ALLIANCE FOR TRADE ENFORCEMENT

October 29, 2020

Edward Gresser
Chair, Trade Policy Staff Committee
Office of the U.S. Trade Representative
Executive Office of the President
600 17th Street, NW
Washington, D.C. 20508

RE: Comments Regarding Foreign Trade Barriers to U.S. Exports for 2021 Reporting (Docket Number USTR-2020-0034)

Dear Mr. Gresser:

The Alliance for Trade Enforcement ("AFTE") is a coalition of trade associations and business groups that advocates for foreign governments to end unfair trade practices that harm American companies and workers from every sector of the economy and supports U.S. policymakers in their efforts to hold our trading partners accountable. Our members operate in the manufacturing, services, technology, and agriculture sectors, among others. On behalf of AFTE, we provide the following comments to the Office of the United States Trade Representative ("USTR") for its 2021 National Trade Estimate Report on Foreign Trade Barriers ("NTE Report").

Expanding U.S. access to global markets in a fair, competitive playing field is essential to U.S. businesses. American exports drive investment in the United States, allowing U.S. businesses to create jobs, increase wages, and expand production facilities. Global economic growth in recent decades has been accompanied by a surge in global demand. American businesses have grown to meet this demand, but they need access to transparent, open, and predictable foreign markets to ensure continued success.

More than 95 percent of the world's consumers live outside the United States. The United States must continue to pursue a multi-faceted trade policy to ensure American products and services reach these consumers. U.S. exports have grown significantly since 1990, driven by global, bilateral, and regional trade agreements that have lowered trade barriers and set the basic rules of commerce. In 2019, nearly half of all U.S. exports were to America's free trade agreement ("FTA") partners.

Despite these advances, U.S. exporters still face a variety of trade barriers, even in those countries with which the United States has negotiated trade and investment agreements. These comments will primarily focus on ways in which the United States can better enforce bilateral and regional trade and investment agreements that are currently in force.

We first provide general comments on foreign trade barriers that are not specific to any single country. The subsequent sections then contain comments specific to each of the following countries: Brazil, Canada, India, Indonesia, Japan, Korea, and South Africa.

I. GENERAL COMMENTS ON MARKET ACCESS

A. Import Policies

U.S. exporters face a wide variety of policies in a number of markets that block or limit imports from the United States, including high tariff rates and tariff-rate quotas, trade remedy proceedings applied in a non-transparent or World Trade Organization ("WTO") inconsistent manner, and non-tariff barriers to trade. Many countries impose very high tariff rates on non-agricultural goods, while others maintain large gaps between their bound and applied rates, allowing them room to set protectionist tariffs and to change tariff rates with little warning and notice. Many countries also impose discriminatory import barriers like import licensing schemes and other restrictions at the border.

Recognizing the breadth of these concerns, AFTE encourages the U.S. government to engage in multilateral fora like the WTO to enforce and enhance trade agreements with the United States' many trading partners.

B. Technical Barriers to Trade

AFTE members face a variety of non-tariff barriers, including unique regulatory and technical standards and conformity assessment requirements, which add significantly to the cost of manufacturing exports and can often impact the overall cost more than tariffs. AFTE encourages the U.S. government to promote and enforce the WTO Agreements on Technical Barriers to Trade ("TBT") and Sanitary and Phytosanitary ("SPS") Measures, as well as the TBT and SPS chapters of bilateral and regional trade agreements – including the recently enacted United States-Mexico-Canada Agreement ("USMCA").

C. Government Price Controls and Discriminatory Pricing

For some markets, including pharmaceutical markets, governments serve as the primary purchaser and can effectively dictate prices. Unfortunately, in a number of jurisdictions this leads to unfair and discriminatory pricing, as governments often undervalue innovative products and depress prices below what a competitive market would provide. Countries are increasingly employing a range of practices, including international reference pricing, therapeutic reference pricing, mandatory price cuts, clawback taxes, and flawed health technology assessments, to depress prices. In addition, governments have implemented policies that benefit domestic drug companies and wholesalers at the expense of American innovators.

