ALLIANCE FOR TRADE ENFORCEMENT

January 31, 2022

Mr. Daniel Lee
Assistant U.S. Trade Representative for Innovation and Intellectual Property
Office of the U.S. Trade Representative
Executive Office of the President
600 17th Street, NW
Washington, D.C. 20508

RE: Comments Regarding the 2022 Special 301 Review (Docket Number USTR-2021-0021)

Dear Mr. Lee:

The Alliance for Trade Enforcement ("AFTE") is a coalition of trade associations and business groups that advocates for foreign governments to end unfair trade practices that harm American workers and companies from every sector of the economy and supports U.S. policymakers in their efforts to hold our trading partners accountable. Our members operate in the manufacturing, services, technology, and agriculture sectors, among others, creating good-paying high-quality jobs. On behalf of AFTE, we provide the following comments to the Office of the United States Trade Representative ("USTR") for its 2022 Special 301 Review.

As described in detail in these comments, AFTE members are concerned regarding policies of a number of countries that deny adequate and effective protection of intellectual property ("IP") rights and deny fair and equitable market access to U.S. persons who rely on IP protection. These policies stifle competition and innovation, thus disadvantaging both the economies of those countries as well as U.S. market participants. The United States is party to important bilateral and multilateral trade agreements with these countries that provide for protection of IP rights and market access, and the United States should take urgent action to enforce those rights.

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. Compulsory Licensing

Compulsory licensing, the mechanism by which governments allow local companies to make, use, sell, or import certain patented products without the authorization of the patent holder, continues to be an issue in a number of countries. In some countries, compulsory licensing is even utilized as a commercial tool rather than a last resort mechanism. USTR opined

on the use of compulsory licensing in its 2021 Special 301 Report, noting that certain requirements established by Article 31 of the TRIPS Agreement must be met in order to engage in this practice, including demonstration of a clear national emergency or extreme urgency that may necessitate a waiver of the requirement to seek prior authorization from the patent holder. Recent evidence suggests, however, that compulsory licensing is not an effective way to improve access or achieve other public health objectives. Moreover, as described in this submission, certain countries are engaging in compulsory licensing without appropriate transparency, process, or adherence with Article 31. Thus, this practice is being carried out for the commercial gain of these countries in a manner that contradicts their commitments pursuant to international agreements.

B. Weak Patent Administration and Enforcement

Inadequate protections for patent holders disadvantage U.S. firms in a number of these countries due to logistical and procedural challenges. Delays and backlogs in the patent review process form a common theme among several of these countries, creating an added hurdle to the already difficult and non-transparent process that U.S. manufacturers must undergo to receive patent recognition. These processes often favor domestic applicants at the expense of U.S. applicants, and in the pharmaceutical context, can even favor companies that conducted domestic clinical trials over those that held their trials in the United States. The countries in question thus undermine their national treatment obligations by creating these market access barriers.

C. Data Localization and Inadequate Data Protections

Many countries continue to engage in practices that threaten data security. Requirements to supply the local government with business confidential and proprietary information is common among a number of countries. Paired with the lack of trade secrets laws or other protective measures to keep this data from unfair commercial use, as well as broad discretion by these governments on how they share the data, inadequate data protection has become a significant deterrent to market access and foreign investments. In many cases, these countries may be violating their commitments under the TRIPS Agreement.

II. BRAZIL

A. Patent Administration

While AFTE commends Brazil on its recent efforts to address its significant backlog of patent applications, including the National Institute of Industrial Property's expansion of the Patent Prosecution Highway pilot program to all sectors, Brazil continues to struggle with long patent backlogs which the U.S. government should engage with their Brazilian counterparts to address. Additionally, the recent Brazilian Supreme Court 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, left patent applicants from all technology sectors with no recourse for unreasonable delays during the examination of future patent applications, and moreover invalidated past patents in key sectors. Therefore, despite some progress, it is important for the U.S. government to continue monitoring Brazil's patent administration system.

B. Compulsory Licensing

Revisions to Brazil's Industrial Property Law through Brazil's PL No. 12/2021, legislation that broadly seeks to expand compulsory licensing avenues in Brazil, continue to raise significant concerns for AFTE. Although President Jair Bolsonaro vetoed some of the most problematic measures, the broad legislation ultimately went into effect suggesting a continued trend towards expanding the use of compulsory licensing by the Brazilian government. Its provisions permit compulsory licensing to a degree that far exceeds what is contemplated under the TRIPS Agreement, which permits compulsory licensing only in narrowly defined circumstances. Furthermore, the Brazilian Congress could override the President's veto, meaning that the provisions that most threaten intellectual property protection could still be implemented.

