having limited or no access to medicines because they are too expensive or because they do not exist. As a medical treatment provider with more than 40 years of experience caring for vulnerable people, MSF is able

to speak about the direct relationship between intellectual property and access to medicines and These include key political, legal, and innovation. commercial barriers that stand in the way of production, distribution, and access to affordable and appropriate medicines, vaccines, and diagnostics as well as that inhibit innovation when it is urgently needed.

We would like to provide testimony in this year's Special 301 hearing regarding the critical importance of respecting countries' rights to uphold the public health safeguards enshrined in the WTO Agreement, TRIPS Agreement, and to implement these safeguards in national law, policies, and practices to balance private commercial interest with the right to life and health.

Specifically, we would like to highlight the important role India plays in the manufacturing of lifesaving medicines and vaccines for millions of people around the world and condemn pressures from the U.S. government and pharmaceutical companies to undermine countries' rights to use strict

compliance, compulsory license, and other
flexibilities, including most recently Colombia,
Canada, and Ukraine.

On India, thanks to price lowering competition from India, millions of people around the world are currently able to access affordable access to medicines and vaccines they need, including two programs funded by ministries of health, humanitarian treatment providers like us, and U.S. government-funded treatment and prevention programs like the U.S. PEPFAR initiative, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and Gavi, the Vaccine Alliance.

This is possible in part due to the public health safeguards in India's patent laws and policies. We urge USTR and the panel to respect legal safeguards such as India's strict patentability criteria, its rights to issue compulsory licenses when deemed necessary in the interest of ensuring the right to health, and a balanced approach to the enforcement of private intellectual property protection.

Additionally, USTR and pharmaceutical corporations' TRIPS-plus demands, such as data exclusivity that go beyond the TRIPS Agreement and create regulatory barriers in the registration of price-lowering generic competition, should not be requested and implemented in India.

Colombia: The U.S. government has

committed to respect the right of countries to use

strict flexibilities to promote more affordable

access to medicines, at least in paper. We are

deeply concerned by the interference of the U.S.

government officials in an effort last year to

prevent Colombia's Minister of Health from issuing a

compulsory license on secondary patents on a

lifesaving cancer medicine to promote generic

competition that is legal and exists in the United

States.

At a time when the high prices of medicines are a concern for countries all over the world, including here in the United States, countries' efforts to ensure people's access to lifesaving medicines they need should not only be

1 respected but strongly promoted and encouraged.

2 | Countries should not be penalized or discouraged

3 | from making use of public health safeguards that are

4 | intended to protect access to medicines and which

5 | are legally permitted in accordance with

6 international trade rules.

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In conclusion, Doctors Without Borders/MSF recognizes the need to reward innovation and the need to finance for certain development. We are a humanitarian medical organization that needs and welcomes biomedical innovation to improve treatment options for our patients. Certain development is important, and we need to pay for it. However, the reality is that relying on high prices for medicines backed by intellectual property monopolies is a flawed paradigm to pay for medical innovation. creates both global access concerns due to high prices, and at the same time it does not stimulate the innovation for many of the diseases affecting people in developing countries where patients have limited purchasing power, or even here in the United States where drugs have to be used sparsely like for

antibiotics.

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Yet, new approaches to medical innovation are demonstrating the significant medical breakthroughs where access and profits are possible, in particular models of innovation that break the link between the cost of research and development and the high price of the end product. Instead of a unilateral pressure to create stronger monopoly protectionisms for pharmaceutical companies and doubling down on a broken innovation system, the U.S. government should seek to establish improved incentives and norms to fix the world's broken research and development system as committed by the U.S. government in WHO negotiations, World Health Organization negotiations over the last 10 years, at the UN Political Declaration on Antibiotic Microbial Resistance from last year and as recommended by the 2016 UN Secretary-General High-Level Panel on Access to Medicines. Every country, including the United

States, has the right to take steps to increase access to medicines and implement a patent and

health system that is in line with its public health priorities. We strongly object to any pressure exerted by the U.S. government, including through the Special 301 process, to try to pressure countries not to exercise legal flexibilities to protect public health.

Thank you.

MR. MEHTA: Thanks very much. For the first question, I'd like to look to the Department of State, please.

MS. DYER: You just addressed the balance between innovation and access to medicine. Your written statement also talks about collaborating between funders of research and development and those innovators as well as those interested in accesses to medicine. Can you describe some specific approaches that you would recommend for this panel to try to address those balances appropriately? Thank you.

MS. RUIS SANJUAN: Sure. There is a lot of positive examples that could respond to that question. I am happy to provide you with a report

1	we wrote last year in 2016. It's called "Life on
2	the Edge." It's a report that highlights innovative
3	approaches to innovation and that promote
4	collaboration as well as access to medicines. I
5	also would like to call your attention on the 2016
6	Report of the UN Secretary-General High-Level Panel
7	on Access to Medicines that we also reference in our
8	report. That report basically really highlights and
9	repeats the conclusions over 10 years of
10	negotiations at the World Health Organization,
11	including many of the recommendations put forward
12	several years ago by an independent group of
13	experts, the Consultative Expert Working Group on
14	Research and Development: Financing and
15	Coordination, of CWEG's report. That provided a
16	variety of different tools to promote both
17	innovation and access and more collaboration on
18	research and development efforts.
19	MS. DYER: Thank you. I'm certain we have
20	a copy of the UN High-Level Panel Report, but we
21	would love to have a copy of the first report you
22	described. Thank you.

1	MS. RUIS SANJUAN: Thank you.
2	MR. MEHTA: Second question, USTR?
3	MS. PETERSON: You noted that you've seen
4	first hand the effects of when medicines are priced
5	too high or when they don't exist, and it's that
6	second piece that this question focuses on. Does
7	MSF have any views on incentives to promote research
8	on treatment or cures for rare diseases such as,
9	well, known as orphan drugs and pediatric drugs,
10	incentives such as providing additional terms of
11	data exclusivity?
12	MS. RUIS SANJUAN: MSF doesn't have much
13	medical experience on rare diseases, but we do have
14	quite a lot of medical experience on neglected
15	diseases, neglected tropical diseases where there is
16	in fact many innovation gaps that occur due to the
17	unfittingness for purpose of a system that just
18	relies on high prices and monopolies to promote
19	innovation. So it's similar challenges.
20	We have had and we are promoting reforms
21	on incentive mechanisms. Just to give you one
22	example, we are currently advocating in front of the
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U.S. Congress with a coalition of I believe it's currently nine organizations. It's a coalition of innovator and treatment providers on neglected diseases to reform the priority review voucher that currently exists. That is a pool incentive for innovation when there is an outcome for neglected tropical diseases. The incentive is ill designed because it is not promoting new innovation, and it doesn't have any access safeguards. So we are advocating and we have written to both the House and the Senate to promote a change on that incentive.

In general, we do not believe that additional exclusivities are the right tool to promote innovation because we do believe that the damage that that causes on payers and patients in terms of lack of affordability of the tools that they create out of those incentives is not the right balance for innovation. So we do not support extension of exclusivities as a tool to promote innovation that will conform into higher prices of medicines.

On neglected tropical diseases,

specifically one where we have quite a lot of 1 medical needs is tuberculosis, especially 2 multidrug-resistant tuberculosis. We have developed 3 4 also in partnership with others, including 5 tuberculosis innovators and tuberculosis treatment 6 providers around the world, a proposal that 7 recognizes the needs for a variety of incentives, 8 both pool push incentives to promote an ecosystem of 9 interventions in the innovation process to fully pay 10 for the research and development costs, to also 11 fully promote the right collaboration and the right 12 approach to innovation, and at the end of the day to 13 ensure that the resulting products are going to be 14 affordable and available by delinking and separating 15 the cost of research and development from the price 16 of drugs. So this principle of the linkage that is 17 referenced in the WHO CEWG report as well as the UN 18 High-Level Panel Access to Medicines report. 19 one of the core norms of principles that we guide 20 our work when we're trying to improve incentives for 21 innovation for neglected diseases.

Thanks very much. Your time

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MR. MEHTA:

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1 has elapsed.

2 If I could now invite Knowledge Ecology 3 International to please approach?

MR. LOVE: Thank you. Do you mind if I make a really short statement so that there will be more time for questions?

MR. MEHTA: Your 10 minutes is up to you.

Can you please introduce yourself for the record and then begin your testimony, Mr. Love?

MR. LOVE: Sure. My name is James Love.

My friends call me Jamie. I work a lot in D.C. for

KEI, Knowledge Ecology International. I've been

here many times before. We have a written

submission. Does everybody have a copy of it,

because I have a few extra copies if you don't have

enough? A lot of what was in the submission were

references to employment data because often I think

there is an assumption that the IP-intensive

industries are economically powerhouses of

employment, and I know that this administration is

really focused on high-paying jobs and employment in

general.

I wanted to just go through and look at that because on the one hand you have the people that work in industries and sell things that are like pharmaceutical drugs or recorded music, and then the other hand you have other industries in the case of pharmaceuticals that have to pay for the drugs for their employees which makes them less competitive in world markets, so it's not like 100 percent a good thing if General Motors has to pay high prices on cancer drugs for their employees.

Then I want to sort of put in perspective like, for example, the recorded music industry, how miniscule their employment is as compared to other sectors that may have a different position on some copyright issues.

And the last thing I just wanted to mention, I address a lot of different topics here, and I'm not going to go through them all, but just on this thing that you talked to Judit about, the last speaking from MSF about how you sort of reconcile getting innovation without high prices. I don't know; prices are really high. Orphan drug

prices are -- we're working on a drug right now,

Spinraza. It's \$750,000 in the first year. It's

four injections a year. It's \$375,000 for

maintenance doses. It was developed -- really the

technology was developed under an NIH grant. Cancer

drugs are coming in over \$10,000 a month.

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If you think your job is to make prices higher, you pick up the phone and talk to the White House because President Trump seems to think his job is to make prices lower. If you think you're going to get everyone else to pay higher prices, you should look at the challenges they face in paying for cancer drugs right now. The difference in a lot of cancer drug prices -- well, I'll stop there except to say that we're in favor of reforming the incentive system so you give money to people, not monopolies, when they develop drugs you care about. We also think the objective of trade policy should be share the burden of pain for R&D, not having high prices because they seem like they're the same thing, but they're really different.

So we subsidize work from drug tax credit

1	for clinical trials. It's a huge percent of drug
2	approvals. It was 47 percent of drug approvals last
3	year or two years ago in 2015. It's a 50 percent
4	tax subsidy on the cost of clinical trials, which is
5	where the biggest expense for R&D comes from. No
6	other country pays for that. That could be a trade
7	topic. You don't have to sort of go after high
8	prices all the time. You could have other people
9	provide the kind of subsidies we need for
10	development instead of high prices.
11	And if you wanted to collaborate on, for
12	example, in providing bigger rewards for people,
13	either downstream research or incentives for
14	products, you can do it without having high prices.
15	But I'll take questions now.
16	MR. MEHTA: Great, thanks very much. For
17	the first question, if we can go to the U.S.
18	Copyright Office, please.
19	MS. STRONG: Thank you. In KEI's written
20	testimony, it states that USTR should consider
21	bringing a case against the European Union and the
22	WTO for imposing trade restricting neighboring

rights that undermine the Berne Convention mandatory
exceptions for quotations and news of the day.

