

January 28, 2021

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

RE: Comments Regarding the 2021 Special 301 Review (Docket Number USTR-2020-0041)

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 companies and workers from every sector of the economy and supports U.S. policymakers in their efforts to hold our trading partners accountable. Our members operate in the manufacturing, services, technology, and agriculture sectors, among others. On behalf of AFTE, we provide the following comments to the Office of the United States Trade Representative (“USTR”) for its 2021 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. 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. Weakening Protections in Multilateral Fora

The World Trade Organization (“WTO”) Agreement on Trade-Related Aspects of Intellectual Property Rights (the “TRIPS Agreement”), which entered into force in 1994, was one

of the most important achievements in strengthening the worldwide protection and enforcement of IP rights, creating for the first time an international minimum standard of protection for IP rights. Through the TRIPS Agreement, the WTO membership sought to create the policy and legal framework necessary for innovation-based economic development of WTO members by rewarding innovation with reliable rights-based systems and permitting the flow of its attendant commercial benefits. Unfortunately, a number of U.S. trading partners have also sought to undermine the TRIPS Agreement, including through policies or practices that deny or would deny adequate and effective intellectual property protection and/or fair and equitable market access for innovative medicines.

In particular, a proposal at the WTO TRIPS Council, sponsored by India and South Africa, calls for the temporary elimination of WTO obligations to grant IP on a wide range of technologies related to COVID-19. The proposal seeks to utilize the COVID-19 pandemic to advance longstanding industrial policies dependent on anti-IP global activism and will inevitably affect IP discussions in countries around the world. We urge the United States to oppose this proposal.

Similarly, efforts at the World Health Organization (“WHO”) to spread plain packaging initiatives and marketing restrictions restrict the use of trademarked brand names, logos, symbols, and packaging on imported products, and consequently increase the risk that counterfeit products could enter the supply chain. Many countries have also advocated before international organizations to expand exceptions, limitations, and flexibilities for patents and other forms of IP in areas outside of the health sector as well.

B. Compulsory Licensing

Compulsory licensing, which allows local companies to make, use, sell, or import particular patented products without the consent of the patent holder, have been issued in a number of countries, while others are considering or have adopted rules that promote or provide broad discretion to issue such licenses. USTR recognized these issues in its 2020 Special 301 Report, noting that actions by “trading partners to unfairly issue, threaten to issue, or encourage others to issue compulsory licenses” and committing to “engage, as appropriate, with trading partners”. Unfortunately, the issue has not abated. Compulsory licenses must be issued only in accordance with international rules and only in exceptional circumstances and as a last resort. Decisions should be made through fair and transparent processes that involve participation by all stakeholders and consider all relevant facts and options.

C. Growth of Counterfeiting

The trade in counterfeit and pirated goods has accelerated massively in recent years. For example, a March 2019 report by the OECD and the European Union Intellectual Property Office found that global trade in counterfeit and pirated goods exceeded \$500 billion in 2016 (or 3.3% of all global trade).¹ This expansion is fueled in large part by online channels that have transformed the way companies connect with customers. Counterfeiters have found it easier to

¹ OECD and EUIPO, [“Trends in Trade in Counterfeit and Pirated Goods.”](#) May 2019.

exploit the online environment by hiding or misrepresenting their identity and other business details; misrepresenting products online (e.g., by posting authentic pictures while shipping fake products); deflecting suspicion by maintaining a small stock of legitimate products to fulfil orders placed by law enforcement officials or brand representatives; and shipping orders through postal channels to avoid customs entry and import processes designed to subject packages to monitoring and inspection.

The United States should work with trading partners to address more directly third-country counterfeiting issues through enforcement, capacity building, and joint advocacy.

D. Geographical Indications and Common Names

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

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

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

II. BRAZIL

A. Copyright Reform

As Brazil continues its public consultation to amend its 1998 Copyright Law, USTR should encourage Brazil to reaffirm its commitment to global norms, such as the Berne Convention and TRIPS Agreement. USTR should also encourage Brazil to ratify and implement

additional international instruments for copyright, such as the WIPO Internet Treaties. In particular, Brazil should clarify that interactive streaming services are outside the collective management organization ECAD's statutory default mandate.