D. Digital Trade

Digital trade, services, and data flows have enabled U.S. businesses, especially small and medium-sized enterprises (SMEs), to expand their global reach by integrating staff around the world, building global customer networks, and securing global payments. The COVID-19

pandemic has magnified the importance of digital trade and underscored how important it is for data to be shared freely across borders, ensuring that important exchanges of information and the delivery of key goods and services are not delayed. Unfortunately, forced data localization requirements are on the rise globally, with increasingly negative developments in India, Indonesia, and other markets that promote local providers and restrict access by U.S. service providers. A number of countries are also implementing measures to regulate online communications and video services as traditional public utilities. The United States should work with its trading partners to eliminate data localization measures and ensure the free flow of data and digital trade.

E. Geographical Indications and Common Names

Many countries, including especially those in the European Union, continue to pursue an increasingly trade-restrictive and protectionist bilateral strategy through the misuse of Geographical Indications ("GIs") to restrict the use of common food terms by foreign producers, (for example, "parmesan" and "bologna" in the EU). On this front, the EU's clear goal is to advance its own commercial interests for food products by advocating for wider use of GIs and by insisting on an extremely broad scope of protection for those GIs, which is designed to award EU companies with the sole right to use many terms that have already entered into widespread, common usage around the world.

The USMCA included a commitment by Mexico not to restrict the generic use of a non-exhaustive list of cheese terms. We urge the strong enforcement of these provisions with Mexico, and encourage USTR to ensure that the prior users letter regarding use of certain generic terms is adhered to fully. Building upon this important step in securing assurances for U.S. food producers to continue using generic terms, AFTE recommends USTR establish a policy of securing in current and future trade negotiations explicit protections for the use of specific widely-used, common food terms. Left unchecked, the European Union's approach has and will continue to impair the value of concessions obtained by the United States in third-country trade negotiations, leading to unjustified technical barriers in many cases.

As the U.S. government continues to develop its approach to this truly global problem, we urge the Administration to examine the degree to which countries' EU-driven GI measures result in non-compliance with their WTO and FTA obligations. We look forward to continuing to work with the U.S. government to combat the EU's efforts to impose restrictions on competition for products that long-ago entered into common use in the United States and many other countries around the world. The EU's attempt to monopolize those terms solely for its own benefit under the guise of intellectual property provisions is simply a thinly disguised barrier to trade.

II. BRAZIL

A. Import Policies

On top of very high tariff rates, Brazil imposes a series of federal and state-imposed taxes, tariff-rate quotas, and import fees that disadvantage U.S. products compared to domestic products. In addition, U.S. exporters have faced inconsistencies in customs-related regulations

and enforcement, especially in customs clearance proceedings and regulations between different ports, different agencies, and even different customs agents. AFTE encourages USTR to work with the Brazilian government to streamline and harmonize customs procedures.

B. Technical Barriers to Trade

AFTE commends the United States and Brazil on reaching the October 20, 2020 Protocol on Trade Rules and Transparency, which includes important provisions on good regulatory practices that AFTE hopes will bring greater transparency to regulatory procedures in Brazil. Nevertheless, AFTE members still face significant hurdles in Brazil on a range of technical barriers to trade, where both technical regulations and testing, certification, and other conformity assessment requirements do not align with international requirements. For example, most regulatory agencies in Brazil have not fully and formally implemented the TBT Agreement requirement to use international standards as a basis for technical regulations. Similarly under Brazil's conformity assessment system, the central body responsible for publishing requirements for conformity assessment programs – INMETRO – often lacks appropriate technical expertise in the regulated field. AFTE encourages USTR to address these concerns in U.S.-Brazil trade negotiations following on the recently-announced trade protocol.

C. Copyright Reform

As Brazil continues its public consultation to amend its 1998 Copyright Law, USTR should encourage Brazil to reaffirm its commitment to global norms, such as the Berne Convention and TRIPS Agreement. USTR should also encourage Brazil to ratify and implement additional international instruments for copyright, such as the WIPO Internet Treaties.

D. Intellectual Property Enforcement

Although Brazil's criminal enforcement of IP protections has historically lagged behind that of other jurisdictions, AFTE commends Brazilian law enforcement for recent increased efforts. Nevertheless, delays and backlogs still plague the Brazilian justice system, and the majority of those arrested on suspicion of criminal IP infringement never face criminal charges or prosecution. AFTE encourages the U.S. Government to engage with its Brazilian counterparts to ensure that effective and timely mechanisms are in place to combat all forms of copyright piracy throughout Brazil.

In a similar vein, the unauthorized camcording of films in theaters, while temporarily reduced in 2020 due to pandemic-related theater closures, further fuels online piracy in Brazil and undermines copyright protections. AFTE encourages the National Congress to pass the anti-camcording bill (No. 2714/2019) that was recently approved by the Committee on Culture.