I would love a clarification. Is your concern here directed at the EU proper or perhaps at particular EU member states which have in one way or another implemented laws that have addressed matters related to what is commonly known as ancillary rights? And as a follow-up, do you have any particular views on those member states' implementation?

MR. LOVE: We made a concern about the German and the Spanish ancillary right approaches, and I think the EU is considering in the copyright, in their negotiations over the copyright directive making this EU-wide. I think it's really -- it's a big deal to us that you're going to create -- I mean the Berne Convention is not exactly like an EFF type document. What you've got here is the bedrock of copyright protection is something that was really designed to protect authors and performers, authors in particular. And always this case of quotations and news of the day have always been held out as

sort of sacrosanct. That's something you didn't
really want to mess with, with the copyright system.
They were mandatory exceptions. As part of the WTO
Agreement, they are mandatory exceptions because the

Berne Convention is part of the WTO Agreement.

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The U.S. has a lot of stake in that because we are the dominant provider of social media on the planet right now. There is nobody even close. It goes to the -- I mean what do people do? Today I was using Twitter. I was putting in links to news articles and blogs and things like that and quoting other people. Anyway, I'm sorry I went on and on about that, but it's sort of surprising to me that there hasn't been a more formal response to the United States with what's happening in Europe. is perceived to set -- one of the reasons it's popular in Europe is because it's an anti-American thing and people resent the fact that Google and Twitter and Facebook and things like that are big success stories that are American. And they're not Americans, and so they see it as a way of sort of leveling the playing field in some way. I wish they

would find some other way, like learning how to tax
big corporations or something like that.

MR. MEHTA: Thanks very much. For our second question, if I can look to USTR, please?

MS. PETERSON: Your submission indicates that China and other countries have used patents to block access to its market and that we should reexamine support for effective patent enforcement in China for that reason. Yet, in other submissions, an array of U.S. industries support greater effectiveness in patent enforcement in China. Can you assist us in squaring your views with the other submissions that we've received?

MR. LOVE: Right. I mean I may quibble with the characterization of our testimony, but it is a case issue. We all know that China is by far and away right now the biggest issuer of patents on the planet. They have taken -- I think what you've seen in China is they look at the United States, and they saw the U.S. is the source of a lot of low-quality patents. We were perceived to have lower standards for granting patents than the European

Patent office and Germany did or the U.K. did. And so for a while people were kind of annoyed by that because they get sued for patent infringement a lot in the United States. They said, well, we can play that game, too.

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So now, as you know, China is cranking out large numbers of low-quality patents, and U.S. firms now are on the receiving end of injunctions and damages in China for violating low-quality Chinese patents. I mean the enforcement of valid patent claims and patent quality is sort of a nuance complicated issue, and it really depends how you feel. At least in our opinion, we're in favor of strong patent protection in some areas, and we are probably in favor of weak patent protection in other areas. But the patent quality issue, I think everyone recognizes it's not a good idea to grant patents on something that has already been invented or is really obviously -- or has a low standard of patentability.

If you look at what's happening in China right now, it's kind of hard to ignore. And also

pay attention to the fact that for several years now
the majority of the patents in the United States are
filed by foreigners, not by Americans, and I think
that's something you need to pay a little bit more
attention to.

MR. MEHTA: Next question from PTO?

MR. SMITH: You note that for both the motion picture and sound recording industries, the ability to provide legal offers for work streamed over the internet, such as Netflix, Amazon, Hulu, HBO GO, SHOWTIME ANYTIME, Spotify, and Pandora have greatly reduced the threats of piracy. Could you explain a bit more how these services have reduced the threats of piracy? Other commenters in this docket have argued that digital piracy continues to present a major problem to businesses, even as the licensed content to these services and the numbers of services offering legitimate content grows?

MR. LOVE: I'm sympathetic to the concerns of people in the copyright industry about theft, whether it's computer games or it's movies or

journals or anything else. I don't want to downplay the seriousness of the problem. I did mention in the motion picture area, they were losing the battle. I mean a time when people -- there's all these issues about time-sharing content or people not wanting to subscribe to really expensive cable services and things like that. The fact is now you can have an internet connection, basically cut the cable with the other cable bundles that you get, and it's just the convenience of doing things on a stream basis where you get it when you want it. 

People don't really care about owning movies anymore. They really just want to watch them. They may have in the attic somewhere a big box of DVDs that they bought that they got tired of cluttering up the living room because nobody wants to use them. I just think it's been revolutionary. I think in the music area, too. You go to a secondhand store and look at the price of used CDs. I mean people just give them away now because they're the same fate as DVDs basically.

And for the gaming industry, it's a little

different for the console industry like Nintendo as 1 opposed to, for example, people that have streaming 2 services, like Microsoft relies a lot on 3 4 subscriptions. But I think that there has been a 5 lot of innovation by the industry. Listen, I think 6 if somebody hacks a computer game, which could be a 7 bigger investment than a movie nowadays, for 8 example, it's a legitimate concern that policy 9 makers should have about those things. It's not the 10 primary that we work on. 11 But certainly in the case of the streaming 12 of movies and music, it has really changed.

of movies and music, it has really changed. And getting those services into developing countries, it also allows a certain amount of price discrimination, which allows you to have more reasonable pricing in areas depending on how they deal with innovative use of VPNs and stuff like that, which everyone who has been stationed in China has probably used themselves. But, anyway, I'll stop there.

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MR. MEHTA: Great, thanks so much. The time for your testimony has elapsed now.

We now have a short break. We will take a 1 10-minute break, and we will reconvene promptly at 2 3 12:30, so please don't go too far. 4 (Off the record at 12:19 p.m.) 5 (On the record at 12:30 p.m.) MR. MEHTA: Welcome back to everybody. 6 7 Our first presenter after the break will be the Intellectual Property Owners Association. 8 9 MS. PIERCE ROLLINS: Thank you. Special 10 301 Subcommittee members, my name is Vanessa Pierce Rollins, and I am Senior Counsel for International 11 12 Affairs for the Intellectual Property Owners 13 Association. IPO is an international trade 14 association representing companies and individuals 15 in all industries and fields of technology who own 16 or are interested in IP rights. IPO's membership 17 spans 50 countries with nearly 200 companies and 18 more than 12,000 individuals. IPO advocates for 19 effective and affordable IPO rights. On behalf of 20 IPO and its members, I would like to thank you for 21 the opportunity to testify today and for your 22 continued work ensuring U.S. trading partners have

effective IP systems.

IPO members make vital contribution to America's economic success by developing the advances that drive exports and create jobs. Innovators assume considerable risk, and we rely on our IP assets to protect our investments in new technology. We were pleased to see that IP is one of the top priorities identified in the recent trade policy report.

In our comments to the Subcommittee, we outline existing and emerging threats to the IP rights of our members. Today I will highlight two areas that if left unchecked could cripple our innovation-driven exports and the U.S. jobs they support.

The first relates to mounting pressure to dismantle the IP systems that enable us to invest in new technologies, bring them to market, and support high-paying U.S. jobs. The second concerns inadequate trade secret protection in many countries which have failed to keep pace with the technological innovation that has enabled modern

cyber theft.

demands to chip away at the rights we depend on within multilateral institutions. Such efforts are largely based on misinformation about the impact of IP rights on innovation and technology diffusion. The principal argument is that IP systems are a barrier that needs to be overcome for developing countries to benefit from innovations and to advance. Yet, this does not accurately reflect the contribution of IP to the innovation and technology diffusion that our members engage in every day. This argument ignores that IP systems have supported life-changing innovations across all sectors for decades.

Demands to chip away at IP rights come in many forms. Some are explicit, calling for the elimination of IP rights for certain technologies or the broader use of compulsory licensing. Others take a more insidious approach, advocating for actions like technology buyouts, vague new IP mechanisms, or a list of technologies that would be

ripe for transfer. These proposals wreak havoc on
the marketplace by introducing additional
uncertainty, which makes it riskier for members to
invest in innovation. This dynamic also discourages
us to share technology and knowledge with our
partners despite such exchanges being essential to
remaining competitive.

For instance, at the World Intellectual
Property Organization, several countries have
relentlessly pursued a work program focused on
expanding exceptions and limitations to patent
protections. Designed in three phases and tabled
initially by Brazil, one specific proposal calls for
a detailed exchange of experiences with exceptions
and limitations, a determination of the most
effective ones, and ultimately the development of a
WIPO how-to guide that would teach countries to
implement and use them as part of their industrial
policies.

We appreciate that the USPTO continues to push back on these proposals. Ironically, these and similar programs aimed at eroding IP rights are

regular themes at WIPO, an organization primarily

funded by PCT applications, including fees paid by

U.S. innovators. Our members remain concerned about

such initiatives as assaults on IP systems are

cropping up in increasing numbers and in a range of

international bodies.

We ask for your vigilance to counter these frequent attacks, including through a robust interagency process that can effectively monitor and push back on IP erosion.

The value of U.S. innovation is not lost on our global competitors. Unfortunately, some countries enable and even encourage their domestic industries to expropriate our know-how. IPO members face threats to their hard-earned trade secrets through both illicit means and forced regulatory disclosure. Even in countries where misappropriation is not encouraged, many trade secret regimes fail to provide adequate protections against theft through cyber channels, suitable avenues for recovery, or meaningful deterrents.

For example, Austria, despite offering

protection for some trade secrets, still fails to safeguard nontechnical but commercially sensitive information. The law offers minimal criminal penalties for misappropriation, only three months even for the most egregious cases. Our members face obstacles gathering evidence and having trade secret cases adjudicated by courts specialized in complex technical and commercial issues.

In China, our members face high burdens of proof, limited discovery, and minimal damages when seeking to enforce their trade secrets. Especially distressing, a trade secret owner has to wait until a significant and possibly irreversible injury has taken place before seeking relief. Our members also face regulatory requirements to submit confidential details as a condition of market access.

India lacks any explicit protections for trade secrets. Instead, our members must rely on contractual obligations to preserve their know-how. But this situation does not match the reality that many of our members face, when there is no relationship between trade secret owner and a

potential thief.

Finally, in Russia, there are onerous burdens on our members to enforce their trade secrets, including exacting standards for how the relevant information must be inventoried and marked. Noncompliance with these requirements, which in many cases is impractical, quashes the ability to recover from theft. Our members also find enforcement inadequate.

