UNITED STATES COUNCIL FOR INTERNATIONAL BUSINESS

October 25, 2017

USCIB Comments Regarding Foreign Trade Barriers to U.S. Exports for 2017 Reporting

The United States Council for International Business (USCIB) is pleased to submit comments concerning significant barriers to U.S. exports of goods, services, and U.S. foreign direct investment for inclusion in the annual National Trade Estimate (NTE) report. Pursuant to Section 1377 of the Omnibus Trade and Competitiveness Act of 1998 (19 U.S. C. Section 3106) and as requested by this notice,[1] we also include comments concerning the operation and effectiveness of U.S. telecommunications trade agreements.

USCIB is submitting combined comments regarding foreign trade barriers to U.S. exports for the following countries: Argentina, Australia, Belarus, Brazil, Canada, Chile, China, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, El Salvador, European Union, Fiji, France, Germany, Ghana, Greece, Gulf Cooperation Council, India, Indonesia, Israel, Japan, Kazakhstan, Korea, Latin America Malaysia, Mexico, Middle East and North Africa, the Netherlands, New Zealand, Nigeria, Norway, Pakistan, Peru, Philippines, Russia, Singapore, South Africa, Thailand, Tonga, Turkey, Uganda, the United Kingdom, Uruguay, and Vietnam.

ARGENTINA

Consistently with the shared understanding that the rapidly converging Telecommunications and Media segments need a legal and regulatory less fragmented and long-term approach, President Macri appointed a Commission to draft a new Bill of Convergent Law. Although the deadline set for the presentation of the new draft law has been postponed twice already there is currently no progress in the drafting process. In the meantime, two major reforms of the Telecommunications and Media laws have been implemented through Presidential Decrees.

On December 29, 2015, President Macri's administration passed the Presidential Decree of Need and Urgency No. 267/2015 (the "DNU"). The Decree amended Argentina's Media Law (2009) and Telecommunications Law (2014). A year later many of the restrictions imposed by the DNU were removed by means of a new Presidential Decree (Presidential Decree No. 1340/2016, the "Presidential Decree"). USCIB recognizes and appreciates Argentina's efforts to restore competition through the enactment of the new Presidential Decree. However, the Presidential Decree failed to remove all restrictions created by the predecessor DNU and most importantly, failed to harmonize Argentina's telecommunications and media regulatory frameworks.

Cable providers maintain their ability to compete by providing bundled services, whereas Satellite providers are banned from offering their services bundled with Internet and other services provided by fixed and wireless telephony providers. -In addition, although Satellite Pay-TV providers continue to be regulated by the Media Law, cable providers are expressly excluded from that law and are now covered by the Telecommunications

[1] Office of the U.S. Trade Representative, *Request for Public Comments To Compile the National Trade Estimate Report on Foreign Trade Barriers*, Federal Register Vol. 82, No. 147, 36069 (2017).

Law. [2] This, in practice, exempts Cable providers from complying with a series of burdensome media obligations (e.g., investing in the local film industry, including offerings for low income customers, etc.) that continue to apply to Satellite providers, and it also frees Cable providers from cross-ownership restrictions.

Given the optimism that many U.S. investors and the U.S. Government expressed towards the Macri administration and the potential that exists for increased investment in Argentina, the existence of such an asymmetric regulatory framework may give a negative signal regarding the investment environment in Argentina. Much work is still to do to improve processes and existing regulations to encourage investments in the telecommunications sector and to benefit the digital economy by creating a more dynamic, open and international market, favorable and accessible to international businesses and investors.

To achieve lasting reform and to promote greater investment and competition in the telecommunication and media markets, the Argentinian Government should accelerate the work of the committee appointed to draft a law establishing regulatory convergence. Such legislation will ensure equal regulatory treatment of all participants in this rapidly converging industry.

USCIB urges USTR to request the Argentine government finalize the Bill of Convergent Law, thereby establishing convergent free market principles and the respect for Argentine Trade commitments with the United States.

In addition, to addressing the shortcomings of the DNU and the Presidential Decree, the new law should address regulations proposed in July 2017 that would cover the rights and obligations of users of ICT services. There are already concerns with the scope of the proposed regulations can be broadly interpreted to create rights for users of all ICT services.

It is also important that Argentina limit the scope of the obligations to consumer-facing, regulated telecommunications services. New services such as IoT and OTTs should also be exempted from these consumer rights obligations as they fall out of the scope of regulated telecommunications services.

Tariff Barriers

Since 2009, Argentina has applied a 21 percent VAT on information technology and electronic products, including mobile phones, cameras, and tablets produced outside the Special Customs Area within Tierra del Fuego province. Additionally, imports of these electronics products were subject to a 35 percent import duty, and imports of electronic components were subject to a 12 percent duty. While Decree 117/2017, issued on February 17, 2017, eliminated the 35 percent duty on imports of a subset of electronic devices, and the 12 percent import duty on electronic components effective April 1, 2017 and February 21, 2017, respectively, tariffs remain on other products, including mobile phones.

Subsidies

Argentina currently has a tax-exempt trading area called the Special Customs Area (SCA), located in Tierra del Fuego province. The SCA was established in 1972 through Law 19,640 to promote economic activity in the southern province. The SCA program, which is set to expire at the end of 2023, provides benefits for established companies that meet specific production, exportation, and employment objectives. Goods produced in Tierra del Fuego and shipped through the SCA to other parts of Argentina are exempt from some local taxes and benefit

2 Decree Section 7/Telecom Law Section 10.

from reductions in other taxes. Additionally, capital and intermediate goods imported into the SCA for use in production are exempt from import duties. Goods produced in and exported from the SCA are exempt from export taxes. Since November 2009, cell phones, televisions, digital cameras, and other electronic items not produced in the SCA are subject to a 21 percent VAT. Some products are brought from outside Argentina to facilities in the SCA where they are taken apart and reassembled for sale inside Argentina in order to qualify for tax benefits. In light of the recent WTO Dispute Settlement decisions WT/DS472/R and WT/DS497/R, Argentina should revise its SCA.

AUSTRALIA

In May 2017, the Australian HTA agency, PBAC, continued to make restrictive decisions regarding reimbursement despite clinical evidence. One company reported a negative decision earlier this year whereby PBAC decided against reimbursing a cancer treatment citing concern about budget impact, uncertainty regarding unmet clinical need since patients derive clinical benefit from endocrine treatments, and evidence.

On March 14, 2014, Australia amended the Personally Controlled Electronic Health Records Act of 2012. In part 5, section 77 of this Act, it requires that a registered repository operator, a registered portal operator or a registered Contracted Service Provider that holds or has access to eHealth records must not hold or take the records outside Australia or process or handle the information relating to the records outside Australia, as required in Section 77. The System Operator is only authorized to hold, take, process or handle records outside Australia for the purposes of the operation or administration of the eHealth record system and only where the records do not contain any personal or identifying information of participants in the eHealth record system. The Act requires local data centers for the personally controlled e-health record system. No electronic health information can be held or processed outside of Australia by an authorized service provider (or third-party contracted by the provider).

In addition, the biopharmaceutical sector is concerned by the Australia Department of Health's actions to seek damages from biopharmaceutical innovators that pursue unsuccessful patent claims. Biopharmaceutical innovators must be able to rely on and enforce patents issued by competent government authorities. Laws or policies that allow governments or other non-parties to a patent dispute to collect "market-size damages" after the fact from innovators that pursue unsuccessful patent claims unfairly penalize and discourage the use of provisional enforcement measures as part of well-functioning early resolution mechanisms. They undermine legal certainty, predictability and the incentive patents provide to invest in new treatments and cures. Australia's Department of Health is seeking damages from biopharmaceutical innovators that pursue unsuccessful patent claims. Those damages are designed to compensate Australia's pharmaceutical reimbursement scheme (PBS) for any higher price paid for a patented medicine during the period of a provisional enforcement measure. The PBS imposes automatic price cuts on medicines as soon as competing versions enter the market, but the policy entails no corresponding mechanism to compensate innovators for losses if an infringing product is launched prematurely.

Australia's market-size damages policy unfairly tips the scales in commercial patent disputes encouraging competitors to launch at risk and discouraging innovators from enforcing their patents. It creates an inappropriate conflict of interest by permitting the same government that examined and granted a patent to seek damages if that patent is later ruled invalid or not infringed. It exposes innovators to additional, unquantifiable and significant compensation claims that were not agreed at the time provisional enforcement measures were granted. The size of these additional claims equates legitimate patent enforcement with patent abuse. Laws or policies that allow governments or other non-parties to a patent dispute to collect market-size damages undermine legal certainty, predictability and the incentives patents provide for investment in new treatments and

cures. They appear to be inconsistent with WTO intellectual property rules, including with respect to provisional measures.

The Australian Competition and Consumer Commission (ACCC) initiated in 2016 a market study to examine a range of interrelated issues that may affect the development of competition in the Australian communication market. Rapidly evolving technology trends, product innovation, and changing consumer preferences are some of the drivers of the study, which will examine how these changes affect competition and what implications they have for the regulator. USCIB is monitoring developments of this effort to ensure that the ACCC enables a flexible regulatory framework that drives competition and economically efficient outcomes, including:

1. Carefully weighing whether additional regulation is necessary beyond existing law, and balancing regulatory protections and flexibility for deployment of services.
2. Enabling delivery of digital services in a seamless manner by embracing innovation with light-touch regulatory approaches.
3. Technology neutral policy frameworks.
4. When deemed necessary, regulations should be light-touch and horizontal in nature to recognize the cross-sectoral employment of digital services.

Australia maintains a variety of protectionist measures in the TV industry. Australia maintains a broadcast quota requiring 55 percent of all free to air television programming between 6 am and midnight to be of Australian origin and has genre-specific sub-quotas, as well. A recent government report recommended eventually phasing the quotas out at some indefinite time in the future, but in the meantime to expand the quotas for drama, documentaries, and children’s programming. Additionally, Australia requires pay television channels with more than 50 percent drama programming to spend a specified percentage of program funds on Australian/New Zealand content.

BELARUS

The Belarusian government has instituted a ban on imported medicines for government tenders if local generic products are available. In addition, there is a 15% price preference in government tenders for locally produced medicines and reimbursement is restricted to local generics. Imported products are also subject to administrative requirements for imported product registration, certification, customs procedures, chemical control, and extended approval timelines.

BRAZIL

Telecommunications – Conformity Assessment Requirements

Pursuant to Resolution 323 of November 2002, the Brazilian National Telecommunications Agency (ANATEL) requires testing of telecommunications products and equipment by designated testing facilities in Brazil, rather than allowing testing by a facility certified by an independent certification body. The only exception is in cases where the equipment is too large or too costly to transport. As a result of these requirements, U.S. manufacturers and exporters must present virtually all of their information technology and telecommunications equipment for testing at laboratories located in Brazil before that equipment can be placed on the Brazilian market, which causes redundant testing, reduced product choice, higher costs and delayed time to market. This advance testing and review process can take several months and severely delay or possibly impede market entry.

The United States has urged Brazil to implement the Inter-American Telecommunication Commission (CITEL) Mutual Recognition Agreement (MRA) with respect to the United States. Under the CITEL MRA, two or more

CITEL participants may agree to provide for the mutual recognition of conformity assessment bodies and mutual acceptance of the results of testing and equipment certification procedures undertaken by those bodies in assessing the conformity of telecommunications equipment to the importing country's technical regulations. The United States and Brazil are both participants in CITEL. If Brazil implemented the CITEL MRA as requested by the United States, it would benefit laboratories in both countries that could test the other country's specifications, suppliers seeking to sell telecommunications equipment globally, and consumers who would have access to new technologies and products more quickly. With respect to the United States, implementation of the MRA would benefit U.S. suppliers seeking to sell telecommunications equipment in the Brazilian market by allowing them to have their products tested in the United States to Brazil's technical requirements, eliminating the need for such testing at laboratories in Brazil.

Further, we urge USTR to raise this issue during other appropriate opportunities and consider alternatives that are available to achieve Anatel's desired outcome. One noteworthy example of regional governments working efficiently with the U.S. Government to achieve desired outcomes is the negotiation of Mexican Mutual Recognition Agreements (MRAs). One such agreement, the Mutual Recognition Agreement between the Government of the United States of America and the Government of the United Mexican States for Conformity Assessment of Telecommunications Equipment that was signed in May 2011, among other terms, reduces redundant and expensive testing by providing for each country's recognition of testing laboratories (and acceptance of test reports). USCIB should encourage the Brazilian and U.S. governments to consider negotiation of a similar agreement to streamline the testing process.

Subsidies

Brazil provides tax reductions and exemptions on many domestically-produced ICT and digital goods that qualify for status under the Basic Production Process (Processo Produtivo Básico, or PPB). The PPB provides benefits for the production and development of goods that incorporate a certain minimum amount of local content. Tax exemptions are also provided for the development and build-out of telecommunications broadband networks that utilize locally developed products and investments under the Special Taxation Regime for the National Broadband Installation Program for Telecommunication Networks (Regime Especial de Tributação do Programa de Banda Larga para Implantação de Redes de Telecomunicações, or REPNBL-Redes).

Tax exemptions have also been provided for exports under the Regime for Predominantly Exporting Companies (Programa destinado a empresas predominantemente exportadoras, or PEC) and the Special Regime for the Purchase of Capital Goods for Exporting Companies (Regime Especial de Aquisição de Bens de Capital para Empresas Exportadoras, or RECAP). The government has also subsidized local technology production through incentives available under the Informatics Law (Lei de Informática); the Semiconductors Incentive Program (Programa de Apoio ao Desenvolvimento Tecnológico da Indústria de Semicondutores e Displays, or PADIS); the Digital TV Development Program (Programa de Apoio ao Desenvolvimento Tecnológico da Indústria de Equipamentos para a TV Digital, or PATVD); and the Digital Inclusion Program (Programa de Inclusão Digital, or PID).

WTO Dispute Settlement decision WT/DS472/R and WT/DS497/R found that policies requiring the production of final products in Brazil established pre-conditions for producers to obtain tax benefits that imposed a higher burden on foreign producers than domestic producers. This resulted in different levels of taxation and impaired the ability of imported products to compete in the market. The decision also found that the rules governing accreditation for domestic production of inputs, requiring firms to perform a minimum number of production steps in-country, constituted WTO-inconsistent local content requirements.

Industrial policies for the information technology sector (as well as the automotive and other sectors) continue to enjoy a high level of domestic support among some sectors of the domestic business economy. Nonetheless, Brazil should revise these industrial policies to bring them into compliance with its WTO commitments.

Local Content Requirements

Various countries – including Brazil -- have proposed or adopted policies that require the use of local content in their telecommunications sector infrastructure. Governments often pursue such policies as a way to boost their respective domestic manufacturing sectors, despite the fact that these policies undermine that long-term objective. Building a globally competitive and sustainable manufacturing sector, and ensuring world-class service suppliers in telecommunications and in sectors that use such services, are key goals of most countries. International experience demonstrates that, to achieve these goals, countries should adopt open, market-oriented policies that encourage the establishment of manufacturing facilities that can be incorporated into global supply chains. Policies that discriminate against imported products, in contrast, discourage firms from establishing new manufacturing facilities, because such facilities would be outside global supply chains.

Policies requiring the use of local content also raise serious questions of consistency with multilateral and bilateral trade rules, including provisions of the GATT and the WTO Agreement on Trade-Related Investment Measures (TRIMs).

Localization Barriers

Past Brazilian governments' interventionist policies have prevented innovation and technological progress. In order to ensure access to innovation and to modern technology, Brazil should be open to the provision of products and services from other nations. In addition to removing the local content requirements detailed above, Brazil should repeal the following laws that serve as barriers to trade:

- The Basic Production Process, which offers government procurement preferences for local ICT hardware and software (Law No. 8248 from October 23, 1991);
- CERTICS Decree (Decree No. 8186, of January 17, 2014), which stands at odds with the global nature of the software industry;
- The Margin of Preferences Decrees (Decree No. 8184, January 17, 2014, Decree No. 8194, February 12, 2014 and Decree No. 7903, from February 12, 2013), which grant ICT Equipment and Information Technology and Communication Equipment preference margins in government procurement;
- And the Presidential Decree 8135 of November 5, 2013 and subsequent Ordinances (No. 141 of May 2, 2014, and No. 54 of May 6, 2014), which requires that federal agencies procure e-mail, file sharing, teleconferencing, and VoIP services from Brazilian "federal public entities" such as SERPRO, Brazil's Federal Data Processing Agency. Decree 8135 required that Federal government communications be provided only by Federal agencies, an apparent localization requirement. Other issues of concern include requirements related to sharing of source code, and standards that appear to deviate from global norms. The uncertainty created by the Decree discouraged foreign investment in the IT sector in Brazil, and risked preventing the Government of Brazil from accessing best-in-class, cloud-based communication and information technology services, with significant costs to the Brazilian government in terms of lost efficiencies and lower productivity. In August 2016, the Ministry of Planning announced that Decree 8135 would be revoked. USCIB urges Brazil to ensure that any new measures avoid provisions that would hinder Brazilians' access to best-in-class cloud-based communication services.

These measures disrupt the global nature of the ICT industry and disadvantage both access to technology in

Brazilian and the ability of U.S. ICT companies to do business in Brazil.

Additionally, locally produced medicines automatically have on average a 25% price preference in government tenders.

450 MHz, 2.5 GHz and 700 MHz Spectrum Auction

As a condition of participation in the June 2012 auction for the 2.5 GHz and 450 MHz spectrum bands, ANATEL required wireless carriers to meet specific milestones for ensuring local content of the infrastructure, including software, installed to supply the licensed service. Specifically, wireless carriers were required to ensure 60 percent local content in 2012, 65 percent in 2015, and 70 percent after 2017. ANATEL also required wireless carriers to use a minimum percentage of technology developed in Brazil, starting with 10 percent in 2012, 15 percent in 2015, and 20 percent after 2017. ANATEL extended these requirements to the 700 MHz spectrum in an auction of that frequency in September 2014. Additionally, ANATEL imposed a condition that 50 percent of deployed technology must meet the requirements of the Basic Production Process (PPB), which provides benefits on the production and development of goods that incorporate a certain minimum amount of local content (discussed above).

