ALLIANCE FOR TRADE ENFORCEMENT

William Shpiece
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 2023 Reporting (Docket Number USTR-2022-0013)

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 and supports U.S. policymakers in their efforts to hold our trading partners accountable. Our members operate in the manufacturing, services, and technology sectors, among others. On behalf of AFTE, we provide the following comments to the Office of the United States Trade Representative ("USTR") for its 2023 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. U.S. 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. Faced with the significant strains placed upon the global economy by the COVID-19 pandemic, massive supply chain hurdles, and uncertainty surrounding economic growth, U.S. companies 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. 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

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

comments will primarily focus on ways in which the United States can better enforce current bilateral and regional trade and investment agreements.

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. 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; weak patent enforcement; unreasonable delays in patent administration; copyright regimes that do not guarantee the minimum protections provided in the international agreements like the TRIPS Agreement; and the absence or severe limitation of regulatory data protection and patent term restoration.

B. 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 mandatory price cuts, regressive 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 U.S. innovators.

C. Technical Barriers to Trade

AFTE members continue to face a variety of non-tariff barriers in foreign markets, including unique regulatory and technical standards, conformity assessment requirements, and localization standards, which add significantly to the cost of manufacturing exports and often impact overall costs more than tariffs. Many of the regulations that create these technical barriers have not been developed using good regulatory practices and are in ways inconsistent with the WTO Agreements on Technical Barriers to Trade ("TBT") and Sanitary and Phytosanitary ("SPS") Measures.

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 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 markets that promote local providers and restrict access to U.S. services. A number of countries are also implementing measures to over-regulate online communications and video services. 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.

II. BRAZIL

A. Patents and Patent Administration

Patent applicants in Brazil have long faced significant pendency times with a recent study showing the average backlog for biopharmaceutical patents continuing to exceed 10 years.[2] AFTE commends Brazil on its efforts to expand the National Institute of Industrial Property's Patent Prosecution Highway pilot program to all sectors and to eliminate the dual examination process associated with the Brazilian National Health Surveillance Agency's examination of pharmaceutical patent applications. However, AFTE urges USTR to monitor that progress and ensure it continues, particularly following the Brazilian Supreme Court's 2021 decision striking down Article 40 of the Patent Law, which ensured a minimum patent term of 10 years from the date of patent grant in Brazil, as 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.

B. Technical Barriers to Trade

AFTE members continue to face significant challenges in Brazil with respect to technical barriers to trade, where both technical regulations, and testing, certification, and other conformity assessment requirements fail to align with international standards. Of great concern, Brazilian regulatory agencies have yet to fully and formally implement the TBT Agreement requirement to use international standards as a basis for technical regulations. Additionally, INMETRO—the central body responsible for publishing conformity assessment requirements—lacks the appropriate technical expertise for its role in Brazil's conformity assessment system. While INMETRO has announced plans to overhaul the management of its conformity assessment program on hundreds of products, this system remains in place. AFTE is concerned that Brazil's conformity assessment program increases the time and cost of testing and certification in a number of manufacturing sectors, thus contributing to Brazil's difficult business environment.

C. Compulsory Licensing

Brazil's National Congress continues to pursue efforts to expand compulsory licensing avenues in Brazil, namely through Brazil's Industrial Property Law. Recent efforts include PL No. 12/2021, which contains unprecedented compulsory licensing provisions that go beyond the TRIPS Agreement.

[2] *See* Philip Stevens & Mark Schultz, GENEVA NETWORK, *Building a predictable, stable patent system in Brazil* (Jun. 20, 2022), https://geneva-network.com/research/building-a-predictable-stable-patent-system-in-brazil/.

D. Regressive Taxes on Medicines

Brazil imposes state and federal taxes that add up to approximately 31 percent of the cost of medicines in Brazil, making it one of the highest rates in the world, dwarfing the global average rate of 6 percent. AFTE understands that the government is currently considering tax reform proposals that would impact the biopharmaceutical sector but fall short of reducing the tax on medicines and its corresponding burden on patients. Worse, one proposed tax reform, approved by the Lower House, 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.