In our global information-based economy, knowledge is often our most valuable currency. Yet, as illustrated here, trade secret laws around the world fail to offer a level playing field for U.S. innovators. Instead, these inadequate regimes enable competitors to use U.S. innovators' hard-earned knowledge at a fraction of the cost. We urge you to work with and encourage our trading partners to adopt much needed upgrades to safeguard U.S. know-how.

In conclusion, innovation-driven jobs depend on high quality IP systems to reinforce them. With the majority of consumers living outside our

1	borders, effective IP protection in foreign markets
2	is vital for U.S. innovators. Our members need your
3	continued engagement to ensure that robust IP rights
4	are available, reliable, and enforceable. We look
5	forward to working with you to secure optimal IP
6	regimes globally and to safeguard the quality,
7	high-paying U.S. jobs they can help to deliver.
8	We again thank the Subcommittee for its
9	efforts to preserve IP rights and promote the
10	innovation that will sustain and grow America's
11	economy. Thank you.
12	MR. MEHTA: Thanks so much. If for our
13	first question we can look to the PTO? And before
14	we start, I would just like to note that Karin
15	Ferriter has now joined us and will be representing
16	PTO. Thank you.
17	MS. FERRITER: Thank you, Probir, and
18	thank you, Vanessa. IPO's written testimony states
19	that South Africa's National Policy On Intellectual
20	Property in 2013 indicates an intent to, I quote,

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"weaken the existing IP system." The statement

further acknowledges South Africa's release of an

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Intellectual Property Consultative Framework in fall 2016. Can you provide additional details on IPO's reactions of the Consultative Framework? MS. PIERCE ROLLINS: Thank you for the question, USPTO. And if I may, I would like to follow up with a supplemental written response on that particular issue. MR. MEHTA: Thanks. For the second question, Department of Commerce, please. MR. MITCHELL: Yes, your submission indicates that U.S. companies can participate in 

indicates that U.S. companies can participate in Chinese standard-setting activities only by invitation. We were hoping you could elaborate on your concerns over this practice.

MS. PIERCE ROLLINS: Certainly. The invitation-only requirement for the standard-setting organizations potentially keeps some of our owners out of the process when they should be involved. That's critical to us that they be involved, that these discussions and standard-setting operations be transparent. Right now it's very unclear, and even some of our owners are involved in standard-setting

without their permission. It's the entire process
that needs to be evaluated, and we urge you to make
it as transparent as possible. Thank you.

MR. MEHTA: Great. And for our final question, DOJ.

MR. LAMBERTI: Thank you. In your testimony, you expressed concerns that China's draft IP abuse regulations under China's Anti-Monopoly Law may cause innovators to exercise an overabundance of caution when exercising their IP rights, including in the licensing context. Can you provide the Committee with some additional detail about that chilling effect? And in doing so, could you also provide the Committee with some specific instances, without mentioning the companies' names, in which Chinese authorities have formally or informally raised the possibility of AML enforcement actions in private conversations with companies?

MS. PIERCE ROLLINS: Certainly. Thank you for the question. We have several concerns about the anti-monopoly provisions, most of which involve again the lack of clarity. Some of the key terms

1	are left undefined, including market dominance.
2	That's what leads our members to have that caution
3	that you indicated and not wanting to get themselves

into any bind under any of the provisions, like I

5 said exercising extreme caution.

One of the issues that we have noted is that there are several administrative agencies that are working -- administrative and legislative agencies that are working on the anti-monopoly provisions. And with the terms of what the violations would be left undefined and vague, and the parallel proceedings at MOFCOM and the NDRC, we are again left with lack of clarity about what actions would constitute violations.

As to specific examples from specific companies, I would be happy to follow up with a supplemental written response on that. We do have examples, but I would like to clear that with them first.

MR. MEHTA: Thanks very much for your testimony.

Next I'd like to invite the Internet

- Association to please approach. Welcome. Can you please introduce yourself for the record and begin your testimony.
- 4 MR. GIOVENCO: Thanks. Good afternoon. 5 My name is Ari Giovenco. I am Director of Trade and 6 International Policy at the Internet Association. 7 We represent over 40 of the world's leading internet 8 companies and support policies that promote and 9 enable internet innovation, ensuring that 10 information flows freely across natural borders 11 uninhibited by restrictions that are fundamentally 12 inconsistent with the transnational, free, and 13 decentralized nature of the internet.
  - U.S. internet platforms are a significant driver of the U.S. economy and U.S. exports. Our industry represents an estimated 6 percent of U.S. GDP and account for nearly 3 million American jobs. Many of these jobs depend on internet-driven exports. Digital trade alone has added up to 2.4 million jobs to the U.S. economy.

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Hundreds of thousands of U.S. small businesses now use the internet to reach customers

1	around the world in ways impossible a generation
2	ago. At the same time, all U.S. industries, from
3	manufacturing to financial services to farming, are
4	increasingly relying on the internet and see
5	internet-enabled tools as critical to their future
6	global competitiveness.

In addition, the internet has helped the United States unlock a massive \$159 billion trade surplus in digitally delivered services in 2014.

And each year, U.S. manufacturers leverage the internet to export \$86.5 billion of products and services through online sales.

To maintain and expand U.S. digital trade leadership, the United States must push back on market access barriers and insufficient legal regimes abroad that threaten the internet's growth. One foundational foreign barrier our members face 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 actions on illicit

activities, it is also critical for USTR to

highlight countries that misuse copyright in a way

that restricts U.S. platforms and small businesses.

In this year's Special 301 Report, we ask that USTR recognize that countries are increasingly distorting the function of IP to deny market access to U.S. companies.

In the U.S., we take for granted a balanced and well-functioning system of IPR that enables the operation and growth of the internet. However, as U.S.-based internet companies expand service around the globe and as all U.S. exporters increasingly rely on the internet to power trade, they are encountering unbalanced copyright frameworks that deny adequate protection of rights and protections granted under U.S. law.

Given that much of the current and future growth of U.S. industry will be generated through overseas business, problematic copyright frameworks in countries present a clear danger to the strength of the U.S. economy.

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.

The proliferation of ancillary copyright or neighboring rights laws in Europe directly threaten U.S. internet platforms as they restrict activities that are clearly permitted by U.S. law. In addition, these new restrictions on quoting text or using snippets runs afoul of Article 10(1) of the Berne Convention. As you know, Berne is incorporated into TRIPS Article 9, raising important enforcement questions at the WTO.

Implementation of ancillary copyright in EU member states such as Germany and Spain have generated direct and immediate market access barriers for U.S. internet services and other U.S. industries, resulting in the shutdown of services like Google News. In Spain, studies show that the law has led to a loss in consumer surplus and an 11 percent drop in valuable traffic for news publishers.

In addition, there is now an EU-wide neighboring rights proposal that shares many of the flaws of previous ancillary copyright laws and is even more expansive in certain respects. This proposal is not limited to search engines and lacks an exception for the kind of short snippets on which many U.S. online services rely. We strongly urge USTR to address these concerns in the 2017 Report.

The European Commission is also proposing changes to the copyright directive that would dramatically shift the landscape of copyright intermediary liability in the EU. The proposed changes would represent a significant departure by the EU from its shared approach with the U.S. and would restrict exports of U.S. online services in the EU.

The EU proposal would require a broad range of online services to monitor and filter content. It also provides for a potentially intrusive process regarding the design and operation of content recognition technologies. Both the United States and the EU created a safe harbor that

protects online services from being liable for what
their users do as long as the service acts
responsibly. This is a core part of U.S. copyright
law established within Section 512 of the DMCA.

We encourage USTR to raise strong concerns about the new proposal, recognizing that it will serve as a damaging market access barrier for U.S.-based services if it is implemented.

In France, the newly enacted image indexation law creates a new legal barrier by creating a requirement that U.S. online services secure a license for the right to index or reference French images. U.S. services usually have no way to know how to distinguish a French image from a non-French image, meaning the territorial scope is unclear. Unfortunately, this law is wracked with ambiguity, and artists and photographers cannot opt out. We urge USTR to address this new legal barrier in the 2017 Report.

We also have concerns about new intermediary liability measures in Ukraine. Ukraine was included on the 2016's Special 301 Report Watch

List due to a lack of transparent and predictable provisions on intermediary liability. recent proposed law includes numerous measures that fall far short of the DMCA standard, including unfeasible timelines for removing content, lack of a clear counter-notice process, and language that would require intermediaries to monitor and filter user content. These and other provisions jeopardize the ability of U.S. companies to serve the market in

Ukraine.

IA members also continue to face significant market access barriers in Australia.

Under the Australia-U.S. FTA, Australia is obligated to provide safe harbors for a range of functions by online service providers. To date, Australia has failed to comply with this commitment. We urge USTR to include this barrier in the 2017 Report and engage with the Australian counterparts to correctly implement this commitment.

Finally, in addition to unbalanced IP policies, U.S. internet services are dealing with a number of problematic measures in China that are

1	forcing cloud service providers to transfer trade
2	secrets as a precondition of operating in the
3	market, all while U.S. cloud service suppliers are
4	already prohibited from using their own trademarks
5	and brands to market their services. We urge USTR
6	to engage with China on the numerous problematic
7	laws and regulations.

To conclude, it is our hope the 2017

Special 301 Report will support the digital economy and recognize the harm unbalanced IP policies have on both internet industry and the U.S. economy as a whole.

With that, thank you for holding today's hearing. I'm happy to answer any questions.

MR. MEHTA: Thanks very much,
Mr. Giovenco. For our first question, can we go to
Department of State, please.

MS. DYER: You just mentioned China and its cloud services requirements. Your written statement also addressed this, and you said they are requiring providers to transfer high-value IP. Can you talk a little bit about the mechanisms for the

transfer that they are requiring? Is it an 1 investment restriction or some other mechanism? 2 3 MR. GIOVENCO: I'm happy to follow up on 4 the specifics of that question. 5 Thank you very much. MS. DYER: MR. MEHTA: Second question, if we can go 6 7 to the U.S. Copyright Office, please. MS. STRONG: Your submission explains that 8 9 IP safe harbors have been critical to the growth of the internet and online trading. When a country 10 lacks a clear safe harbor provision, how does it 11 12 affect your members' decisions to operate or invest 13 in the market, and if you could, if you could 14 identify particular markets? I realize you already 15 mentioned a couple of those developments in the 16 European Union and you also mentioned Australia. So 17 if you can elaborate? Thank you. 18 MR. GIOVENCO: I think when we see these 19 unbalanced frameworks put in place and an 20 intermediary liability safe harbor is maybe not 21 tailored for the digital economy, our companies see

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significant risk in operating in that market and

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1	possibly launching in that market if they haven't
2	been there previously. I would just I noted in
3	my testimony, yes, the EU, and the proposals in the
4	EU are very problematic.

