ALLIANCE FOR TRADE ENFORCEMENT

October 26, 2021

William Shpiece
Acting Assistant USTR for Trade Policy and Economics
Office of the U.S. Trade Representative
Executive Office of the President
600 17th Street, NW
Washington, D.C. 20508

RE: Comments on Significant Foreign Trade Barriers to U.S. Exports for 2022 Reporting (Docket Number USTR-2021-0016)

Dear Mr. Shpiece:

The Alliance for Trade Enforcement ("AFTE") is a coalition of trade associations and business groups that advocates for the end of unfair trade practices that harm American companies and workers from every sector of the economy. We also support 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 2022 National Trade Estimate Report on Foreign Trade Barriers ("NTE Report").

Expanding U.S. access to global markets on a fair, competitive playing field is essential to U.S. businesses and their workers. American exports and direct sales in local markets drive investment in the United States, allowing U.S. businesses to create jobs, increase wages, and expand production facilities. Despite the significant strains placed upon the global economy by the COVID-19 pandemic, economic growth is expected to surge in 2021, 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, especially in the face of new logistics and supply chain hurdles facing companies around the world.

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. Approximately 40 percent of all U.S. exports are to America's free trade agreement ("FTA") partners.[1]

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, Mexico, 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. Still others impose tariffs that are inconsistent with their commitments under key WTO agreements such as the Information Technology Agreement. Many countries also impose discriminatory import barriers like import licensing schemes and other restrictions at the border.

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. Many of these technical barriers take the form of regulations that are not developed using good regulatory practices or in ways inconsistent with the WTO Agreements on Technical Barriers to Trade ("TBT") and Sanitary and Phytosanitary ("SPS") Measures.

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

[1] Department of Commerce, International Trade Administration, "U.S. Free Trade Agreement Partner Countries," https://www.trade.gov/us-free-trade-agreement-partner-countries.

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 SMEs, to expand their global reach by building global customer networks, securing global payments, and integrating staff around the world. 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. services. A number of countries are also implementing measures to regulate online communications and video services as traditional public utilities. Finally, strong intellectual property protections have made the "digital transformation" possible, from licensed hardware products to the production of creative content that everyone around the world can enjoy.

E. Intellectual Property

AFTE members continue to face uneven and inadequate protection of intellectual property in every jurisdiction addressed below. These concerns include, among others, insufficient enforcement of intellectual property, such as the failure to adequately combat online and camcording piracy and judicial backlogs for IP infringement cases; unreasonable delays in patent administration; copyright regimes that do not guarantee the minimum protections provided in the international agreements like the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), the Berne Convention, the World Intellectual Property Organization ("WIPO") Copyright Treaty, and the WIPO Performances and Phonograms Treaty; and the absence or severe limitation of such important concepts as regulatory data protection and patent term restoration.

F. Investor-State Dispute Settlement

AFTE members remain concerned regarding the lack of effective tools to ensure fair and non-discriminatory treatment in many jurisdictions. As described throughout this submission, AFTE members face a wide variety of laws and regulations that restrict their ability to invest and trade abroad. Investor-state dispute settlement ("ISDS") provisions in trade and investment agreements are an important tool to help U.S. businesses increase exports abroad while supporting U.S. jobs at home, and should remain a U.S. trade and investment policy priority. The provisions provide businesses the ability to challenge discrimination, denial of fair treatment, contract breaches, and seizure of private assets, particularly in the absence of domestic legal measures to address these concerns. Without effective ISDS provisions, U.S. businesses are often left without a remedy for treatment that is inconsistent with trading partners' international obligations. AFTE members have flagged these views both broadly and in the context of recent trade agreements such as the USMCA.

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.

Brazil's *de minimis* threshold – for which no duty or tax is charged on imported items – only applies to postal shipments under $50, a very low value that serves as a barrier to e-commerce, increasing the time and cost of the customs clearance process for businesses of all sizes. This problem is made more acute by the current import duty rate of a flat 60 percent charge levied on all express shipments, an extremely high rate compared to other countries.

B. Technical Barriers to Trade

AFTE members continue to 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. The Brazil National Telecommunications Agency (*Anatel*), meanwhile, does not accept test data generated outside of Brazil, except in those narrow cases where the equipment is too large and/or costly to transport.

AFTE was pleased to see the United States and Brazil sign in 2020 a trade protocol that included important provisions on good regulatory practices that could address many of these issues.

C. 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 – particularly for trademark infringement.

In a similar vein, the unauthorized camcording of films in theaters – while temporarily reduced in 2021 due to pandemic-related theater closures – further fuels online piracy in Brazil and undermines copyright protections.