B. Intellectual Property Enforcement

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

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

The Brazilian National Congress introduced in 2018 a proposal (Bill 9744) to increase enforcement over advertising intermediaries who contribute to copyright infringement on local pirate sites. The bill was based on a reputable report that revealed high ad-network revenues originating from rogue websites. The bill is pending in the House Committee on Constitutional Affairs and awaits a final report. The bill remains dormant pending progress on voluntary agreements among Federal Administration, copyright-holders associations, and advertising associations to curb online piracy. USTR should encourage Brazil to pass and implement the bill. Similarly, USTR should encourage Brazil to pursue 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.

The sale of counterfeit goods continues 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, we support continued coordination between the National Council to Combat Piracy (CNCP) and local authorities to address IP infringement. The U.S. government should also support greater capacity-building and information-sharing between authorities.

C. Patents and Patent Administration

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

As the government of Brazil addresses this backlog, however, Article 40 of the Brazilian Patents Act has been key to securing a full patent term for rightsholders. Currently, this provision is being challenged in federal court, and there are legislative proposals afoot to abolish it entirely. The premature removal of Article 40 could invalidate thousands of patents in Brazil—undermining legal certainty for American innovators. In addition to the issue of backlogs, Brazil’s standards of patentability are widely known to be incompatible with international norms. For example, biopharmaceutical patents can be examined twice – once by the Brazilian National Health Surveillance Agency (ANVISA) and once by the Brazilian Patent Office (“INPI”). This is a clear violation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”). AFTE urges the U.S. government to engage with its counterparts in Brazil to ensure its patent protection and approval process are consistent with global standards.

III. CANADA

A. Patent Enforcement and Resolution

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

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

B. Patent Term Restoration

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

While initial drafts of the USMCA included provisions on patent term restoration, the final agreement pared back these restoration requirements. Under the terms of the final agreement, the patent term restoration requirement was revised to include a non-exhaustive list of examples of limitations on the adjustment of patent term to compensate for regulatory delays.

AFTE encourages USTR to continue to work with Canada to implement a PTR system commensurate with that of other developed economies.

C. Copyrights

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

In addition, pursuant to the USMCA, Canada is required to ensure that within 30 months of implementation (i.e., by January 1, 2023), the Copyright Act is amended to extend the term of protection for all copyrighted works to the life of the author plus 70 years. As of January 2021, Canada has not yet extended term of protection for all copyrighted works, contrary to its obligations under USMCA Art 20.62 (a). Industry is concerned about this transition period, as well as the threat of registration requirements on the additional 20-year period, introducing amendments related to reversion and/or termination rights, and other measures. Because of this, USTR should monitor Canada's progress closely in this regard.

D. The Patented Medicine Prices Review Board (PMPRB)

The Patented Medicines Prices Review Board ("PMPRB") sets maximum prices for patented medicines in Canada. These prices are not the prices that are actually paid—they are instead a maximum ceiling, and American companies must then negotiate with government payers province-by-province and obtain even lower reimbursement. In August 2019, the Canadian government published final regulations that would greatly exacerbate the problem by (1) removing the United States from the basket of comparator countries that the PMPRB uses to set drug prices; (2) imposing additional "economic factors" to substantially regulate prices further; and (3) requiring patentees to report price and revenues, net of all price adjustments (e.g., confidential rebates). The regulations are scheduled to be implemented on July 1, 2021 and are estimated to devastate the market for innovative medicines in Canada. AFTE strongly encourages USTR to engage the Canadian government through USMCA mechanisms to ensure that Canada is sufficiently respecting the rights of American IP owners through its domestic pricing policies.

IV. INDIA

A. IP Enforcement

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

in India for years, the country has not taken meaningful enforcement steps to tackle the pervasive problem.

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

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

B. 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. And under India's pre-grant patent opposition system, "interested parties" may challenge a patent application before it is granted. This has the unfortunate effect of delaying patent approvals and reducing patients' access to biopharmaceutical products. USTR should engage with the Indian government to ensure that its patent administration is commensurate with its obligations under the TRIPS Agreement and other international norms.

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

C. Compulsory Licensing and India's Voice in Multilateral Fora

Indian companies continue to seek compulsory licenses for a variety of innovative biopharmaceuticals. Although India has not issued new compulsory licenses in recent years, government officials continue to assert aggressively their ability to do so, both in Delhi and in Geneva. Recently, the government of India requested that the WTO TRIPS Council call for the "suspension" of intellectual property policies during the COVID-19 pandemic. Although AFTE understands the intention, such a proposal would slow the research, development, and production of treatments and medicines at a time they are needed most. The TRIPS Agreement provides a framework for countries to work alongside rightsholders, and should be upheld during this important time. Moreover, India's aggressive behavior in Geneva hampers efforts to both improve the innovation environment at home and dissuades investment from innovative industries.