In Australia, I think that we see a commitment that was made to make their safe harbor appropriate for internet service providers. That commitment has not to this date been implemented correctly. Right now I believe that it is carriage providers in their definition, which is just mostly broadband providers. So we really see that if that were to be implemented, our companies would be able to operate with lower risk, and launching these services would be much easier.

MR. MEHTA: Thanks so much for your testimony today, Mr. Giovenco. Your time has elapsed.

MR. GIOVENCO: Thank you.

MR. MEHTA: Next, if I can invite the International Intellectual Property Alliance to the front? Welcome, sir. Please introduce yourself for the record and begin your testimony.

1	MR. ROSENBAUM: Thank you. Good
2	afternoon, my name is Kevin Rosenbaum. I am counsel
3	to the International Intellectual Property Alliance.
4	Thank you for the opportunity to present the views
5	of the IIPA in this year's Special 301 process. We
6	applaud the U.S. government for making the Special
7	301 Review a catalyst for positive change, to
8	address the challenge faced by the U.S. creative
9	industries in key markets abroad. We welcome the
10	chance to participate again in this crucial annual
11	dialogue.
12	IIPA is a private sector coalition formed
13	in 1984 of five trade associations representing U.S.
14	copyright-based industries. The core copyright
15	industries combined, according to a December 2016
16	study, contribute over \$1.2 trillion to the U.S.
17	economy, providing 5.5 million jobs and nearly
18	7 percent of gross domestic product.
19	Our members are Association of American
20	Publishers, Entertainment Software Association,
21	Independent Film and Television Alliance, Motion
22	Picture Association of America, and the Recording

Industry Association of America. These associations
comprise over 3,200 companies producing and
distributing materials protected by copyright laws
throughout the world.

To reach foreign markets through

legitimate and state-of-the-art 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 more products and services 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 protections."

It is crucial for the Special 301 process to maintain this focus on intellectual property protection, in our case copyright protection. There are those who ask you to dilute this focus 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. This is not the approach that has made the Special 301 so successful. And the Special 301 process is not the place to advocate that our trading partners weaken the copyright

regimes, especially in countries where legitimate copyright holders cannot get a toehold due to grossly inadequate copyright protection or enforcement.

In this year's submission, IIPA recommends that 16 countries be identified in the 2017 Special 301 Report. All these are listed in our hearing statement with capsule summaries on the eight countries we recommend for inclusion in the Priority Watch List, including Chile, China, India, Mexico, Russia, Taiwan, Ukraine, and Vietnam.

Our submission highlights two crosscutting challenges facing the United States in
today's trade and copyright environment. The first
is the troubling gaps and shortfalls in compliance
with obligations taken on by U.S. trading partners
in bilateral and multilateral agreements, including
the WTO TRIPS Agreement, a score of free trade
agreements, and a wide range of other bilateral
agreements that are intended to open markets to U.S.
goods and services dependent on copyright
protection.

Our trading partners are already enjoying the benefits of these agreements, including enhanced access to the lucrative U.S. market. But the United States has not fully realized the corresponding benefits because the creative sector that is so critical to our economy has yet to achieve the full access to these markets that was bargained for.

U.S. trade agencies should make it a top priority in 2017 to reverse this unfortunate trend, including by carefully monitoring and actively enforcing compliance with these obligations.

Second, in many countries around the world, copyright reform efforts have become a

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 exceptions and limitations to copyright protection that satisfy the well-established three-step test. The U.S. government must urge U.S. trading partners to adhere to current and evolving global norms, including in areas such as term of copyright protection and protections for technological controls that

1 copyright owners use to control access to their 2 works.

Our submission also lists 11 key challenges that we urge the United States government to prioritize in its bilateral engagement with our trading partners, starting of course with internet and mobile network piracy, an overarching challenge for all businesses that depend on copyright. The growth of new fully licensed and legitimate channels for consumers around the world to access creative content in a variety of new and innovative ways has been one of the most encouraging trends in global markets for copyright material.

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 licensed 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 to combating systematic online copyright theft. And we urge you to redouble efforts to encourage our trading partners to adopt legal frameworks that create incentives for legitimate network service providers to work with right holders in advancing 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 in 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 off-shoring 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 unavailing 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 makes it easier for pirate operations to fill the void. U.S officials should continue to strive to eliminate or phase 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 the U.S. Trade Representative and other U.S. agencies to advance these goals. I'm happy to answer any questions. Thank you.

MR. MEHTA: Thanks very much. The first question, if we can look to the Department of Treasury, please.

MR. CHANG: Thank you for your submission. In your submission regarding Mexico, it seems as if the primary change in Mexico that you identify in past years is a rise in unlawful camcords. To what do you attribute this change, and how would you recommend that the Mexican government resolve this problem?

MR. ROSENBAUM: Thank you for that question. I think it's unclear what may be contributing to the explosive growth of camcording in Mexico, but it certainly is disturbing to us coming from such a significant trading partner. As

- 1 for solutions, we encourage Mexico as well as the rest of our trading partners to implement criminal 2 3 liability for camcording, a time and place 4 violation. So I think that would be one major step 5 they could take, as well as encouraging cinema 6 personnel and others to be involved in combating the 7
- Second and last MR. MEHTA: Thanks. 8 9 question, DOJ, please.

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MR. LAMBERTI: Thank you very much. Wе talk a lot about pirated and counterfeited goods coming from China. Your testimony, though, highlights practices whereby individuals and companies in China are exporting devices and software that facilitate IP infringement outside of China, so we're talking about set-top boxes filled with pirate apps, illicit streaming devices. talking about circumvention devices. Could you give the Committee a little more detail about the trends in this area? Do you see a need for legislation? What kind of enforcement would you like to see?

MR. ROSENBAUM: Thank you for that

question. Yes, this has become a problem that continues to grow. At one time it was confined to particularly referring to ISDs, illicit streaming devices. What we used to call set-top boxes, we refer to as illicit streaming devices to really focus on the fact that these are used to facilitate piracy. And it used to be confined to the Asia-Pacific region, but now we're seeing them in all kinds of other markets, Peru, the South America region. And we think that there are measures that need to be taken in China. Certainly more can be done under existing legislation focusing on the distribution of these devices both within China and as you say with customs and the exports around the world.

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Also, I think something that goes along with this is a focus on the app ecosystem, so a lot of these devices depend on apps that facilitate the access to the pirated content. Very often those also come from China. Certainly under existing legislation, there is more than can be done. And also as well, China is undergoing a copyright reform

1	process, and there are certainly measures that they
2	could take that would enhance enforcement in this
3	area, too. I'm happy to follow up with specifics or
4	that.
5	MR. MEHTA: Great. Thanks so much for
6	your testimony today.
7	If I could now invite the Global
8	Intellectual Property Center at the U.S. Chamber of
9	Commerce to approach. Welcome. If you could please
10	state your name for the record and begin your
11	testimony.
12	MR. KILBRIDE: Good afternoon. I'm
13	Patrick Kilbride with the Global Intellectual
14	Property Center at the U.S. Chamber of Commerce.
15	Thank you for the opportunity to testify and for the
16	ongoing government-wide efforts to help promote and
17	sustain an intellectual property-led innovation
18	model around the world. The Chamber's 2017
19	submission to the Special 301 process is intended to
20	shed light on both systemic and country-specific
21	challenges to a strong global innovation ecosystem.

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Our comments are informed by the fifth

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1	edition of the U.S. Chamber's International IP Index
2	which was released on February 8th. The index
3	assesses the strengths and weaknesses of the IP
4	environments in 45 diverse economies collectively,
5	representing almost 90 percent of global GDP.
6	By benchmarking countries against 35
7	indicators across the spectrum of intellectual
8	property rights, the index creates a roadmap for
9	countries wishing to stimulate domestic spending on
10	research and development, generate
11	knowledge-intensive jobs, and improve access to
12	innovation products, services, and technologies.
13	Supporting the principle that IP enforcement is not
14	a concession that countries make but rather an
15	investment in jobs, development and growth, the
16	index includes a robust set of statistical
17	correlations that demonstrate the relationship
18	between a country's IP strength and a host of
19	important socioeconomic outcomes that all
20	governments share.
21	The findings suggest positive
22	correlations, for instance, between IP strength and

benefits such as innovative output, access to

innovation, and human capital development. We found

that these apply at every level of development and

income.

The Chamber's 301 submission identifies both some positive and negative trends in the global environment. On the positive side, we've seen increased utilization of specialized IP courts, including China, Pakistan, the United Arab Emirates, and Sweden. We've seen increasingly countries joining patent prosecution highways in countries including Argentina, Chile, Colombia, Mexico, Peru, the Philippines, and Vietnam. We have also seen more attention to the trade secrets space in an area that had I think been underdeveloped.

On the negative side, we're encountering more and onerous forced localization requirements as a condition for intellectual property protection, including in Ecuador, Indonesia, Nigeria, Russia, and South Africa. Some governments are actively promoting routine, discretionary use of compulsory licensing in a manner that we believe to be

inconsistent with global rules.

We are also concerned, as the last commenter said, about the proliferation of illicit streaming devices primarily manufactured in China, as well as the flooding of the market especially in the e-commerce space with counterfeit and fake goods that are a direct danger to consumer health and safety.

Beyond these in-country developments, we are also keeping a critical eye on the global policy environment shaped by both trade agreements and multilateral institutions. Trade agreements will continue to be critically important for building consensus to strengthen intellectual property standards internationally. The WTO TRIPS Agreement is now more than 20 years old, yet important provisions of the agreement have been waived repeatedly for a significant portion of the WTO membership.

Some would suggest that post-TRIPS, intellectual property has been tried. I believe our index shows that this is absolutely not the case.

In fact, of 45 countries measured, no 2 countries

achieved the same score despite the TRIPS Agreement

having been in effect for 45 years. This goes to

show that TRIPS represents a minimum standard, a

floor, not a ceiling, for countries that want to be

active, successful participants in the global

knowledge economy.

U.S. trade policy leadership along with willing partners is fundamental to advancing an IP-led innovation model globally. It is also critical that the U.S. government work together with other nations at the leading multilevel institutions to reinforce and promote IP standards. Discussion of international IP standards should appropriately be the jurisdiction of those organizations with an established member state mandate, including the World Trade Organization, the World Intellectual Property Organization, and where applicable, the World Health Organization.