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.

D. Patents and Patent Administration

Patent applicants in Brazil have long faced significant pendency times, with a backlog exceeding 10 years. AFTE commends Brazil on its recent efforts to address delays, including the National Institute of Industrial Property's expansion of the Patent Prosecution Highway pilot program to all sectors and the elimination of the dual examination process associated with the Brazilian National Health Surveillance Agency's examination of pharmaceutical patent applications. However, AFTE urges the U.S. government to ensure that progress continues, especially following the recent Brazilian Supreme Court decision finding that Article 40 of the Patent Law, which ensured a minimum patent term of 10 years from the date of patent grant in Brazil, is unconstitutional. In the wake of this decision, patent applicants from all technology sectors have been left with no recourse for unreasonable delays during the examination of patent applications.

E. Compulsory Licensing

In August 2021, the Brazilian Senate passed legislation to broadly expand compulsory licensing avenues in Brazil in was that raise significant process concerns. Although President Jair Bolsanoro vetoed two of the most problematic portions of the legislation in September, the broad legislation went into effect in early October, and continues a trend of efforts in Brazil to expand the use of compulsory licensing.

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, but that these proposals would not help reduce the tax on medicines and its corresponding burden on patients. Worse, the proposed tax reform would impose new taxes on approximately 18,000 medicines that are currently exempt from taxes, increasing the costs to patients from 12 to 18 percent.

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 (Dispute Settlement decisions: WT/DS472/R and WT/DS497/R, Brazil – Certain Measures Concerning Taxation and Charges), the law still preferences local content in a discriminatory manner. In addition, Brazil imposed local content requirements on bidding for spectrum bands. Brazil's 2011 Plano Maior Brasil, meanwhile, includes specific local content requirements for exports to qualify for tax incentives and extends

policies that provide higher tax rates for autos that cannot meet certain criteria for local content, required levels of local engineering or R&D, fuel efficiency and emissions standards or labeling standards.

H. Pay-TV Content and Screen Quotas

Since 2011, Law 12.485/2011 has imposed strict local content quotas for Pay-TV channels airing films, series, and documentaries. In addition, Brazil has for years imposed burdensome screen quotas on the film industry. While these quotas expired in September 2021, a draft bill (5092/2020) pending in the legislature would reinstate screen quotas, and Brazil's Supreme Court ruled in March 2021 that such a quota is constitutional. AFTE opposes local content requirements and screen quotas, which limit consumer choice and encourage consumers to utilize illegitimate and/or illegal content sources.

I. Video on Demand Tax & Regulatory Framework

Brazil has also sought for years to regulate and tax the video on demand ("VOD") market. While Brazil's Congress recently voted to eliminate the existing tax model for audiovisual works (Condecine) to VOD services on a per-title basis, bills continue to gain traction that would apply special taxes and additional regulations to VOD platforms.

J. Digital Services Taxes

The Brazilian Congress 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.

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.

Most of Canada's major trading partners, including the United States, the European Union and Japan, offer forms of PTR which generally allow patent holders to recoup a valuable portion of a patent term where time spent in clinical development and the regulatory approval process has kept the patentee off the market. In these countries, up to five years of lost time can be recouped.

B. Digital Services

Prior to the federal election being called in August 2021, Parliament was in the final stages of considering proposed legislation that would impose 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. The proposed legislation would grant the Canadian Radio-television and Telecommunications Commission the power to make regulations that would impose financial, discoverability, and reporting obligations in order to support the Canadian broadcasting system. The re-elected Liberal Party of Canada has promised, within its first 100 days, to reintroduce legislation to reform the Broadcasting Act to "ensure foreign web giants contribute to the creation and promotion of Canadian stories and music."

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, but instead are a maximum ceiling. 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 greatly exacerbate the problem by (1) changing the basket of reference countries to include those with onerous price controls, (2) introducing flawed economic factors to determine whether a price is "excessive," and (3) requiring manufacturers to report all indirect price reductions for the purpose of a national ceiling price regulation.

The PMPRB subsequently issued Guidelines that implement the regulations and contain concepts and price tests which are beyond the PMPRB's jurisdiction. These Guidelines, which further compromise the rights of patent holders, are subject to ongoing litigation. The PMPRB also proposed new and arbitrary changes in July 2021 to the international price tests for existing medicines and their line extensions. If implemented on January 1, 2022, it is expected that the regulations and the PMPRB Guidelines will significantly undermine the marketplace for innovative pharmaceutical products, delay or prevent the introduction of new medicines in Canada, and reduce investments in Canada's life sciences sector.