The Brazilian Government must do more to combat trademark infringement, including counterfeit footwear manufactured in the city of Nova Serrana, in the state of Minas Gerais. The city, which receives fiscal incentives from the Brazilian government, remains the largest producer of counterfeited products. AFTE recommends the National Congress approve Bill 333/1999, which would impose criminal penalties and fines for trademark infringement,

commensurate with those already established for copyright infringement, and allow for the ex officio seizure and destruction of infringing goods.

Brazil is currently reviewing and restructuring its national artificial intelligence ("AI") strategy at the federal level, and several bills governing AI have been introduced in the Congress. There is a concern that some policymakers have taken positions on these initiatives that could isolate Brazil with unique standards, onerous certification or localization requirements, or heavy-handed regulations. We advocate the adoption of a flexible and diversified regulatory approach that encourages strong public-private collaboration and responsible development of AI. Further, to promote innovation, we also encourage the facilitation of data sharing, advancement of structured and standardized AI R&D, and support for STEM-informed workforce development.

E. Patents and Patent Administration

To begin to address its 10-year patent examination backlog, Brazil has implemented several initiatives, including a "Backlog Fight Plan," a Patent Prosecution Highway program, and ratifying the Madrid Protocol on International Marks. AFTE commends Brazil on these efforts and urges the U.S. government to ensure that progress continues and Brazil meets its obligations under international agreements.

As it seeks to streamline its examination system, Brazil instituted a minimum 10-year effective patent term from the date a patent is granted through Article 40 of the Brazilian Patents Act. This measure is an important stop-gap. Unfortunately, AFTE understands that Brazil's Supremo Tribunal Federal is hearing a case on the constitutionality of Article 40. Should Article 40 be abolished, around 35,000 products would see their patent protection retroactively reduced or, in some cases, voided altogether.

In addition to the issue of backlogs, Brazil's standards of patentability are widely known to be incompatible with international norms. For example, biopharmaceutical patents can be examined twice – once by the Brazilian National Health Surveillance Agency (ANVISA) and once by the Brazilian Patent Office ("INPI"). This is a clear violation of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"). AFTE urges the U.S. government to engage with its counterparts in Brazil to ensure its patent protection and approval process are consistent with global standards.

F. Regressive Taxes on Medicines

State and federal taxes add up to around 31 percent of the cost of medicines in Brazil. This is one of the highest rates in the world, and dwarfs the average rate of 6 percent. AFTE understands that the government is currently considering tax reform proposals that would help lower costs to patients and boost productivity and investment. The U.S. government should encourage its Brazilian counterparts to pursue these necessary reforms.

G. Localization and Tax Incentives

The Brazilian government provides tax incentives on many domestically-produced ICT and digital goods under the Basic Production Process law. Although this law was reshaped after

it was found to be inconsistent with WTO rules, the law still preferences local content in a discriminatory manner. In addition, Brazil imposed local content requirements on bidding for spectrum bands. Consistent with its WTO obligations, Brazil should eliminate policies that obstruct fair access to its market and generate competitiveness for local content.

H. Screen Quotas

For years, Brazil has imposed burdensome screen quotas on the film industry. The current quotas, which are set to expire in September 2021 but may be renewed, are facing a constitutional challenge.

I. Video on Demand Tax & Regulatory Framework

Brazil has also sought for years to regulate and tax the video on demand ("VOD") market. The Brazilian cinema regulator, ANCINE, is considering extending the existing tax model for audiovisual works (Condecine) to VOD services, whereby taxes are levied per title every five years on theatrical, Pay-TV, and home entertainment releases, and levied annually on audiovisual ads. If this model was implemented for VOD, it would be extremely burdensome on the industry and would limit the choices available to Brazilian consumers in the online content market.

J. Digital Services Taxes

Brazil is considering a legislative proposal entitled the "Contribution for Intervention in the Economic Domain" or CIDE. If adopted, CIDE would apply to the gross revenue derived from digital services provided by large technology companies, with U.S. digital companies as the key target. Such discriminatory actions go against the norms of international trade, undermines the existing multilateral OECD process, and stifles cross-border digital trade.