Machine to Machine (M2M) permanent roaming:

Through a 2012 letter ruling, the Brazilian Telecommunications regulator ("ANATEL"), ordered local wireless carriers to prevent machine-to-Machine (M2M) permanent roaming (i.e. foreign based carriers using foreign numbering Subscriber Identity Models (SIMS) for Internet of Things (IoT) or M2M purposes within Brazil on a permanent basis) over their respective networks. ANATEL opined that FISTEL, a local regulatory tax applied to active SIMs within Brazil, may only be applied to domestic carriers utilizing domestic SIMs with corresponding local numbering. As foreign based carriers utilizing foreign SIMs are not subject to FISTEL, ANATEL concluded that these value-added services may only be provided by locally licensed carriers using local SIMs. Essentially, ANATEL is relying on an aggressive interpretation of its FISTEL law to unnecessarily restrict permanent roaming options for international M2M or IoT providers, thus thwarting IoT device manufacturer's to either develop devices and establish service infrastructure solely for the Brazilian market or forego providing services in Brazil. This aggressive interpretation of local tax laws places Brazil outside global regulatory norms as other jurisdictions have consistently permitted foreign carriers to utilize foreign SIMs to provide permanent roaming for M2M or IoT services to their respective OEM customers.

USCIB urges USTR to encourage Brazil to promote an international, interoperable policy framework for IoT and M2M solutions that includes permanent roaming. Many IOT and M2M solutions will only reach their optimal scale if they can operate around the globe. Monitors on airline cargo or shipping containers must be able to operate wherever their freight travels. Automakers sell vehicles across many different countries and operators drive vehicles across national borders for commercial and personal purposes; automakers and customers alike need a single communications platform to support their connected vehicles. The Brazilian government should support providers of IoT and M2M services and devices and allow them to choose between various available options for numbering and device management, rather than imposing a single, one-size alternative for all cases. Given that restrictions on permanent roaming are intended to favor Brazil's local telecommunications industry, USCIB urges USTR to request the Brazilian government to review its approach to M2M permanent roaming in a manner that supports an international, interoperable policy framework for IoT that facilitates the global deployment of IoT products and services and is not detrimental of foreign investment and continues promoting the scale and interoperability required for the deployment of M2M services.

Various discriminatory policies in the media and entertainment sector

Brazil maintains a variety of discriminatory policies in the media and entertainment sector, primarily led by the regulator, ANCINE. Brazil imposes local content quotas in the pay television sector. In an era where cable and satellite providers have the technology to offer their customers hundreds of channels, these quota requirements are an anachronism, restricting consumer choice. Further, in 2011, Brazil modified the definition of local content, requiring Brazilian ownership of underlying intellectual property rights – a very harmful "indigenous intellectual property" standard. Brazil also has sought to tighten its screen quotas to favor local films and limit the number of screens available to consumers for wide releases. Additionally, ANCINE has sought to impose special taxes and local content quotas on VOD distribution of films, and impose non-commercial and discriminatory requirements in the digital cinema space.

Arbitrary and anticompetitive Tariff barriers imposed on foreign-owned satellites

Since 2004, foreign-owned satellite operators have been subject to arbitrary, excessive and unpredictable landing rights fees as a result of the regulatory framework[1] adopted in by the Agência Nacional de Telecomunicações ("ANATEL"), the telecommunications sector regulator of Brazil. Under the framework, the foreign-owned satellite operators pay a fluctuating annual landing rights fee based upon the reservation price, or minimum price allowed at auction, for the right of a Brazilian operators using a Brazilian filed ITU satellite at a given orbital location.[2]

This fee methodology effectively raises an artificial tariff barrier to foreign-owned satellite operators. Although landing rights and orbital slot reservations are both component parts of satellite TV distribution, these elements are distinct, and foreign operators do not compete for Brazilian slots. The fees should be similarly distinct. Further, reservation prices at auction for Brazilian ITU satellite network filings at a given orbital slot increased 17-fold between 2006 and 2015, and more than doubled between 2014 and 2015. Given this extraordinary price increase, existing and potential new satellite operators in the country, including U.S. satellite operators, face high costs when providing services in Brazil and are denied the regulatory certainty required to promote existing investments. Because the rate for landing fees on the reservation price is entirely arbitrary, the reservation prices are set at the discretion of the auctioneer ANATEL, and the price is driven up by intense competition, foreign operators are also unable to predict and budget for the annual expense of landing rights fees.

In contrast, when comparing with U.S. rules, it is important to note that all foreign-owned satellite operators, including those licensed in Brazil, are not required to pay a comparable fee to be included in the U.S. "Permitted Space Stations List" and thus, are not subject to the artificial tariff barriers US operators face in Brazil. Instead of creating artificial barriers to entry into the critical and strategic market of telecommunications services, ANATEL and the Brazilian government should adopt a pro-competitive framework to establish landing rights fees for foreign-owned satellites based on the administrative costs that ANATEL incurs in order to issue such authorization and regulate the use of foreign satellites in the Brazilian market. Such policy would be consistent with U.S. law which states that regulatory fees are based on regulatory costs recovery and, therefore, their

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[1] Resolution No. 386, 2004. "Regulamento de Cobrança de Preço Público pelo Direito de Exploração de Serviços de Telecomunicações e pelo Direito de Exploração de Satélite".

[2] Resolution No. 386, 2004. Article 10.

The fee calculation formula is *V = PREF x (BE/BREF) x (TE/TREF)*, where: *V* is the fee for the right to exploit a foreign satellite and use the associated radiofrequency, relating to the provision of space capacity in Brazil; *PREF* is the reservation price (or minimum bid price allowed at auction) for the right to operate a satellite using a Brazilian ITU satellite network filing at a given orbital location, fixed in the most recent bid from which exploitation rights were granted; *BE* is the sum of the bandwidth in MHz to be used by the foreign satellite for the provision of capacity in Brazil; *BREF* refers to 1872 MHz, or the sum of the bandwidth of a transponder of a reference satellite; *TE* is the time, in years, corresponding to the term of the right to exploit a foreign satellite and use the associated radiofrequency, taking, in case of fractioned term, the next complete one; and *TREF* refers to 15 years (the maximum authorization term allowed by applicable regulation).

assessment is driven exclusively by the costs of enforcement activities, policy and rulemaking activities, user information services, and international activities incurred by the regulator.[3]

De Minimis

Brazil's *de minimis* threshold (the level below which no duty or tax is charged on imported items) of USD $50 remains applicable only to the Consumer to Consumer transaction (C2C) and does not apply for both Business to Consumer (B2C) and Business to Business (B2B) transactions. There is a legal controversy related to the way the rule is being construed; there exists some case law stating that the exemption should apply for both B2C and C2C transactions and that the *de minimis* threshold should be raised to USD $100. This differentiated treatment of the threshold between transactions and the low *de minimis* threshold for imported items into Brazil of USD $50 (contrary to the United States which is $800 USD) creates unnecessary barriers to trade through increased transaction costs for Brazilian businesses, and acts to restrict consumer choice and competition in the Brazilian market. The Brazilian Government should remove this barrier to trade by expressly extending the application of the *de minimis* threshold to both B2C and B2B transactions and to increase the *de minimis* threshold to a rate more in line with international standards and consumer shopping behavior.

Drug Pricing & Reimbursement

July 2017, Brazil's MoH is investigating the introduction of new price criteria for public purchases of certain types of drugs in a bid to cut spending. The MoH plans to begin with drugs for the treatment of rheumatoid arthritis, and has already contacted the industry to discuss the new measure. Health minister Ricardo Barros said that six of the eight drugs currently included in the treatment protocol for the disease would be dropped as a consequence of the new price criterion. No official statements about a new cost-cutting mechanism have been published by the MoH as of yet, and it is unknown which and how many other therapeutic areas are being considered for cost-cutting.

In June 2017, Brazil's Ministry of Health (MoH) announced that all drug purchases as part of the country's Unified Health System (SUS) will have to be registered and the prices made public through an open online platform, the Health Prices Bank (BPS). Under the mandatory price transparency policy, all SUS buyers will need to register and/or update their prices in the system between September and November this year, while the registration of new purchases referring to the period from 2017 onwards will begin in December. The MoH plans to extend the policy to other health products and services in the future.

Weak Patent Enforcement

In March 2017, ANVISA and INPI reached agreement regarding the role of ANVISA in the examination of patents with respect to ANVISA's prior consent under Article 229C of the Intellectual Property Law. Under the settlement, INPI will no longer deem patent applications that were reviewed by ANVISA as being tainted and therefore requiring inactivation. Also, ANVISA will no longer issue opinions rejecting applications (with rare exception of inventions that themselves pose a severe risk to public health). However, it does not appear that ANVISA will now dismantle its teams of patent examiners. Patent application review by ANVISA will continue and it will continue to issue opinions regarding patentability but these would now only be taken into consideration by INPI when conducting its own examination. ANVISA's opinions would not be considered

[3] 47 U.S.C. § 159(a). "Recovery of Costs: The Commission, in accordance with this section, shall assess and collect regulatory fees to recover the costs of the following regulatory activities of the Commission: enforcement activities, policy and rulemaking activities, user information services, and international activities."

binding on INPI. Given ANVISA's continued role, it is unclear whether this settlement will have any positive impact on the backlog or the granting of pharmaceutical patents.

Nutrition Labeling

In January 2017 Canada published its Pre-Consultation on Front-of-Package Nutrition Labeling. USCIB members have noted that Canada's current pre-consultation on FOP nutrition labeling considers only "interpretive" labels, incorporating words and symbols that serve as warning statements for products deemed "high in" nutrients of concern. This is not consistent with international nutrition labeling standards, nor with the preponderance of nutrition science which agrees that consumers must be encouraged to consume an overall balanced diet. As per Codex Guidelines on Nutrition Labeling, FOP labels "should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather to convey an understanding of the quantity of nutrients contained in the product. A more exact quantitative delineation for individuals is not valid because there is no meaningful way in which knowledge about individual requirements can be used in labelling."

A focus on individual nutrients is unlikely to improve nutrition outcomes or achieve Canada's stated goal of reducing obesity. The draft measure's nutrient limits that trigger labeling appear to be based on limits first developed by the Pan American Health Organization (PAHO) as a tool for assessing marketing to children and without risk assessment to support their application in labeling regulations for the general population. The draft measure is also inconsistent with Canada's obligations to ensure technical regulations achieve a legitimate objective and are no more trade restrictive than necessary. Despite the advanced state of policy considerations in the pre-consultation, Canada has not notified this draft measure to the World Trade Organization (WTO) in order to ensure opportunity for robust consultation with stakeholders and WTO member states.

CANADA

USTR should continue to encourage the Government of Canada to successfully resolve competitive issues in Canadian telecommunications. In 2012, Canada's Telecommunications Act was amended to allow foreign ownership in telecom companies with less than 10 percent of total Canadian telecom market revenue. This legislation was a positive first step; however, complete removal of Canada's foreign investment restrictions for (non-sovereign) investors and operators in both telecommunications and broadcasting would greatly increase market entry and investment in Canada, open broad access for Canadian carriers to international capital markets, and encourage greater facilities-based competition in the Canadian telecommunications industry.

In addition, USTR should urge the Canadian government to address the discriminatory policy of remaining foreign investment restrictions. Policies aimed at increasing the number of players through subsidies and mandated access may compare unfavorably with the simpler policy of opening up the market completely to direct foreign investment. We ask USTR to use every opportunity to urge the Government of Canada to prioritize the complete removal of foreign ownership restrictions as a more certain, direct, means to a more competitive and innovative market for Canadians and increased capital investment.

We also urge Canada to regulate in a manner to maximize a light touch approach. For example, Canada should not apply more burdensome licensing requirements on a company providing more than one regulated service where a less burdensome option is available for each of the services individually. Canada currently imposes Competitive Local Exchange Carrier (CLEC) obligations on resellers of VoIP services even if they also own telecom infrastructure that is not used in the provision of VoIP. Ideally, the reseller would be able to file a

simple registration as a non-dominant facilities based carrier for the network assets, but not be bound by those obligations for the VoIP services it resells.

Other areas of concern vis-à-vis Canada include application of a heightened standard of utility for pharmaceutical patents by the Canadian judiciary, also known as the Promise Doctrine, as well as an ongoing consultation by the Patented Medicines Review Board, which could have significant implications for pharmaceutical pricing in Canada.

Intellectual Property

To date, 28 decisions invalidating pharmaceutical patents, either solely or in part, for lack of utility have been issued since 2005 when the Promise Doctrine began to emerge out of Canadian Federal Court case law. The Promise Doctrine raises concerns not only in terms of a lack of predictability for innovative companies doing business in Canada, but it is also inconsistent with Canada's international trade treaty obligations because it imposes onerous and unjustified patentability criteria, narrowing the scope of inventions that receive patent protection; and discriminates against innovative pharmaceutical companies, as this additional requirement has disproportionately impacted pharmaceutical patents.

Patented Medicines Pricing

The PMPRB is an independent quasi-judicial body, created under the Canadian Patent Act, with a mandate to ensure that prices charged for patented medicines sold in Canada are not excessive. It does so by regulating the "ceiling price" – the maximum allowable price – for a patented medicine according to established policies, regulations and guidelines. The PMPRB has proposed changes to how price ceilings are determined for patented medicines in Canada on the basis of international comparators, which may exert downward pricing pressure on innovative pharmaceutical manufacturers.

Canada plans to make changes to the basket of seven comparator countries traditionally used for pricing comparison purposes. Currently, and in accordance with the *Patent Act* and *Patented Medicines Regulations*, patentees must report publicly available prices of patented drug products for a "basket" of seven foreign comparator countries: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. The federal Minister of Health recently indicated that the U.S. may be removed from this "basket", to be replaced by one or more jurisdictions with lower pricing. This could have the effect of reducing the potential price ceiling for all patented medicines in Canada.

As part of proposed regulations put forward by Canada's Health Minister in 2017, it is proposed that Canada's pricing regulations be amended to require patentees to report to the PMPRB all indirect price reductions, given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts, or any other benefit in Canada.

Regarding restrictive patentability, the Canadian Supreme Court ruled that the "Promise Doctrine is not the correct method of determining whether the utility requirement under . . . the Patent Act is met." The Court indicated that in Canada, as in other major jurisdictions, satisfying the utility requirement is a low threshold that requires a mere "scintilla of utility." Additionally, the final regulations implementing PTE have now been published and Certificates of Supplementary Protection (CSPs) will be available as of 21 Sept 2017.

De Minimis

Canada's *de minimis* threshold (the level below which no duty or tax is charged on imported items) remains at

CAD $20 (approximately USD $15), the lowest of any industrialized country and among the lowest in the entire world. For comparison, the *de minimis* threshold for items imported into the United States is $800 USD -- over 40 times higher than Canada's. This low threshold, which has not been adjusted since the 1980s, creates an unnecessary barrier to trade through increased transaction costs for Canadian businesses, and acts to restricts consumer choice and competition. Raising the *de minimis* would help Canadian small businesses participate more fully in global trade and ecommerce, growing Canada's digital economy. Recent studies have also shown that any gains realized by collecting additional duties are often outweighed by the cost of assessing and processing of the high volume of shipments that fall below the low threshold. In fact, proposals to increase the *de minimis* threshold have been shown to be revenue neutral or even positive for the Canadian Government.

CHILE

Cell Phone Labeling and Emergency Warning Alerts

In June 2016, the Ministry of Transport and Telecommunication, via the Subsecretariat of Telecommunications (SUBTEL) published External Resolution 1.473, which calls for a mandatory and universal emergency alert (vibration) to be included in all cellphone or mobile devices that access Chile's public telecommunications services. The Resolution also mandates duplicate testing for every shipment by a Chilean laboratory of two (already homologated) phones from every shipment to effectively re-test for compliance with the earthquake notification standards. The requirement appears to be unique in the world, is more onerous than necessary, and adds to the costs of supply chains and logistics, which ultimately are expected to be passed on to consumers. The requirement to test two mobile phones from every import shipment also would impose a disproportionate burden on SMEs that may import in smaller quantities and that do not have the financial ability to establish their own testing facilities.

In July 2017, SUBTEL issued guidelines, "Manual of Graphic Standards: Broadband Label" pursuant to Resolution Nº 1.463. As of September 23, 2017, all mobile phone vendors must include a label on their packaging and advertising indicating that device's compatibility with all mobile networks (e.g. 2G, 3G, 4G). The label requirement is unduly broad and costly. It is required on all phones, even those that operate in all bands. It thus is not justified by providing additional information to consumers who, without such a label, would correctly assume that the phone would work in whatever band the consumer uses.

The guidelines further define the exact specifications of the label – design, colors, size, and placement. The specifications apply to the mobile phone's physical packaging, in-store promotional and displays, TV advertisements, and internet advertising and sales. They thus impose country-specific obligations for products marketed and sold in Chile. The requirements, so far, do not appear to extend to print advertising.

These labeling requirements were not previously notified to the impacted industries. Article 7.7 of the United States-Chile Free Trade Agreement (FTA) on Technical Barriers to Trade states that "each Party shall allow Persons of the other party to participate in the development of standards, technical regulations and conformity assessment procedures." The FTA requires parties to "provide information regarding the objective of, and rationale for, a standard, technical regulation, or conformity assessment procedure that the Party has adopted or is proposing to adopt." Articles 2 and 10 of the WTO Agreement on Technical Barriers to Trade (TBT), establish norms for transparency related to a government's preparation and adoption of technical regulations. While consumers should be aware of the available mobile bands in the store upon purchase, mandating such information on packaging and advertising, particularly when prepared for pan-regional use, is overly onerous and ineffective. Further, the specifications regarding label placement on display phones are not thoughtfully conceived; they may result in blocking phone functions.

Nutrition Labeling

Chile adopted Decree No. 13 on June 26, 2015, making final amendments to its Food Health Regulations that had been previously notified to WTO members (as G/TBT/N/CHL/282). The Decree establishes limits for calories, added sugar, sodium and saturated fat, above which processed food and beverages must include front-of-package octagonal, black and white labels (resembling stop signs) warning that the product is "high in" these nutrients, and further subjects labeled products to marketing and advertising restrictions, and prohibitions on the use of images deemed appealing to children under 14 years of age, including possibly trademarked characters. The Decree entered into force in June 2016.

In January 2017, Chile notified the WTO of further implementing measures that appear to greatly expand the scope of marketing restrictions, including by requiring additional statements ("Choose products with fewer warning signs") and prohibiting marketing of any labeled product without regard to whether the marketing is directed at children.
The United States, other WTO members, and other stakeholders have repeatedly raised concerns with the provisions of Decree No. 13 in the WTO Committee on Technical Barriers to Trade (TBT). Chile has not meaningfully addressed these concerns or presented scientific justification for the regulation's departure from international standards.

The regulation's nutrient limits are not based on available international standards, nor has Chile made available the methodology or risk assessment by which the limits were developed. Further, restrictions on marketing and advertising and prohibitions on the use images violate intellectual property rights and are inconsistent with Chile's international agreement. The regulation grants MINSAL unacceptably broad discretion to undermine the intellectual property rights of well-recognized brand identities and registered trademarks.