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 2021-2022 budget, reducing tariffs on a few manufacturing inputs but primarily increasing tariffs on manufacturing inputs in sectors such as electronics, automotive, chemicals, plastics, industrial equipment, textiles and energy products. Import duties for active ingredients and finished pharmaceutical products average approximately 10 percent and, when combined with the Integrated Goods and Services Tax, the effective tax can range from 0 to 28 percent.

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.

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, proposed regulations in some areas reflect troubling approaches in other markets, such as draft chemical management regulations that reflect a European-style precautionary principle approach.

India's in-country test requirements for telecommunications equipment, in particular, impose unnecessary burdens on international commerce. The sweeping requirements, which were introduced in 2018 and have become effective over the subsequent three years, impose needless costs on ICT companies, which already conduct such tests in internationally accredited labs in other locations.

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, more than two years later, the amendments remain pending.

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.

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.

E. Compulsory Licensing

Indian companies continue to seek compulsory licenses for a variety of innovative biopharmaceuticals. The grounds for issuing a compulsory license in India are broad, vague, and include criteria that do not appear directly related to legitimate health emergencies. Although the Indian government has taken an increasingly measured and cautious approach in recent compulsory licensing cases, the routine initiation of requests for voluntary licenses under Section 84(6)(iv) of the Patents Act as a precursor to seeking a compulsory license, which reduces compulsory licenses to a commercial tool rather than a measure of last resort.

F. Regulatory Data Protection

Regulatory authorities in India rely on test data submitted by originators to seek approval in India and/or another country when granting marketing approval to follow-on pharmaceutical products to third parties, in violation of India's obligations under the TRIPS Agreement. This reliance results in unfair commercial use prohibited by the TRIPS Agreement and discourages the development and introduction into India of new medicines for unmet medical needs.

G. 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.

H. Digital Trade Barriers

Foreign firms in all industries continue to face mounting digital trade barriers in India. For example, India uses indigenous standards and local testing requirement to discriminate and

limit market access for U.S. manufacturers, including with respect to 5G technology and domestic certification requirements for trusted electronic technology that differ from international standards. India has also used tariff barriers to protect local digital industries, increasing tariffs in multiple rounds on information technology products that should be allowed to enter tariff-free under India's commitments under the Information Technology Agreement.

India is also taking multiple approaches to require data localization. For example, the Reserve Bank of India requires all system providers, including notable banks, to ensure that the entirety of data relating to the payment systems they operate are stored in a system only in India.

In addition, 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 Indian government 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 NPD. Because it provides such an expansive definition of NPD, 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. India's FTA with Singapore prohibits the imposition of customs duties on electronic transmissions. India has 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.

Finally, since the mid-2010's India's DPIIT has publicly considered expanding that country's statutory licensing scheme for radio and television broadcasts (as provided for in Section 31D of the country's Copyright Act) to internet transmissions. Such an expansion would contravene India's international obligations under the recently-ratified WIPO Internet Treaties – not to mention affect its ability to attract investment in its dynamic creative content sector. For this reason, DPIIT should reconsider this approach and instead adopt a fair, open framework for content creators doing business online.

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 Indonesian parliament passed 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.

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 as well as 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.

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.

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 local language. In September 2019, however, the government issued the "Ministerial Regulation Concerning the Procedure for the Distribution, Exhibition, Export, and Import of Film" without official notice. This regulation maintains 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 ICT Products and Electronic Transmissions

Since 2018, Indonesia has assessed customs duties on ICT products in excess of its obligations under its schedule to the General Agreement on Tariffs and Trade 1994. For example, certain routing and switching products under HTS Code 8517.62 are being assessed a 10 percent duty, when Indonesia has committed to provide duty-free treatment in its goods schedule.

In addition, Indonesia has indicated that it may oppose 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.

G. Localization and Domestic Content Requirements

In a 2016 presidential decree, Indonesia laid out a number of restrictions on foreign investment in a "negative list." Although that list was revised to open fully a number of sectors, key restrictions remain that impact company size, location, and sector (e.g., medical device manufacturing, energy, and telecommunications services). In addition, Indonesia continues to use local content requirements that distort competitive conditions and create challenges for U.S. manufacturers. For example, Indonesia bans foreign biopharmaceutical products unless the producer partners with an Indonesian firm and transfers relevant technology so that the medicines can be domestically produced within five years.

Indonesia continues to propose data localization measures through the draft implementing regulations of GR71/2019, which require Electronic Systems Providers to acquire prior approval from the Minister to store and process data offshore. This imposes a significant market access barrier and inhibits foreign firms from participating in Indonesian e-commerce.