III. CANADA

A. Intellectual Property Rights

1. Patent Enforcement and Resolution

A number of long-standing deficiencies persist with Canada's linkage system, despite the 2017 amendment to the Patented Medicines (Notice of Compliance) Regulations. First, the Canadian listing requirements for its register (similar to the U.S. Orange Book) allow a limited number of patents to be included. Specifically, timing requirements and the fact that late listing is not possible limit the number of eligible patents.

Second, the Canadian linkage system does not impose a deadline for generic producers to notify the innovator of its regulatory filing. Once a notification (notice of allegation) is given, the innovator has 45 days to file a judicial review application to resolve patent issues, triggering an automatic 24-month stay. If infringement is not found, Canadian courts allow a generic/biosimilar producer to claim disproportionate, and arguably punitive, damages. This

dissuades patent holders from defending their rights, and a failure to successfully defend these rights may result in excessive damages.

2. Patent Term Restoration

Patent term restoration ("PTR") provides additional patent life to compensate for the time lost during clinical trials and the regulatory approval process. Although recent law allows for some compensation for delays in obtaining marketing approval, significant areas of concern remain. First, the Canadian government retains broad authority to reduce the term of protection at its discretion. Second, the amended statute set a timeline for the submission of applications, which in effect makes the availability of PTR contingent on early market entry. Third, the statute contains a carve-out that exempts the infringement of PTR protection if the activity is for purposes of export.

While initial drafts of the USMCA included provisions on patent term restoration, the final agreement pared back these restoration requirements. Under the terms of the final agreement, the patent term restoration requirement was revised to include a non-exhaustive list of examples of limitations on the adjustment of patent term to compensate for regulatory delays. AFTE encourages USTR to continue to work with Canada to implement a PTR system commensurate with that of other developed economies.

3. Copyrights

Canada remains one of the most permissive jurisdictions for copyright infringement, with a historically lax copyright enforcement framework. Rightsholders face significant hurdles enforcing copyrights for both digital property and physical goods. Although Canada has had a few successes cracking down on pirating websites in recent years, infringers will continue to evolve if adequate deterrents are not established. The U.S. government should commit to greater engagement with the government of Canada to discourage copyright infringement, or support for their activities in other ways, on the internet.

B. Digital Services

The Canadian government is considering imposing obligations on non-Canadian digital services delivered over the internet through proposed legislation and regulations. Digital media services are currently exempt from most requirements under the Broadcasting Act. However, under the proposed reforms, digital media services would become subject to requirements to contribute financially to the creation of programming that qualifies under a narrow definition of "Canadian programs." Moreover, non-Canadian digital service providers would receive no credit towards their financial or discoverability contributions from their considerable investments in production activity already carried on in Canada.

C. Biopharmaceutical Market Access

The Patented Medicines Prices Review Board ("PMPRB") sets maximum prices for patented medicines in Canada. These prices are not the prices that are actually paid—they are instead a maximum ceiling, and American companies must then negotiate with government

payers province-by-province and obtain even lower reimbursement. In August 2019, the Canadian government published final regulations that would greatly exacerbate the problem by (1) removing the United States from the basket of comparator countries that the PMPRB uses to set drug prices; (2) imposing additional "economic factors" to substantially regulate prices further; and (3) requiring patentees to report price and revenues, net of all price adjustments (e.g., confidential rebates). The regulations are scheduled to be implemented on January 1, 2021 and are estimated to devastate the market for innovative medicines in Canada. AFTE strongly encourages USTR to engage the Canadian government through USMCA mechanisms to ensure that Canada is sufficiently respecting the rights of American IP owners through its domestic pricing policies.

D. Dairy

Although the USMCA made key advances in opening Canada's dairy market, it leaves in place Canada's vast and complex web of dairy tariff and problematic nontariff policies. It is critical that the Administration closely monitors the continued implementation of Canada's dairy trade commitments under the USMCA and enforce the benefits secured under the agreement.

Outstanding concerns with Canada center upon: (1) the announced dairy tariff-rate quota ("TRQ") administration procedures which discourage full utilization and value of the market access provided to the United States; and (2) ensuring that new dairy policies put in place by Canada do not effectively recreate the harmful impacts of its Class 7 dairy product pricing program. Strong enforcement of these provisions is critical to ensure U.S. exporters realize the full benefit of the USMCA as negotiated. We stand ready to work alongside the Administration in addressing these important issues and preserving market access against unjustified barriers to trade.