C. Regulatory Data Protection

AFTE members are concerned that Brazil does not apply regulatory data protections to biopharmaceutical products despite the fact that it does apply such protections for veterinary, fertilizer, and agrochemical products. Brazil should expand these protections to include all of these areas.

D. OTT Regulations

The Brazilian Chamber of Deputies and Federal Senate are considering legislation that would impose national content quotas and minimum investment requirements on OTT platforms. The version under review by the Chamber of Deputies has advanced to a Special Committee. If this goes into effect, these requirements would unduly burden a relatively new industry and may effectively block or significantly limit market access for U.S. content.

Furthermore, in May 2021, Brazil's National Congress approved Executive Order 1025/2020, which extends until 2023 the deadline for movie theaters to offer accessibility resources to patrons with visual and hearing disabilities. Brazilian policymakers are discussing imposing similar obligations on OTT platforms. While this is an important objective, AFTE is concerned about rushing this process, as the technological ability to meet these accessibility requirements are still relatively nascent on OTT platforms. Rushing this could impede these platforms' ability to expand their content and negatively impact consumers' access to a diverse catalogue of viewing options.

E. Regressive Taxes on Medicines

State and federal taxes comprise around 31 percent of the cost of medicines in Brazil, one of the highest rates in the world, far exceeding the global average of 6 percent. AFTE understands that tax reforms proposed by the executive branch would not help reduce these taxes. These reforms would even impose additional taxes on approximately 18,000 medicines that are currently exempt from taxes, increasing the costs to patients from 12 to 18 percent.

F. Restrictive Government Pricing, Reimbursement, and Access Policies

Brazil continues to pose market access barriers for pharmaceutical companies, including delayed pricing decisions, government price ceilings on medicines as a condition of market entry, capped price increases below inflation, and strict requirements by the National Committee for Technology Incorporation that ignore value-based considerations to evaluating and paying for health care. As a result of these market access barriers, only 33 percent of new medicines launched globally since 2011 are available in Brazil, potentially undermining IP rights to U.S. producers and thus necessitating significant reforms.

G. Government Purchasing and Product Development Partnerships

While AFTE recognizes that Brazil's regulatory framework for the establishment of Product Development Partnerships ("PDPs") provides improved transparency, AFTE remains concerned about the lack of clear rules regarding purchasing preferences offered to PDPs. Furthermore, the Ministry of Health, which is responsible for reviewing and approving PDPs, can do so for PDPs submitted by third parties for products with valid patents in Brazil, despite the fact that it is restricted from purchasing those products through third parties.

H. Copyright Reform

As Brazil continues its public consultation to amend its 1998 Copyright Law, USTR should encourage Brazil to reaffirm its commitment to global norms, such as the Berne Convention and TRIPS Agreement. USTR should also encourage Brazil to implement additional international instruments for copyright, such as the WIPO Internet Treaties. In particular, Brazil should clarify that its collective management organization ECAD's statutory default mandate does not encompass interactive streaming services.

I. Intellectual Property Enforcement

While AFTE commends Brazilian law enforcement for recent increased efforts to criminally enforce IP protections in areas such as copyrights and trademarks, delays and backlogs nevertheless continue to plague the Brazilian justice system, and the majority of those arrested on suspicion of criminal IP infringement never face criminal charges or prosecution.

In particular, AFTE encourages Brazil's National Council to Combat Piracy (CNCP) to build on its 2021 work, develop a strategic plan to give top priority to combating widespread online enterprises dedicated to copyright infringement, and engage all rights holders and other players in the Internet ecosystem (including ISPs, hosting providers, domain name registrars, search engines, advertising networks, payment providers, etc.) to develop better standards and effective voluntary agreements to fight online piracy. AFTE urges the Brazilian government to adequately fund the CNCP and increase the CNCP's capability to operate with more human resources and infrastructure.

USTR should encourage ongoing efforts by ANCINE and ANATEL to implement a system for administrative and judicial site-blocking for pirate sites, and encourage proposed site blocking bills that would expressly authorize Brazilian courts to issue orders requiring ISPs to block access to websites hosted outside Brazil that are dedicated to copyright infringement. Such

initiatives would enable Brazil to utilize enforcement tools that are emerging as best practices in Europe and the Asia-Pacific region.

Similarly, online piracy continues to undermine copyright protections, including via the unauthorized camcording of films in theaters, despite a temporary reduction of this activity in 2020 and 2021 due to pandemic-related theater closures. AFTE encourages the National Congress to pass bill No. 2714/2019 that would criminalize the act of camcording in theaters.