In contrast to Chile's international trade obligations under the WTO Agreements and in other international investment agreements, the amended provisions are not based on science or internationally-recognized standards (such as those established by the General Guidelines of Codex Alimentarius) and appear to be more trade restrictive than necessary to meet Chile's legitimate objective of reducing obesity and non-communicable diseases, thus compromising Chile's obligations under the TBT Agreement. Moreover, the marketing and advertising restrictions may contradict Chile's obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Likewise, the regulation appears to violate Chile's commitments under the investment chapter of the U.S.-Chile Free Trade Agreement, including guarantees relating to the minimum standard of treatment, national treatment, and non-expropriation.

CHINA[3]

Since its accession to the World Trade Organization (WTO) in 2001, China has conducted a comprehensive reform of its services trade policy. Nevertheless, China's WTO compliance record in services is hurt by incomplete implementation of its accession commitments; by remaining telecommunications services trade barriers; and increasingly restrictive regulations that raise market access barriers to foreign companies. With its accession, China promised to abide by the WTO's basic principles of non-discrimination, pro-trade, pro-competition and so on. However, China's narrow interpretation of value-added services, high capitalization

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[3] Please also see USCIB's Comments on China's Compliance with Its WTO Commitments, submitted to USTR under Docket No. USTR-2017-0011-0012 on September 20, 2017.

requirements for basic telecommunications services, lack of an independent regulator, and restrictions that specifically apply to the non-Chinese companies for provision of value-added services remain key outstanding issues. Moreover, additional concerns are raised by recently announced pending changes to China's law on ICT services, including requirements for data localization, government review and approval of encryption measures and a "security" review of software by government officials. China's publication of a new Telecom Services Catalog in December 2015 further expands regulation and market access barriers to a host of new services not typically regulated, including cloud computing, content delivery networks, and online platforms (under a broadly written provision entitled Information Services).

These new policies will create significant new barriers for foreign firms seeking to provide ICT services in China and continue to raise questions regarding China's commitment to open trade policies. China's indiscriminate filtering and blocking of online services for political purposes not only constitute online censorship but also a trade restriction for U.S. firms while the Chinese firms are often operating on the U.S. market. China's increasingly restrictive approach to the Internet is negatively impacting services that rely on the cross-border flow of data and, as a result, is impeding the operations of foreign companies in China that depend on online communications. Such restrictions contradict the goals of China's Internet Plus strategy that is aimed at promoting e-commerce and increasing the role of the Internet in China's economy.

Market Access

China continues to restrict its telecommunications market for both Basic- and Value- added services. China continues to restrict market access through its licensing requirements, high capitalization requirements, and through the continuing absence of an independent regulator.

China should remove its joint venture requirements and FDI limits for Value Added Services. These requirements inhibit market access, competition, and innovation. Moreover, in classifying service characteristics as Basic or Value Added (VAS), China should eliminate the intentionally restrictive distinction between international and domestic services to determine whether a service is Basic. For example, China defines International Virtual Private Line service as a Basic Telecommunications Service, whereas the exact same VPN service provided domestically is defined as Value Added. This distinction is material, because foreign companies are required to partner (49 percent joint venture) with a domestic telecommunications company (that holds a Basic License), as compared to VAS licenses where foreign companies can partner (50 percent joint venture) with any Chinese company irrespective of whether it holds a Basic Telecommunications license or not. It is critical that MIIT interpret the definition of VAS in a manner that is consistent with China's explicit WTO commitment and widely accepted international standards. Replacing these conservatively applied vertical service classifications with more objective and transparent guidelines for Type I (facilities-based) and Type II (non-facilities based) services would allow more foreign carriers to invest in China which eventually would stimulate economic growth in the Chinese market.

The requirement that a foreign company select a state-owned and licensed telecom company as a joint-venture partner should be eliminated under the Basic Service license regime because the requirement is a significant market access barrier and Incumbent licensees have only limited incentive to partner with foreign competitors. China limits foreign ownership to 49 percent and 50 percent respectively for a basic service license and VAS license. These ownership limits place a significant market access barrier from an operational and economic perspective. Service Providers are unable to establish operational control, protect their brand, and deliver services in China that are seamlessly integrated in the service provider's global network offerings. Foreign entities thus established as Joint Ventures then become a horizontal competitor of their joint venture local operator, further eroding the value of the foreign investment. USCIB should urge USTR to encourage China to

remove this provision and allow foreign companies to partner with any legally operating telecom entity they find suitable.

The Chinese government also imposes strict limitations on non-Chinese companies that wish to offer Voice over Internet Protocol (VoIP) services in China. No non-Chinese company may offer any kind of VoIP service in China, as VoIP requires a VAS license, which foreign companies may obtain only through a joint-venture with a Chinese company. Connection to the public switched telephone network (PSTN) requires a basic service license. Only a few small pilot VoIP projects -- involving the dominant Chinese telecom operators -- are allowed to offer PSTN-interconnected VoIP services to Chinese consumers. USTR should urge the Chinese government to remove restrictions in the efficient use of IP technologies, including voice applications.

In 2008, the Chinese government announced a reduction in the capitalization requirement for a basic service license from 2 billion RMB (approximately US$291 million) to 1 billion RMB (US$145.9 million).[4] While the reduction in the capitalization requirement for a basic service license is a step in the right direction, China's requirement is still extremely high and continues to be a significant barrier to entry. The reduced capitalization requirement is 100 times the capital requirement for value added service licensees, which is itself many times the actual level of capital investment needed to build a national, non-facilities-based value added network. The reduced capitalization requirement in basic services continues to be excessively burdensome and unjustified restriction that violates the GATS. A narrowly tailored performance bond would be sufficient to address any existing concerns. China should take additional steps to reduce the capitalization requirement to a reasonable level, and can consider other monitoring methods such as a tailored performance review to determine an enterprise's qualifications to provide telecom services.

Expanding Scope of Regulation

China's revised Telecommunications Services Catalog released in 2015 expands regulatory oversight of new services not typically regulated as telecom services. China's classification of Cloud Computing, online platforms, and content delivery networks as Value Added Telecom Services, not only has far reaching consequences for market access and the development of online services in China, but also calls into question whether these classifications are consistent with China's WTO commitments. For example, Cloud computing is traditionally classified as a Computer and Related Service, not a telecommunications service. Applying licensing obligations to online platforms imposes a number of market access limitations and regulatory hurdles, making it more difficult for online companies to participate in the Chinese market. The Catalog subjects a broad set of services to cumbersome, unreasonable, and unnecessary licensing restrictions, imposes new conditions on telecommunications service suppliers with longstanding business in that country, and impedes market access to foreign suppliers of computer and related services by classifying certain computer and related services such as cloud computing as VAS. We urge the USG agencies to encourage China to remove the onerous, non-transparent licensing regime for value-added services and open the market to any company with competitive products and services in accordance with international norms, including eliminating equity caps for foreign companies.

Cybersecurity

In recent years, a significant number of new Chinese laws, regulations, policies, and proposals have been announced that ostensibly relate to IT security and which affect have implications for companies across economic

[4] State Council, Decisions on Amending the Regulations for the Administration of Foreign-invested Telecommunications Enterprises (FITEs), issued on September 10, 2008.

sectors that employ digital technologies in their operations and in serving their customers. These measures are having a significant negative effect on U.S. ICT companies' market opportunities in China, as well as on these companies' customers in China who currently rely on U.S. products in their IT systems. The most significant measure has been the entry into force this year of China's Cybersecurity Law, a broadly written instrument that will impose significant restrictions on the cross-border flow of data and impose a complex and burdensome cybersecurity review regime on companies integrating new technologies into their internal networks.

Given the broad definition of what constitutes operators of Critical Information Infrastructure, many companies across an array of economic sectors could potentially be subject to the laws very restrictive data localization requirement if they employ cloud computing or big data technologies, for example. There is no reason to believe that these measures will serve its claimed purpose improving IT security in China; on the contrary, because they could restrict the use of certain technologies and exclude or delay many more advanced or secure products to enter into the market, they have the potential to significantly weaken cybersecurity in China across all sectors. They also erect substantial market access barriers by imposing sweeping indigenous technology requirements, data flow restrictions, and other burdens on ICT products.

China also has adopted other new laws that will significantly limit the ability of foreign companies to provide ICT and other services in China, namely the Counter Terrorism law adopted in 2016, and the National Security Law adopted in 2015. Those laws cover a range of IT issues, including data privacy regulations, cyber-security standards, data-breach requirements, and cross-border data transfer requirements. Each of these laws is a significant obstacle to providing service in China, and their cumulative effect is to create a major barrier to operating and competing in the China market.

China's National Security Law requires foreign firms to submit to Chinese government review of their software and contains a number of other provisions that impose unnecessary cost on foreign competitors and explicitly promote Chinese companies. Additionally, the Cyber Security law is highly discriminatory and presents a significant opportunity for misappropriation of Intellectual Property in that it requires that providers of Critical Information Infrastructure services pass an undefined inspection, which requires, among other elements, providing access to source code information based on "standards" issued by a Chinese company advisory committee (TC260). These restrictions will impose new restrictions on commerce, strain regulator resources, and adversely affect China's evolving innovation environment. These policies provide significant competitive advantages to Chinese companies – indeed, Article 24 of the National Security Law acknowledges that the policy is intended to "strengthen indigenous innovation capabilities."

We urge USTR to encourage China to take the following steps to remove the bottlenecks to development of value added services in China:

- Remove all provisions of the Cyber Security Law, National Security Law and Counter Terrorism law that favor local Chinese companies and discriminate against foreign companies, including, but not limited to:
    - Data Localization;
    - Access to source code; and
    - Approval for the use of ICT software used by financial services and other service providers
- Adopt approaches that enable cross border data flows, refrain from data localization requirements and enables the use of global standards in a manner that supports an international, interoperable policy framework that is not detrimental to foreign investment;
- Take an open approach to value added services, streamlining licensing requirements. Expand the list of value-added services in the Catalogue to include such services as managed International IP VPN, in conformity with international standards for categorizing basic and value-added services

while eliminating cloud computing, content delivery networks, and information services from the catalog and the licensing requirements;
- Lift the prohibition on resale, enabling all carriers to acquire capacity at wholesale rates and interconnect their networks to deliver services to a broader reach of the country;
- Remove remaining caps to Foreign Direct Investment (as noted above), and
- Allow full market access for resale of mobile services.

Independent Regulator

China also has not implemented its WTO Reference Paper commitment to establish an independent regulator. The Chinese Government still owns and controls all major operators in the telecommunications industry, and the MIIT still regulates the sector, and the State-owned Assets and Supervision Administration directly controls the three major operators. USCIB encourages USTR to place a high priority on working with China to establish an independent regulatory body that is separate from, and not accountable to, any basic telecoms supplier, and that is capable of issuing impartial telecom decisions and rules. Specifically, it is important that the regulatory body adopt the following: transparent procedures for drafting, finalizing, implementing and applying regulations and decisions; appropriate measures, consistent with the WTO Reference Paper to prevent dominant suppliers from engaging in, or continuing, anti-competitive practices. USTR noted several of these concerns in the 2015 Section 1377 review and USCIB encourages USTR to continue to urge China to address these issues.

Since 1999, China has tried to promote network convergence between its telecom, Internet and broadcast networks without success. Conflicts between the broadcast and cable television regulator, State Administration of Radio, Film and Television (SARFT), and the telecom regulator, MIIT, have not been resolved despite guidance from the State Council under the Three-Network Convergence plan. We encourage China to explore business models that merge resources between broadcasting and telecommunications and Internet networks that create new markets and allow end-users to realize that network's full potential. We recommend that China create a converged ICT regulator merging the functions of SARFT and MIIT to eliminate and resolve the disruptive conflicts that have occurred.

Internet Policy

In addition, China's National Development and Reform Commission (NDRC) and the Ministry of Commerce (MOFCOM) jointly issued a revised Catalogue for the Guidance of Foreign Investment Industries that places some Internet services under the prohibited foreign investment industries category. More specifically, the revised foreign investment catalogue indicates that foreign investment in "[n]ews websites, Internet-based video and audio program services, Internet services establishments, and Internet cultural operations" is prohibited. At this time, it is unclear to what extent the new classification of these Internet services will impact the ability of foreign investors to offer Internet services in China. What is clear is that these policies create additional barriers to market entry in the telecom sector and discourage foreign investment.

Moreover, China's indiscriminate filtering and blocking for political purposes of online services not only constitute online censorship but also a trade restriction for U.S. firms while the Chinese firms are often operating on the U.S. market. The 2016 National Trade Estimate Report, USTR's annual publication highlighting significant foreign barriers to U.S. exports, concluded that increasingly: "China's filtering of cross-border Internet traffic has posed a significant burden to foreign suppliers, hurting both Internet sites themselves, and users who often depend on them for their businesses. Outright blocking of websites appears to have worsened over the past year, with 8 of the top 25 most trafficked global sites now blocked in China. Much of the blocking appears arbitrary; for example, a major home improvement site in the United States, which would

appear wholly innocuous, is typical of sites likely swept up by the Great Firewall."

Anti-Monopoly Law (AML)

While the Chinese leadership continues to pledge that the market will play a greater role in China's economy, competition regulators continue to use the AML to intervene in the market in an effort to advance industrial policy goals. Recent developments suggest that these efforts are part of broader and coordinated effort by Chinese authorities to use a variety of policy tools – including technology standards policies, IPR enforcement practices, and licensing and investment reviews–to reduce China's perceived dependence on foreign IP while protecting and promoting domestic Chinese companies. National Development Reform Commission (NDRC) officials in particular have been publicly outspoken about the important role that industrial policy considerations should play in antitrust enforcement in China and their intention to broaden significantly the scope of their review of competitive practices in a wide range of "strategic sectors," including automobiles, telecommunications, banking and petroleum.

Admittedly, Chinese authorities have also used the AML to prevent undue concentrations of market power, combat cartels and abuse of market dominance, and pursue other legitimate antitrust goals. However, in many cases involving foreign companies, China's anti-monopoly enforcement agencies have skewed implementation of the AML and related statutes to advance China's industrial policy goals, including in cases where there is no evidence of abuse of market power or anti-competitive harm.

The Chinese companies that benefit from these policies are often national champions in industries that China considers strategic, such as commodities and high-technology. Through its AML enforcement, China seeks to strengthen such companies and, in apparent disregard of the AML, encourages them to consolidate market power, contrary to the normal purpose of competition law.[5] By contrast, the companies that suffer are disproportionately foreign. Moreover, the curtailment of IP rights and related demands that have been imposed on U.S. and other foreign companies in several recent AML cases and settlements appear designed more to strengthen the bargaining position of domestic licensees than to address any true market distortions or anti-competitive harms. While USCIB welcomes the 2015 Strategic & Economic Dialogue (S&ED) outcome recognizing that the objective of competition policy is to promote consumer welfare and economic competition, continued U.S. government focus on this important issue is warranted.

Financial Services

China's financial services market remains relatively closed to foreign participation. China committed to allow U.S. and other foreign banks incorporated in China to broadly access the local market by eliminating barriers. These generally broad commitments have not come to pass. China maintains tight control over branch expansion and licensing for new areas of participation in the financial sector. Domestic financial services companies, however, enjoy more relaxed rules or receive licenses without the same rigorous approval process.

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[5] NDRC, Ministry of Industry and Information Technology ("MIIT"), and other agencies have an official policy to achieve industrial concentrations in the automobile, steel, cement, shipbuilding, electrolytic aluminum, rare earths, electronic information, pharmaceuticals, and agriculture industries. *See* Guiding Opinions on Accelerating the Promotion of Mergers and Reorganizations of Enterprises in Key Industries, issued by MIIT, NDRC, Ministry of Finance; Ministry of Human Resources and Social Security, Ministry of Land and Resources, MOFCOM, People's Bank of China ("PBC"), State-owned Assets Supervision and Administration Commission ("SASAC"), State Administration of Taxation ("SAT"), SAIC, China Banking Regulatory Commission ("CBRC"), and China Securities Regulatory Commission ("CSRC") (Jan. 22, 2013), Gong Xin Bu Lian Chan Ye [2013] No. 16 (*hereinafter* "2013 MIIT Joint Opinions"). Indeed, all three AMEAs are among the authors of this document. Companies and local governments may oppose this policy, but there is no indication that the AML constitutes an impediment to implementing it. *See* David Stanway, "China ditches steel industry consolidation targets in new plan," Reuters (Mar. 25, 2014) (quoting Xu Leijiang, the chairman of Baoshan Iron and Steel, as stating that the policy created "huge monsters" lumbered with debt and unprofitable investments).

China also limits foreign participation in its bond market. While "commitments" were made in the S&ED to open this area, those commitments appear to be largely hortatory.

China limits ownership in the securities sector whereas the right to enter a market and establish a 100 percent owned presence in a firm's corporate form of choice is the norm in today's global markets. U.S. companies seek to own 100 percent of their operations in China.

Enacted in December of 2002, the Qualified Foreign Institutional Investor (QFII) Act permits qualified foreign institutional investors to invest in the securities of Chinese companies. Implementing a Strategic & Economic Dialogue (S&ED) II commitment, China raised the quota for QFIIs from US$ 30 billion to US$ 80. Representing further efforts ostensibly aimed at attracting capital to the mainland, in June 2016, China announced that it will give a 250 billion yuan ($38 billion) investment quota to the United States, which is the largest after Hong Kong. Although this represents some progress, this area of foreign participation nevertheless continues to be limited and warrants continued monitoring.

Food Safety Law

In January 2015, comments were submitted to the U.S. Department of Agriculture on the second reading of China's food safety law. We believe there are some crucial issues still to be resolved to achieve real advancement in food safety outcomes and to facilitate U.S. food and agricultural exports to China. In addition to other specific concerns raised: China should strengthen the Food Safety Law's overall emphasis on science-based standards and implementation; China should include a definition of risk as "a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food," or words to that effect (per page 109 of the Codex Procedural Manual, twenty-first edition); and national food safety legislation should refer, wherever appropriate, to the international food safety standards and guidelines of the Codex Alimentarius Commission, particularly where a relevant national food safety standard has not been implemented.