IV. INDIA

A. Import Policies

While Prime Minister Modi has taken steps to improve the business environment in India, the country maintains high tariff rates, restrictive border measures, and digital trade barriers that harm U.S. companies. India applies high tariff rates to a variety of products, and utilizes trade remedy actions in non-WTO-compliant ways. In certain industries, such as information technology products, pharmaceuticals and medical devices, and chemicals, India adjusts tariffs as an industrial policy to protect domestic businesses. It most recently did this in its 2020-2021 budget, affecting manufactured products such as automobiles and trucks, mobile phone components, medical devices, toys and chemicals. Even during the COVID-19 pandemic, Indian government ministries proposed additional, across-the-board tariffs in key sectors such as chemicals to protect domestic industry at the expense of fair treatment for U.S. businesses.

Additionally, inconsistent and inefficient customs and border practices continue to hinder goods and digitally enabled services exports from the United States. Many of these actions are not consistent with India's WTO obligations – for example as applied to ICT products in contravention of the Information Technology Agreement – and AFTE encourages USTR to

continue to engage with their Indian counterparts, and where appropriate the WTO, to counter the actions.

B. Technical Barriers to Trade

India's standards and technical regulations present a number of challenges to U.S. exporters. India's local testing and certification requirements often deviate from global norms, imposing mandatory standards that apply burdensome testing and certification requirements on foreign companies that are more restrictive than those applied to domestic producers. A number of India's standards are unique and outdated, applying a one-size-fits-all regulatory approach that disadvantages foreign producers. Such standards and technical regulations are inconsistent with India's obligations under the WTO TBT Agreement. Moreover, Indian proposed regulations in some areas reflect problematic approaches in other markets, such as draft chemical management regulations that reflect a European-style precautionary principle approach.

C. IP Enforcement

In February 2019, following years of advocacy by industry stakeholders, the Indian Cabinet approved proposed anti-camcording provisions in amendments to the Cinematograph Amendment Bill 2019. However, the amendments remain pending. USTR should encourage India to swiftly enact the legislative amendments to outlaw unauthorized recording of all or part of an audiovisual work in a cinema.

AFTE is also concerned by the Department of Industrial Policy and Promotion's June 2020 proposal to decriminalize copyright infringement offenses as listed in the Copyright Act 1957. This proposal would weaken copyright protections, remove an important deterrent for copyright infringers, and disincentivize investment in the creative industries.

Although it acceded to the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty in September 2018, India has yet to implement its obligations under those treaties. The U.S. government should work with its counterparts in India to ensure that India fulfills its obligations under these important agreements.

D. Patent Administration

India's patent law establishes requirements to patentability that go beyond the internationally-recognized requirements of novelty, inventive step, and industrial applicability. By including a fourth requirement of enhanced efficacy under Section 3(D) of the Indian Patent Act, India's patent law is inconsistent with the TRIPS Agreement and deters foreign investment. In addition, the Indian Patents Act imposes additional, unique disclosure requirements for inventions using biological materials, placing an undue burden on the patent applicant. USTR should engage with the Indian government to ensure that its patent administration is commensurate with its obligations under the TRIPS Agreement and other international norms.

The U.S. government should also work with its counterparts in India to reform and modernize other aspects of India's patent regime, including the development of Patent Prosecution Highways and streamlining the pre-grant patent opposition process.

E. Compulsory Licensing

Indian companies continue to seek compulsory licenses for a variety of innovative biopharmaceuticals. Recently, the government of India requested that the WTO TRIPS Council call for the "suspension" of intellectual property policies during the COVID-19 pandemic. Although AFTE understands the intention, such a proposal would slow the research, development, and production of treatments and medicines at a time they are needed most. The TRIPS Agreement provides a framework for countries to work alongside rightsholders, and should be upheld during this important time.

F. Government Pricing and Procurement

AFTE members are concerned that India's pricing regime is discriminatory, unpredictable, and opaque. Significant delays in implementing the amendment to Paragraph 32 of the Drug Price Control Order 2013 (which provides exemptions from price controls for five years from the commencement of marketing in India for patented products, and for life for orphan drugs) have undermined the anticipated improvements to the regulatory environment. Moreover, the broad authority granted to the National Pharmaceutical Pricing Authority and continued lack of transparency and predictability in the decision-making process, especially with regard to the National List of Essential Medicines, inhibits further investment in India.