Furthermore, counterfeit markets continue to operate unabated in major Brazilian cities, with São Paulo's Shopping 25 de Março and Avenida Paulista as the most egregious examples. To address continued enforcement challenges, AFTE encourages continued coordination between the National Council to Combat Piracy (CNCP) and local authorities to address IP infringement. USTR should also support greater capacity-building and information-sharing between authorities.

III. CANADA

A. Digital Services

Canada's Broadcasting Act currently exempts most digital services from its requirements. However, Parliament is currently considering legislation that would impose obligations on non-Canadian digital services delivered over the internet, including requirements pertaining to their finances, discoverability, and reporting. AFTE is concerned about the national treatment implications of this legislation, which the Liberal Party has stated will "ensure foreign web giants contribute to the creation and promotion of Canadian stories and music."

B. Copyrights

To date, Canada has afforded shorter terms of protection for copyrighted works than its major trading partners, including the United States. When it joined the USMCA, Canada committed to extend its term of protection for all works measured by the life of the creator plus 70 years. However, Canada was afforded a 30-month period in which it would implement this measure. AFTE hopes Canada will rapidly implement this extension by the USMCA-prescribed deadline and refrain from including any additional provisions that would undermine this step in the right direction.

C. Patent Term Restoration

Patent term restoration ("PTR") compensates for delays during clinical trials and the regulatory approval process by providing applicants with additional patent duration. Although Canadian law allows for compensation, the Canadian government has broad authority to impose restrictive time limits and eligibility criteria, and the government has used this authority to limit access to PTR for innovators. The USMCA requires Canada to provide PTR for unreasonable delays during prosecution and issuance of any patent. Similarly, under the Canada-EU Comprehensive Economic and Trade Agreement, Canada is required to compensate innovators for delays in marketing approval for pharmaceuticals. Thus, AFTE encourages USTR to

continue working with Canada to implement a PTR system that effectively compensates for lengthy regulatory processes.

D. Patent Registration

Canada has also made patent registration more burdensome, with the Patented Medicines Pricing Review Board implementing new reporting requirements for patent holders and excluding the United States from its list of reference countries, despite it being a comparable market. Although we welcome the Federal Court's December 2020 decision striking down reporting requirements for all indirect price reductions, AFTE is concerned that the other measures, which are similarly burdensome, have been allowed to proceed. These provisions have been delayed until July 2022, and we urge the Canadian government to reconsider imposing requirements that will overly burden those registering for and maintaining patents.

E. Patent Enforcement

The Canadian Patented Medicines (Notice of Compliance) Regulations contain several provisions that significantly weaken Canada's patent enforcement, such as windfall damage awards to generic litigants and limitations and inequitable eligibility criteria for listing patents in the Patent Register. Patent owners have been hit by excessive liability akin to punitive damages in recent cases. AFTE members have also expressed concern about potential damage awards stemming from common law theories (including Statute of Monopolies, Trademarks Act, unjust enrichment, and others) within Canadian provincial courts that would exceed the compensatory threshold.

F. Regulatory Barriers to Patient Access to New Medicines

AFTE members have expressed concern about the many bureaucratic barriers that delay the regulatory approval process and thus the availability and administration of newly discovered medicines and vaccines through public reimbursement plans. These include the Patented Medicine Prices Review Board process, health technology assessments, price negotiations through the pan-Canadian Pharmaceutical Alliance, and the execution of Product Listing Agreements with individual public and private drug plans.

G. Regulatory Data Protection

In recent years, Canada has required various manufacturers, particularly those in the pharmaceutical industry, to supply business confidential information that the Canadian government does not sufficiently protect. The Workplace Hazardous Materials Information System is one such example which requires companies to share with the government proprietary information, such as exact chemical concentrations, or pay a per-product application fee in order to maintain confidentiality. Similarly, the 2014 Protecting Canadians from Unsafe Drugs Act

gave the Minister of Health broad discretion to share test data without a system in place to protect that data against unfair commercial use.

IV. INDIA

A. Compulsory Licensing

Although India has taken a more measured approach to compulsory licensing in recent years, it continues to insist on its unfettered right to issue them on grounds that stretch well beyond international best practice, allowing it to use compulsory licensing as a commercial tool rather than a measure of last resort. Despite the U.S. government advocacy on this issue, India continues to insist on broad authority to issue compulsory licenses, particularly for biopharmaceuticals, relying on criteria that is vague and unrelated to legitimate health emergencies.