We remain very concerned that China has inconsistently notified implementing regulations and other substantive documents relevant to implementation of the Food Safety Law to the WTO Sanitary and Phytosanitary (SPS) Committee to provide all WTO members with the opportunity to review the proposal and provide comments. Furthermore, in instances when notifications have been made, deadlines for comments often coincide with effective or enforcement dates effectively disenfranchising any opportunity for comments received to influence the final regulation. China has also failed to uphold its commitment to consistently publishing English (or other WTO language) translations of trade-related laws and administrative regulations. It is essential that China notify proposed implementing regulations and allow sufficient time for authoritative translation (in the absence of official translations) and preparation of comments before final decisions are made. It is also essential that China notify (as amendments to the initial notification) each final regulation and publish the dates of implementation and enforcement. These WTO transparency obligations are necessary for exporters to fully understand China's import requirements and the effective date.

We note that Chinese Food and Drug Administration (CFDA) has recently notified a revised draft of implementing regulations for the Food Safety Law (G/SPS/N/CHN/1055). These regulations appear to make changes to fundamental aspects of the law including, but not limited to, general principles; risk monitoring and assessment for food safety; food safety standards; the production and marketing of food; food inspection; food import and export; handling of food safety incidents; supervision and management; legal responsibility and supplementary provisions. We urge the United States to examine these proposed changes closely and ensure that they do not contribute to a less transparent system that disadvantages U.S. companies wishing to export product

to China.

Certificates for Imported Foods

In April 2016, China notified the U.S. and other foreign embassies in Beijing of China's intent to require new certificates for imported foods beginning in October 2017. The draft measure was not notified to the WTO until June 2017. Comments submitted by USCIB members noted grave concern about the potential trade barriers created by the draft requirements. China has not provided justification or risk assessment for requiring certificates for imported foods, nor for the onerous information requirements on its template certificate (including attestations of "fit for human consumption," as well as shipment-specific information inconsistent with how U.S. processed food manufacturers can obtain certificates of free sale). Many U.S. exported products would not be able to comply with China's proposed requirements, since the U.S. Food and Drug Administration does not issue certificates making the required attestations or including shipment-specific information. Some companies estimate they would not be able to export any products from the United States to China if the draft requirements enter into force without amendments.

Drug Pricing & Reimbursement, and Transparency

In the 2016 U.S.-China JCCT China affirmed that drug registration review and approval shall not be linked to pricing commitments and shall not require specific pricing information; however, there is concern that China is not fully implementing the outcome.

From April 8, 2017, Chinese authorities plan to implement a new "Sunshine" drug-procurement platform in public medical institutions in Beijing. The Sunshine drug-procurement platform includes an online trading interface to be adopted by all medical institutions in Beijing and also allows for the real-time monitoring of drug-procurement prices, as well as the differences between the original drug price. The platform effectively links a drug's national minimum procurement price with procurement prices from Beijing-based medical institutions.

Hong Kong

Hong Kong notified the WTO in June 2017 of two regulatory measures ("the measures") to restrict the marketing of formula and child nutrition products: (1) the Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants & Young Children ("the Code") and (2) the Regulatory Framework on Nutrition and Health Claims for Formula Products and Foods for Infants and Young Children ("Cap. 132W Amendments"). These measures have been implemented and will each have significant and far reaching impacts on intellectual property and innovation and are inconsistent with Hong Kong's WTO obligations.

The Code represents sweeping new restrictions, equivalent to a complete prohibition, on the branding, promotion, advertising, and labeling for imported formula milk and foods for infants, toddlers and young children up to three years of age, despite the fact that these products are specifically formulated, consistent with Codex standards, to meet the developmental and cognitive needs of babies and young children during the critical period of brain growth. Although Hong Kong has categorized compliance with the Code as voluntary, in effect compliance will be mandatory given implementation of a monitoring mechanism and requirements impacting participation in government tenders.

Hong Kong's Cap. 132W amendments also impose sweeping restrictions on the branding, promotion,

advertising, and labeling of imported formula and complementary foods for infants, toddlers and young children up 36 months old. The amendments prohibit nutritional and health claims for imported formula and complementary food products (despite scientific evidence supporting such claims), exempt domestic competing products (e.g., fresh milk), and ignore readily available policy alternatives that have scientific evidence of improving breast feeding rates.

In addition to departing from relevant international standards without scientific justification and discriminating against imported products, these measures deny Hong Kong consumers access to important information that enables them to identify formula and complementary food products that are reputable, safe, and effective. The measures also increase the risk that counterfeit formula will enter the Hong Kong supply chain.

COLOMBIA

Excessive and asymmetric regulatory fees in the Pay-TV market

USCIB praises the efforts undertaken by Colombia ICT Ministry, starting in 2016, to design a new public policy for the audiovisual industry with the objective of tackling current regulatory asymmetries that undermine competition and investment in the Pay-TV market. However, and despite the ICT Ministry's willingness to work decisively on the matter, Colombia's regulatory framework remains unchanged, perpetrating –or even worsening—burdensome regulatory charges and discriminatory asymmetries among providers of audiovisual services.

One of said asymmetries is directly and exclusively impacting DIRECTV Colombia (DTV), a subsidiary of AT&T. According to the latest regulatory proposal published in May 2017 by the National Television Authority (ANTV—Colombian audiovisual regulator), regulatory fees imposed on Pay-TV providers should be assessed in a way that assures collection of the resources needed to finance operation of state-owned broadcasters—whose yearly budget is set by the Federal government and has been steadily increasing over the years—. In order to do so, ANTV's proposed methodology was designed in a way that (1) targets providers whose subscribers reside mainly in big cities, and (2) is based on gross revenues (as opposed to the current regime that imposes a fixed per subscriber fee).

As a consequence, ANTV's proposed methodology resulted in unreasonably excessive regulatory fees whose main portion would be absorbed by a single provider, DTV. Even if DTV has almost 45% of its users in small cities (<100,000 inhabitants), and these towns have a lower fee, the final results would be negative for the company, with an increase of 13% of the currently paid in regulatory fees, while benefiting DTV's direct competitors (other DTH and Cable Pay-TV providers). These other operators are expected to see an average decrease of 47% of the currently paid fees, which would partly subsidized by DTV increased in regulatory fees. Besides being unreasonably discriminatory, the proposed methodology puts DTV in a competitive disadvantage which could ultimately force it out of the market.

While trying to accomplish the ultimate goal of funding state-owned broadcasters, the ANTV's proposal is far from encompassing the reality of the Pay-TV market. The ANTV's calculation omits the evident fact that growth of the Pay-TV subscribers base in Colombia began to stagnate[6], as a consequence of the increasing penetration of Online Video Content service providers in the market, and a high degree of informality in practices such as piracy and underreporting.

[6] Colombia is currently experiencing a remarkable slowdown in Pay-TVsubscribers' growth rates (from 11.3% in 2012 to 5.9% in 2016), even when the service availability is still limited in the country. Calculations based on numbers published by the National TV Authority (ANTV).

USCIB urges USTR to encourage the Colombian government and more specifically the ANTV, to reconsider the methodology to establish regulatory fees for Pay-TV providers and design a new model which would not foster further market asymmetries, instead encouraging equal and reasonable fees for all providers of video services (telecoms and Pay-TV included).

Regulatory Uncertainty Caused by Lack of a Convergent Regulator

The existence of two different regulators with different sometimes conflicting roles remains an obstacle to the development of the industry, in spite of recommendations formulated by international organizations, such as the OECD. The Comision de Regulacion de Comunicaciones (CRC) regulates telecommunication services and networks, and the Autoridad Nacional de television (ANTV) is in charge of regulating television services. Such dual structure led to a fragmented television regulatory framework with two authorities deciding and exerting their powers on intrinsically related matters. In the case In the case of the regulatory fees of the Pay- TV segment, the CRC concluded that there were some asymmetries between the Pay-TV sector and the ICT services and it recommended matching the fees between these markets; however the ANTV reiterated its decision to maintain higher regulatory fees for Pay-TV providers than those paid by telecommunication services providers. In addition to the uncertainty and confusion created by the coexistence of two regulators, there also is the duplication and overlapping of information reporting obligations, which imposes inefficient burdens on providers subject to the control of both entities.

In this sense the recent announcement of President Santos regarding the plans of the Colombian government to initiate the process for the creation of a new convergent regulator is welcomed as a step forward in the economic growth and competitive positioning of Colombia in the global scenario. USCIB urges USTR to encourage the Colombian government to decisively promote the legislative or regulatory modifications required to create Colombian convergent regulator.

Community Television Services

Under the provisions of Annex 1 of the U.S.-Colombia Free Trade Agreement, Colombia committed to limit the so called “community television” services in light of their local, non-commercial nature. In order to avoid a negative impact on the commercial television market, Colombia agreed to set a quota for each “community television” to no more than 6,000 members (i.e., subscribers) and for these to be providing their services only in certain geographical areas and under specific guidelines concerning the number and type of channels that these operators could carry.

Despite existing domestic regulation implementing these obligations, Colombian authorities have not been effective to date in enforcing such restrictions on the existing “community televisions operators,” which frequently exceed the number of subscribers and the number of channels that they are allowed to have. Such lack of enforcement distorts the television market by allowing the “community televisions operators” to fully compete with the commercial providers while allowing them to enjoy substantial benefits applicable to their non-commercial nature (e.g., tax exemptions, reduced license and regulatory fees, etc.)

The CRC and the National Department Planning (DNP) recommended the ANTV to conduct a regulatory revision of conditions and restrictions imposed on “community television” operators; different market analysis showed that their product (including an average of 75 channels) is directly competing with pay-TV providers’ basic packages in the same relevant market. Given the current circumstances, both authorities concluded that conditions under which such “community television” providers operate need to be reviewed in order to avoid market distortions.

Granting “community television” operators beneficial treatment when official evidence shows their direct competition with pay-TV providers, may constitute an infringement of the equal treatment provisions agreed between the U.S. and Colombia under the Free Trade Agreement.

USCIB requests USTR to urge the Colombian government to effectively enforce limitations on “community television” operators in order to comply with the obligations under the U.S-Colombia Free Trade Agreement. Additionally, the Colombian government should work on eliminating the benefits applicable to “community television” operators which compete with pay-TV providers in the same relevant markets with evident advantages and at unequal conditions for the players involved.

Burdensome and onerous Must-Carry Obligation

Concerning the U.S.-Colombia Free Trade Agreement obligations on Market Access (Article 11.4), Local Presence (Article 11.5) and Performance requirements (Article 10.9), Colombia clearly stated in its Annex 1 that subscription television services “must make available to subscribers, at no additional cost, [those] free-to-air Colombian national, regional, and municipal television channels available in the authorized area of coverage”. In addition, the Trade Agreement clarified that “the transmission of regional and municipal channels will be subject to the technical capacity of the subscription television operator.” These terms are consistent with precedents established by the Constitutional Court (C-654/03) and the television services regulator (ANTV- through Resolucion 2291/2014).

In 2016, in contravention of the Free Trade Agreement and prior precedent, a decision enacted by Colombia’s antitrust authority (SIC), required Pay-TV providers to not only obtain broadcaster’s prior retransmission consent for must-carry channels, but also allegedly concedes that broadcasters have the right to impose retransmission fees on Pay-TV providers for the transmission of must carry channels.

Pay-TV operators appealed the SIC decision and on March 23rd, the second instance Judge revoked the SIC's ruling on the grounds that the must carry rule was already upheld by the Constitutional Court and was also supported by the CAN (within its Treaty for IP matters).

Despite the clear language of the Free Trade Agreement, the existence of undisputable domestic regulation and the validation of two judicial decisions, legal uncertainty remains and must carry national channels continue to file claims and challenge decisions concerning the legality of the Resolution 2291/ 2014 issued by the ANTV. Since any administrative or judicial decision requesting a U.S. pay-TV provider to pay retransmission fees to comply with its must carry obligation would be a violation of commitments made in the U.S.-Colombia Free Trade Agreement, USCIB urges USTR to request to the Colombian government to ratify that broadcasters have no right to charge retransmission fees to pay-TV providers for must carry signals.

Taxes and Importation restrictions on Telecommunication Devices

Another issue of concern is Colombia’s VAT exemption for computers, tablets, and other computing devices below a specified price. Today, smartphones (or intelligent mobile devices) often substitute for such devices, but are still subject to the full 16 percent VAT rate. Intelligent mobile devices or smartphones (e.g. mobile phones which offer more functionalities than basic telco ones) should be afforded the same VAT exemption as other computing devices. Elimination of the VAT also would enable more Colombians to purchase smartphones, and enhance digital connectivity. Failure to afford the VAT exemption has the potential to restrict electronic commerce and constitutes a barrier based on the type of device, rather than on its functionalities.

On October 16th, 2015, the Government of Colombia published Decree 2025, which “establishes measures to

control the import and export of intelligent mobile phones, cellular mobile phones, and their parts, susceptible to classification under Customs Tariff subheading 8517.12.00.00 and 8517.70.00.00", as part of its strategy to address the theft of mobile phones. While USCIB applauds Colombia's focus on this public policy and its will to address a security concern, Decree 2025 itself creates burdensome restrictions and administrative requirements for trading of mobile phones, without significantly deterring or limiting the illegal market for stolen phones.

For example, Decree 2025 prohibits all imports and exports of mobile devices and parts via mail or express mail, and more generally prohibits all mobile phone exports with only limited exceptions for travelers, temporary export for outward processing, and for waste electrical and electronic equipment (WEEE), all of which create barriers to export for legitimate purposes such as exports for repairing or refurbishing. In addition, the measure requires that each mobile phone is issued a government-issued IMEI verification certificate at the time of import, and that all importers and exporters pre-register with the National Police as a condition of being allowed to trade in mobile phones, without having already established the systems required to implement these new regimes.

As noted in last year's submission, there was significant commercial uncertainty created by the fact that the decree was scheduled to enter into force on December 1, 2015, even before the expiring of some of the deadlines to implement new systems and in all cases prior to verification that any of the systems were in fact up and running. In fact, implementation of the Decree has been extremely disruptive to businesses, as the time frames set out by the law were systematically eluded and no single agency owned responsibility for addressing such shortcomings. While several sets of changes were made to the Decree over the course of 2016, it still includes provisions that impede regular trade and commerce. We urge the government to rethink this burdensome approach which still seems not to bring an efficient solution to the issue.

With respect to the biopharmaceutical sector, in March 2016, a Technical Committee (TC) of the Colombian Ministry of Health (MoH) issued a recommendation that it would be in the public interest for the MoH to grant a compulsory license (CL) for a patent covering a particular form of imatinib (Novartis' leukemia medicine Glivec). The TC contended that a CL would create generic market competition and lead to a lower price, and hence, in the public interest. There was no assertion that any patient in Colombia who needs Glivec was unable to access it, or identify any other access problems. In the face of international criticism of the threatened CL issuance, the TC then recommended in the alternative that the MoH begin immediate price negotiations with Novartis, suggesting the price be lowered to a level that approximates free market conditions (i.e., conditions that would exist absent a patent). Ultimately, rather than recommending a compulsory license or continuing to negotiate, on June 20, the MoH issued a Declaration of Public Interest (DPI) stating that henceforth the target Glivec price will be based on an average of the generic drug prices in the region. We are concerned that the invoking of the DPI sets an unwarranted and dangerous global precedent.

VAT in Over-the-Top Applications and digital content

Law 1819 (December 2016) made major changes to the tax regime. In particular, it requires direct VAT compliance by foreigners providing digital services and Over-The-Top (OTT) applications. If the service provider does not comply with that system, financial entities that manage credit and debit cards are required to withhold VAT on payments to foreign suppliers of digital services. The obligation on financial entities is required to take effect by June 2018 (18 months after the law was enacted).

The regulatory decree defining when the new requirements take effect and further implementing details has not yet been issued. Taxing such services risks the goal established by the Ministry of ICT in its Digital Economy

Agenda and potentially creates a system where the regulatory arbitrage is possible, affecting the adoption of digital services in the country. The United States government should engage with the GoC as it implements its tax reform to facilitate digital trade and information services development.

VAT application to technology products

Colombia offers a VAT exemption for computers, tablets, and other computing devices below a specified price. The December 2016 tax reform also included smartphones in the same VAT exemption as other computing devices.

At the same time, the law reduced the thresholds measured in Tax Value Units – UVT (currently 50 UVT for PCs and 22 UVT for Tablets and Smartphones). While these exemptions are an effective way to promote access and adoption to technology, the reduced thresholds have the unintended effect to incentivize access to low entry-level technology, increasing costs to consumers to access technology with better and broader performance characteristics. Elimination of the VAT (or a higher threshold level) would better incentivize the adoption of and access to technologies.

Prior Notice and Comment on Ministry Regulations and Similar Instruments

Regulatory commissions, like those created by Law 142, must follow specific rules designed to promote participation through public consultations when drafting regulations. They also must explain the reasons behind accepting or rejecting input received in that process. However, Ministries and other agencies, that have the ability to impact the regulatory landscape, are not subject to such rules. Law 1437 (2011) provides ample room for Ministries and agencies to decide the public consultation period for draft regulations, which in practice has proven to be as short as two-days. Specific and sufficient notice and comment procedures that allow industry participants and the general public to participate, raise concerns, and propose improvements would result in more efficient and effective regulations. Similarly, other government rules, technical interpretations, guidance, policies, and the like, can be issued without prior notice or an opportunity for input. They often have the same effect as regulations, and should be subject to a defined consultative process.

Mobile Phone Black/White Lists and Import Decree

On October 16, 2015, the Trade Ministry published Decree 2025, which "establishes measures to control the import and export of smart phones and their parts" as part of its strategy to address phone theft. The Decree established extensive administrative requirements for trade in mobile phones and created barriers to export them even for legitimate purposes, such as warranty repairs or recycling. In particular, the Decree mandates that each mobile phone have a government-issued International Mobile Equipment Identity (IMEI) verification certificate at the time of import and requires all importers and exporters to pre- register with the National Police in order to trade in mobile phones.

On December 23, 2016, the Trade Ministry published Decree 2142, which modified a number of Decree 2025's provisions. In particular, it reversed the prohibition on imports of mobile devices and parts via mail or express delivery, with some limitations as to the number of devices that can be shipped by those means, and allowed more flexibility with respect to the documentary requirements for the export of used phones, e.g., for servicing and repair, or recycling and safe disposal of electronic waste. However, the limit on how many devices travelers can carry into the country remained in place, as did requirements for IMEI verification and registration of importers and exporters with the National Police.

Thus today, Colombia maintains a system of black (mobile phones reported as lost or stolen) and white (mobile phones with homologation, valid International Mobile Equipment Identity - IMEI) lists. It requires that each mobile phone have a government-issued verification certificate at the time of import. This system is challenging the operational capacity of the government and recently civil society organizations denounced privacy and security concerns about the system.