However, international activists are increasingly working to diminish global IP standards through institutions that lack the mandate or

1	expertise to make IP policy, leading to a confused
2	policy environment and a deeply misinformed global
3	dialogue. The UN Development Programme, despite its
4	lack of specialized expertise or mandate, this past
5	year issued guidelines for the examination of patent
6	applications relating to pharmaceuticals, guidance
7	which reportedly informed policy decisions in
8	Indonesia and South Africa and we expect is
9	continuing to influence other nations' decisions.
10	Similarly, the UN High-Level Panel on
11	Access to Medicines relied on a flawed premise to
12	develop a set of recommendations that, if
13	implemented, would undercut the legal framework for
14	investment in innovation research and development.
15	Despite the non-endorsement of this report by the UN
16	General Assembly, the Secretary-General, and the
17	World Health Organization, activists and some
18	country missions continue to venue-shop this panel's
19	recommendations.
20	Delegates from Brazil, India, and South
21	Africa, to name a few, are working actively to
22	undermine support for the IP standards that underpin

the knowledge economy by restricting patent 1 eligibility and encouraging routine use of 2 compulsory licenses and other exceptions and 3 4 limitations. In the last five months alone, we can 5 point to at least a dozen instances where those 6 delegates have used the flawed UN panel 7 recommendations to advance an anti-IP agenda at institutions, including the UN Conference on Trade 8 9 and Development, the UN Development Programme, the 10 WTO, the WHO, the WIPO, and UNAIDS, among others. Their proposals would unduly narrow the scope of 11 12 patent-eligible innovations and foster the legal 13 uncertainty that is anathema to investment in innovation. 14 15 Taking root at these multilateral 16 institutions, these flawed ideas are then replicated 17 around the world in countries like Colombia and 18 Indonesia, doing a disservice to the legitimate

20 made in the name of access actually serve to

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21 suffocate innovation activity and harm access to the

development goals of those nations. These efforts

22 very innovations they purport to advance. At a time

1	when the world desperately needs solutions to common
2	global challenges of hunger, disease, climate, and
3	poverty, we need more, not less, partners in
4	innovation.

Accordingly, American leadership in these multilateral organizations, together with likeminded nations, is critical to counter the false narratives that are circulating around IP and cultivate a global understanding of the innovation model that allows for high-risk, high-cost, and long-term investment in innovative and creative activities so that we can enjoy the full creative and innovative capacity to all the world citizens.

Thank you very much.

MR. MEHTA: Thanks very much. For our first question, Department of Commerce, please.

MR. MITCHELL: Yes. Your submission underscores the importance of voluntary agreements for reducing online piracy and counterfeiting.

We're hoping you could take a moment to expand upon that. Where are such agreements in place? Where are such arrangements being considered? And what is

their overall impact?

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MR. KILBRIDE: As I mentioned, the 2 3 e-commerce space is where we have seen piracy really 4 take off, especially taking advantage of the 5 relative difficulty of policing small parcel 6 traffic. And so it's clear that we need cooperation 7 from all participants in the ecosystem. Every 8 entity that benefits from or profits from 9 participation in the supply chain needs to be part 10 of the solution.

Various companies in the e-commerce space, including some of the larger platforms, have indicated a willingness to work on this. We want to take them at their word, but we also want to use that old maxim of trust but verify. So I think that is an underdeveloped space but one that desperately needs more attention.

MR. MEHTA: Second question, USTR.

MS. PETERSON: On India, you noted that India's performance on the U.S. Chamber's Innovation Index improved this year from 24 to 25 percent in the most recent report, and this is despite the

numerous new and longstanding challenges described
in your submission. Can you explain what factors
may have contributed to India's slightly improved

score?

MR. KILBRIDE: Sure. As a technical matter, the index added five new indicators this year that included industrial design coverage, licensing of intellectual property rights, patent opposition frameworks, and so a number of countries improved their numerical score based on strength in those indicators.

But I do want to note, as my colleague from the U.S.-India Business Council did this morning or early this afternoon, that India has made some important commitments in the context of its national IPR policy that we find valuable, including raising awareness among Indian entrepreneurs, streamlining administration of intellectual property rights, facilitating licensing arrangements. On the other hand, we haven't seen the attention we believe is needed to some of the structural, legal frameworks underlying India's approach to IP,

1	including Section 3(d), which unnecessarily limits
2	patentability and we believe is not consistent with
3	India's international commitments, the computer-
4	implemented invention guidelines that Dr. Mukesh
5	pointed out Dr. Aghi, excuse me as well as in
6	some other areas regarding civil and criminal
7	remedies for copyright infringement, for instance.
8	So we appreciate very much the leadership
9	of the U.S. government engaging India, helping to
10	develop the constructive framework to address some
11	of these issues, and we think it needs to continue.
12	MR. MEHTA: Thanks very much for your
13	testimony, Mr. Kilbride.
14	MR. KILBRIDE: Thank you.
15	MR. MEHTA: If we can next invite the
16	Footwear Distributors and Retailers of America to
17	the presentation table, please.
18	Welcome, sir. Please introduce yourself
19	for the record and begin your testimony.
20	MR. CROCKETT: Thank you. Good afternoon.
21	My name is Thomas Crockett. I am Director of
22	Government Affairs for the Footwear Distributors and

Retailers of America. Thank you for the opportunity
to testify at today's Special 301 hearing.

Founded in 1944 by the U.S. footwear industry, today FDRA represents more than 130 footwear companies and 250 brands. We support the entire width of the industry, small family-owned footwear businesses, manufacturers, retailers, and global brands reaching consumers worldwide. Our member companies manage supply chains that span the globe, providing our companies with hands-on familiarity with the importance of intellectual property and innovation. They also incorporate cutting edge designs and technology into their products and rely upon the integrity of their brands.

We are acutely aware of the need to aggressively challenge the failure of other nations to protect patents, trademarks, and copyright in both law and practice. Attention to these issues supports U.S. footwear jobs and communities nationwide.

Global trade in counterfeits increasingly

targets American footwear brands. The World Customs

Organization's Illicit Trade Report found that

seizures of counterfeit footwear increased by

174 percent during the latest 3-year reporting

period and that footwear went from being the 12th

most seized product for IP violations in the world

to the 9th over the 3-year period.

FDRA members have noted five general concerns globally, some of which have been noted by USTR in past Special 301 Reports. First, over the past several years, the industry has seen a growing trend whereby labels and tags are shipped separately from infringing products and are attached to the infringing products in the domestic market.

Infringers apparently believe that shipping tags and labels separately helps to avoid brand identification by customs.

Second, infringers often use express mail and postal services to deliver counterfeit goods in small packages. Sellers often fraudulently report the contents or break shipments up into smaller packages to avoid detection. The tremendous

acceleration and growth of e-commerce globally will only exacerbate this already troubling trend.

Third, in numerous countries, legal and procedural obstacles exist to securing and enforcing trademark rights.

Fourth, often penalties are inadequate to deter criminal enterprises from engaging in trademark counterfeiting operations.

And finally, counterfeiters now commonly register domains that advertise and sell counterfeit goods. Many of these counterfeiters use a country code top level domain to avoid detection and to avoid the reach of the U.S. judicial system. FDRA companies face significant trademark infringement and lose valuable internet traffic because of misleading and fraudulent domain names.

In addition to these issues, FDRA notes that theft of trade secrets has become an increasingly important issue for global brands. In May 2016, Congress and the President took action on this issue with the enactment of the Defend Trade Secrets Act. FDRA believes that this law will have

a deterring effect on overseas competitors, who may otherwise engage in trade secret theft and will better equip the U.S. government to advocate for strong trade secret protection with foreign governments, particularly through trade agreements.

Now, I'm going to touch on a few specific country issues. In China, China continues to be the number one source of counterfeit and pirated goods imported into the U.S., accounting for 52 percent of the value seized, while Hong Kong rates second, accounting for more than 35 percent. Amazingly, the number of footwear units detained by customs for IP violations doubled in the last 3-year reporting period and now represents 10 percent of the total.

All too often, local officials turn a blind eye to counterfeiting activity, and knockoff footwear purportedly from America's best known sportswear brands is commonly found in brick and mortar Chinese retailers and well-trafficked markets. China's legal landscape can pose many challenges for U.S. brands. U.S. rights holders that try to work with the system and file claims in

Chinese court face a difficult, unpredictable,
lengthy, and costly process which is highlighted in
greater detail in our written testimony.

E-commerce sites are also a significant and rapidly escalating source of counterfeit goods to U.S. and global consumers. All Chinese e-commerce platforms need to take a more proactive approach to counterfeit products, an approach that requires filtering and removing illicit products rather than relying on brands to trigger a time-intensive and expensive takedown process.

In Russia, massive markets of counterfeit goods, both physical and online, continue to flourish. Enforcement procedures are generally slow and inefficient. There is an apparent reluctance to take action against large infringers, and the poorly staffed IP and economic crime police have led to deterioration in the level of enforcement. 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.

This is particularly important because the Russian e-commerce market was worth more than 9 billion euros in 2015, and sporting goods, clothing, and footwear are the fastest growing categories. As Russia prepares for the World Cup in 2018, it is more important than ever that the country makes commitments to address its significant counterfeit problem ahead of the games. 

In Brazil, despite its presence on the Watch List, the infringement of IP rights is still pervasive and flagrant, and the government has done little to combat the problem. There is minimal government funding and staff for IP enforcement and a lack of IP expertise among judges and law enforcement authorities. Because of a complex customs and regulatory system, imported consumer goods in Brazil are often more highly priced than in other markets. These high prices fuel the smuggling of counterfeit goods onto the black market.

FDRA members, which are among the more popular consumer brands in Brazil, often must compete with a flourishing black market. Online

counterfeiting activity in Brazil also remains a
major problem. In addition, the Government of
Brazil needs to provide adequate resources to
address the extremely lengthy delays and backlogs in
the processing of trademark registrations, design
patents, and utility patents.

In conclusion, FDRA appreciates the opportunity to testify on the challenges faced by our member companies around the world and the protection of their IP rights. As leading global innovators, our members are driving advancements in product design never before seen. Our industry stands on the cusp of innovations that will alter the way global footwear manufacturers produce footwear and deliver footwear to consumers. Now more than ever, it is vitally important that the U.S. government takes all actions necessary to protect these innovations, designs, brands, and images worldwide.

We stand ready to work with USTR to bolster respect for and enforcement of IP by our trading partners. Doing so protects American jobs

1	and benefits consumers.	Thank you,	and I'm	happy t	0
2	answer any questions.				

MR. MEHTA: Thanks very much. For our first question, if I can look to the Department of State, please.

MS. DYER: What, if any, best practices can you highlight for fighting counterfeiting and piracy globally, and which, if any, trading partners have you worked with in your efforts? You highlighted some deficiencies in certain trading partners.

MR. CROCKETT: Sure.

MS. DYER: I wondered if there were any good news stories that you can share.

MR. CROCKETT: I think as far as best practices, providing United States -- reports in the past have indicated transparency and consistency and involvement with stakeholders throughout the process. I think that's important and critical for our industry. I'm happy to provide some further examples and specific examples of countries, where I know we focused a lot on the negatives, but also the

1 positives where we've seen some good success
2 stories.

MS. DYER: Thank you very much.

MR. CROCKETT: Sure.

MR. MEHTA: For our second question, if I can look to the Department of Labor, please.