B. Patent Administration

Despite welcomed progress by Indian officials in substantially reducing patent pendency, delays in granting patent approvals continue to be a challenge in key sectors. AFTE urges continued monitoring of India's patent review processes to alleviate concerns that its reviewing body, the Office of the Controller General of Patents, Designs & Trademarks, may favor domestic industries in its efforts to reduce backlog. One such example is the 2015 Patent Rule Amendments, which offered expedited patent review for applicants manufacturing their invention in India.

Moreover, India's legal and regulatory framework for IP protection poses significant barriers to patentability such as Section 3(d) of India's Patent Act, 1970, onerous patent application disclosure requirements, and subjective requirements that disfavor foreign patent applicants. Furthermore, marketing and manufacturing approvals for pharmaceutical products lack transparency and coordination between federal and state agencies. India also allows the Central Drugs Standard Control Organization to approve third-party manufacturers to commercialize copies of innovator products even if those products infringe on patents. The lack of requirements to inquire whether the drug approval is being granted to a patent-protected product risks irreparable harm to patients, innovators, and competition.

C. Regulatory Data Protection

India continues to lack appropriate protective measures for confidential business information despite the fact that its regulatory authorities often rely on such data in approving products such as pharmaceutical products. Such a lack of regulatory data protection exposes market participants to unfair commercial use, falling short of its obligations under the TRIPS Agreement and reducing competition.

D. Government Pricing and Procurement

India's pricing regime continues to be discriminatory, unpredictable, and non-transparent. While AFTE members welcomed the Department of Pharmaceuticals' ("DoP") decision to

amend 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), its potential benefits have yet to be seen due to delays in implementing the amendment. Furthermore, the National Pharmaceutical Pricing Authority's lack of transparency and predictability in the decision-making process, as well as its broad authority, are deterrents to further investment in India.

AFTE members are also concerned about the Make in India policy, which continues to discriminate against suppliers that do not manufacture their products in India by barring them from participating in tenders. A 2020 amendment to India's General Financial Rules requires the exclusion of foreign suppliers (defined as those that do not meet the 20 percent minimum local content requirement) from government procurement when the value of the goods in question is less than INR 2 billion. Moreover, as of December 2020, the DoP requires a minimum 80 percent local content to qualify as a favored Class 1 supplier and a minimum 50 percent local content to qualify as a Class 2 supplier, both of which are favored at the expense of foreign suppliers.

E. Unpredictable Drug Approval Process

India continues to grant waivers of its local clinical trials requirements in a highly subjective and unpredictable manner. The Indian government proposed in 2019 to waive the local clinical trial requirement if clinical trials had been previously conducted in certain countries, but it has yet to publish a list identifying those countries. Furthermore, the process by which India allows for deemed approval of clinical trial applications discriminates against drugs whose research and development was conducted outside of India. These processes effectively reduce the availability of new treatments and vaccines for Indian patients.

F. Copyright Protection and Streaming

India's Ministry of Commerce and Industry published amendments to the Copyright Rules (G.S.R. 225(E)) in March 2021. These amendments excluded proposals that would have extended statutory licenses for literary and musical work and sound recordings to online transmissions. However, in August 2021, the Department for the Promotion of Industry and International Trade solicited comments from stakeholders on a proposed amendment to Section 31D of the Copyright, which would extend the statutory license for radio and television broadcasting of literary and musical works to internet or digital broadcasters. This came as a result of the Parliamentary Standing Committee on Commerce's recommendation that the Copyright Act be amended to ensure a "level playing field . . . for traditional and internet broadcasters alike." These amendments are antithetical to commercial norms around the world and would violate India's commitments under the TRIPS Agreement and international copyright treaties and should thus be abandoned.

AFTE welcomes the February 2019 addition of anti-camcording provisions to the Cinematograph Amendment Bill 2019. However, USTR should encourage India to swiftly enact the legislative amendments to outlaw unauthorized recording of all or part of an audiovisual

work in a cinema. Despite the fact that illegal camcording has been a problem in India for years, the Indian government has not made meaningful progress in addressing this pervasive problem.

In June 2020, the DPIIT proposed decriminalization of copyright infringement offenses in the Copyright Act 1957. Although the proposal has yet to gain any traction, if passed, it would weaken copyright protection, remove an important deterrent for copyright infringers, and disincentivize investment in the creative industries. India should abandon such a proposal as it would also run counter to India's TRIPS obligations.

Furthermore, India has yet to implement its obligations under the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty, which it acceded to in September 2018. USTR should work with its counterparts in India to ensure that India fulfills its obligations under these important agreements.