While the concern about phone theft is valid, the current system imposes unnecessary and undue burdens and impedes regular trade and commerce of communications devices. Additionally, it is not delivering on reducing the market for potentially illicitly acquired spare parts. In early August 2017, the General Attorney stated that "Simply, the IMEI blocking is not working" as deterrent of mobile theft. Rather than continue to address legitimate concerns about phone theft through processes that are not working, Colombia should explore other approaches – many that have proven effective in other countries. These could include focused efforts on the illicit spare parts market, educational campaigns about technology based solutions (such as those that allow the user to block the phone, remotely erase the content, and make the devices unable to connect to the network), and cooperation beyond national borders.

Food safety risk classifications and plant registrations

Colombia's food safety regulatory authority, INVIMA, adopted Resolution 719 in March 2014. The regulation introduces high, medium, and low food safety risk classifications for food and beverage categories and bases the duration of a plant's registration with INVIMA on the level of risk established for the food or beverage produced in that plant.

Under Resolution 719, plants producing high risk products must renew their registrations every five years, half the previous ten-year registration period. While current plant registrations remain valid until their expiration date, plants must re-register under Resolution 719 three months prior to the expiration of their current registration.

Extensive technical comments were submitted to the government of Colombia during the World Trade Organization (WTO) comment period on Resolution 719 (notified to both the Technical Barriers to Trade and Sanitary and Phytosanitary committees as G/TBT/N/COL/191/Add.2 and G/SPS/N/COL/249/Add.2, respectively). Colombia's designation of certain products as "high risk" is not based on internationally-accepted science or standards. These comments, therefore, questioned the "high risk" categorization of products including:

- Dairy products, including those that are pasteurized.
- Fortified products, including cereals and breads.
- Drinks, including bottled waters, sweetened and carbonated beverages, and fruit juices.

Nevertheless, Colombia adopted the regulation without any revisions to the risk classifications or explanation of why these classifications depart from existing international standards. Furthermore, it is unclear how the government of Colombia will determine compliance of foreign plants, as Resolution 719 calls for the completion of new questionnaires (as yet unavailable) and inspections of plants manufacturing products deemed to be "high risk".

Drug Pricing & Reimbursement

In November 2016, the Plenary Chamber of Colombia's Constitutional Court confirmed the power of the

country's Ministry of Health (MoH) to regulate prices of high-cost medicines, a function given by articles 71 and 72 of the 2014–18 National Development Plan (NDP). This decision enables further MoH intervention in medicine pricing in Colombia, a policy that has already had negative implications for the country's innovative pharma industry. Thus far, the measure has brought more than 500 additional medicines under price control. Colombia's Constitutional Court has issued a ruling that endorses the Ministry of Health's ability to conduct HTA assessment prior to marketing authorization in order to set the prices of high-cost medicines. This decision enables further intervention in medicine pricing in Colombia, a policy that has already had negative implications for the country's innovative pharma industry.

On November 22, 2016, the National Pricing Commission issued Circular 03 of 2016, which sets out a general pricing methodology that will apply to all medicines subjected to a DPI. This methodology is the same as the price reduction imposed on Glivec and likewise, unduly targets patented products rendering their patents worthless.

COSTA RICA

As reported for the past several years in the Section 1377 report, the Costa Rican telecommunications regulator, *Superintendencia de Telecomunicaciones* (SUTEL), continues its unique requirement for retesting and recertification of hardware after a software or firmware update, focusing in particular on certain electromagnetic compatibility (EMC) testing and certification requirements. Such updates are often frequent, and allow users to protect their equipment from security threats and improve their experience with their ICT devices. As a matter of international best practices, such updates do not require re-testing or re-certification. These country specific requirements can also lead to redundant testing, particularly where a product is required to undergo testing to the same standard in both the exporting and importing country. The WTO TBT Agreement, Article 2.2 requires WTO Members to ensure “technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade”.

In August 2017, Costa Rica's chamber of deputies proposed a tax on mobile and fixed telephony and broadband services with a view to funding the country's 911 emergency and security system. This is still under review. It is, however, disconcerting since the Dominican Republic approved a similar measure to impose a tax of USD 0.02 on international voice minutes to finance the country's 911 service in May 2017.

DOMINICAN REPUBLIC

The vagaries of the regulatory regime in the Dominican Republic, coupled with the lack of action by the regulator in implementing its own regulations, results in an anti-competitive marketplace in the Dominican Republic. Specifically, high, non-cost-oriented mobile termination rates, nontransparent spectrum auction practices, and the failure by INDOTEL to renew concession agreements are significantly restricting the commercial viability of mobile operators.

Mobile terminations rates, according to Dominican regulations, must be cost-based. However, this is not true in practice. Dominant carriers are charging fees well above their costs. Simultaneously, each of those carriers offers reduced rates for calls their customers make to other subscribers on the same network. This price discrimination puts other smaller carriers at an inescapable competitive disadvantage. Because other carriers have a relatively small base of subscribers, who frequently call the more numerous customers of the dominant carriers, the high mobile termination rates prevent non-dominant carriers from pricing off-net calls as cheaply as the dominant carrier’s price on-net calls. Moreover, the lack of spectrum for non-dominant carries has led to higher network costs and has frustrated non-dominant carriers’ plans to launch new generations of wireless

technology, which, in turn, has curtailed their ability to expand their network footprint. Lastly, INDOTEL has failed to fulfill its obligations regarding license renewals for over a decade, despite carriers meeting their legal obligations. This has put carriers with expired licenses in a regulatory limbo that undermines investment.

USTR should advocate for lower, cost-based mobile termination rates in a way that allows smaller providers to compete with dominant players; in line with previous USTR recommendations. Additionally, USTR should recommend that INDOTEL comply with objective, timely, transparent, and non-discriminatory spectrum management policies consistent with the Dominican Republic's international trade commitments. Lastly, the USTR should urge INDOTEL to renew concession agreements as soon as possible where all carrier obligations have been met. In prior Section 1377 Reports, the USTR has noted that operating under expired concession agreements "creates regulatory uncertainty for the companies and can impair their ability to continue to secure outside financing for their operations, especially in cases in which licenses expire due to inaction by the regulatory authorities."

Adding to the negative impact of high termination rates, in May 2017, the Dominican Republic's Chamber of Deputies approved a tax of US$0.02 on international voice minutes to finance the expansion of its 911 national emergency system. The fixed tax is to be paid by all operators registered at the Dominican Telecommunications Institute (Indotel) and is assessed per minute of international voice traffic, with USD 0.0025 also payable for each international SMS received by the operators. The Dominican Republic's high termination rates are not in accordance with its obligations under the WTO or CAFTA, which requires that the provision of interconnection services by major suppliers be at cost-oriented rates. Further, the discriminatory application of the tax to only international traffic places the cost burden to build out the national 911 system on foreign consumers, rather than on the domestic consumers who will benefit from this new service.

ECUADOR

Ecuador has recently enacted regulation aimed at protecting State-owned Enterprises ("SOEs") from competition. There are exceptions and exemptions that apply to SOEs to shield them from the increasing cost of doing business in Ecuador, which threatens U.S. investment in the country.

State-owned Enterprises (SOEs)

Recently Ecuador's balance of trade has been unstable due to the decrease of oil prices. This has led the country towards a more protectionist path in public policy. The result is a series of exceptions and exemptions that favor national SOEs in the marketplace. This has impaired competition and is inconsistent with Ecuador's national treatment obligations under the U.S.-Ecuador Bilateral Investment Treaty.

As way of example, the Ecuadorian government has put in place regulatory burdens on the private telecommunication sector while granting preferential treatment to CNT, Ecuador's SOE.[7] Such preferential treatment exempts CNT from complying with the following general obligations:

- Participate in public auctions for spectrum
- Pay federal license and spectrum fees
- Comply with municipal permitting requirements and taxes to deploy network infrastructure

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[7] Expert market reports confirm that Ecuador's regulatory measures to favor CNT are part of a protectionist scheme sustained over time. See for example BMI Research's analysis for Ecuador, available at http://www.bmiresearch.com/ecuador, last accessed August 27, 2015. ["Regulatory changes at the beginning of 2015 continue to advance the more controversial aspects of operating in Ecuador's telecoms market. In the past, the government has shown a tendency to protect *CNT* from private competition and the new regulation instituted during 2015 will not change this trend, with additional taxation and high cost of 4G spectrum licenses."].

- Pay a gradually increasing fee based on market share participation above 30 percent
- Reduce the amount of telecommunications equipment imported into Ecuador
- Comply with sector specific accounting requirements

CNT has traditionally been the incumbent operator for the fixed-line services in Ecuador with more than 2 million subscribers (86 percent), while its competitors combined have approximately 500,000 subscribers. In the Pay-TV market, CNT has rapidly grown to become the second-largest provider with approximately 380,300 subscribers (27 percent).

In order to assure fair market access to private operators in Ecuador, USCIB urges USTR to encourage the Ecuadorian government to adopt equitable and nondiscriminatory measures that allow U.S. investments in Ecuador to compete fairly with SOEs.

Discriminatory tax on the telecommunications sector: Market Share Tax

Foreign investment in Ecuador's telecommunication market is at high risk due to the country's excessive and discriminatory taxation policy. Particularly, a law passed in 2015 (Ley Organica de Telecomunicaciones) imposed a new tax on providers whose investments and presence in the country have allowed them to grow over 30% of the market. Art. 34 of the Ley Organica de Telecomunicaciones ordered that those providers with 30% market share must be charged an additional regulatory fee equal to 0.5% of gross revenues, and for each 5% of additional market share thereafter, are charged an additional tax equal to 1% of gross revenue. The 30% threshold only impacted two foreign providers; the Mexican Claro in the telecommunications market and the local subsidiary of AT&T, DIRECTV Ecuador, in the Pay-TV market.

By the time the bill was under discussion, opposition lawmakers criticized Art. 34 as an attempt to target foreign telecommunication entities whose growth in the country was putting competitive pressure on the state-owned and local telecommunication providers. As the local press reported," the opposition lawmaker, Patricio Donoso, stated that "the bill has a dedication" referring to the fact that it is made to harm companies like Claro, who should now pay a 7% tax. … The Civic Movement lawmaker, Henry Cucalón, stated that the bill is unconstitutional because it is discriminatory and inefficient because it exempted the state-owned companies from the new tax."[8]

USCIB urges USTR to request Ecuadorian government to dismantle the market share tax so that all telecommunication providers can compete on a level playing field which would ultimately enhance competitiveness in the sector besides offering users a wider variety of options.

Illegal Regulatory Fee on Private Sector, and Uncertainty of the Rule of Law

The rule of law is at risk in Ecuador because several municipalities are assessing arbitrary and excessive fees, such as taxes for use of airspace and taxes for the establishment of business in clear violation of the Federal law. Even though, most of the municipalities that established taxes for use of airspace during 2014 and 2015 have started to revoke their own decisions in response to judicial claims brought by the industry and the support of the federal government—which reaffirmed the illegality of such taxes—; at least two municipalities, Eloy Alfaro and San Lorenzo, are arbitrarily imposing a new tax for the establishment of telecommunication businesses on service providers with no commercial establishment in those municipalities. Indiscriminate

[8] See: https://es.panampost.com/panam-staff/2014/12/18/ecuador-castiga-con-impuesto-a-empresas-de-telecomunicaciones/. Last accessed: Sept.6, 2017.

enforcement of these taxes is illegal under Federal Law provisions[9] expressly mandating that airspace taxes can only be implemented by the Federal government and that taxes for commercial establishment can only be imposed on merchants that conduct a commercial activity and have a commercial establishment in the jurisdiction where the tax is enacted.

The Judiciary system and the Federal Executive Government have been alerted of the matter, but have yet to take effective action to stop the abuse by the municipalities. Inaction towards this situation will weaken Ecuador's regulatory environment, affecting investment in the telecommunications sector.

USCIB urges USTR to encourage the Ecuadorian government to enforce the rule of law by taking action to prohibit government entities from assessing fees on private businesses that are illegal under Ecuadorian law.

Technical Standards

In the area of technical standards, Ecuador adopted RTE INEN 105 that makes mandatory the compliance with several voluntary international standards regarding secondary cells and batteries. It enters into force December 27, 2016, thus provides an unreasonably short time to comply. Moreover, it will severely disrupt trade in secondary cells and batteries, and thus the ability of companies to support their clients' needs for replacement batteries.

To obtain the certificate from the Ecuadorian certification entity *SAE, an importer of record would need:
- (i) evidence of compliance with IEC 61960, IEC 62133, US EPA 7471B, and ASTM E536-04a
- (ii) evidence of compliance with marking requirement
- (iii) register as generator of hazardous waste
- (iv) register of operations

The stated purpose of RTE INEN 105 is to "set forth the safety requirements applicable to all primary or secondary cells and batteries, for the purpose of protecting the life and health of individuals…"However, the scope of IEC61960 "specifies performance tests, designations, markings, dimensions and other requirements for secondary lithium single cells and battery for portable applications." It is not necessary to refer a "performance standard" in a "safety standard". Thus, the IEC61960 portion should be removed from RTE INEN 105 or this part should be made voluntary.

While referencing international standards is a sound practice, countries should avoid making voluntary standards mandatory and, in all cases, should provide sufficiently long transition periods for companies to implement the necessary requirements for compliance. These should be at least one year for technical standards.

Nutrition Labeling

As of November 2014, Ecuador requires all food products to comply with Executive Decree No. 4522 of the National Agency of Regulation, Control, and Sanitary Surveillance (ARCSA), an agency in Ecuador's Ministry of Health. The decree requires processed and pre-packaged food products to bear a label as set out in technical regulation RTE-INEN-022. The Executive Decree establishes several new labeling provisions. Labels must include a set of colored bars, commonly referred to as traffic light symbols that reflect a low, medium, or high content of salt, sugar, and fat in the product, based on limits established for these nutrients. For food packages smaller than 14.4 cm, instead of a traffic light label, an advisory message is required

[9] Article 547 of the Organic Law of Territorial Organization (COOTAD).

stating, "For your health, reduce the consumption of this product." An advisory statement is also required for foods that contain less than 50 percent "natural" content. Ecuador defines a "natural food" as "a food as presented in nature that has not been transformed." Despite concerns raised by many trading partners both bilaterally and under the framework of the WTO TBT Committee, the Executive Decree entered into force in August 2014.

Upon implementation of the Executive Decree, Ecuador also began enforcing previously existing, but unenforced Ecuadorian Service for Standardization (INEN) requirements for a certificate to demonstrate compliance with the labeling elements. The certificates of conformity (COC) may only be issued by the Ecuadorian Accreditation Agency (OAE), or an OAE accredited inspection body or designee, as established under existing mutual recognition agreements with Ecuador. There are no OAE accredited laboratories in the United States. All processed and pre-packaged foods with the new traffic light labels must also be reregistered under Ecuador's cumbersome Sanitary Registration process. Ecuador and the United States continue to explore alternatives to the COC, including use of State or Federal Certificate of Free Sale, a Supplier's Declaration of Conformity, or a determination of equivalence with INEN's requirements.

Sanitary and Phytosanitary Barriers

All agricultural imports require an SPS certificate issued by Ecuador's animal and plant health service (AGROCALIDAD). Importers complain the certification process is lengthy and burdensome. They also complain that the certificate process lacks scientific basis, is at odds with World Organization for Animal Health and Codex Alimentarius Commission standards, and is used to block imports that compete with domestic production of meat products, dairy products, and produce. COMEX Resolution 019, issued September 10, 2014, mandates that AGROCALIDAD require an SPS certificate for processed agricultural products, including low-risk (cooked) products. Ecuadorian customs officials began enforcing Resolution 019 on October 9, 2014. Importers of U.S. products, especially U.S. fast food franchisees, reported import processing delays caused by confusion among government agencies over how to enforce the resolution and by officials intentionally delaying the entry of imported products as part of Ecuador's policy of import substitution.

EGYPT

Import Registrations

In March 2016, Egypt implemented two Ministerial Decrees introducing new registration requirements for a variety of imported products not intended for private or personal use. The Decrees introduced new registration requirements for both manufacturing plants located outside of Egypt, and for products imported into the country. As the Decrees require registration of individual manufacturing plants, it is difficult for companies to compel manufacturing partners with which they have contracts to submit an application for registration and accept the possibility of a verification visit by the Egyptian government or other entity approved by Egypt's Minister of Foreign Trade.

In addition to these general concerns, the following uncertainties have yet to be addressed by Egypt:

- Is there a standard format for the required "application for registration"?
- What is considered acceptable in terms of the "license issued for the manufacturing plant" (i.e., which competent regulatory authorities will Egypt recognize to issue these licenses?)
- Can manufacturers or owners of trademarks be exempted from these requirements?

- How long will it take for the Egyptian authorities to confirm a registration?
- Will imports be allowed while one is in the process of registering?

Lastly, while Egypt notified these measures to the WTO in February 2016, the new requirements entered into force March, prior to the end of the WTO comment period. This contradicts WTO procedures that require notification well before the entry into force of the relevant measure, and did not allow time for exporters to Egypt to transition to and comply with the new requirements.

EL SALVADOR

In 2008, El Salvador increased international termination rates by approximately 100 percent by imposing a $US 0.04 per minute tax on those calls to fund domestic social programs. The tax is paid by domestic operators in El Salvador that receive inbound international traffic and is passed through to U.S. and other non-El Salvador carriers sending traffic to that country in the form of higher termination rates. The El Salvador legislation imposing this tax, Decreto No. 651, expressly seeks to shift the funding costs for these domestic social programs away from domestic end users in that country and to impose these costs on U.S. and other foreign consumers. The introductory paragraph to the legislation states: "Charges for interconnection services for inbound calls from outside the country are paid for outside the country and therefore have no impact on the cost of calls made by domestic end-users because these charges are not made part of the domestic charges."

The impact of this tax has been severe. According to FCC data, in 2008, the United States sent 959,600,176 minutes of traffic to El Salvador.[10] Since then, however, the number of U.S. outbound minutes on this route have fallen by 50 percent and payouts to El Salvador carriers have dropped by over 35 percent.[11]

The tax violates El Salvador's international trade commitments under both the WTO and CAFTA agreements. First, because El Salvador does not apply the tax to calls from other Central American countries, the tax violates El Salvador's Most-Favored-Nation (MFN) obligations under Article 2 of the GATS. Second, Section 2.2 of El Salvador's WTO Reference Paper commitment is titled "[i]nterconnection to be ensured" and states that, with respect to commercial telecommunications services, "[i]nterconnection with a major supplier will be" provided at "cost-oriented rates." Since there is no relationship between the domestic social programs funded by the tax and the costs of interconnection services provided to cross-border suppliers, the new tax fails to be cost-oriented.[12] Accordingly, by imposing this tax, El Salvador is preventing its major supplier carrier, CTE, from charging cost-oriented rates for inbound international calls, and fails to comply with its WTO commitment under the Reference Paper that, for the types of international service covered by Section 2.2, interconnection with its major supplier at cost-oriented rates is "to be ensured."