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. 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 also concerned that, under the new company 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 December 2020, the Japanese government announced a new rule that applies annual price cuts to all medicines with more than a 5 percent difference between the government

reimbursement price and the surveyed wholesaler price available to purchasers. The scope of these cuts goes far beyond anything proposed for discussion by the Ministry of Health, Labour and Welfare, and was never shared with the industry prior to its formal announcement.

Similarly, 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.

B. Anti-Piracy

While AFTE applauds Japan's efforts to combat piracy through link ("leech") sites through the June 2020 revisions to the Copyright Law and the Law Concerning Special Provisions on the Registration of Program Works, AFTE remains concerned that the enhanced law has not been effective in addressing piracy that emanates from overseas.

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.

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, 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.

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. Patent Enforcement

Recent court decisions have undermined patent enforcement in Korea, denying rights holders the appropriate damages in the event that a patent-infringing generic product launches on the market. In Korea, the price of an innovator product is automatically reduced when a generic product enters the market. In November 2020, the Korean Supreme Court ruled that generic companies are not liable for damages caused by a mandatory price reduction to a patented product, even if a court upholds the patent and thus determines that the generic company entered the market illegally and forced the price cut in question. As a result, damages are neither adequate to serve as a deterrent to further infringements, nor sufficient to cover the innovator's losses, contrary to Korea's international obligations.

F. "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 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 percent 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 is obligated to 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 "(e) 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.

G. Cloud Services

To host public sector workloads, the Korean government requires cloud services provides to secure certification under its Cloud Security Assurance Program ("CSAP"), which is de facto discriminatory against non-Korean cloud providers. Despite the fact that U.S. cloud service providers are certified to the highest international security and privacy standards, no U.S. cloud service provider has been able to obtain CSAP certification.

VIII. MEXICO

A. Government Procurement Practices

In 2020, Mexico determined to outsource a significant proportion of its public procurement of medicines to the United Nations Procurement Office, which has generally lacked transparency and predictability. This raises significant questions about Mexico's compliance with its commitments under the USMCA, as well as with its own public procurement and antitrust laws. The substantial change and unreasonable implementation timelines have resulted in significant market access barriers for AFTE members and led to supply chain challenges and shortages for Mexican patients.

Mexico has also acted inconsistently with its USMCA commitments with respect to government procurement of telecommunications goods and services. For example, a subsidiary of the Comisión Federal de Electricidad (CFE), implementing its "Internet Para Todos" project in mid-2020, issued Requests for Information for telecommunications products seemingly with the express goal of having these contracts go to Huawei Technologies. The CFE neglected to publish public notices, named and/or described Huawei products rather than using vendor-neutral criteria, and left a period of only days between the release of the RFI and the selection of a vendor, all in violation of Mexico's obligations under Chapter 13 of the USMCA.

B. Patent Enforcement and Regulatory Data Protection

Consistent with its USMCA commitments, Mexico took a welcome step in November 2020 by promulgating the Federal Law for Protection of Industrial Property. Unfortunately, the implementing regulations for this law have yet to be issued, leaving AFTE members to wait for details regarding how relevant authorities will implement mechanisms to strengthen patent enforcement and the ability to resolve outstanding patent concerns prior to marketing approval and launch of follow-on products. In addition, AFTE members report continued difficulties obtaining effective preliminary injunctions or final decisions on cases regarding IP infringement within a reasonable time, as well as collecting adequate damages when appropriate. Finally, Mexico still lacks measures to restore a portion of the patent term lost during the regulatory approval process, despite its commitments under the USMCA.

C. Technical Barriers to Trade

Manufacturers continue to face a range of technical barriers to trade in Mexico. These include efforts to expand food labelling requirements, curtail advertising and intellectual property, and curtail U.S.-Mexico food and agriculture trade under new standards for nutritional labelling. In addition, a number of Mexican states have begun implementing sales bans of packaged foods to minors, while federal legislative proposals would expand operational restrictions that negatively impact food producers and processors in the United States. These actions do not appear consistent with Mexican commitments under Chapter 111 of the USMCA.

Mexico has also issues a number of regulatory and administrative measures that appear designed to protect Mexican state-owned companies and government agencies in ways that harm U.S. energy producers and downstream manufacturers whose U.S. and Mexican operations depend on a competitive energy market in Mexico. Similarly, President Andrés Manuel López Obrador has continued to publicly call for eliminating or absorbing certain independent and autonomous regulators, such as Mexico's telecommunications and broadcasting regulator (IFT) and the antitrust regulator (COFECE), despite the fact that the independence of such agencies is protected under the USMCA. Other examples of technical barriers to trade include decisions by Mexico's Secretariat of Environment and Natural Resources to deny or delay decisions on permits for key chemical products used in pesticides without robust interagency consultation, ongoing delays in approval processes for innovative health products by the Comisión Federal para la Protección contra Riesgos Sanitarios, and new regulations (NOM-116) to require burdensome new labels for motor oil products in Mexico.