G. Streaming

The Indian government appears to be seeking to extend the statutory license available to radio and television broadcasting to cover internet transmissions by online streaming sources. Should it succeed, the streaming of music and other creative content would be subject to non-commercial rates set by a government tribunal, denying U.S. rights holders the freedom of contract to negotiate commercial terms for the use of their creative content. Extending statutory licensing to internet transmissions by online streaming platforms would be incompatible with India's obligations under the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty.

H. Dairy

Last year, the United States exported $60 million-worth of U.S. dairy products to India, but this is only a fraction of the potential opportunity that U.S. dairy producers see in this market. U.S. dairy exports to India have been restricted by artificial barriers to trade, namely the Indian dairy health certificate. Although Indian dairy tariffs are a hindrance to trade, India's refusal to work in good faith to negotiate a viable health certificate for dairy products is by far the largest barrier to U.S. exporters seeking to meet the growing dairy demands in this market. Since late 2003, most U.S. dairy exports have been blocked from the Indian market by onerous and largely unjustified certificate requirements.

Over the course of long-running discussions, the United States has provided considerable scientific data documenting the safety of U.S. dairy products, multiple compromise solutions to address India's concerns, and information demonstrating that many countries around the world accept our dairy products and recognize them as safe. Despite these efforts, India persists in

refusing access for U.S. dairy products due to unscientific import requirements. Should Generalized System of Preferences ("GSP") eligibility be reconsidered for India, AFTE strongly recommends that benefits are not reinstated until these blatant trade impediments are adequately addressed.

I. Digital Trade Barriers

Foreign firms in all industries continue to face mounting digital trade barriers in India. Most recently, in August 2020, a government-appointed committee tasked to look into the issue of non-personal data ("NPD") issued a report proposing a framework that would force global companies to share their data with the Government of India and Indian businesses. The policy suggestions, which are being considered the basis for a comprehensive data governance regime, are tantamount to the expropriation of proprietary business information. They undermine intellectual property rights and would hamper innovation. In addition, the report recommends mandatory local storage of critical and sensitive "non-personal data." Because it provides such an expansive definition of "non-personal data," valuable company-held data – including intellectual property, trade secrets, processes, and insights – would be subject to broad data localization measures.

Concerningly, India has also called for a re-examination of the WTO Moratorium for customs duties on electronic transmissions and questioned other Members' attempts to extend or make it permanent. It is worth noting that India's FTA with Singapore prohibits the imposition of customs duties on electronic transmissions. In an official communication to the WTO in the September round of the U.S.-India ICT Dialogues, India underscored the importance of empowering developing countries with the right to impose levies as a tool for economic development. The Government also stated that removing the moratorium will enable the growth of domestic businesses which are currently unable to attain competitiveness and economies of scale because of overseas companies. Levying customs duties on electronic transmissions will hurt e-commerce companies as it will be a deterrent for buyers and sellers to transact on online platforms.

V. INDONESIA

A. Intellectual Property Rights

Indonesia appears to have made positive steps to improve enforcement against counterfeit and pirated goods, and some legislative changes to address highly problematic provisions in their Patent Law mandating local production of patented products. However, many aspects of Indonesia's current approach to IP, including particularly with respect to patents and trade secrets, present concerns similar to those found with other troublesome countries in the region. For example, Indonesia's Patent Law continues to contain provisions authorizing compulsory licensing on vague and arbitrary grounds, narrowing the scope of patentable subject matter and requiring disclosure of the origin of genetic resources. The U.S. government should engage with its counterparts in Indonesia to ensure the latter's IP policies are consistent with international norms.

The Indonesian parliament passed recently the government-initiated Omnibus Bill that revises Article 20 of the 2016 Patent Law, such that a manufacturer is no longer required to locally produce the product in order to be considered "working" the patent in Indonesia. This is a very positive development to strengthen the IP environment in Indonesia. We look forward to working with the government of Indonesia to make the intellectual property environment stronger.

B. Protectionist Policies

In recent years, AFTE has observed a pattern of Indonesian regulations that provide a framework for protectionist measures, including many that target ICT goods and services and pharmaceuticals. For example, the Indonesian government has proposed or implemented local content requirements in the context of Internet of Things devices, online content providers, and telecom providers. The U.S. government should engage with its counterparts in the Indonesian government to ensure that Indonesia does not impose local content requirements that are incompatible with its requirements under the TRIPS Agreement.