V. INDONESIA

A. 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, and without official notice, Indonesia issued the "Ministerial Regulation Concerning the Procedure for the Distribution, Exhibition, Export, and Import of Film," which maintained these restrictions and imposed additional limitations on screen time by a single distributor, importer, or producer to 50 percent. These measures are inconsistent with Indonesia's obligations under the WTO agreements to provide national treatment to U.S. exporters, as well as international norms on transparency and due process.

B. OTT Regulations

Indonesia's Ministry of Communication and Informatics has promulgated 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. Non-compliance carries substantial penalties under these regulations. Furthermore, in August 2019, the Indonesian Broadcasting Commission suggested that it would subject subscription video on demand providers to strict censorship and classification requirements. These regulations would stifle exports and effectively block or severely limit market access for U.S. content.

C. Compulsory Licensing

Indonesia continues to authorize compulsory licensing on arbitrary grounds, particularly with respect to patented pharmaceutical products. Recent regulations have further increased the risk of forthcoming compulsory licenses, including a July 2020 regulation allowing government agencies to request compulsory licenses for pharmaceutical products to address emergency needs in the public interest, which Indonesia issued during the COVID-19 pandemic without consulting interested stakeholders. Moreover, the Indonesian government has failed to demonstrate a

serious need for such licensing, such as when President Widodo invoked compulsory licensing for two COVID-19 treatments despite having sufficient imports of those products.

D. Localization and Domestic Content Requirements

Indonesia continues to impose local content requirements that disfavor competition and unduly challenge 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.

E. Trademarks

Indonesia has created a number of practical challenges for manufacturers wishing to register their trademarks with the Directorate General of Customs and Excise. Furthermore, AFTE has observed a continuing pattern of weak enforcement against counterfeit products by the Indonesian government, reflecting poor government coordination and a lack of political will to tackle this issue.

F. Patents

Additionally, Indonesia's 2016 amendments to the Patent Law preclude patents on new uses and establish additional criterion for patents for certain forms of innovation, such as new salts or dosage forms. These restrictions are overly broad and discriminate against particular classes of technology. Although the Patent Office has been implementing guidelines to remove these restrictions, the underlying provisions of the 2016 Patent Law remain unchanged.

G. Cost-Focused Formulary Decisions

While AFTE welcomes Indonesia's decision to develop guidelines and an online portal for listing new medicines on the Indonesian National Formulary, these listing decisions are primarily based on price and the Social Insurance Administration Organization's budget. USTR should urge Indonesia to make listing decisions more holistically, considering scientific data on safety and efficacy.

H. Disclosure of Confidential Business Information

Last year, 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. Covered businesses operate in a variety of sectors, including chemicals, cosmetics, food and

beverages and pharmaceuticals. The mandatory disclosure of such information raises important intellectual property concerns and could lead to delays in patient access to medicines.

I. Copyright Protection

Furthermore, Indonesia's Copyright Law provides that rights in musical works and musical performances that are transferred under sale agreements shall revert to the authors / performers after 25 years. AFTE is concerned that this reversion rule threatens freedom to contract. Moreover, Indonesia should extend the term of copyright protection for sound recordings and all copyrighted works from 50 to 70 years, in line with international norms. Finally, Indonesia should clarify its Copyright Law to align with the WIPO Performances and Phonograms Treaty distinction between the rights to "make available" and to "[communicate] to the public."

VI. JAPAN

A. Online Piracy

AFTE is concerned with the level of piracy targeting internet-based film and television in Japan. While AFTE applauds Japan's efforts to combat piracy through link ("leech") sites, we urge the Japanese government to take further action to address this serious issue, which hurts competition and affects both domestic and foreign content providers.

B. Copyright Reform

In May 2021, the Japanese Diet passed an amendment to the Copyright Act which includes a presumptive license to retransmit content online, as well as "catchup" viewing services. The law went into effect at the beginning of this year, posing a significant risk to contractual freedom. This comes as Japan's Agency for Cultural Affairs is also considering a proposal to extend collective licensing.

C. Biopharmaceutical Market Access

AFTE members continue to express concern over a number of policy proposals that Japan has announced since 2017 as part of a drug-pricing policy package. As part of these proposals, Japan reformed the criteria and timing for its Price Maintenance Premium ("PMP") System, thus reducing the number of U.S. biopharmaceutical companies that qualify. Furthermore, these revised criteria for the PMP System are non-science based and discriminate against U.S. companies in violation of Japan's WTO obligations to afford national treatment to U.S. firms.