D. Streaming

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

V. INDONESIA

A. IP Legislation

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

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

B. Compulsory Licensing

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

C. Copyright

The 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. This reversion rule frustrates the freedom to contract and should be revoked. In addition, the term of copyright protection for sound recordings and all copyrighted works should be extended 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 “communication to the public” of sound recordings.

D. Film Law

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

E. “Over-the-Top” Regulations

AFTE understands that the Ministry of Communication and Informatics has drafted onerous “Over-the-top” (“OTT”) regulations that require foreign OTT service providers to obtain certification, set up local permanent establishments, localize data, and use local national payment gateways, in addition to providing content filtering and censorship mechanisms. These regulations also contain significant penalties for non-compliance. Furthermore, in August 2019, the Indonesian Broadcasting Commission suggested that it would subject subscription video on demand (“SVOD”) providers to its strict censorship and classification requirements. These regulations would stifle exports and effectively block market access for a great deal of U.S. content.

VI. JAPAN

A. Biopharmaceutical Market Access

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

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

B. Patent Term Restoration (PTR)

AFTE appreciates that Japan’s PTR laws generally provide term extensions for subsequent marketing approvals for additional indications or medical uses, or modifications of previously approved products. Unfortunately, as the Japanese Patent Office’s interpretation of the laws often results in extensions for subsequent marketing approvals that are shorter in term than the extensions for the original approval, and can thus act as a disincentive to conduct research on additional medical uses and indications, including new formulations for an approved product.

VII. KOREA

A. 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.

B. Transparency and Due Process

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

C. 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.

D. Selection Inventions

Compared to other countries, Korea sets overly strict patentability requirements for a selection invention and falls short of substantially protecting useful chemical, biological, and pharmaceutical inventions. As a result, a number of important inventions in the chemical, biological, and pharmaceutical fields that are filed worldwide are unable to meet Korea's strict requirements. This practice should be harmonized with the standards in other countries to ensure that valuable inventions are protected.

E. Screen Quotas

Prior to the KORUS negotiations, in 2006, the Korean government agreed to reduce its screen quota requiring exhibition of Korean films to 73 days per year. Now, over a decade later, amidst rapid development of its cultural industries and the success of many Korean film and television productions internationally, is the time for Korea to show leadership in the region, trust the choices of its consumers, and further reduce or eliminate its screen quota. In 2016, 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. The focus of the amendments appears to have shifted to market dominance by conglomerates, with proposals to restrict conglomerate-owned or -operated multiplexes from allocating more than 40 percent of screens to the same film at any given time. The draft amendments fail to clarify how the proposal would promote the diversification of the Korean film industry. In April 2019, a bill was introduced by lawmakers proposing to 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, 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.

F. Copyright

Last year, the 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.” In addition, rather than remove the right of “digital audio transmission,” which as caused legal and commercial uncertainty, the MCT has proposed to

extend the right. The proposed revisions would also designate public institutions as “remuneration bodies,” which would allow undistributed revenues to be given to third parties completely unconnected to the rights in questions.

G. “Over-the-Top” Regulations

In May 2020, Korea’s National Assembly passed the Telecommunications Business Act Amendments (Articles 22-7), which require content providers to take responsibility for “network stability and consumer demand.” The Enforcement Decree of the Telecommunications Business Act, which entered into force in December 2020, does not stipulate a network usage fee. It instead requires content providers to work with ISPs to ensure network stability. AFTE reiterates that the stipulation of network usage fees represents an unnecessary intervention into the commercial relationship between content providers and ISPs. Worse still, it may hamper foreign investment flows in the country’s sophisticated digital media sector. We continue to urge the Government to apply KORUS-compliant, light-touch regulations for OTT services.