E. Localization and Tax Incentives

The Brazilian government is working to eliminate tax incentives for international programmers despite the fact that local producers benefit from these incentives by coproducing works that comply with Brazil's quota requirements. One such proposal, House Bill 4367/2020, which awaits consideration by a Special Committee, would eliminate tax incentives in the Audiovisual Law. AFTE is concerned that the elimination of these tax incentives will generate significant losses for both local producers and their international coproduction partners.

F. Pay-TV Content and Screen Quotas

Since 2011, Law 12.485/2011 has continued to impose strict local content quotas for Pay-TV channels airing films, series, and documentaries. Specifically, it requires those channels to air at least 3.5 hours per week of Brazilian programming during primetime, in addition to other restrictions that favor local producers. While these quotas are set to expire in September 2023, they could be renewed once again. 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) would reinstate screen quotas. AFTE opposes local content requirements and screen quotas, which limit consumer choice and encourage consumers to utilize illegitimate and/or illegal content sources.

G. 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 voted in September 2021 to eliminate its tax model for audiovisual works (Condecine) to VOD services on a per-title basis, the legislature continues to discuss applying special taxes and additional regulations to VOD platforms. Moreover, Brazil's National Film Agency (ANCINE) has yet to update its internal regulations to reflect the September 2021 legislative action.

III. CANADA

A. Intellectual Property Rights

1. Patent Enforcement and Resolution

The Canadian Patented Medicines (Notice of Compliance) Regulations continue to contain several key deficiencies, including excessive and windfall damage awards to generic litigants, and limited, inequitable eligibility requirements to list patents in the Patent Register. Moreover, recent jurisprudence under these regulations has imposed heightened liability for patent owners, resulting in damages akin to punitive damages.

AFTE is also concerned by Canada's use of the Canada-EU Comprehensive Economic and Trade Agreement ("CETA") to implement reforms beyond those that the Agreement requires, thus exposing innovators to greater potential liability.

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 the CETA requires Canada to compensate innovators for delays in obtaining marketing approval for pharmaceutical products, Canada has implemented an "export" exception that defeats the purpose of restoring part of the lost patent term, adopting only the minimum term of PTR under the CETA. Moreover, under the United States-Mexico-Canada Agreement ("USMCA"), Canada is required to provide PTR for unreasonable delays during the prosecution and issuance of a patent, but Canada has yet to meet this obligation. AFTE encourages USTR to continue to work with Canada to implement a PTR system that meets Canada's obligations under the CETA and the USMCA and that is commensurate with that of other developed economies.

B. Biopharmaceutical Market Access

The Patented Medicines Prices Review Board ("PMPRB") sets maximum prices for patented medicines in Canada, leaving U.S. companies to negotiate with government payers province-by-province and obtain even lower reimbursement. In August 2019, the Canadian government enacted arbitrary regulations that further exacerbate the problem by 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 is required to issue new Guidelines to reflect the August 2019 regulations, and they are expected to be implemented by the end of 2022. AFTE is concerned that any new Guidelines could undervalue and discourage medical advances, delay or prevent the introduction of new medicines in Canada, and reduce investments in Canada's life sciences sector, thus further undermining its marketplace for innovative pharmaceutical products.

IV. INDIA

A. Import Policies

While Prime Minister Modi has taken steps to improve the business environment in India, the country continues to apply import duties for active ingredients and finished pharmaceutical products that average approximately 10 percent. Combined with the Integrated Goods and Services Tax, the effective tax can range from 0 to 28 percent.

Moreover, India continues to apply high tariffs—around 4.8 times the U.S.-applied rate—on non-agricultural goods such as information technology products. Over the last year, India's applied tariffs on non-agricultural goods jumped from 11.9% in 2021 to 14.9% in 2022. As a result of these high tariffs, U.S. manufacturers exported fewer goods to India (worth approximately $22.8 billion in 2021) than to far smaller economies such as Belgium and Singapore.