MS. PETTIS: Hi. You have identified
Russia as a particular problem with respect to trade
in counterfeit goods. What specific improvements
would you like to see? Do you see any opportunities
for that improvement in Russia; for example, do any
specific agencies appear to be engaged in trying to
improve Russia's performance in enforcement actions
against counterfeits? And are there any legislative
proposals that can help this?

MR. CROCKETT: Sure. It's a very -- it's a significant problem, especially with the World Cup coming up. That's a very important event for our member companies who are looking to supply footwear for that event, so it's a very timely issue for Russia, and it has consistently had deficiencies in protecting IP. I know there have been some advances

in legislation recently, and we're happy to

elaborate on that more in our post-hearing comments.

MR. MEHTA: For our third question,

Department of Justice, please.

MR. LAMBERTI: Thank you. In your written submission, you expressed concern about local favoritism in China's courts in terms of IP enforcement. Can you elaborate on this? Does this problem extend to China's specialized IP courts?

And is there any way you can make this challenge a little bit more concrete for the Committee? Can you identify any particularly noteworthy cases in which such favoritism was apparent in the court system?

MR. CROCKETT: I think one of the -- you know, as we point out, the process can be particularly difficult and challenging as in China it is a first to file jurisdiction, which presents challenge to U.S. companies that find out someone else has already registered their name or their image. I'll note the case, a very well-known case with Michael Jordan and a Chinese brand that hit recent news in December that had actually registered

his image and his name and his likeness. That's something when there is a well-known company and well-known athletic figures, oftentimes there can be an effort to take advantage of that and to force companies to pay a buyback fee to the rights to their own trademark. That's a very key issue for our members and for the athletes that they work with and the footwear industry in general. 

MR. MEHTA: Thanks very much for your testimony, Mr. Crockett.

MR. CROCKETT: Thank you.

MR. MEHTA: We'd like to next invite the Consortium for Common Food Names to please approach. Welcome. Please state your name for the record and begin your testimony.

MS. MORRIS: Thanks. I'm Shawna Morris with the Consortium for Common Food Names. I thank you for the opportunity to testify here today. I appreciate the opportunity to present the views of the Consortium for Common Food Names on a matter of critical importance to our members: the aggressive pursuit by the European Union to misappropriate the

right to use common food names worldwide and the actions of several of our trading partners in response to that pressure.

CCFN is a global nonprofit alliance of consumers, farmers, food producers, and retailers. Our mission is to preserve the legitimate rights of producers and consumers to use common names to protect the value of internationally recognized brands and to prevent new barriers for commerce. We submitted for the record a detailed examination of the scope and breadth of the EU's efforts to harm U.S. farm, food, and manufacturing sectors by monopolizing common food names through geographical indications. So in the time available today, I will just touch on some key points.

First, let me say that CCFN is not at all opposed to the concept of GIs. Many countries protect legitimate GIs, including the United States through its certification mark system. When properly targeted to protect unique, regional products, GIs can be a useful intellectual property tool for some producers. But the EU's approach to

1	this issue is far from properly targeted. Rather,
2	it's a system designed to steal commonly used names
3	from those who built markets for those products and
4	instead monopolize use of those terms in foreign and
5	domestic markets. What better way to erase
6	competition in those third country markets than to
7	ban the use by competitors of commonly used names?
8	And make no mistake, this is not about the
9	quality of the products being sold under those
10	terms. In fact, when a Wisconsin-made parmesan went
11	head to head against all Italian Parmigiano-
12	Reggianos in a cheese competition in the EU a few
13	years ago, it was the Wisconsin cheese that beat out
14	its competitors. The Italian response to this was
15	not to applaud a worthy competitor and up their own
16	game next year; instead, it was to force the
17	competition to eliminate the parmigiana category
18	entirely so that such a travesty could never happen
19	again.
20	Not content to strip competitors from
21	using long-established and widely used food terms in

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its domestic market alone, for the past few years

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1	the EU has also been pursuing through its many FTAs
2	and through the World Intellectual Property
3	Organization an increasingly aggressive strategy to
4	restrict the worldwide use of common food names by
5	non-EU producers. As a result, several of the EU's
6	FTA partners and WIPO Lisbon Agreement members have
7	bypassed their normal IP procedures and approved
8	lists of GI names in the context of those

agreements.

This approach has often made it very difficult, if not impossible, for interested parties to register objections to the registrations or to influence decisions regarding the scope of protection. The fact that these countries have taken these actions in response to pressure from the EU does not alleviate those countries' own obligations to uphold their commitments to provide certain levels of market access for American-made products and follow critical IP due process procedures.

This is an issue that threatens to impact a variety of sectors from dairy, to wine, to meat,

to horticulture, to rice, and more. GI systems

cover all manner of food and agricultural products

and are poised to continue an expansion into

covering non-food manufactured products, such as

textiles and apparel, ceramics, and other products

as well.

Existing IP trade restrictions on the use of common names across broad categories of products will continue to expand if efforts of GI proponents are not properly checked with robust due process procedures and safeguards for commercially important common terms.

As critical as IP rights are, all companies also rely on a variety of common names, and undermining those bedrock safeguards which are so essential to well-functioning trade and IP systems will also threaten the production of a variety of U.S.-made products and the jobs of the American workers that produce them.

We strongly condemn the EU's policies and actions. But we also believe that those countries that are flagrantly disregarding their trade and IP

commitments to curry favor with the EU must be held to account for the unjustified market access restrictions they are creating against U.S. exports. The EU-Canada FTA is a prime example of this where fault lies with the EU for insisting on GIs for generic terms such as muenster and asiago, but considerable fault also lies with Canada for caving to the siren song of securing greater market access to the EU and in the process abandoning its due process procedures for IP and prior market access commitments.

In the context of these challenges, it is worth noting that the U.S. is by far the largest foreign destination for EU food and agricultural products. In addition, the U.S. runs a trade deficit in goods with the EU of \$146 billion, with well over a billion dollar dairy deficit alone. Intentionally trying to hamstring its largest customer and make them less globally competitive is certainly an interesting way to show appreciation for the strong market the EU enjoys in this country.

As trade policy strategy is developed this

year, we would urge the Administration to build further upon its past successes in pushing back against the EU's global GI agenda. This work should continue to include both bilateral engagement with our trading partners and incorporation into any future trade agreement discussions. A strong starting point for the latter is the groundbreaking GI text that was included in the Trans-Pacific Partnership.

In conclusion, our organization strongly supports the government's efforts to ensure that GI and other similar regulatory additions are properly notified and applied, that they do not prevent the use of common terms, the clear and reasonable scope of protection is established that preserves the use of common terms, and most importantly that they do not violate prior rights and obligations under international agreements. We cannot allow our trading partners to chip away at the value of prior WTO or FTA concessions through the imposition of unjustified restrictions on common terms.

We look forward to continuing to work

closely with the Administration to achieve these ends. Thank you.

MR. MEHTA: Thanks very much. If I could ask the Department of Commerce to ask the first question.

MR. MITCHELL: Thank you. You mentioned market access concerns globally due to the EU GI agenda, and some of these arise not with respect to EU countries proper but other countries because of agreements that they may have with the EU. You used as a primary example of that Canada.

We were hoping you could give us some other markets where the implementation of EU GI policies have had a harmful effect, and what are the industries that are the most affected?

MS. MORRIS: Sure. I can give you a few examples, perhaps. My testimony lists some others. For instance, in Mexico, as a result of how Mexico is handling its WIPO Lisbon Agreement obligations and has not in the past provided any sort of due process evaluation of GIs submitted through that agreement, they had registered GI for asiago, for

1	instance. This is despite the fact that our
2	companies have been exporting that product to
3	Mexico, and it was being sold in supermarkets down
4	there. We are in the process of challenging that
5	through the Mexican court system, focused on the
6	lack of due process in particular, but at the same
7	time those customers are in a hard spot and facing
8	legal challenges referencing to the WIPO Lisbon
9	Agreement registration.

On the FTA side of things, we have also had to contend with restrictions such as the one included in the EU-Korea Agreement, for instance, which similarly did not provide for examination and opposition procedures. And so as a result of that, U.S. companies cannot export things like feta or gorgonzola to Korea if those products are properly labeled.

MR. MEHTA: Second question, if I could look to the U.S. Department of Agriculture.

MR. KARAWA: Thank you. In your submission under the section regarding the abuse of GIs by the EU, you stated in conclusion with the

following paragraph. I quote, "These harmful impacts on American companies and bans on what types of products they can freely sell in a variety of countries around the world are not collateral damage of the EU's GI policy agenda. Rather, they are the express intent of the way in which the EU has pursued its GI agenda."

Could you elaborate further on how you arrived at that conclusion?

MS. MORRIS: Sure. Thank you for the question. Our concerns from that part of our testimony are really reflected in the fact that it is very well known that a lot of the products that are facing challenges as a result of these policies are widely produced around the world. These are not attempts to pass off those products as being produced in certain European countries. Rather, it's that these terms refer to product categories, for instance parmigiana describing a type of cheese, not a particular product made in one portion of the world.

The EU is as well aware of that fact as we

1	are. The globally available production figures are
2	available. There are even cases where we are
3	contending in the EU specifically with efforts to
4	restrict terms that are so generic that there is an
5	international recognized product standard set by
6	Codex for those products. That poses a very
7	significant concern and to us seems to clearly
8	illustrate that the intent is to hamstring
9	competition, not to protect unique producers in
10	certain regions.
11	MR. MEHTA: Thanks very much, and thank
12	you for your testimony today, Ms. Morris.
13	MS. MORRIS: Thank you.
14	MR. MEHTA: If we could next invite the
15	Computer and Communications Industry Association.
16	Welcome, sir. If you could state your name for the
17	record, and please begin your testimony.
18	MR. SCHRUERS: Sure. My name is Matthew
19	Schruers. I am Vice President for Law and Policy at
20	the Computer and Communications Industry
21	Association, which is a trade association of
22	internet and technology firms which includes some of

the most recognizable brands in the world, and 1 producers and distributors of high-valued creative 2 3 content. The services are increasingly very 4 successful exports of services and goods. They 5 provide platforms for other exporters of services 6 and goods and, although beneficiaries of the 7 intellectual property system, also increasingly encounter aspects of policy that, although 8 9 represented as intellectual property protections, 10 are increasingly shaping up to be protections 11 barriers. 12 Our written submission discusses these in 13 greater length. I will focus on two. The first is deviations from established international 14 15 limitations and exceptions norms and how those 16 affect our constituencies. Secondly, failures to 17 comply with either stated or commonly accepted

On the first item, you've already heard at some length from previous speakers about what is sometimes referred to as ancillary rights or

international norms with respect to intermediary

reliability protections.

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1	neighboring rights or so-called snippet tax where
2	both Germany and then Spain have instituted a form
3	of exclusive rights over what was commonly
4	established as a mandatory international exception.
5	That is to say that both Germany and Spain created
6	an exclusive right in either quotations or indexing
7	snippets from publicly available internet content in
8	a way that violates a mandatory commitment under the
9	Berne Convention Article 10(1) and also arguably
10	Article 2(8).