Third, Section 5 of the WTO Annex on Telecommunications requires El Salvador to "ensure that any service supplier of any other member is accorded access to any use of public telecommunications transport networks and services on reasonable and non-discriminatory terms and conditions." The increased rates for access to public telecommunications transport networks in El Salvador resulting from the new tax are also contrary to the WTO Annex on Telecommunications. The WTO Dispute Settlement Body has found that "access to and use of public telecommunications transport networks and services on 'reasonable' terms include questions of *pricing*

[10] *See* FCC International Traffic Report for 2008, Table A1.
[11] *See* FCC International Traffic Report for 2012, Table A1. In contrast, total U.S. outbound international traffic declined by only 17 percent between 2008 and 2010.
[12]WTO, El Salvador, Schedule of Specific Commitments, Supplement 1, GATS/SC/29/Suppl.1, Apr. 11, 1997.

of that access and use."[13] The tax has increased international termination rates by approximately 100 percent without any demonstration of increased costs. These increased rates fail to provide the reasonable terms for access and use required by the Annex.

The tax also violates similar requirements of the CAFTA entered into by the United States, El Salvador, Costa Rica Guatemala, Honduras, Nicaragua, and the Dominican Republic. Article 13.4 (5)(a) of the CAFTA requires the provision of wireline interconnection services with major supplier carriers at cost-oriented rates. Further, Article 13.2 (1) of the CAFTA requires that "enterprises of another Party have access to and use of any public telecommunications service… on reasonable and non-discriminatory terms and conditions."

USTR has raised concerns regarding this tax in several prior Section 1377 reviews, and USCIB encourages USTR to continue to press El Salvador to remove this tax immediately.

EUROPEAN UNION

Up until recently EU Member States made significant progress to reduce their termination rates for international calls terminated on fixed and mobile networks. Unfortunately, in the last few years we have seen an increasing number of EU operators charging higher rates to terminate calls originating outside the EU than those charged for calls originating inside the EU. These increased rates do not appear to reflect incremental costs for terminating such traffic, and are generally higher than rates charged by carriers in the United States to terminate international calls. This practice raises concerns that these termination rate increases are not in accordance with Europe's commitments in the General Agreement on Trade in Services.

A large number of EU-based operators charge such higher rates for U.S.-originated traffic. This includes operators from Croatia, Cyprus, the Czech Republic, Estonia, Greece, Hungary, Latvia, Lithuania, Poland, Portugal, and Slovenia. In these countries, the respective National Regulatory Authorities (NRAs) permit these practices. Across the EU, however, NRAs take conflicting positions in this area, which result in an unpredictable and fragmented situation.

In addition to the aforementioned countries, there is also a group of countries that includes Belgium, Bulgaria, Finland, and Italy, where despite the fact that the NRAs allow higher differentiated rates, the operators do not charge these higher rates to US originated traffic, because US termination rates are extremely low. Only in a very small group of countries – Denmark, Ireland, and Sweden – NRAs (rightfully) completely forbid differentiation of rates. Romania and the United Kingdom are currently considering following the same path. In another group of countries – Austria, France, Luxembourg, and the Netherlands – NRAs allow higher rates but only based on a reciprocal approach, which in most instances means that US-originated traffic will not be affected. Spain also intends to follow this approach. Last, Germany allows differentiation but only under very strict conditions that includes a requirement to obtain prior approval from the German NRA.

Neither the European Commission nor BEREC so far have taken initiatives to resolve the issue. While the EC strongly opposed a proposal from the Austrian TKK for differentiation with the European Union, it didn't take a position so far on differentiation of rates for calls originating outside the EU.

In 2017, Ofcom published two consultations for comment – the Narrowband Market Review and the Mobile Call Termination Review. In both consultations, Ofcom proposes not to allow UK operators to apply differential termination charges for calls originating outside the EU/EEA but instead to require them to apply

[13] WTO, *Mexico – Measures Affecting Telecommunications Services*, WT/DS204/R, Apr. 2, 2004, ¶ 7.333

the same termination rate to all calls regardless of the country of origin. This is cited in Annex 11 (p. 74) in the following pdf (https://www.ofcom.org.uk/__data/assets/pdf_file/0014/103343/mobile-call-termination-consultation-annexes.pdf). We are encouraged by these developments and look forward to Ofcom's final decision.

Higher termination rates for calls originating outside the EU than for calls originating inside the EU, reciprocity-based or otherwise, appears to be aimed at addressing the significant discrepancy between the termination rates paid and received by European operators when they exchange international calling traffic with operators in some countries outside the EEA. USCIB notes, however, that this problem is shared by U.S. operators when they exchange international calling traffic with operators in all, or virtually all, countries. For many years, U.S. operators have paid higher rates to terminate outbound international calls on foreign operators' networks than they are able to charge foreign operators to terminate inbound international calls. USCIB hopes that European NRAs will address the concerns resulting from the rate discrepancies now being experienced on some international routes by maintaining pro-competitive regulation and mandating that European operators use the regulated termination rates for traffic from outside the EEA, rather than allowing differentiation in an unconditional manner or allowing for reciprocity-based approaches.

As USTR has noted in the last three NTE/1377 Reports that charging higher rates to terminate calls originating outside the EU than those charged for calls originating inside the EU also raises concerns regarding compliance with the WTO commitments entered into by the European Communities and their Member States. Article II of the WTO GATS Agreement requires EU Member States to provide to "services and service suppliers of any other member treatment no less favorable than it accords to like services and services suppliers of any other country." Requiring European operators to charge cost-oriented rates for calls from end-users within the EEA, while also authorizing those operators to charge rates higher than cost-oriented levels to terminate calls from end-users outside the EEA, does not appear consistent with the "most-favored-nation" (MFN) treatment required by this obligation.

Such measures are also inconsistent with the requirements of the WTO Reference Paper, which requires EU Member States to ensure that interconnection with major supplier operators is provided "under non-discriminatory terms, conditions . . . and rates" and at "cost-oriented rates."[14] Additionally, such measures are inconsistent with the EU commitments under the GATS Annex on Telecommunications, which require EU Member States to "ensure that any service supplier of any member is accorded access to and use of public telecommunications transport networks and services on reasonable and non-discriminatory terms and conditions."[15]

USCIB hopes that USTR will continue to highlight this issue and that it will draw these concerns to the attention of the European Commission and the relevant EU Member States.

In addition, the European Union has repeatedly rejected the notion of 'termination fees' for Internet content.[16] USTR should encourage the EU to continue along that path in its telecom framework consultation and reject the imposition of fees or other new burdens on content providers.

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[14] WTO, European Communities and Their Member States, Schedule of Specific Commitments, Additional Commitment, Sect. 2.2. An operator incurs the same cost to terminate an international call on its domestic network regardless of the call origination point. Pursuant to this commitment, cost-oriented termination rates required for EEA-originated calls should also apply to calls originating in other WTO Member countries.

[15] WTO GATS Annex on Telecommunications, Sect. 5. The WTO Dispute Settlement Body has found that the "reasonable" terms for access and use required by the GATS Annex on Telecommunications include "questions of pricing of that access and use." WTO, *Mexico – Measures Affecting Telecommunications Services*, WT/DS204/R, Apr. 2, 2002, ¶ 7.333.

[16] See, e.g., http://berec.europa.eu/files/document_register_store/2012/11/BoR_(12)_120_BEREC_on_ITR.pdf.

Midterm Review of the Digital Single Market (DSM) Initiative

In May 2017, the European Commission presented a mid-term Review of the Digital Single Market Strategy, to take stock of the progress to date and to outline the way forward. With the key objective of creating a truly horizontal regulatory environment across the European Member States and eliminating barriers that hinder digital innovation, the Commission has thus far adopted 35 legislative proposals and Parliament and Council continue to negotiate additional proposals (e-privacy Regulation and the Electronic Communication Code). For example, the Commission released the "Proposal for a Regulation Of The European Parliament And Of The Council on a framework for the free flow of non-personal" and the EU Cybersecurity Strategy in September 2017. Although the Council and Parliament have stated a joint goal of finalizing pending proposals by the end of 2017, the multiple, iterative consultations will take time, and have the potential to stifle innovation. The EU should proceed cautiously so as not to sacrifice quality at the expense of consistent, flexible regulatory policies.

Further, it is critical that as regulators review the Digital Single Market and address important data protection, privacy and cyber security initiatives, the Commission should avoid the introduction of policies that inadvertently stifle innovation through regulation and fragment the European Market. As an example, as the ePrivacy Directive review continues, the EU should be encouraged to adopt rules addressing personal data that are consistent with GDPR. to create a standardized approach to privacy in electronic communications across the European Union, which is predictable and consistent for business.

Every policy or regulatory framework should distinguish between consumer and enterprise services. Generally, enterprise services should be explicitly excluded from the scope of consumer-focused legislation.

Business, including US business operating in the EU, would benefit from a flexible environment that allows for investment in new technologies and services, as opposed to requiring investment in multiple, overlapping, compliance programs. Connected devices are rapidly expanding, improving our lives and industrial operations. The vast potential of the IoT, Big Data and other emerging technologies for consumers and the economy will be realized only in a flexible regulatory and policy climate that apply to equally to services across the ecosystem, bringing us closer to a level regulatory playing field and focus on managing risk, not blocking change.
Government policymakers on both sides should strive to better understand the benefits and potential issues that arise in the context of new technologies including cloud computing, Big Data, IoT, and the continued growth of platforms and search tools. Forward-looking policy positions should include a review of legacy regulation with a rigorous economic analysis of changed market conditions. Wherever possible such regulation, including vestigial legislative and regulatory barriers, should be eliminated and only extended to new and evolving services in rare circumstances when supported by sound economic analysis. This review should support evolving business models and new technologies and ensure consistency with the rule of law and good practice which will spur economic growth and social benefit. Governments should carefully consider both policy and regulation to assure that needless burdens and unintended consequences do not occur from such new policies or regulations.

In particular, we urge the Commission to carefully reflect upon the OECD's Internet Policymaking Principles[17], a comprehensive and balanced set of principles developed by the OECD with input from all stakeholders including the Business and Industry Advisory Committee to the OECD, of which USCIB is the U.S. affiliate, to guide development and implementation of effective and compatible approaches to Internet policymaking and governance both at the national and international levels. The Commission should ensure that policy and

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[17] See https://www.oecd.org/sti/ieconomy/oecd-principles-for-internet-policy-making.pdf

regulatory elements of the DSM remain consistent with these OECD Principles. USTR should work with European counterparts to ensure that any legislative proposals are consistent with international obligations and avoid creating uncertainty for businesses.

One recent proposal under the DSM is the draft Regulation that would establish a framework for the free flow of non-personal data. Free flow of data is the blood of digital industry and is vital for the economic growth. Various countries have introduced server and data localization requirements and similar measures in recent years, often under the false pretense of improving data security. Such measures not only create a self-imposed economic handicap but also set a dangerous precedent for other countries, thereby encouraging them to adopt similar restrictions. Such 'digital data protectionism' undermines global trade in goods and services, and threatens the development of a truly global digital economy.

The proposal aims to establish a framework of free cross-border data flows within the EU, which would limit the scope of data localization requirements imposed by EU Member States to those required on grounds of public security grounds. We welcome the ambition of the proposal, which would require Member States to notify any draft legislation or measure introducing new data localization requirements or any plans to repeal existing national data localization requirements within a year of the application date of the draft proposal. We believe this proposal is a good start to removing unjustified requirements and bringing transparency to EU Member State practices.

We would further welcome a proposal from the Commission, enabling data to flow freely between the EU and the US. In this regard, the EU-US Privacy Shield Framework is a step in the right direction. USCIB strongly supports the Framework and welcomed its positive review on the occasion of the 1st annual review on September 18-19, 2017.

Last but not least, as the Commission and member states move forward with DSM implementation, they should take care to support creativity and innovation and apply the rule of law while maintaining an inclusive environment for ICT products and services from both within and outside Europe.

Geographic Indications (GI)

We share the concern expressed in previous NTEs that the EU's system applies GI protections to an over-broad swath of food products and negatively impacts trademark protection and market access for U.S. products with generic names. The European Union has been pursuing increasingly aggressive bilateral and multilateral strategies to restrict the use of common cheese names by non-EU producers, which we urge the United States to strongly oppose.

Meursing Table Tariff Codes

We note the U.S. comments in previous NTEs remain relevant and concerning:

> "Many processed food products, such as confectionary products, baked goods, and miscellaneous food preparations, are subject to a special tariff code system in the EU. Under this system, often referred to as the Meursing table, the EU charges a tariff on each imported product based on the product's content of milk protein, milk fat, starch, and sugar. As a result, products that the United States and other countries might consider equivalent for tariff classification purposes sometimes receive different rates of duty in the EU depending on the particular mix of ingredients in each product. The difficulty of calculating Meursing duties imposes an unnecessary administrative burden on, and creates uncertainty

for, exporters, especially those seeking to ship new products to the EU."

Supplemental Protection Certificates

The EU has recently proposed revisions to the Supplemental Protection Certificate (SPC) that may weaken exclusive rights conferred under an SPC. SPC's are integral to the European IP system and restore effective patent term to compensate for a portion of the time incurred during the testing and regulatory review period that may "make[] the period of effective protection under the patent insufficient to cover the investment put into that research."[18] Effective SPC protection, conferring the same legal protections as those available during the regular patent term, must be retained in order to ensure the ability of the system to continue to meet its policy objectives.

Pharmaceutical Procurement

In May 2016, a number of European health ministers signed the "Valetta Agreement" stating their political will to establish a Technical Committee to explore possibilities for voluntary cooperation, which will include but not be restricted to information sharing, looking at potential mechanisms for joint procurement and price negotiation, and horizon scanning for innovative therapies. This follows a December 2016 Lisbon meeting of health ministers who conducted discussions on how to ensure access to innovative medicines at more transparent prices, including the possible creation of a European drug procurement process. The countries present at the meeting were Austria, Belgium, Greece, Ireland, Italy, Latvia, Malta, the Netherlands, Portugal, Slovenia, and Spain. In addition, we are monitoring developments related to launch of the BeNeLuxA joint website, which will facilitate joint procurement of medicines in some European countries. France is considering joining.

FIJI

In 2011, the Fiji Commerce Commission directed Fintel, the incumbent government-controlled carrier, to increase the minimum termination rate for inbound international traffic from $0.165 to $0.22 per minute without showing that the rate increase was cost-justified. Instead, the stated purpose of the increase was to ensure that consumers outside Fiji bear the costs of increasing telecommunications service penetration in Fiji. USTR called attention to this unreasonable trade barrier in the 2015 Section 1377 Review and USCIB encourages USTR to continue to press Fiji to rescind this increase.

FRANCE

On July 12, 2017, the Council of State handed down a judgment ruling that net prices of medicines refers to the price published by the official gazette, minus discounts offered by pharmaceutical companies as per agreement with the Economic Committee for Health Products (CEPS). The ruling has negative implications for the pharma sector in terms of whether discounts can be counted in taxes affecting corporate entities, such as the added value contribution.

GERMANY

Again in 2017, Germany remains a difficult market for new entrants. USCIB urges USTR to continue to urge Germany to comply with its WTO commitments.

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[18] See EC Regulation No. 469/2009 concerning the supplementary protection certificate for medicinal products (May 6, 2009) at Recital 4.

The absence of an independent and effective regulator continues to have a negative impact on the development of competition, even many years after liberalization of the market. The German Federal Network Agency, BNetzA, continues to be subject to inappropriate political pressure in 2017 despite continued claims to the contrary by the Ministry of Economies. The German Government in 2017 still holds a direct and indirect ownership interest of 31.9 percent in Deutsche Telekom AG ("DTAG"), the incumbent operator. The German Government's equity stake has even slightly increased in 2017 from last year's 31.7%.

Under German law, BNetzA itself is a subordinated authority of the Federal Ministry of Economics. Although the decisions of its ruling chambers cannot be overruled by the Ministry, BNetzA remains bound by the Ministry's directives. It should be noted that other agencies, such as the Federal Competition Authority (FCO), are not bound by direction from the Ministry. Thus, market players under the oversight of the FCO are able to enjoy the competitive benefits of a more independent and effective regulator. With no end to the Government's ownership in sight and with this year's vectoring and termination rate rulings by BNetzA, market participants continue to be adversely affected by the absence of an independent and effective regulator in such an important and influential market in Europe.

In addition, despite our 2016 comments, we also continue to be concerned that the lack of opportunities for U.S. companies to participate in the majority of proceedings still has a direct and substantial impact on their business plans. Due to the Administrative Court's rules of procedure, competitors have little or no opportunity to participate as third parties in the court's proceedings, and therefore have no opportunity to defend their direct interest court. In contrast, DTAG always is a party to the cases and can therefore influence decision making at the court level. Even in cases rate approvals issued by BNetzA are being appealed by other market participants, competitors are not made parties to the proceeding, creating unnecessary financial risks and legal uncertainty. Despite BNetzA introducing an online register for proceedings last year (which still is not updated regularly), market participants remain concerned about the lack of transparency regarding pending administrative proceedings and the short deadlines established by BNetzA to submit comments. In contrast to the long duration of most proceedings (see recently BNetzA's proceeding to review DTAG's "Stream On" service pending since April 2017), market participants are forced to quickly review complex proceedings within days, significantly impacting their ability to follow and participate in them. USTR should continue to monitor BNetzA's progress in this area (if any) and encourage it to follow international best practices of a 30-day minimum for comments and further improve the electronic publication of the reasoning behind its decisions and information about pending court proceedings.

Market participants continue to be concerned about data localization requirements proposed by the German government. USTR properly drew attention to these concerns regarding the government's guideline requiring a "no spy declaration" for companies to qualify for data services procurement contracts with the German Federal Government in the 2014 review and the localization requirement in the context of new data retention obligations in the 2016 review. The latest cause for concern in this series of issues is the introduction of a notification requirement for the usage of non-German mobile numbers used for M2M purposes within the territory of Germany, which will create unnecessary hurdles for US providers of global M2M and IoT services. BNetzA will introduce a new national regulation[19] that "allows" permanently using foreign Telephone Numbers for Mobile Services (e.164) in Germany as long as the foreign Service Provider who received the numbering resource from a foreign Regulatory Authority (e.g. a US wireless operator using US telephone number ranges assigned by the FCC) notifies the numbers and a local representative of BNetzA before these numbers are used

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[19] https://www.bundesnetzagentur.de/SharedDocs/Downloads/DE/Sachgebiete/Telekommunikation/Unternehmen_Institutionen/Nummerierung/Rufnummern/M2M/Vfg_80_2017_Exterritoriale_Nutzung_von_ausl_Rufnummern.pdf?__blob=publicationFile&v=1

in Germany.