In addition to import duties, AFTE is also concerned about India's use of strict quality control measures that limit imports of U.S.-origin products such as toys and footwear. These quality control measures generally require in-person factory inspections at foreign sites, despite the fact that India has halted travel by factory inspectors and refused to accept virtual inspections. Thus, many U.S. businesses have virtually no way to meet India's assessment requirements.

B. Technical Barriers to Trade

India's standards and technical regulations for clinical research and new drug approval present a number of challenges to U.S. exporters. India's local clinical trial 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. Furthermore, the granting of waivers of the local clinical trial requirements is subjective and unpredictable. While the "New Drugs and Clinical Trials Rules, 2019" suggested that these requirements could be waived if the clinical trials were conducted in certain countries, India has yet to publish a list of countries. In addition, the government agency that reviews clinical trials and new drug applications in India does not have standard operating procedures or guidelines, thus creating an opaque approval process that undermines the availability of new treatments and vaccines for Indian patients.

India also continues to expand local testing and certification requirements in other sectors, such as information technology, telecommunications, and toys. These mandatory standards, which deviate from global norms, significantly raise costs for U.S. manufacturers. In some cases, such as for information technology products, foreign products must undergo screening, testing, and certification under multiple programs—e.g. the Bureau of Indian Standards rules as well as the Mandatory Testing and Certification of Telecom Equipment scheme.

C. IP Enforcement

Following years of advocacy by industry stakeholders, India has included anti-camcording provisions in the 2021 Cinematograph Amendment Bill, which the Parliament is considering. AFTE urges USTR to work with India to swiftly enact this legislation to outlaw the unauthorized recording of all or part of an audiovisual work in cinemas.

AFTE is also concerned by a proposed amendment to Section 31D of the Copyright Act to extend the existing statutory license for radio and television broadcasting of literary and musical works to "internet or digital broadcasters". The Department for the Promotion of Industry and Internal Trade held a stakeholder consultation on the proposed amendment in August 2021. AFTE is concerned that this amendment would violate India's obligations under international copyright treaties and the TRIPS Agreement.

D. Patent Administration

India's patent law continues to pose procedural and substantive barriers in every step of the patent process, going 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, deters foreign investment, and delays patent grants. In addition, doubts over the validity of biological species patents beyond the term of any genus patent on products have led to arbitrary decisions by the Indian judiciary. USTR should engage with India to ensure that its patent administration is commensurate with its obligations under the TRIPS Agreement and other international norms.

Moreover, biopharmaceutical innovators seeking marketing approval in India face a non-transparent approval process that federal and state agencies fail to coordinate on. Worse, Indian law gives the Central Drugs Standard Control Organization (CDSCO) the authority to approve copies of innovator products regardless of potential patent infringements. Four years after a medicine's first approval in India, a license from any state territory drug regulators is sufficient to manufacture and market, with no required inquiry into whether the drug approval would infringe on a patent. AFTE is concerned about India's inattention to these patent considerations and the ensuing increase in patent infringements.

E. Compulsory Licensing

While India has taken a more measured approach to recent compulsory license cases, Indian companies continue to routinely seek compulsory licenses under Section 84(6)(iv) of the Patents Act 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. These routine practices reduce compulsory licenses to a commercial tool rather than a measure of last resort.

F. Regulatory Data Protection

Indian regulatory authorities rely on test data submitted by originators seeking approval in India and/or another country when granting marketing approval to follow-on pharmaceutical products to third parties. This violates India's obligations under the TRIPS Agreement, 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. Digital Trade Barriers

U.S. companies continue to face increasing digital trade barriers in India, including its Preferential Market Access policy on computers and electronics and local production requirements for telecommunications equipment. It is also specifically imposing indigenous standards and local testing requirements with respect to 5G technology in order to aid its development of a local version of 5G technology. Moreover, India continues to use tariff barriers to protect local digital industries, increasing tariffs in multiple rounds on information technology products, contrary to its commitments under the Information Technology Agreement.

H. Government Pricing

AFTE members continue to be concerned that India's pricing regime is discriminatory, unpredictable, and opaque. India has yet to implement 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) for importers of patented medicines and orphan drugs. Moreover, the recently announced National List of Essential Medicines 2022 contains four patented medicines which will become subject to price controls like generic medicines. India's continued discriminatory government pricing practices and the unviable business environment they create will only further inhibit investment in India.