A December 2020 rule was similarly far-reaching, applying annual price cuts to all medicines with more than a 5 percent difference between the government reimbursement price and the wholesaler price available to purchasers. The scope of these cuts surpassed anything

proposed for discussion by the Ministry of Health, Labour and Welfare, and was never shared with the industry prior to its formal announcement.

Moreover, Japan's Health Technology Assessment ("HTA") system, implemented in April 2019, remains incompatible with international norms. This HTA system revises the price premium granted at the launch of innovative products, focusing exclusively on cost-effectiveness while ignoring many aspects of a product's value. Furthermore, the HTA system was developed without meaningful opportunities for public commentary. AFTE remains concerned with this new system and its potential for significant undervaluation of U.S. products.

Finally, as Japan developed plans to carry out drug pricing reforms, it failed to make enough formal attempts to seek input from stakeholders, including the pharmaceutical industry. The industry has not been able to make public comments on the proposed new rules, nor has it had adequate opportunities to testify before the Chuikyo.

D. Drug Approval Regulations

In order for Japanese patients to have prompt access to the newest drugs and support the pharmaceutical industry, Japan should develop a more flexible approach to its drug approval process. This includes utilizing a pooled region approach for clinical data, increasing the number of drugs that receive early approval under the Sakigake designation as well as expanding the conditional early approval system, and developing a new innovative expedited approval system focusing on the clinical risks and benefits of the drugs in question. The COVID-19 pandemic has highlighted the importance of having an expedited approval system for emergency use.

E. Vaccines

USTR should urge Japan to execute the National Vaccine Plan and develop a system that provides permanent funding for all recommended vaccines, transparency in the evaluation process for new vaccines, and a science-based process for these evaluations.

F. Patent Term Restoration ("PTR")

AFTE members commend Japan for having PTR laws that provide term extensions for subsequent marketing approvals as well as modifications of previously approved products. While AFTE welcomes this flexible process that recognizes the importance of additional approvals, the Japanese Patent Office's ("JPO") interpretation of these laws often result in

shorter extensions than the original approvals received. This could deter continued research on additional use cases and new formulations for approved products.

G. Patent Enforcement

Japan's decision in 2020 to approve generic versions of an innovative product despite the JPO's upholding of two of the four claims on relevant patents raise concerns about Japan's commitment to effective patent enforcement.

VII. KOREA

A. Biopharmaceutical Market Access

Drug pricing in Korea is determined using outdated thresholds for cost-effectiveness and often ignore the clinical benefit and values that innovative medicines offer. Instead of updating these metrics and using a more appropriate pricing method, Korea's Health Insurance Review and Assessment Service announced in September 2021 that it would instead look to past assessment results in making its pricing determinations. Furthermore, the National Health Insurance Service has the authority to impose additional price concessions. Therefore, Korea's government-determined drug prices are among the lowest in the OECD, and thus a deterrent to competition and market access.

B. Transparency and Due Process

Under KORUS Article 5.3(5)(e) and its side letter, Korea is obligated 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." Despite establishing such a process, Korea has exempted from the process reimbursed prices negotiated with pharmaceutical companies. Thus, Korea continues to undermine its KORUS commitment to apply the independent review mechanism to the negotiation process for prices of all reimbursed drugs, and this particularly disadvantages patented medicines.

C. Patent Term Restoration

Although Korea has implemented patent term restoration ("PTR"), its effectiveness continues to be undermined in two ways. First, Korea's PTR calculation fails to include all relevant essential clinical trials used for the approval of the product. This failure by the Korean Ministry of Health to recognize all clinical trials, including those conducted outside Korea, discriminates against foreign drug innovators, thus violating Korea's national treatment obligations under KORUS and its WTO obligations. Second, Korea discourages innovators to appeal determinations that grant PTR durations that fall short of the full amount they requested

as Korea revokes the PTR entirely if the appeal fails. This "all-or-nothing" approach undermines appellee's rights and reduces certainty in the process.

D. Patent Enforcement

Recent court decisions have denied patent holders appropriate damages in the event that a patent-infringing generic product launches on the market, even when those products have entered the market illegally. 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. Therefore, AFTE members continue to express concern that damages in these enforcement cases are neither adequate to deter future infringements, nor sufficient to cover the innovator's losses, contrary to Korea's international obligations.

E. OTT 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. This legislation could force content providers to assume responsibility for parts of the network they do not control, and a recent proposal to amend the Act would require payments of redundant network usage fees to internet service provider. AFTE is concerned that these measures, which will disproportionately affect high-volume U.S. content providers, conflict with Korea's obligations to provide national treatment pursuant to KORUS and GATS.