According the reasons given by BNetzA, this obligation shall help German law enforcement authorities (LEAs) to shortcut the mutual legal assistance treaty process[20] and provide German LEAs with a direct access to international service providers that so far do not fall under the German Telecommunications Act. This notification requirement is legally questionable and an extremely burdensome obligation on foreign providers of M2M services in Germany

The German data retention law, which entered into force on December 18, 2015, continues to create significant uncertainties for US companies doing business in Germany. Despite German regulator BNetzA announcing that it would not enforce the law following a court ruling issued a few days before the law entered into force on July 1, 2017, the law remains in effect. While the court held that the implementation of the German data retention obligations (again after the 2010 Constitutional Court ruling) was incompliant with European law, market participants in Germany again had to invest to upgrade their systems (with investments being non-recoverable) to ensure continued legal compliance. Despite the law currently not enforced by BNetzA, US companies continue to be concerned about the data localization requirement which likely will not be part of the court's full review.

The legislation also has been criticized strongly by the European Commission (EC), which openly doubts that the requirement to store the retained data in Germany rather than anywhere else in the EU is in line with relevant EU law. However, neither the EC nor the German Government has taken any actions to withdraw the requirement. USCIB urges USTR to challenge the original data localization requirement in case a revised data retention law comes into force after a final court ruling.

As noted in previous years, market participants are seriously concerned with these issues beyond the immediate business impact due to i) Germany's important role in Europe and globally and ii) the landmark character of Germany's example, which, if left unchallenged, might open the door to other countries applying similar measures, or worse. USCIB urges USTR to continue to monitor these developments and, if necessary, to remind Germany of the requirements of its "most favored nation" (MFN) and national treatment obligations under the GATS.

Drug Pricing & Reimbursement

New innovative reimbursed drugs are freely priced for 12 months after launch. Manufacturers of new innovative reimbursed drugs must submit an early benefit dossier to the Federal Joint Committee (G-BA), which (following an initial assessment by the Institute for Quality and Efficiency in Health Care [IQWiG]) conducts an early benefit assessment to evaluate the additional benefit offered by the drug versus comparators. For products with an additional benefit, reimbursement price negotiations between manufacturers and the Federal Association of Health Insurance Funds (GKV-Spitzenverband) ensue. A drug with no additional benefit is automatically included in the reference price reimbursement system: it can then be freely priced, but reimbursement is limited to the reference price. As of the end of 2016, 43% of the 228 reviews completed concluded "no additional benefit." The process is so unfavorable that it has prompted some manufacturers to shelve planned launches for a number of innovative drugs. By the end of 2016, the number of new medicines withdrawn during the course of the evaluation and negotiation procedure was reported to be 29. Diabetes, cancer and neurological drugs are most affected. Under the draft AM-VSG, early benefit assessment may be extended to existing drugs authorized for new indications.

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[20]MLAT - https://www.state.gov/documents/organization/188782.pdf

Following implementation in April 2017 of the Pharmaceutical Care Strengthening Act Germany imposed a price moratorium on non-reference priced drugs, which was set to end at the end of this year. Recently, it was announced that the price moratorium will be extended until 2022, and as such, non-reference priced drugs must remain at the same (realized) price as in August 2009 until 2022.

On Price Transparency, the draft Pharmaceutical Care Strengthening Act recommends that confidential discounted reimbursement prices of drugs negotiated following AMNOG assessments no longer remain confidential.

GHANA

Ghana enacted legislation on December 31, 2009 requiring network operators to charge a minimum rate of US$0.19 per minute for all incoming international electronic communication traffic.[21] U.S. carriers had previously negotiated rates below US$0.07 for termination on fixed networks and below US$0.14 for termination on mobile networks.

Ghana has attempted to justify the $0.19 rate as being necessary to curb fraud and the use of "grey market" termination. However, commentators have noted that the measure is more likely to encourage the increased use of alternative routes. FCC data also demonstrate that reductions in international termination rates have stimulated huge increases in inbound and outbound international calling to and from Ghana, all providing significant benefits to the consumers in the U.S. and Ghana who make and receive those calls, and to carriers in Ghana through increased termination payments.

In 1997, the year before Ghana's WTO basic telecom commitments became effective, U.S. carriers paid carriers in Ghana an average per minute termination rate of $0.39, resulting in 50,269,789 minutes of U.S.-Ghana calling and total payments to carriers in Ghana of $19,638,574.[22] In 2009, more than ten years after Ghana's WTO commitments became effective, U.S. carriers paid carriers in Ghana an average per minute termination rate of $0.12, resulting in 325,582,418 minutes of U.S.-Ghana calling and total payments to carriers in Ghana of $39,298,038.[23] Thus, the 69 percent reduction in the level of Ghana's termination rate between 1997 and 2009 resulted in an *approximate 550 percent* increase in call volumes from the U.S. to Ghana and an *approximate 100 percent* increase in U.S. termination payments to carriers in Ghana.

The Ghana rate increase, like the El Salvador tax described above, has drastically impacted U.S.-outbound calling volumes to Ghana. FCC data show that U.S. carriers sent only 138,082,534 minutes to Ghana in 2013, a reduction of 57 percent from 2009 volumes.[24] Additionally, between 2009 and 2011, U.S. carrier payouts to Ghana's carriers declined by 50 percent, plunging from $39,298,038 to $19,800,016.[25]

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[21] Electronic Communications (Amendment) Act, 2009, Act 786, December 31, 2009 Network operators that charge a lower rate are subject to a penalty of "twice the difference between the specified rate and the rate actually charged.". *Id*., Sect. 1 (2). The statute requires that 32 percent of this required interconnection rate is "kept by the Authority." Additionally, a portion of the increased rate reportedly is paid to a third party entity providing call monitoring services to the Ghanaian government. *See* Ghana Business News, June 2, 2010, *Vodafone raises Red Flag Over calls Monitoring by Foreign Company*, http://www.ghanabusinessnews.com/2010/06/02/vodafone-raises-red-flag-over-calls-monitoring-by-foreign-company/

[22] *See* FCC International Traffic Report for 1997, Table A1.

[23] *See* FCC International Traffic Report for 2009, Table A1.

[24] *See* FCC International Traffic Report for 2013, Table A1.

[25] *See* FCC International Traffic Reports for 2009 & 2013.

Ghana's measure raising negotiated rates not only adversely impacts U.S. calling volumes to Ghana benefiting consumers at both ends of this route but, as USTR has noted in prior Section 1377 reports, is contrary to this country's WTO commitments under the Annex on Telecommunications. This requires the provision of access to telecommunications networks and services in Ghana on reasonable terms and conditions. This measure also is contrary to commitments under the WTO Reference Paper requiring, for the types of international services covered by Section 2.2, the provision of interconnection services with major supplier carriers at cost-oriented rates.[26] The new tax has increased rates for termination on fixed networks by more than 200 percent and rates for termination on mobile networks by approximately 50 percent, without any demonstration of increased costs. These increased rates fail to provide the reasonable terms for access and use required by the Annex or, as applicable, the cost-oriented rates required by Ghana's Reference Paper commitment. USTR should continue to press Ghana to remove this mandated rate increase.

Customs Treatment of Software

Ghana is one of a number of countries in West Africa that has used inconsistent methodologies for valuation of software for the purposes of assessing Customs duties. A 1984 Decision of the then-GATT Committee on Customs Valuation enables countries to calculate the customs value of software based only on the value of the underlying carrier medium.[27] In some instances, countries are using this method, while in others they are assessing duties based on the IP value of the loaded software. To ensure wide availability of best-in-class technologies, Ghana and other West African countries should consistently apply the valuation method provided for in Decision 4.1.

GREECE

Greece now uses a "9+6+3" health technology assessment (HTA) system, introduced recently into law in association with the latest bailout memorandum. In order for new medicines to enter the Greek healthcare system, they must be marketed in at least nine EU countries, and reimbursed in six of them, three of which must have fully functioning HTA systems. This is coupled with a 25% discount on new drugs before conclusion of price negotiations and new criteria in the assessment process relating to unmet medical need; added therapeutic value compared with existing treatments; reliability of clinical data; and cost-benefit ratio in light of the impact of the assessed technology on pharmaceutical spending in Greece.

Additionally, in June 2017, a new system of clawbacks was announced that would target high-value products. The combined rebates and clawback on high-cost medicines used in hospitals and available from Greek National Organization for Healthcare Provision (EOPYY)pharmacies are reported to be up to 43% of their price in certain cases while the maximum combined total is estimated at around 30% for drugs in the open-care sector.

While new measures to reduce healthcare spending in 2018 are scheduled to be decided by December, in May 2016, the Greek government and troika agreed on a series of measures to reduce the volume of high-cost medicines used within the Greek public healthcare system including a "consolidated volume rebate" which would be imposed, with an additional 25% discount for new patented medicines until their price has been negotiated. The 25% discount to be applied before prices are negotiated will – when added to the existing rebates and discounts, and clawback, result in a comparatively very low earning potential for producers of originator products in Greece.

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[26] WTO, Ghana, Schedule of Specific Commitments, Supplement 1, GATS/SC/35/Suppl.1, Apr. 11, 1997.
[27] WTO Decision 4.1 (Valuation of Carrier Media Bearing Software for Data Processing Equipment).

GULF COOPERATION COUNCIL (GCC)

Guide for Control on Imported Foods

As noted in the 2015 NTE, the GCC notified the WTO Committee on Sanitary and Phytosanitary (SPS) Measures of their intention to implement a new "GCC Guide for Control on Imported Foods." Some USCIB members submitted comments in response to WTO notification G/SPS/N/OMN/44/Rev.1. They noted the regulation's broad scope and the need for stakeholders to have appropriate time to understand and adapt to these new requirements. The Gulf Standards Organization (GSO) should substantially clarify the intent of these requirements and their scientific basis, as well as clearly delineating implementation plans.

As of July 2017, we understand the GCC countries have committed to postpone implementation of the Guide until further notice. While this is a positive step, not all GCC countries have formally notified the WTO of the suspension of the draft Guide.The United States should continue to ensure the GCC should upholds its obligations to base regulations on science and harmonize regulations with the Codex standards on Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995). In accordance with these and other specific concerns listed in our comment, the GCC should consider fully all comments received and derive a new implementation date that allows sufficient time to comply with the new regulations, three years at minimum.

Food Additives

In June 2015, comments were submitted on the GCC's draft standard on additives permitted for use in foodstuffs. Our comments noted a number of specific additives for which the draft standard either omitted or is inconsistent with science-based food additive standards established by the Codex Alimentarius.

General Requirements for Halal Foods

In February, 2015, comments were submitted on the GCC's draft standard on general requirements for halal foods. We have serious concerns with some provisions in the draft regulation and believes the regulation would significantly disrupt food and beverage trade, impact the operations of manufacturers of all sizes in the region, and potentially affect product availability and price. USCIB members requested that GSO substantially clarify the intent of these requirements and clearly delineate implementation plans (the current implementation date.

We are particularly concerned by the requirements in Section 4.12 related to the use and cleaning of equipment, tools, or production lines used for halal and non-halal foods. The requirements would, in practice, require dedicated production lines and supply chain infrastructure for halal products and could represent an undue barrier to trade. The GSO should also clarify the applicability of these requirements to naturally halal foods, such as nuts, dried fruits, and juices.

Drug Pricing & Reimbursement

The high council of GCC health ministers is considering the harmonization of drug prices in all member countries and reduction of the prices to match the lowest in all GCC states. Drug prices are expected to be brought down to match those in Saudi Arabia, given that each of the Gulf countries currently sets its own prices.

INDIA

The Government of India's roll out of initiatives, such as Digital India, accelerated broadband deployment, and

the creation of one hundred Smart Cities, in conjunction with the explosive growth of mobile broadband and the emergence of technology formats such as machine-to-machine (M2M) computing, the Internet of Things (IoT), and cloud computing, have the potential to put the Indian economy on a growth trajectory. However, India must implement policies that foster an innovative environment and are compatible with global standards.

It is important to keep encouraging the Indian government to support further market liberalization and to remove remaining market access barriers. India should be urged to continue its efforts to provide legal and regulatory policy certainty both in the development of a body of clear and consistent laws and regulations, and in the transparent and equitable application and enforcement of those laws and regulations. Unfortunately, in recent years the Government of India has implemented a number of policies that constitute significant market access barriers to U.S. companies.

National M2M Roadmap

The National Telecom M2M Roadmap document issued by the Department of Telecommunications (DOT) in May 2015 is a roadmap document intended to foster healthy growth of M2M. While DOT acknowledges the importance of aligning with the evolving global standards and has adopted a forward-looking approach generally to policymaking, DOT must continue to recognize the global essence of these services as well as the critical importance of creating a policy environment that allows for flexibility and use of commercial arrangements to the healthy proliferation of M2M and IoT services.

We urge the Government of India to take a light-touch regulatory approach in devising an implementation framework for M2M. In addition, we urge the Government of India to keep in mind the following principles:

i. Avoid restrictions on the free flow of information across borders and does not disrupt the global nature of these flows.
ii. Avoid imposing any restrictions on permanent international roaming to provide flexibility for differing service models, e.g., some SIM cards will be embedded in manufacturing devices that are stationary; some will be embedded in cars -- others in unforeseen combinations. The GOI should avoid imposing any technology mandates or requirements and favor a flexible and a light-touch approach.
iii. Avoid prohibiting the use of foreign SIMs for permanent roaming, as this will impede the growth of M2M services. Further, requiring the use of a local number will not enhance the availability of data significantly. We were disappointed that the Telecommunications Regulatory Authority of India in a recommendation to the Department of Telecommunications (DoT) published in August 2017 suggested a three-year limit on permanent roaming. Setting a limitation on permanent roaming will have a negative impact on the ability of foreign suppliers of M2M services to operate in India.
iv. Avoid requiring the use of local Indian SIM for M2M, as it would not be technically and commercially viable to retrofit devices embedded with foreign SIMs with local SIMs. That would be a costly and lengthy process. In addition, there may be design elements associated with the SIM that would need to be considered such as proprietary nature of SIM or the design which cannot be replicated or replacement may endanger or impede SIM functionality.
v. No specific mandate on data localization and no time-bound usage of global SIMs to support permanent M2M roaming as recommended by TRAI.
vi. Avoid market access limitations. We are also concerned that the recent TRAI recommendations to DoT include suggestions that the Indian government should identify critical services in the M2M sector and that the provision of these services be restricted to be provided only by connectivity providers using licensed spectrum. Should India move to limit market access for certain services to

> only licensed spectrum users, we urge a very narrow definition of critical services that is consistent with India's trade obligations and maintains flexibility for new and innovative services. Any limitations on market access should be conducted through a thorough stakeholder consultation. Furthermore, the recent TRAI recommendations also suggest that the government should establish comprehensive guidelines for the manufacturing/importing of M2M devices in India. Any eventual policy should aim to enable consumers in India to choose from the best available M2M devices and not limit choice. It would also be helpful if DoT clarifies any eventual policy will alter the current custom clearance procedures and mechanisms.

In July 2016, DOT released for limited circulation draft guidelines aimed at registering M2M service providers in India. We understand that such guidelines apply to Indian companies that plan to enter the M2M space in India. Despite the "Roadmap" of 2015 clearly acknowledging the international services dimension of M2M and IoT services, the draft guidelines represent an extensive regulatory interference in the marketplace by establishing registration requirements for M2M service providers. In addition, the draft guidelines include data localization requirements that only local telecommunications resources (e.g. numbering) be used in the provision of mobile–network enabled devices, both of which would complicate the ability of companies to offer globally interconnected M2M/IoT services. This localization requirement is consistent with other jurisdictions, which instead have supported a framework that would allow foreign carriers to utilize foreign SIMs to provide permanent roaming for M2M or IoT services to their respective OEM customers. Industry has provided comments on the guidelines and continues to engage with the Indian government as it continues to review the guidelines.

USCIB urges USTR to request that the Indian Department of Telecommunications officially clarify that the use of foreign SIMs shall be permitted for use in permanent roaming and that they shall not be required to be converted/reconfigured into an Indian Telecom Service Provider's SIM. We note that the TRAI in its August 2017 Recommendation has noted that the Authority/Licensor shall review this issue at a later date based on market and technological developments and requirements. We note that the TRAI recommendations also allow flexibility for permanent roaming of foreign SIMS in cases where there is a strategic need, bilateral or multilateral trade commitments, and in cases of bilateral reciprocity.

USCIB further urges the USTR to encourage India to promote an international, interoperable policy framework for IoT and M2M solutions that includes permanent M2M roaming. Many IoT and M2M solutions will only reach their optimal scale if they can operate around the globe. Monitors on airline cargo or shipping containers must be able to operate wherever their freight travels. Automakers sell vehicles across many different countries and operators drive vehicles across national borders for commercial and personal purposes; automakers and customers alike need a single communications platform to support their connected vehicles. The Indian government should support providers of IoT and M2M devices to choose between various available options for numbering and device management, rather than imposing a single, one-size alternative for all cases.

Finally, USCIB calls upon USTR to request the Indian government to review its approach to permanent M2M roaming and to discourage India from imposing any rules that would restrict international trade in M2M services. Instead, USTR should encourage India to adopt approaches that enable cross border data flows, refrain from data localization requirements, remain technology neutral, enable the use of global standards in a manner that facilitates the global deployment of IoT products and services, is not detrimental to foreign investment and continues promoting the scale and interoperability required for the deployment of M2M services.
As other countries begin to consider regulating M2M and IoT around the world, we urge USTR to engage them to ensure that they adopt flexible approaches that enable the deployment of this innovative new service on a global basis.

Remote Access Policy

Global telecom operators have made significant investments in establishing India's network infrastructure. However, sudden changes in policies pertaining to Remote Access (RA) negatively impact network security and compliance, and ultimately hamper telecom operators' ability to efficiently operate networks in India. There has been a continuous backtracking on RA policies even though the same policy was developed by way of a Government-Industry consultative process.