At least in Spain, that had the effect of causing one U.S. company to exit the market. And it has cast a cloud of uncertainty over ongoing business operations in both of those countries where operations could be subject to accumulating liability under the existing standard.

In addition to this, we have seen further efforts which have not yet gestated into actual legislation but legislative initiatives which could, and it is our view that this has occurred in part because there has been no pushback to the German and Spanish experiments, which I think as a previous

speaker pointed out, the empirical evidence suggested that that experiment has not succeeded, but these countries haven't shown any interest in rolling it back.

The follow-on initiatives that I'm referring to include an effort under a French law which has been notified to the European Commission but has not yet entered into force, which creates a similar type of regulation on image indexing, which is widely accepted in the United States and around the world. Similar to these ancillary rights, it creates a mandatory collectivization by a quasi or at least a government-endorsed entity which is then empowered to make demands against U.S. exporters. If that goes into effect, we're going to also encounter problems for U.S. businesses exporting services into those markets.

Another initiative that is falling on this as was mentioned is the European Commission is presently -- the European Parliament is presently considering an overhaul of various copyright -- their copyright laws, including a proposal to have a

European-wide ancillary right which would do great damage to U.S. service exporters who are trying to provide internet, social media, news aggregation, and a variety of other online services in that That is an ongoing problem, and we ask that market. the Special 301 process identify this as a market access barrier for U.S. services and urge the Europeans to remedy this.

The second issue that I will mention very briefly is deviation from established norms on intermediary liability protections. The United States in 1998 established what has been a highly successful model protecting intermediaries from liability. What is sometimes referred to as a don't shoot the messenger rule provided that intermediaries undertake certain activities to prevent misconduct by users online. We have insisted on that in our FTA commitments since at least 2003.

The Australia approach to this, however, has been to implement a system under their FTA obligation that only protects their domestic

broadband providers, so-called carriage service
providers, but not exporters of U.S. services.

Another issue identified in our comments is that Colombia, which has an obligation under its FTA, still has not implemented their protections, and legislation that was put forward I believe last year to implement many of their obligations said nothing about intermediary liability protections.

Finally, also, we are seeing proposals internationally that depart from the norm that has been established through our FTAs of providing intermediary protections through overly stringent obligations to either police, monitor, surveil users or so-called shop clock.

Now, the Ukrainian proposal in particular has a 24-hour obligation, which while that may be feasible for very sophisticated online services that have entire departments devoted to policing content, that is not going to be the case for all exporters of services. Our approach in U.S. law and in the FTAs has been to require adherence to an expeditiousness standard which is more flexible. It

makes a greater demand of more sophisticated

entities and a more flexible demand of smaller

companies. We believe that is something that should

be promoted internationally.

I'm happy to take any questions.

MR. MEHTA: Thanks very much. Our first question goes to USTR.

MS. PETERSON: The CCIA submission does not focus on China, but observers in this process are examining a proposed e-commerce law as it would affect safe harbors. Does CCIA have a view on that measure or on the effectiveness of safe harbor protections in China generally?

MR. SCHRUERS: As you point out, our comments don't take a particular position on the Chinese proposal. And without comment -- I don't want to comment without having access to the latest text. I'll just say generally intermediary liability protections are a crucial aspect of the online marketplace, and they are embodied in a norm that is evident in U.S. law in Section 512 and Section 230, in European law, in the e-commerce

1	directives, in our FTAs which have incorporated
2	intermediary liability protections since 2003. The
3	TPP contains language on this front as well. So I
4	would say that these are an established and evolving
5	norm. To the extent that there are proposals being
6	advanced that are inconsistent with that, that is
7	something worthy of consideration. But I don't want
8	to comment on specific language.

MR. MEHTA: For our second question, the U.S. Patent and Trademark Office.

MS. FERRITER: Thank you. You discussed earlier the snippet tax, and you asserted that ancillary copyright laws in Germany and Spain limit market access to U.S. services by vesting rights in the quotation of news content to domestic press publishers, independent of the author's copyright. But the Special 301 statute refers to countries that deny fair and equitable access to U.S. persons that rely on intellectual property protection. How do you square your position with the statutory text?

MR. SCHRUERS: I don't think anybody would dispute that the CCIA companies that are having

- 1 difficulty exporting to these markets are U.S.
- 2 | persons, they rely on intellectual property
- 3 protection, and that violations of the Berne
- 4 Convention Article 10(1) are actionable trade
- 5 violations. We have established WTO case law on
- 6 that principle. The only question is whether or not
- 7 | the statute contains some explicit requirement of a
- 8 connection. And if indeed it does, is that
- 9 connection established between the U.S. persons and
- 10 the denial of market access.
- One could argue that it is implicit in the
- 12 | text, but I would point out that it's not actually
- 13 there. In any event, the mandatory quotation right
- 14 that's in Article 10(1) should be considered a right
- 15 for purposes of the statutory application. Many of
- 16 the services that are being provided here are
- 17 themselves facilitating access to other content,
- 18 which is to say that when a U.S. news aggregator
- 19 pulls out of Spain, then that effectively denies
- 20 their ability to export copyright protected goods
- 21 and services into that market.

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MR. MEHTA: Thanks very much for your

testimony today, Mr. Schruers.

If I could next invite the Software

Alliance, the BSA to approach? Welcome. If you can
please state your name for the record and begin your
testimony.

MS. LEWIS: Sure. Good afternoon. My name is Leticia Lewis. Thank you, Mr. Chairman and members of the Committee, for the opportunity to testify on behalf of BSA, the Software Alliance, the leading advocate for the global software industry.

BSA and our members share your goal of protecting

U.S. innovative companies that create jobs and fuel the U.S. economy.

Software innovation is transforming every sector of the American economy and enriching every aspect of our lives. A recent BSA study shows that software industry contributes more than 1 trillion to the U.S. GDP, nearly 10 million jobs, and 52 billion in research and development, with significant impact in each of the 50 states. The industry success also expands America's economic potential across numerous other sectors.

1	Today you have heard from many
2	distinguished witnesses that effective intellectual
3	property protection enforcement is critical to
4	innovative companies. BSA absolutely agrees with
5	this. I dare say, however, that being able to
6	access foreign markets is even more important to BSA
7	members and other companies that rely on
8	intellectual property. A large portion of
9	innovative companies' annual revenues derive from
10	overseas. Removing barriers to trade is essential
11	to BSA members' long-term success, but more
12	importantly essential to the American economy.
13	Companies would soon have a huge problem
14	if they could not access foreign markets, even if we
15	could wave a magic wand and every country's
16	intellectual property regime became perfect.
17	Intellectual property protection and enforcement is
18	very important, but they only go so far when fair
19	and equitable market access is compromised. The
20	market access requirements of the Special 301 law
21	should be used to help American innovative
22	companies.

The Special 301 statutory mandate requires

USTR to notify countries that deny fair and

equitable market access to U.S. companies. Yet, the

second component of the Special 301 has been

underutilized despite its importance. Further,

leveraging this component is consistent with the

Administration's 2017 Trade Policy Agenda released

last week.

For the third consecutive year, BSA's submission raises not only issues pertaining to intellectual property protection but also market access barriers that companies encounter in far too many countries around the globe. Due to the limited time available today, I will only highlight some of these issues, but BSA looks forward to answering any questions you may have after you have a chance to review our entire submission.

BSA is deeply concerned about policies
that restrict data flows. Barriers to cross-border
data flows are often disguised as privacy or
security measures. BSA urges the U.S. government to
work with its trading partners to prevent or reverse

such practices. Our available trade mechanisms, including the Special 301, should be leveraged for this purpose.

In addition, we are concerned that governments around the world are using or proposing to use security concerns to justify the creation of trade barriers. China's recently enacted counterterrorism and cybersecurity laws are key examples.

On intellectual property protection and enforcement, the main issue is the continued use of unlicensed software by government agencies, state-owned enterprises, and businesses. According to the latest information available, illicit use of software is 39 percent of total global software use. The losses are extremely large as this represents a commercial value of unlicensed software globally exceeding \$60 billion. BSA urges the U.S. government to continue working with its trading partners to address this issue.

BSA also remains highly concerned about the inadequate enforcement of unlicensed use of

software in a wide variety of countries. 1 addition, it is paramount that countries provide 2 3 effective patent protection to eligible computer 4 internet inventions in line with their international 5 obligations. Negative developments in this area 6 hurt innovative companies and need to be addressed. 7 For example, India's current detrimental approach to patentability of computer-related inventions is out 8 9 of step with international practices and will 10 prevent most computer-related inventions from being 11 eligible for patent protection.

We appreciate USTR's efforts on this issue to date and urge the engagement to continue so that patent protection becomes available for computer-related inventions in India consistent with global practices.

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In our submission, we recommended a number of countries be placed on the Priority Watch List and other countries to be placed on the Watch List.

We are also closely following developments in the EU that could pose significant barriers to providing digital services in the region and ask that these

1 | concerns be noted on the Special 301 Report.

In many cases, we have identified market access issues as equally or more important for your review and consideration than whether the trading partners provide adequate and effective intellectual property protection and enforcement.

agencies of the Special 301 Subcommittee for their efforts to address inadequate and ineffective intellectual property protection in countries that are U.S. trading partners. We also urge you to use the Special 301 mechanism to focus even further on policies that deny fair and equitable market access for BSA members who rely on intellectual property which will help U.S. innovative companies to continue creating jobs and benefiting the U.S. economy. Thank you very much for your time.

MR. MEHTA: Thanks very much. For our first question, if I could look to the Department of State, please.

MS. DYER: Certainly. You mentioned China in both your remarks and your written testimony, and

you brought up security concerns as trade barriers. 1 There are a number of measures in China you've 2 mentioned that assert national security as a pretext 3 4 to foreign access barriers. Are you seeing adverse 5 effects -- are your members seeing adverse effects right now, or is this a future-oriented concern? 6 7 MS. LEWIS: The concern is very real right In terms of the impact, I think it is too 8 now. 9 early to tell what the impact will be, especially 10 because a lot of the regulations, they have very 11 broad definitions, and they are right now being 12 implemented through intermediary regulations, so 13 broad terms to be further defined, and we need to see how enforcement of these measures will take 14 15 place. But to answer your question, the concern is 16 very real and very current. We are not able to tell 17 right now how they will -- how great the impact will 18 be, but the concern is very real currently. 19 Thanks. For our second MR. MEHTA: 20 question, Department of Treasury, please. MR. CHANG: 21 Thank you for your submission.

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To what do you attribute the sharp increases of

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piracy in Russia? In your members' experience, do
you believe that there is political will in Russia
to address this issue? And are there examples you
are comfortable providing to this panel?