F. Screen Quotas

In 2006, prior to the KORUS negotiations, the Korean government agreed to reduce its screen quota requiring exhibition of Korean films to 73 days per year. Today, amidst rapid development of its cultural industries and the success of many Korean film and television productions internationally, Korea should show leadership in the region, trust the choices of its consumers, and further reduce or eliminate its screen quota. In 2016, Korean lawmakers proposed amendments to the Motion Pictures and Video Products Act that would restrict vertical integration of film distribution and exhibition and would "fairly" allocate screens to all movies. These draft amendments failed to clarify how the proposal would promote the diversification of the Korean film industry. In April 2019, Korean lawmakers proposed legislation that would limit the ratio that the same film may be shown in theaters (with a minimum of six screens, during prime-time period from 1pm to 11pm) to 40-50 percent of all showings. While the 2016 and 2019 bills did not pass, AFTE members are concerned that the National Assembly is likely to continue discussions on similarly restrictive amendments. The United States should discourage

Korea from implementing such restrictions, which impede the free market and have the unintended effect of encouraging piracy.

G. Copyright Amendments

In 2020, Korea's Ministry of Culture, Sport and Tourism ("MCT") proposed troubling revisions to the Copyright Act, including for an extended collective licensing regime for fields such as "online music services." Additionally, instead of removing the right of "digital audio transmission," which has caused legal and commercial uncertainty, the MCT proposed to extend the right. These revisions would also designate public institutions as "remuneration bodies," which would allow undistributed revenues to be given to third parties completely uninvolved with the rights in questions.

H. Regulations on Digital Economy Innovators

In September 2021, Korea passed the Telecommunications Business Act, which mandates that app developers include support of third party payment systems to process sales of digital products and services on their platforms. While this legislation may benefit a small number of large, well-known app developers, it will place a heavy burden on smaller app developers that will be forced to promptly adjust their platforms to ensure compliance. AFTE members are concerned about the negative impact that the Telecommunications Business Act will have on U.S. small business digital economy innovators.

VIII. MEXICO

A. USMCA

AFTE commends Mexico on its commitments under the USMCA to implement important reforms related to patent protection, copyright, trade secrets, GIs, and enforcement against fake and counterfeit products. However, AFTE members continue to express concerns about subsequent efforts to undermine core IP implementing legislation, including specific changes that hindered important policy progress. Additionally, separate proposed revisions to the Federal Procurement Law favor procurement of health products from international organizations such as the Pan American Health Organization and the United Nations Office for Project Services (UNOPS), undermining the public bidding process envisioned in the USMCA. USTR should engage directly with the Mexican government to raise concerns with these developments and to ensure that Mexico lives up to its commitments under the agreement.

B. Television Broadcasting Restrictions

Mexico continues to impose more stringent restrictions for advertising on Pay-TV channels than it does on free-to-air broadcast, recently reversing the industry practice of including up to 12 minutes of advertising per hour and a daily limit of 144 minutes. Instead of that long-held practice, which a Mexican court upheld in 2015, Mexican regulators have imposed a strict 6-minute per hour limit, including during "primetime." Given the importance of advertising for foreign programmers, these restrictions significantly reduce revenue for foreign

film and television program producers, including those based in the United States. While facially neutral, such regulations may violate the USMCA due to their discriminatory impact.

Mexico has also discriminated in this area with respect to restrictions on foreign ownership of broadcast networks. In general, foreign entities are only permitted 49% ownership of broadcast networks; however, if applicable, that number is further reduced to match the limit imposed on Mexican companies by the foreign company's country of origin. This reciprocity does not apply in circumstances where the foreign company's country of origin permits ownership rights higher than Mexico's 49% limit. While also facially neutral, in practice, this restriction discriminates against the United States, which permits foreign entities full ownership of broadcast networks, subject to case-by-case reviews.

C. Cultural Heritage Law

Mexico recently enacted a Cultural Heritage Law, which aims to register and protect the traditional cultural expressions of indigenous and Afro-Mexican communities. While this is an important objective, the statutory language lacks clear guidelines for obtaining authorization for use of these cultural expressions. It carries criminal liability and also contains a list of ambiguous administrative infringements, thus risking unintentional violations. Mexico should implement this initiative transparently and ensure regulations provide clarity.

D. USMCA Copyright Implementation

In the context of its USMCA implementation, Mexico passed two pieces of copyright legislation, which AFTE members strongly support. While one of those pieces of legislation implements critical aspects of Mexico's copyright commitments under the USMCA, it has been challenged in the Mexican constitutional court. This law should be upheld and fully implemented, including with respect to the promulgation of necessary regulations.