V. INDONESIA

A. Intellectual Property Rights

Indonesia's Patent Law continues to contain provisions precluding patents on new uses and establishing an additional patentability criterion of "increased meaningful benefit" for certain innovations, such as new salts or dosage forms. While Indonesia's Patent Office has been implementing guidelines that remove these restrictions, the underlying provisions in the 2016 Patent Law remain in effect. Additionally, the 2016 Patent Law imposes patent disclosure requirements regarding the source and origin of genetic resources, further inhibiting innovation.

Although the Indonesian government revised 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, other forced localization requirements persist, namely in Decree 1010. AFTE is also concerned that Indonesia is considering more drastic measures. For example, a letter from the Coordinating Minister for Maritime and Investment Affairs instructed

the Minister of Health to cap the value of imported products in government procurement to 5 percent of total spending in 2023.

Furthermore, AFTE understands that Indonesia's Directorate General of Intellectual Property Rights (DGIPR) is considering a partial revision of its Copyright Law. AFTE urges the U.S. government to work with Indonesia to ensure that any new exceptions or limitations in the revision follows the three-step test in accordance with international best practice. Moreover, any revision should ensure that copyright ownership for films reside with producers absent an agreement to the contrary and that rights-holders may govern any collective management organization without interference by the Indonesian government.

B. Compulsory Licensing

Indonesia has a history of issuing compulsory licenses on patented pharmaceutical products and its regulatory framework continues to enable government agencies to request compulsory licenses for pharmaceutical products in the public interest. In the middle of the COVID-19 pandemic, the Indonesian government issued a new presidential regulation on government use of compulsory licensing without consulting with interested stakeholders. The new regulation enables the Indonesian government to use the patent of pharmaceutical products patented in Indonesia.

C. 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. However, in September 2019, Indonesia 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 are inconsistent with Indonesia's obligations under the WTO agreements to provide national treatment to American exporters, as well as international norms on transparency and due process. AFTE urges USTR to work with Indonesia to remove these barriers.

D. "Over-the-Top" Regulations

AFTE members are concerned about 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, as evidenced by platforms that Indonesia temporarily blocked in July 2022.

Furthermore, while an Indonesian court rejected calls by Indonesian broadcasters to subject videos on demand ("VOD") to the Broadcasting Act, AFTE understands that Indonesia may revise the Broadcasting Act in 2023. AFTE members are concerned that such a revision could seek to extend content quotas, content censorship, and ownership restrictions on television services to VOD services.

E. Disclosure of Confidential Business Information

In November 2020, Indonesia passed the Omnibus Law on Job Creation, which would require, among other things, covered businesses to disclose confidential business information to Indonesian government agencies to secure their approval prior to marketing their products. Affected businesses include those that operate in chemicals, cosmetics, food and beverages, and pharmaceuticals. Mandating the disclosure of such information raises important intellectual property concerns and implicates patient health and broader public health priorities.

VI. JAPAN

A. Biopharmaceutical Market Access

Since December 2017, Japan has announced a number of new policy proposals 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 are unique, non-science based, and favor Japanese companies at the expense of U.S. companies in violation of Japan's WTO obligation to provide national treatment to U.S. firms.

Moreover, in December 2020, Japan announced a new rule that applies annual price cuts effective April 1, 2021, 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, in April 2019, Japan implemented a new Health Technology Assessment ("HTA") system that is inconsistent with international norms. Japan developed the new HTA system, which revises the price premium granted at the launch of innovative products, without meaningful opportunities for public commentary. By September 2022, 12 of 16 innovative medicines that were subject to the HTA system had had their prices cut. AFTE remains concerned that this new assessment system denies producers fair value for innovation.

B. Patent Term Restoration ("PTR")

AFTE commends Japan for its PTR laws, which provide term extensions for subsequent marketing approvals for additional indications or medical uses, or modifications of previously approved products. However, the Japanese Patent Office currently interprets Japan's PTR laws in a manner that often results in extensions for subsequent marketing approvals which are shorter in term than the extensions for the original approval. Thus, this can act as a disincentive to conduct research on additional medical uses and indications.