C. Compulsory Licensing

Indonesia has a history of issuing compulsory licenses on patented pharmaceutical products, and recent regulations dramatically increase the risk of additional compulsory licenses. In the middle of the COVID-19 pandemic, the Indonesian government issued a new presidential regulation on government use of compulsory licensing without consultation with interested stakeholders. The new regulation enables the Indonesian government to use the patent of pharmaceutical products patented in Indonesia. AFTE understands that the Ministry of Law and Human Rights has initiated a process to amend the existing Patent Law, which presents an opportunity to address these concerns.

D. Film Law

The Indonesian government has stated that it intends to amend its 2009 Film Law, which contains a 60 percent local screen quota and prohibits imported films from being dubbed into the local language. In September 2019, however, without official notice, the government issued the Ministerial Regulation Concerning the Procedure for the Distribution, Exhibition, Export, and Import of Film. These regulations maintain the 60 percent local screen quota and dubbing restrictions and added further limitations on screen time by a single distributor, importer, or producer to 50 percent. These rules fly in the face of Indonesia's obligations under the WTO agreements to provide national treatment to American exporters, as well as international norms on transparency and due process.

E. "Over-the-Top" Regulations

AFTE understands that the Ministry of Communication and Informatics has drafted onerous "Over-the-top" ("OTT") regulations that require foreign OTT service providers to obtain certification, set up local permanent establishments, localize data, and use local national payment gateways, in addition to providing content filtering and censorship mechanisms. These regulations also contain significant penalties for non-compliance. Furthermore, in August 2019,

the Indonesian Broadcasting Commission suggested that it would subject subscription video on demand ("SVOD") providers to its strict censorship and classification requirements. These regulations would stifle exports and effectively block market access for a great deal of U.S. content.

F. Customs Duties on Electronic Transmissions

Indonesia has indicated that it may not agree to a two-year extension of the WTO e-commerce moratorium on customs duties for electronic transmissions and has raised the possibility of charging customs duties on electronic services such as SVOD. Such duties would likely raise prices for consumers, place Indonesia out of step with regional and international best practices, and stifle the growth of Indonesia's digital market.

VI. JAPAN

A. Biopharmaceutical Market Access

Since the end of 2017, a number of new policy proposals have been announced in Japan as part of a drug-pricing policy package. It appears that, as a result of these proposals, the number of innovative products that qualify for the Price Maintenance Premium ("PMP") System has decreased significantly. AFTE is concerned that, under the new requirements, fewer U.S. biopharmaceutical companies will qualify for the full benefit of the PMP System. Moreover, revised eligibility criteria appear to favor Japanese companies at the expense of U.S. companies in violation of Japan's WTO obligation to provide national treatment to American firms.

In addition to these pricing changes, the Japanese government implemented a new Health Technology Assessment ("HTA") system in April 2019 that is inconsistent with international norms. The new HTA system, which revises the price premium granted at the launch of innovative products, was developed without meaningful opportunities for the public to provide comments. AFTE remains concerned that this new assessment system could deny producers fair value for innovation. At the very least, USTR should engage with the Japanese government to ensure that, consistent with its WTO obligations, Japan implements regulations through transparent and open processes that guarantee interested parties the opportunity to participate.

VII. KOREA

A. Technical Barriers to Trade

While the U.S.-Korea Free Trade Agreement ("KORUS") included a number of important TBT and SPS provisions, AFTE members remain concerned regarding its full implementation. For example, U.S. auto exporters face unfair barriers in Korea due to the regulation of SUVs under the same fuel economy target category as passenger vehicles rather than light trucks. Similarly, Korea's chemical management continues to appear to be more trade restrictive than necessary. AFTE encourages USTR to engage with its Korean counterparts to ensure KORUS is fully and effectively implemented.

B. Biopharmaceutical Market Access

Drug prices in Korea are determined by a two-step process that focuses primarily on cost reduction, rather than a holistic assessment of a drug's value. This two-step process – which first involves a "pharmaco-economic" ("PE") analysis, followed by negotiations with pharmaceutical manufacturers (using the PE analysis price as a ceiling) – has the effect of inappropriately depressing the price of innovative medicines. For example, the PE analysis links the prices of newly patented drugs (which require significant investment in R&D, in addition to the overall risk and costs of bringing a new drug to market) to heavily discounted, off-patent and generic drug prices. Through these and other pricing mechanisms, the Korean government limits the viability of marketing new drugs in the company, thus denying market access to U.S. producers.