E. Patent Enforcement

AFTE members have continued to express concerns regarding the difficult process by which manufacturers must attempt to obtain preliminary injunctions or final decisions on cases regarding IP infringement with a reasonable time and with adequate damages. Moreover, the continued prevalence of counterfeit markets and the Mexican government's lack of IP enforcement with respect to those markets has made AFTE members continue to question Mexico's willingness to strengthen enforcement. Although Mexico took a welcome step in November 2020 by promulgating the Federal Law for Protection of Industrial Property, it has yet to issue implementing regulations. Therefore, there remains uncertainty among pharmaceutical companies regarding how the Mexican authorities will strengthen patent enforcement.

F. Market Access Delays

Mexico's Federal Commission for Protection against Health Risks has severely delayed marketing authorizations for pharmaceutical products since the beginning of the López Obrador administration. In addition, the delay, lack of transparency, and unpredictability in Mexico's procurement process create additional market access barriers.

G. Government Procurement Practices

Starting in 2020, Mexico decided to outsource a substantial proportion of its public procurement of medicines to the United Nations Procurement Office, which uses a process that has historically lacked transparency and predictability. Thus, AFTE members are concerned about Mexico's compliance with its USMCA commitments, as well as its own public procurement and antitrust policies. This change in the procurement process has significantly hindered market access for U.S. pharmaceutical companies and created supply chain challenges and shortage for Mexican patients.

H. Trademarks

AFTE members continue to express concerns about updates to Mexico's front-of-pack labeling regulations and rules banning advertising. Due to restrictions on the use of trademarked brand names, logos, symbols, and packaging that consumers depend on to identify safe and effective products, these rules raise serious IP concerns for AFTE. USTR should discuss and discourage these regulations during bilateral and regional consultations with Mexico, including those under the USMCA.

I. Copyright Regulations

The USMCA obligates Mexico to implement a number of key copyright provisions. As mandated by copyright reform, enacted on July 1, 2020, the Mexican Government was given 180 days to publish implementing regulations. However, the relevant agencies have not begun developing the regulations. Meanwhile, the full implementation of the USMCA reforms to the copyright act and criminal code are endangered by constitutional challenges and legislative initiatives aiming to counteract the aforementioned reforms. If the constitutional challenges or the legislative initiatives were to succeed, it would create a significant setback for IP rights holders and make Mexico less globally competitive. AFTE urges Mexican policymakers and lawmakers to robustly defend these USMCA reforms and ensure these laws are properly enforced and adjudicated, with proper staffing and resources.

J. Federal Cinematographic and Audiovisual Law

A February 2021 bill aimed to repeal the Federal Cinematographic Law and create the Federal Cinematographic and Audiovisual Law. This bill would have imposed a local content quota on streaming/OTT services and installed a range of theatrical restrictions intended to limit U.S. film exports and grant market-distorting preferences to local films. Such policies, if implemented, would unfairly restrict U.S. exports, in violation of Mexico's USMCA commitments. While this particular bill has lost viability, there remains significant local pressure to install protectionist policies in the audiovisual sector. Instead, AFTE encourages Mexican policymakers to pursue open markets, investments and collaborations that would result in job creation, and the internationalization of the local industry for the benefit of both the U.S. and Mexican industries.

IX. SOUTH AFRICA

A. Intellectual Property Rights

In May 2018, the South African government approved a follow-up IP Policy that included many of the positive and negative aspects of its predecessor (the 2018 IP Consultative Framework). Among other proposals, 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 sought to greatly broaden the grounds and uses of TRIPS flexibilities and their scope in an effort to encompass other areas of law beyond the scope of the TRIPS Agreement.

B. Copyright Amendments

The South African Parliament is again considering legislation that would significantly weaken the country's copyright and contract frameworks, a measure that would harm the domestic creative community as well as foreign copyright holders. 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.

C. Compulsory Licensing and South Africa's Activity in Multilateral Fora

The South African government continues to advocate for the WTO TRIPS Council to call for a "suspension" of intellectual property policies during the COVID-19 pandemic. While AFTE understands the intention of this request, such a proposal would hinder research, development, and production of treatments and medicines at a time they are greatly needed. The United States should oppose this effort to undermine the TRIPS Agreement and should encourage South Africa to partner with rights holders within the bounds of the agreement.

IX. CONCLUSION

Thank you for this opportunity to provide comments on the Special 301 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.