MS. LEWIS: It's hard to tell what a country -- I think it's a number of factors, and I think that one of them is the lack of proper enforcement, so there is no deterrents, so it's very hard to enforce some of these measures. We don't see a lot of willingness of the Russian government to work on matters that would address this issue.

MR. MEHTA: Great. For our final question, USTR, please.

MS. PETERSON: The BSA's submission
highlights the challenge of unlicensed software by
foreign governments. BSA calls out problems with
under-licensing with certain government agencies in
South Korea and disappointing implementation by
China of its commitments to address this issue. BSA
urges us to use all available trade mechanisms,
including Special 301, to engage with our trading
partners. What additional mechanisms do you have in

1 mind? I think all your bilateral 2 MS. LEWIS: 3 dialogues that you have are definitely a tool that 4 can be used and any other mechanism that you -- any 5 opportunity that you have to raise these issues I 6 think that would be very welcome. Once again, we 7 appreciate USTR and other agencies' approach to industry every time that you will have one of these 8 9 meetings or dialogues because it is really good to 10 continue to highlight it and show the governments how they can address these issues and comply with 11 12 their obligations. 13 MR. MEHTA: Ms. Lewis, thank you very much 14 for your testimony today. 15 And for our final presenter of the 16 afternoon, if I can invite the Alliance for Fair 17 Trade with India up to the presentation table. 18 MR. POMPER: Last but hopefully not least. 19 MR. MEHTA: And for the record, if you 20 could please state your name and then begin your 21 testimony.

MR. POMPER: My name is Brian Pomper.

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Good afternoon, and thank you for providing me with the opportunity to testify on behalf of the Alliance 3 for Fair Trade with India, or AFTI. I serve as the Executive Director of that coalition.

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AFTI is a coalition of trade associations that works to improve the U.S.-India commercial relationship by supporting increased action to address the barriers to trade and investment U.S. companies are facing in India, including with respect to intellectual property rights. AFTI serves as a mechanism for engaging with U.S. policymakers on these issues. AFTI's diverse membership is comprised of organizations representing a range of U.S. industries adversely impacted by India's IPR policies and practices. light of this mandate, I am here to call on USTR to again place India on its Priority Watch List and to conduct an out-of-cycle review of India's IPR regime.

AFTI and its members appreciate India's recognition of certain shortcomings in its IPR protection scheme as reflected in the final draft of

of Industrial Policy and Promotion released in May 2 3 In particular, the final draft of the of 2016. 4 policy demonstrated significant improvements over an 5 earlier draft in certain specific areas of concern, 6 including increasing capacity in IPR agencies and 7 efforts to strengthen enforcement through procedural reforms. 8 AFTI also notes that no compulsory 9 licenses have been issued on any patents in India 10 for some time, although the threat and the legal 11 ability to do so remains. 12 Despite these positive notes, however, the 13 Indian government still has not taken any 14 significant steps towards improving several 15 longstanding irritants in the bilateral trade. 16 These include forced localization policies that 17 discriminate against foreign IPR holders in India, 18 lack of protection of confidential and other

the National IPR Policy that the Indian Department

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agricultural industry, measures in Indian law that

add an onerous and unnecessary additional criterion

regulatory data, especially with respect to

undisclosed tests in the biopharmaceutical and

for the patentability of medicines, and weak
copyright protection policies and enforcement that
harm both U.S. and Indian IPR holders alike.

Prime Minister Modi has on several occasions pledged his commitment to improving the regulatory landscape for the protection of intellectual property rights in India but has not taken the requisite steps to translate these commitments into concrete actions. AFTI believes that the new administration in the United States provides an opportunity for USTR to reassess significant steps that India has yet to take in order to emerge from its current status under the Priority Watch List.

AFTI urges USTR to continue engaging in bilateral discussions with India to productively address the issues we have highlighted repeatedly in these and other fora. In particular, we urge a robust Special 301 action plan for India to finally and at long last move in the direction of addressing the deficiencies in its domestic IP environment.

Finally, AFTI believes an out-of-cycle

review of India is needed so that USTR can conduct a 1 thorough review of India's new National IPR Policy, 2 3 identify areas for regulatory improvement in the 4 policy, ensure that the improvements that India has 5 promised through the policy and commitments made 6 during the U.S.-India bilateral dialogues are 7 enforced, and inform the Special 301 action plan for India called for under the Trade Facilitation and 8 Trade Enforcement Act of 2015. 9

Thank you for your time. I'm happy to answer questions.

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MR. MEHTA: Thanks very much. For our first question, can I look to the U.S. Copyright Office, please.

MS. STRONG: Sure. Your written testimony mentions and you mentioned right now the weak copyright protection policies and enforcement that harm both U.S. and Indian rights holders. First, can you provide more detail by identifying those specific policies or enforcement problems that harm U.S. copyright right holders? And as a follow-up, to the extent you have identified an OCR as your

recommendation, what specific benchmarks or measures would you recommend that this Committee consider?

MR. POMPER: Sure. So the issue I should make clear you understand, AFTI is a coalition of associations, so these aren't companies, these are the associations themselves, many of whom have actually testified here today. The issue that I hear most about is anti-camcording legislation and sort of the longstanding repeated promises, including in the National IPR Policy, to consider amendments to address that specific issue.

There are other issues that are mentioned, the copying of textbooks in India. But I would say honestly that the issue that's of most concerning copyright is the anti-camcording issue.

In terms of benchmarks, it's hard to -- I would have to think more carefully and find that out. I just am struck by really the vast number of plans in the IPR policy and how many, maybe it's too much to call them commitments, but plans that the Indian government has undertaken. It has been nearly a year since those commitments were

undertaken, and it strikes me as an appropriate
endeavor for this Committee and for USTR to delve
deeper and see just how effective or how much of
that India has managed to accomplish in the past
year.

MR. MEHTA: Thanks. Our second question will come from the U.S. Patent and Trademark Office.

MS. FERRITER: Thank you. You noted in your submission and just now Prime Minister Modi's 2015 statements calling for India to align its patent laws with international standards in order to encourage foreign investment. In your statement, you also discussed onerous requirements. In my notes, I wrote 3(d). But can you expand upon that; are there other challenges that you see as being out of step with international standards and which warrant priority attention in order to realize Prime Minister Modi's goals?

MR. POMPER: First, let me say I think that it's not all bad news. I have testified before this Committee three or four times, Probir, how many times? So but I would say at least the environment

1 | is more positive and the words are more positive.

2 | We have a National IPR Policy. We are having robust

3 engagements between the United States and the Indian

4 government on these and other difficult issues, so I

5 | think it's a positive environment in which to have

6 these sorts of discussions.

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You are right to write down 3(d). That is a real irritant. I was taken, in just reviewing the National IPR Policy earlier today in preparation for testifying here, how many times it is mentioned in the policy and elsewhere that India is fully compliant with all of its WTO obligations. I think AFTI members believe that Section 3(d) is an extra WTO requirement and that it does not comport with the WTO obligations to which India is subject.

I think also the lack of regulatory data protection both for pharmaceuticals and for agricultural chemicals is another source of real concern for AFTI members that I often hear about.

Both of these are longstanding irritants that have been in our submissions and submissions before AFTI was created in 2013, where we have seen really no

- impact whatsoever. In fact, I would just note on
  the protection of undisclosed test data, the draft
- 3 National IPR Policy talked about protecting
- 4 regulatory data and purposefully excluded, I
- 5 believe, biopharmaceuticals. The final policy
- 6 doesn't have any mention, as I recall, of regulatory
- 7 data protection.
- 8 MR. MEHTA: Thanks very much. If I could
- 9 look to HHS for our final question.
- 10 MS. BLEIMUND: Thank you. Just I wanted
- 11 to follow up on that question of the issue of
- 12 regulatory data protection. Could you just explain
- 13 | how you feel that this issue affects or inhibits the
- 14 operations or investments of U.S. companies in
- 15 India?
- 16 MR. POMPER: I think I don't work
- 17 | specifically for one of the companies and don't make
- 18 those sorts of decisions, but I generally think that
- 19 a stable secure environment where a company's
- 20 investments can be protected against copying and/or
- 21 unpermitted use is something that will encourage
- 22 | investment. I know India's economy is growing, and

1	I know they will sometimes say privately, I think
2	there is some discussion of, well, why do we need to
3	change our environment when we've got all this
4	investment coming in? But I think from the
5	standpoint of the associations that I work with who
6	are the ones directly talking to their companies,
7	there is real concern about the long-term viability
8	of continuing to invest in countries that don't have
9	these kinds of base-level WTO-required protections.
10	MR. MEHTA: Thank you very much for your
11	testimony today, Mr. Pomper.
12	MR. POMPER: Thank you.
13	MR. MEHTA: And that concludes our hearing
14	today, so let me make some brief closing remarks.
15	On behalf of the Special 301 Committee,
16	thank you for taking the time out of your day to
17	have this exchange with us. We appreciate the
18	comprehensive research, the thought, and the
19	problem-solving efforts that went into your written
20	testimony, your written submissions, and oral
21	testimony.
22	The Special 301 docket will reopen this

- 1 afternoon and remain open until midnight, until next
- 2 Tuesday, March 14th. Post-hearing briefs by
- 3 | interested parties that testified today are
- 4 optional, but the docket will remain open till next
- 5 Tuesday for those submissions. Please follow the
- 6 | instructions on the agenda or in the original
- 7 Federal Register notice for submitting those written
- 8 post-hearing comments. Again, the docket number is
- 9 [USTR-2016-0026], I believe, yeah.
- 10 So a transcript and the video of today's
- 11 | hearing will be available free of charge at
- 12 USTR.gov. We will do our best to get that posted
- 13 | within the next two weeks.
- Just on my behalf, I would like to thank
- 15 | everyone on the panel today, my colleagues, and
- 16 again of course to everyone who testified for your
- 17 | contributions and your time and attention. A very
- 18 special thanks to personnel at USTR, including our
- 19 very talented intern Paulina Starostka, a third year
- 20 law student at George Washington Law, and Anita
- 21 Kyler, who I don't believe is here.
- 22 Finally, I would be remiss if I didn't

1	thank Chairting Detaurant 11 D'
1	thank Christine Peterson, the Director of our
2	Special 301 Program, who has spent countless hours
3	and leading our efforts on the 301 Review as well as
4	organizing today's hearing, so thanks very much,
5	Christine.
6	So with that, ladies and gentlemen, the
7	2017 Special 301 hearing is now adjourned.
8	(Whereupon, at 2:09 p.m., the meeting was
9	adjourned.)
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1	<u>CERTIFICATE</u>
2	This is to certify that the attached
3	proceedings in the matter of:
4	2017 SPECIAL 301 PUBLIC HEARING
5	March 8, 2017
6	Washington, D.C.
7	were held as herein appears, and that this is the
8	original transcription thereof for the files of the
9	Office of the United States Trade Representative.
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