C. Transparency and Due Process

KORUS contained a number of transparency and due process obligations. Under KORUS Article 5.3(5)(e) and the side letter thereto, Korea agreed to "make available an independent review process that may be invoked at the request of an applicant directly affected by a [pricing/reimbursement] recommendation or determination." While Korea has established such a process, it has exempted reimbursed prices negotiated with pharmaceutical companies from the process. This undermines Korea's KORUS commitment, which requires Korea to apply the independent review process to the negotiation process for prices of all reimbursed drugs, particularly patented medicines. AFTE encourages USTR to engage with the Korean government to help update its domestic biopharmaceutical pricing regime consistent with its KORUS obligations.

D. Patent Term Restoration

Although PTR exists in Korea, its effectiveness is undermined in two important ways. First, the PTR calculation does not include all relevant essential clinical trials used for the approval of the Korean product. The Korean Ministry of Health's failure to recognize all clinical trials – including those conducted outside Korea – has a discriminatory effect on foreign drug innovators, in violation of Korea's KORUS and WTO obligations. Second, Korea discourages appeal of determinations that grant a certain duration of PTR that is less than the full amount originally requested, by revoking the PTR entirely if the appellee loses the appeal. This "all-or-nothing" approach undermines a patentee's right to appeal and leads to uncertainty in the term of protection.

E. "Over-the-Top" Regulation

In May 2020, the National Assembly passed the Telecommunications Business Act Amendments (Articles 22-7), which requires content providers to take responsibility for network stability and consumer demand. Depending on how the Enforcement Decree is ultimately structured, content providers may be obligated to be responsible for parts of the network they do not control, which would inevitably lead to requirements to pay network usage fees to an internet service provider (ISP), for which consumers are already paying and content providers are already compensating in the form of a third-party or proprietary content delivery network. As the Enforcement Decree is currently drafted to target providers with more than 1 million average

users and 1% of Korea's total web traffic volume, the measure would subject U.S. suppliers to costly and burdensome requirements that will not apply to their primary Korean competitors.

Pursuant to KORUS and the General Agreement on Trade in Services ("GATS"), Korea must provide U.S. service providers and services national treatment and most-favored nation treatment. In addition, KORUS prohibits the imposition of a local presence requirement, and requires that service suppliers not be treated in a discriminatory way and be allowed to "use operating protocols of their choice in the supply of any service." Consistent with its international obligations, including under KORUS, Korea should avoid unnecessary intervention into the commercial relationship between content providers and ISPs and apply light-touch regulation to OTT services.

VIII. SOUTH AFRICA

A. Patents

South Africa should implement patent term extension rules to enable innovative companies to recover the patent life lost during the regulatory approval process. As the South African government evaluates the efficacy of the Bolar exception under the 2002 Patents Act (which provides an important mechanism for generic companies to conduct pre-market testing prior to an innovative company's patent expiration), AFTE encourages the government to also include a patent term extension mechanism.

B. Copyrights

Two bills – the Copyright Amendment bill, first introduced in July 2015, and the Performers' Protection Amendment Bill, first introduced in July 2016 – threaten to impose a number of damaging provisions that would curb incentives for film production in South Africa and violate international copyright norms. The bills contain numerous, vast, and overlapping copyright exceptions that would deprive creators of the economic value of their work by permitting extensive use of copyright-protected creative content without authorization or remuneration. AFTE is concerned that these exceptions would be incompatible with South Africa's international treaty obligations, including the TRIPS Agreement, the Berne Convention, the WIPO Copyright Treaty, and the WIPO Performances and Phonograms Treaty.

The bills, which were approved by the Parliament and Council of Provinces, but referred back to the Parliament by the President in June 2020 due to constitutional concerns, also fail to provide adequate criminal and civil remedies for infringement, including online piracy. As review of the bills progresses in Parliament, the U.S. government should stress to its counterparts that the bills must comply with South Africa's commitments under international agreements.

C. Compulsory Licensing

Recently, the government of South Africa requested that the WTO TRIPS Council call for the "suspension" of intellectual property policies during the COVID-19 pandemic. Although AFTE understands the intention, such a proposal would slow the research, development, and production of treatments and medicines at a time they are needed most. The TRIPS Agreement

provides a framework for countries to work alongside rightsholders, and should be upheld during this important time.

IX. CONCLUSION

Thank you for this opportunity to provide comments on the NTE Report. If you have any questions about these comments, please do not hesitate to contact Joshua Teitelbaum at 202-887-4081 or jteitelbaum@akingump.com.