VIII. MEXICO

A. USMCA

AFTE commends Mexico on its commitments under the USMCA to implement important reforms related to patent protection, trade secrets, GIs, and enforcement against fake and counterfeit products. However, AFTE members are concerned about subsequent efforts to undermine core IP implementing legislation, including specific changes that muffled important policy progress. Additionally, separate proposed revisions to the Federal Procurement Law undermined the public bidding process envisioned in USMCA in favor of procurement from international organizations such as the Pan American Health Organization and the United Nations Office for Project Services (UNOPS) for health products. The United States 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. Patented Medicines Procurement

The government of Mexico has outsourced its purchase of medicines to the UNOPS. The organization uses both “international open invitation to bid” (ITB) orders as well as direct, “sole source” negotiations with rightsholders for public procurement. Sole source negotiations are similar to the “limited tendering processes” outlined in the USMCA or direct adjudication processes in Mexican law. Despite the conclusion of “sole source” negotiations in December 2020, a subsequent UNOPS ITB listed nearly 20 products that were still covered by patent protections. Under the ITB arrangement, there is no mechanism to ensure that patented products are sold only by the rightsholders, creating the possibility of patent infringements in violation of Mexico’s international obligations under the TRIPS Agreement, USMCA, and other free trade agreements.

C. Trademarks

Mexico's recent updates to its front-of-pack labeling regulations and rules banning advertising raise serious IP concerns by restricting the use of trademarked brand names, logos, symbols, and packaging that consumers depend on to identify safe, effective products. USTR should make concerns with these regulations known through bilateral and regional consultations with Mexico, including those under the USMCA.

D. Copyright

The USMCA included a number of key copyright provisions that Mexico must implement under domestic law. As mandated by copyright reform, enacted on July 1, 2020, the Mexican Government was given 180 days to publish implementing regulations. However, after more than three months since the date the new legislation was enacted, the relevant agencies have not begun developing the regulations. The copyright reform legislation faces three constitutional challenges that, if successful, would undermine the commitments Mexico made under the USMCA. USTR should encourage the Mexican Government to continue with the required reform.

E. IP Enforcement

Counterfeit markets in Mexico have driven the widespread sale of fake and counterfeit goods in Mexico. Despite this longstanding concern, the Mexican government has done little to combat the problem, initiating a relatively small number of cases and providing insufficient resources to key IP enforcement agencies.

Online piracy is also a serious, widespread problem in Mexico. The increasing presence of piracy devices and apps in Mexico's electronic-hardware grey markets denote increased preference for this type of illegal consumption. While there are some local infringing websites, many of the infringing sites and services routinely accessed by Mexican users are hosted outside of Mexico. Overall, 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.

The number of illicit camcords in Mexican theaters appeared to fall in 2019, in part due to rights holder activities with law enforcement and exhibitors to target some of the more active release groups. The COVID-19 pandemic, which necessitated the widespread closure of cinemas in Mexico for much of 2020, has temporarily halted camcording activity. However, as cinemas reopen to moviegoers, rights holders anticipate that this illicit camcording activity will resume. The USMCA contains strong anti-camcording commitments that, if properly implemented, should greatly enhance enforcement against camcording in Mexican theaters.

F. "Over-the-Top" Legislation

A bill pending in Mexico's Senate would amend the Federal Telecommunications Act to require a 30 local content quota for Over-the-Top ("OTT") platforms operating in Mexico. Such a local content quota for OTT platforms would violate Mexico's commitments under USMCA

(Articles 14.10 and 19.4.1), limit free expression and consumer choice, distort the growing audiovisual market, and stifle investment and competitiveness. The draft bill also proposes to extend the Federal Telecommunications Institute licensing requirement for restricted TV and audio services to OTT services, including even those operating from abroad. Imposing such onerous new licensing requirements on OTT services appears to be inconsistent with USMCA Article 18.14.1, which discourages imposing requirements of public telecommunications to value-added services which are not public telecom services.

IX. SOUTH AFRICA

A. Patents

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

B. Copyrights

Two bills – the Copyright Amendment bill, first introduced in July 2015, and the Performers' Protection Amendment Bill, first introduced in July 2016 – threaten to impose a number of damaging provisions that would curb incentives for film production in South Africa and violate international copyright norms. This is unfortunate, as the bills initially intended to implement the WIPO Internet Treaties into South Africa's domestic laws. The bills contain numerous, vast, and overlapping copyright exceptions – including a hybrid “fair use” and “fair dealing” exception – that would permit extensive use of copyright-protected creative content without authorization or remuneration. This would have the unfortunate effect of depriving creators of the economic value of their work. AFTE is concerned that these exceptions would be incompatible with South Africa's international treaty obligations, including the TRIPS Agreement, the Berne Convention, the WIPO Copyright Treaty, and the WIPO Performances and Phonograms Treaty.

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

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

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

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

IX. CONCLUSION

Thank you for this opportunity to provide comments on the 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.