C. Copyright

In May 2021, the Japanese Diet amended the Copyright Act to include a presumptive license for simultaneous or delayed transmission of broadcasts over the internet, among other types of transmissions. The amendment and implementing guidelines became effective on January 1, 2022. AFTE members oppose this amendment due its adverse impacts on voluntary licensing and appropriate compensation for each and every form of transmission.

VII. KOREA

A. Technical Barriers to Trade

Although the U.S.-Korea Free Trade Agreement ("KORUS") contains a number of important TBT and SPS provisions, AFTE members remain concerned regarding the Korea's implementation of KORUS. For example, U.S. auto manufacturers face unfair barriers in Korea due to the country's regulation of sport utility vehicles ("SUVs") under the same fuel economy target category as passenger vehicles, while the United States regulates SUVs as light trucks. Similarly, Korea's chemical management continues to be more trade-restrictive than necessary in its design and implementation.

B. Biopharmaceutical Market Access

Korea determines its drug prices by using a two-step process that focuses primarily on cost reduction, rather than a holistic assessment of a drug's value. Its 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) – inappropriately reduces the price of innovative medicines. Moreover, rather than adopting more appropriate assessment methods, in September 2021, Korea announced that it would turn to past assessment results in making these determinations. As a result of these practices, Korea's government-set prices are among the lowest in the OECD, and its price controls run contrary to its commitments under KORUS.

C. Transparency and Due Process

Under KORUS Article 5.3(5)(e) and its 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. Furthermore, Korea does not provide a satisfactorily informative written basis for the decisions it makes when companies apply for reimbursements.

D. Patent Term Restoration

Although Korea has implemented PTR, its effectiveness is undermined in three important ways. First, its PTR calculation fails to include all relevant essential clinical trials used for the approval of the Korean product, including international clinical trials that are submitted as a part of the Korean dossier for approval of the product. The Korean Ministry of Health's failure to

recognize all clinical trials – including those conducted outside of 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. Third, the scope of PTR in Korea is unnecessarily narrow, restricted to claims necessary to the "working of the patented invention of a product whose approval was the basis for [PTR]," and its "specific use."

D. Patent Enforcement

Recent decisions by the Korean Supreme Court 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, when a generic product enters the market, the price of an innovator product is automatically reduced. 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 both inadequate to deter further infringements and insufficient to cover the innovator's losses, contrary to Korea's international obligations.

Moreover, while Korea has implemented a patent linkage mechanism pursuant to its KORUS obligations, certain key issues persist. These include the Ministry of Food and Drug Safety's broad discretion to determine whether to list a patent in the Green List or to permit a change in patent listing. Additionally, Korea limits sale stays to a period of only nine months, and if an innovator elects not to seek a stay of a second or subsequent generic drug or biosimilar, they must forfeit any stay granted against the first generic or biosimilar application.

E. "Over-the-Top" Regulation

In May 2020, the National Assembly passed the Telecommunications Business Act Amendments (Articles 22-7), which require content providers to take responsibility for network stability and consumer demand. As currently drafted, the Enforcement Decree does not require content providers to pay a network usage fee to internet service providers ("ISPs"), but the National Assembly is considering several amendment bills that would force content providers to pay network usage fees.

Both KORUS and the General Agreement on Trade in Services obligate Korea to provide U.S. service providers and services national treatment and most-favored nation treatment. Additionally, 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.

VIII. MEXICO

A. Government Procurement Practices

Since 2018, Mexico has made a number of nontransparent changes to its public procurement procedures. 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 created numerous supply chain challenges and shortages for Mexican patients, raising concerns about pharmacovigilance and patient safety.