In February 2021, new guidelines from the Instituto Federal de Telecomunicaciones ("IFT") went into effect that pose a significant barrier to trade for mobile telecommunications products. The guidelines restrict sales from U.S. companies and delay time to market by requiring in-country testing for Specific Absorption Rates that are redundant, unrelated to consumer safety, and based on outdated standards. The guidelines appear inconsistent with Mexico's commitments related to conformity assessment procedures under the USMCA.

D. Electronic Payments Services

Pursuant to Chapter 17 and Annex 17-A of the USMCA, Mexico committed to provide market access and national treatment to foreign suppliers of electronic payments services ("EPS"). Nevertheless, AFTE members report significant barriers to entry and discrimination in the domestic processing of card payments. For example, new suppliers are required to be certified by domestic incumbent suppliers (i.e., their direct competitors), to be able to operate in the market, effectively giving the incumbent competitors a veto of whether, and which, foreign companies may enter the market. In addition, services suppliers are required to process all domestic transactions under a single set of technical standards and rules that are set by direct domestic competitors, rather than the suppliers' own standards and rules, which are based on internationally accepted standards. The ability to set its own standards and rules is essential for a new EPS supplier to differentiate its business offerings and intellectual property.

E. Import Policies

Mexico has yet to fully implement several USMCA commitments, including to reduce customs formalities and simplify processing to shipments valued up to $2,500 (Articles 7.1.2, 7.7, 7.8, and 7.8.2); allow periodic assessment and payment of duties (Article 7.8.1); and permit the ability to self-file without a broker and remove the "local" broker rule (Article 7.20). In addition, Mexico's June 2020 increase of its "Tasa Global" – a combination duty and charge on all shipments entering under simplified clearance methods – to 17-19 percent increases trade costs and seriously undermines the the USMCA's customs chapter. Moreover, Mexico has yet to implement Article 7.8.2 of the USMCA, as its latest regulatory update failed to include a key facilitation for shipments valued between $1,000 and $2,500. Finally, Mexico does not yet permit the periodic assessment and payment of duties for express shipments, despite its USMCA commitments.

F. Advertising on Television

In Mexico, Pay-TV channels, which are primarily operated by foreign suppliers and are less likely to exhibit domestically-made content, face strict daily and hourly advertising limits, whereas domestic and free-to-air counterparts are allowed almost twice the daily advertising limit and are not subject to hourly caps at all. This benefit to domestic service suppliers over U.S. service suppliers raises concerns about compatibility with non-discrimination principles in the USMCA.

G. Anti-Piracy

Online and camcord piracy remain concerns in Mexico. Piracy devices and apps have become increasingly present in Mexico's electronic-hardware grey markets, denoting increased preference for this type of illegal consumption. At the same time, although camcord piracy has mostly halted as a result of theater closures during the COVID-19 pandemic, rights-holders anticipate that illicit camcording activity will resume, depite strong anti-camcording commitments in the USMCA.

IX. SOUTH AFRICA

A. Intellectual Property Rights

In May 2018, the South African cabinet approved a follow-up IP Policy that included many of the positive and negative aspects of its predecessor (the 2018 IP Consultative Framework). Of note, the framework incorporated troubling themes such as a "flexible" approach to patents, compulsory licensing, and localization, including language calling for South Africa to "balance" IP policy with objectives to promote local manufacturing, increase broad use of TRIPS flexibilities, set unique patentability requirements, and use patent disclosure to facilitate technology transfer. The policy also includes provisions that subject patent applications to heightened scrutiny and implement lower-quality utility model patents. The South African government continues to work to translate provisions in the IP strategy into an update of South Africa's IP laws.

South Africa has also continued to vocally challenge the value of IP rules in multilateral for a, seeking to broaden as much as possible the grounds and uses of TRIPS flexibilities and the scope of these flexibilities to encompass other areas of law (such as competition law) beyond the scope of TRIPS.

In addition, two bills – the Copyright Amendment bill, first introduced in July 2015, and the Performers' Protection Amendment Bill, first in 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.

B. Express Delivery

The state-owned South African Post Office ("SAPO") has asserted a monopoly over the conveyance of any shipment under 1kg, and has opened a bidding process for other operator to access its monopoly area. Not only would this disrupt a successful private market, it would violate South Africa's obligations under the GATS to refrain from placing market access restrictions on "courier services."

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.