B. Patent Enforcement and Regulatory Data Protection

While AFTE welcomed Mexico's promulgation of the Federal Law for Protection of Industrial Property in November 2020, Mexico has yet to issue the implementing regulations for this law. This has left AFTE members waiting 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 the launch of follow-on products. Moreover, the Federal Law for Protection of Industrial Property only appears to provide regulatory data protection for chemical compounds and combinations thereof, but not biologics, which is also inconsistent with its USMCA obligations. In addition, AFTE members are concerned about 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, despite its commitments under the USMCA, Mexico still lacks measures to restore a portion of the patent term lost during the regulatory approval process.

C. Market Access

The Mexican government continues to impose advertising limitations on Pay-TV channels, as well as incentives that promote domestically-made programming. 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, while domestic and free-to-air counterparts are allowed almost twice the daily advertising limit and are not subject to hourly caps at all. AFTE members are concerned about the compatibility of this benefit for domestic service suppliers over U.S. service suppliers with the USMCA's non-discrimination principles.

Mexico also maintains a 49 percent foreign equity cap for broadcast networks. In comparison, the U.S. Federal Communications Commission permits up to 100 percent foreign ownership of a broadcaster, subject to a case-by-case review.

D. Anti-Piracy

Online and camcord piracy remain serious concerns in Mexico. Piracy devices and apps continue to be present in alarming numbers in Mexico's electronic-hardware grey markets,

suggesting increased preference for this type of illegal consumption. Worse, the use of hardware devices, social networks, illicit streaming devices, and software to pirate television programming, including subscription streaming services, is increasingly sophisticated and ubiquitous. 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, despite strong anti-camcording commitments in the USMCA.

E. Technical Barriers to Trade

Despite Mexico's commitments under Chapter 11-1 of the USMCA, Mexico continues to expand food labelling requirements and curtail U.S.-Mexico food and agriculture trade under its restrictive nutritional labelling standards. These efforts include a September 2022 Ministry of Health decree revising the Regulation for Sanitary control of Products and Services and the Regulation of the General Law of Health in the Matter of Advertising. In addition, a growing number of Mexican states, led by Oaxaca and Tabasco, have implemented sales bans of packaged foods to minors, while the federal government has made a range of legislative proposals that would expand operational restrictions that negatively impact U.S. food producers and processors. AFTE members are concerned that these efforts are inconsistent with Mexico's obligations under Chapter 11 of the USMCA as well as Article 2.2 of the TBT Agreement.

F. USMCA Energy Consultations

AFTE commends USTR for initiating formal consultations under the USMCA to address Mexico's alarming and discriminatory energy policies. Mexico's recent approach to the energy sector favors state-run energy companies, thus hindering private sector investment and hurting U.S. energy companies and their workers. AFTE urges USTR to continue holding Mexico accountable for these policies and request a formal USMCA panel.

IX. SOUTH AFRICA

A. Intellectual Property Rights

South Africa's National Assembly first introduced the Copyright Amendment Bill in May 2017 and the Performers' Protection Amendment Bill in July 2016. Both of these bills contained a number of damaging provisions that curb incentives for film production in South Africa and violate international copyright norms. Specifically, the Copyright Amendment Bill contained a broad range of limitations on contractual freedom; a time limitation to certain assignments; a provision concerning ownership of works by the state; weak protection of technological protection measures for the licensing of legitimate content; and, a hybrid fair use and fair dealing system of exceptions to copyright, including a broad and invasive regime of new statutory copyright exceptions, the net effect of which constitutes an unlawful deprivation of property. It also provided inadequate criminal and civil remedies for infringement, including online piracy, that will limit the ability to effectively enforce against infringers, thus thwarting the ability for legitimate markets to develop copyrighted works. The Performers' Protection Amendment Bill contained many similar problematic provisions that severely limit contractual freedom and disincentivize the production of audiovisual works in South Africa.

Although minor revisions have since been made, the National Assembly ultimately adopted similar language that was not properly assessed for constitutionality. Moreover, the Department of Trade, Industry and Competition failed to produce an economic impact assessment study on the Copyright Amendment Bill, as required by the government's Socio-Economic Impact Assessment System guidelines. The National Council of Provinces and the nine provincial governments are now considering the bills. AFTE members are concerned that these bills will be approved as is and once again be presented to the President for his assent.

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.