Despite complying with the new requirements pertaining to setting up an in country storage server, the DOT is has attempted to introduce additional requirements which are not part of any stated policy. As a result, some operators are experiencing complete uncertainty regarding the RA policy. Clearances of some operators are not being granted even after meeting the requirements. Instead, carriers are required to perform additional activities, which are not part of the guidelines. This has affected some operators' ability to execute future deployments of services and investments in the network. It is requested that the Government of India clear the approvals, based on the existing guidelines with future approvals granted based on earlier demonstration of compliance. If inspection is required, it should not delay clearances. Additionally, the current process of seeking prior approval for clearance is extremely time consuming (1 – 2 years), restricts the ability of member companies to compete and establish new services, and impinges on Service Provider's ability to proactively and efficiently manage and protect the networks, including to mitigate cyber threats. The process must be modified to a prior intimation process that allows service operators a platform upon which they may fairly compete and to manage the network without fear of running afoul of unnecessary restrictive access policies.

It is important to mention that Remote Access related permission requirements which are part of a Foreign Direct Investment policy is unique to India. No other country in the world has restrictions on Remote Access. Despite a specific policy permitting on Remote Access, the Indian companies with network centers outside India are discriminated vis-à-vis the other Indian companies who have local centers. The networks of our members are left vulnerable due to delays and uncertainties on the policy front.

Convergence of Services/Networks/Devices

There is a need for consistency between the proposed Unified License Regime proposal (ULR) and the objectives of the 2012 National Telecom Policy (NTP). USCIB notes that the proposed technology neutral approach under the ULR framework has been qualified with specific restrictions on PSTN and VoIP/IP telephony networks in general and more specifically extending to the Closed User Group (CUG) environment. To realize the true potential of converged services, networks and devices and to achieve the stated objectives for convergence, the present restrictions and barriers among different PSTN/IP/CUG-PSTN networks should be removed under the proposed Unified License-Phase II in order to ensure seamless interconnection. This will certainly help provide some of the necessary momentum towards achieving the government's goals under its "Digital India" plan. As India embarks soon on a review of the NTP-2012, we urge it to address this imbalance and enable IP-PSTN convergence by permitting VoIP-PSTN interconnection.

In 2016 the Telecommunications Regulatory Authority of India (TRAI) initiated a public consultation on the use of Internet telephony, or Voice over IP (VoIP). An important element of the TRAI consultation is the removal of the existing barriers on the PSTN-IP convergence for voice services. Removal of these barriers would bring India's regulatory regime on VoIP more in line with leading digital economies, which have long permitted VoIP-PSTN interconnection. USCIB will continue to monitor developments in this area and urges USTR to encourage India to remove this regulatory obstacle to the growth of converged digital services in India.

Cloud Computing

Cloud Computing is increasingly relied upon by many economic sectors to deploy digital solutions in today's digitally enabled economy. Recognizing the increased use of cloud computing in the deployment of different types of services and applications, the Telecommunications Regulatory Authority of India initiated a consultation paper in 2016 examining numerous policy issues surrounding Cloud Computing services. Recently, TRAI issued its recommendations, which are before DoT to approve. They suggest that a light touch regulatory approach should be adopted to regulate cloud services. However, TRAI has recommended that the DoT prescribe a framework for registration of Cloud Service Providers, a mechanism TRAI suggests it would set criteria for in the future. USCIB objects to creating a registration obligation for cloud service providers as it can lead to increasing regulatory burdens that create inefficiencies, impede market access, and restrict innovation. \
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We continue to encourage consideration of industry views on the importance of creating an enabling environment for Cloud computing in India and globally. USCIB encourages India to enable open and competitive markets through existing legal and regulatory frameworks. Additionally, India needs to avoid, and where necessary, eliminate barriers to seamless cross-border data flows as well as avoid restrictive data localization requirements that adversely impact investment and innovation. It is further important that, when applying any consumer protection regulation, India distinguishes between services that are offered to individual consumers and those sold to businesses to avoid automatically extending consumer protection obligations to enterprise providers.

OTT Regulations

Including the cloud computing and VoIP papers described above, TRAI has issued several consultation papers seeking input on whether there is a need for regulation of Over-the-Top (OTT) providers that offer cloud, VoIP, and other services. However, regulators have provided little feedback or response to industry submissions. Given that many of these consultations and drafts could generate restrictive rules and market access barriers for U.S. services seeking entry to the Indian market, we encourage USTR to engage with counterparts in India and promote a light-touch regulatory framework for OTT services that is consistent with the U.S. approach.

Telecommunications Network Security

We continue to draw USTR's attention to the fact that certain elements of the May 31, 2011 amendment to the telecommunications service provider licenses deviate from global practice, while others require clarification to understand how they will be implemented to ensure that these elements do not become barriers or have unintended consequences. While the most egregious provisions of the May amendments were rescinded by the Indian government, there remain problematic legacy provisions that could undermine the ability of U.S. ICT companies to compete fairly in India's telecommunications sector.

Most concerning is the mandatory requirement to test certain ICT technology (the exact scope and coverage of this testing requirement remains unclear) in Indian labs by October 1, 2018. Moreover, DOT officials, in a number of meetings with U.S. industry representatives, indicated that source code audit inspections may be included in future testing requirements, although no further details have been provided. Indeed, the Indian government has failed to issue any guidance or details about this in-country testing requirement. U.S. ICT companies require significant lead time to adjust complex global supply chains to meet these types of requirements. Moreover, it appears that India lacks a sufficient testing ecosystem to implement this requirement by the 2018 deadline. In addition, it is important that this testing requirement will not impact the supply chain framework of the operators.

There is no evidence that the geography of development or testing of a product corresponds with the level of security assurance provided by the product. Thus, the government's insistence on having products tested locally will not provide greater security assurance. USTR should emphasize that there are longstanding internationally accredited/recognized laboratories conducting testing in this area, and that the location where the testing is performed, in accordance with global best practice, has no bearing on the accuracy of the test in question, as long as the laboratory has achieved the appropriate certification. We urge USTR to suggest that the Indian government to examine these issues carefully and establish close consultation with industry stakeholders to find a practical and flexible approach.

Submarine Cable Landing Stations Access & Collocation Charges

USTR has in the past properly commended India for taking important steps to reduce access facilitation and collocation charges at submarine cable landing stations (SCLS) in India to more reasonable and cost-based levels. TRAI issued its decision revising these charges in December 2012. Tata Telecommunications Ltd. and Bharti Airtel Ltd., which own the majority of cable landing stations in India, have since appealed this decision in the Madras High Court. We are happy to report that in November 2016, the High Court rejected the appeal and the TRAI decision is now in force. The reduction of the CLS charges by TRAI will result in unlocking of idle bandwidth available with the telecom operators in a cost-efficient manner. We thank USTR for raising this important issue in its past NTE/1377 Reports.

Despite the rejection of the petition, however, Indian carriers are refusing to abide by the TRAI regulations and have filed an Appeal before the Chennai high court challenging the dismissal of the petition through delay tactics. This has caused undue hardship to network operators seeking access to these landing stations as the SCLS operators continue to charge significantly high prices and ignored requests by network operators to be refunded for payments in excess of the TRAI order. This is a serious issue which is negatively impacting those seeking access to cable landing stations in India. India must do more to enforce compliance with the TRAI order.

Defining the Revenue for Payment of License Fee

USCIB urges India to examine the methodology it currently uses to calculate the annual license fees to ensure that India's license fee regime does not frustrate the goals of promoting competition, creating a level playing field among all service providers, and reducing the sales price of services to consumers. Under the current methodology, license fees are based on revenues from both licensed and unlicensed activities, which make the calculation of such fees unnecessarily burdensome. Also, the current definition leads to double payment of license fees to the Indian government as it does not allow deduction of wholesale charges from retail revenues.

USCIB applauds India's decision in 2016 to enable Virtual Network Operators (VNOs) to enter the market as a positive step to increasing competition in the marketplace. However, it is important for DOT to review the impact of the effective double assessment of licensing fees on the economic viability for VNOs to enter the market if they are unable to deduct the inputs they rely on to offer their service. The double assessment of licensing fees currently operates as a multi-stage and cumulative tax. Facilities-based operators, relying on their own networks, only pay the license fee once, while the services that operators such as VNOs buy from other operators are subject to the license fee twice – once when they are sold from the first network owner to the second operator (e.g. a VNO), and then again when the second operator sells them to the end user. Thus, a telecom operator who buys inputs from other licensed operators is placed at a competitive disadvantage with those who do not need to buy those inputs to provide their service.

To avoid this double assessment, we urge USTR to impress upon the Indian government the importance of seriously considering this long-standing request and urge the Indian government to clarify that such license fees apply only to revenues from retail sales transactions where the service is provided to an end user. The resolution of this issue has a direct bearing on the ability of operators to compete effectively in the market.
In a favorable development, the TRAI issued recommendations in September 2017 "Introduction of UL (Virtual Network Operator, "VNO") for Access Service Authorization for Category B License with Districts of a State as a Service Area," wherein it has recognized the issue of double taxation in the VNO license and has recommended DoT to review the AGR components to allow deduction of charges paid by VNOs to Network Service Operators for procurement of services to be allowed as a pass-through expense. We urge the USTR to impress upon DoT to consider such recommendations in the context of all relevant categories of licenses.

Encryption

The freedom of business and consumers in India to use strong encryption protects their corporate and personal information. Strong encryption also enables India's rapidly growing IT and business processing industries to secure their global clients' confidential information. The Government of India should be urged to more appropriately reflect the needs of next generation data and IP services providers and the considerations of their business enterprise customers by allowing for the robust use of encryption to protect data and privacy. At the time of this submission, USCIB understands that the Ministry of Electronics and Information Technology is in the process of preparing a draft encryption policy for consultation with industry. In developing its encryption policy, the Government of India must recognize the need to distinguish enterprise services from consumer services USCIB opposes any effort to weaken or limit the effectiveness of commercial encryption technologies that are essential to modern business. We encourage the Government of India to work with the U.S. and other governments to share best practices in this area.

Cybersecurity is a true common cause, as industry shares many risks and objectives with governments, users, and other stakeholders. The breadth of cybersecurity threats is vast; from cyber terrorism to online safety and conventional cybercrimes. A key component in strengthening networks against cybersecurity threats is strong encryption. So that businesses may employ the measures to reasonably protect information, a critical component of India's updated encryption policy must include updating the permissible level of encryption for enterprise services beyond the current 40-bit level. Businesses must instead be permitted to apply encryption consistent with industry standard guidelines, such as the Advanced Encryption Standard (AES).

USCIB requests USTR to urge India to recognize that it is essential that enterprise services providers be permitted to offer and provide network services that employ more robust encryption to allow business customers to better secure customers' networks and communications from cyber threats. The current encryption limitation reduces the ability of business customers to apply industry-standard encryption to network services to help defend against cybersecurity threats, which are increasing in volume and sophistication at exponential rates. Moreover, the government should support the use of internationally-accepted encryption standards and algorithms, rather than those mandated by the government.

New National Telecom Policy – 2018

As India moves forward with reviewing its National Telecom Policy, we encourage it do develop a framework that is flexible and balanced to ensure the future growth of new and emerging data services. Any new licensing regime should be future proof, technology neutral, forward looking and flexible to adapt to new technologies, new services and platforms, while embracing global best practices.

FDI in Business-to-Consumer e-Commerce:

E-Commerce models must be allowed to enable small and medium businesses across the country to reach national and global consumers. However, foreign direct investment (FDI) in business-to-consumer e-commerce is still restricted in India. In order to facilitate e-commerce in India, the government should allow at least 51 percent FDI in e-commerce —and ultimately 100 percent.

Restrictions on the Import of used and refurbished ICT and medical device component parts:

In July of 2015, the Indian Ministry of Environment, Forest and Climate Change (MoEFCC) issued a rule banning the importation of used ICT and medical device parts and equipment. The Ministry justified this ban by stating that these imported products constitute "E-Waste", a ruling which grossly mis-classifies these products. U.S. companies import spare and refurbished parts to service and repair installed ICT and medical device equipment. By banning the importation of these parts, MoEFCC is severely disrupting the ability of multinational companies to service customer equipment and meet basic warranty obligations. After intensive international lobbying, in September, MoEFCC reversed this import ban. However, the Ministry continues to require companies to apply for individual licenses to import this equipment creating a burdensome regulatory approval process for USCIB companies.

Compulsory Registration Order for ICT Products

Of significant concern to the tech industry in India is the Compulsory Registration Order which requires most ICT equipment to be tested and certified in India for safety, regardless of whether it had already been certified in other countries. This measure is blatantly inconsistent with international norms and provides no utility to Indian consumers. Double testing ICT equipment is not necessary for helping India meet its regulatory objectives and is incredibly costly to U.S. firms. We request that the U.S. government reflect the state of play on this issue in 2016 NTE in order to urge India to bring its testing and certification regime in line with international norms.

Procedure for Certification of Telecommunications Equipment
In 2017, the Department of Telecommunications issued new, draft requirements for in-country testing and certification of certain ICT equipment (Department of Telecommunication's "Procedure for Certification of Telecommunications Equipment"). Similar to other testing regimes noted in this submission, these new requirements would require redundant and costly in-country testing for any company seeking to sell ICT products in India. These new requirements are separate from and in addition to the Compulsory Registration Order and the 2011 Telecom License Amendments.

If the *Procedure for Certification of Telecommunications Equipment* is implemented, USCIB members will face three distinct testing requirements that deviate from international norms and serve as significant market access barriers: (1) Compulsory Registration Order for safety testing; (2) telecommunications security testing under the 2011 Telecom License Amendments; and (3) the Department of Telecommunication's Procedure for Certification of Telecommunications Equipment.

Intellectual Property

USCIB supports the Government of India's efforts to strengthen the innovation ecosystem and IP legislative and regulatory environment in the country. The National IPR Policy ("the policy") addresses a comprehensive range of objectives, from raising awareness on the benefits of intellectual property to strengthening the country's

legal, administrative and enforcement capabilities. Overall, the National IPR policy acknowledges the importance of IP as a driver of economic growth and articulates the aspirations of the Indian Government in calling for educational programs aimed at building awareness on the importance of IP to India. However, in practice, the policy lacks specificity with respect to inter-ministerial coordination on implementation, budget allocation, and does not address some of the most important outstanding IP policy issues including with respect to Section 3(d)'s enhanced efficacy requirements for pharmaceutical patents. We hope that the policy will serve as a platform for continued engagement and enhanced dialogue with the Indian government towards more concrete legislative, regulatory and related reforms to address pharmaceutical IP issues – for example, with respect to clarifying Section 3(d) of India's patent law, providing for early resolution of patent disputes, and simplifying administrative requirements.

Food – Product Approvals

The Supreme Court of India upheld a court ruling striking down India's food safety agency's (FSSAI) product approvals process. We remain concerned about the status of products with pending applications and how India intends to proceed after the Supreme Court's ruling. The United States should encourage India to adhere to international standards and scientific evidence for ingredient safety approvals, rather than requirement product-by-product approval. In general, we are very concerned by India's frequent failure to notify regulations to the WTO and its non-science-based approach to processed food regulations.

Batch-by-Batch Import Testing

Some USCIB members and their suppliers continue to face market access challenges due to the FSSAI batch-by-batch inspection requirements at the port of entry. These requirements often result in costly delays at the port, even for low risk products and products like food additives that will almost always undergo further processing. We support the planned transition to a risk-based imported food inspection protocol and encourage the U.S. to continue to work with India to speed this transition.

Food Additives

FSSAI has initiated updates to its food additive regulations, including standards for use and specifications. In many cases, FSSAI has opted to adopt or omit standards for additives that are inconsistent with the Codex Alimentarius General Standard for Food Additives (Codex Stan 192-1995). Furthermore, FSSAI has included food additive specifications in its regulation that are inconsistent with specifications promulgated by the Joint Expert Committee on Food Additives (JECFA) and other reference texts that list food additive specifications like the Food Chemicals Codex (FCC).

Taxation

USCIB members are also concerned about India's recent vote on an "equalization levy," aimed at creating an additional 6 percent withholding tax on foreign online advertising platforms. While this levy was introduced with the ostensible goal of "equalizing the playing field" between resident service providers and non-resident service providers, one significant problem is that its provisions do not provide credit for tax paid in other countries for the service provided in India. Another problem is that this levy will result in taxes on business income even when a foreign resident does not have a permanent establishment in India, and even when underlying activities are not carried out in India, in violation of Articles 5 and 7 of the US-India tax treaty.

The current structure of the equalization levy represents a shift from internationally accepted principles, which

provide that digital taxation mechanisms should be developed on a multilateral basis in order to prevent double taxation. This levy is likely to impede foreign trade and increase the risk of retaliation from other countries where Indian companies are doing business. In addition, there is a risk that the levy will be extended more broadly to cover a broader range of foreign e-commerce services. We urge USTR to recognize that this levy may serve as a market access barrier for foreign services, and engage with counterparts in India to develop taxation principles that are consistent with global best practices.

Drug Pricing & Reimbursement, and Procurement

The Indian National Pharmaceutical Pricing Authority (NPPA) has announced the new ceiling prices of 761 essential pharmaceuticals after removing the excise duty on them, ahead of the rollout of the new goods and services tax. NPPA seeks to regulate the prices of drugs on an ever-expanding National List of Essential Medicines (NLEM) for which it lacks market data. Expansion of the NLEM would result in price controls on non-scheduled drugs including patented products. This could be the first step in a broader price control regime for patented products.

Also, in a draft pharmaceutical policy proposal currently under consideration, the Government of India has proposed that formulations made from indigenously produced API in India and its intermediates be given preference in government procurement processes.

Privacy and Data Protection

We are encouraged that TRAI's recommendation with respect to Cloud Computing services refers to the importance of adopting globally accepted data protection principles as was stated in the Planning Commission's Report to the Group of Experts on Privacy in 2012. India currently does not have a specific legislation on Privacy. Pursuant to a judgement by the apex court making Right to Privacy a fundamental right, Government of India is in the process of enacting a specific legislation. An expert committee within the Information Technology (IT) ministry has been set up in this respect. In parallel, TRAI has also initiated a consultation with the industry.

USCIB members will participate in these opportunities by providing specific and international best practices. We urge USTR to strongly encourage the Government of India to work on a collaborative process and evolve a policy which emphasizes the free flow of data, identifies different stakeholders in the matter, and embraces norms which facilitate trade and commerce.

India needs to avoid, and where necessary eliminate, barriers to seamless cross-border data flows as well as avoid restrictive data localization requirements that adversely impact investment and innovation. It is further important that, when applying any consumer protection regulation, India distinguishes between services that are offered to individual consumers and those sold to businesses to avoid automatically extending consumer protection obligations to enterprise providers.

INDONESIA

Indonesia imposes local content requirements in the telecom sector that are not consistent with its WTO obligations and is currently considering further such requirements. The Indonesian Ministry for Communications and Information Technology issued two decrees, a wireless broadband decree and a telecommunications decree, that place restrictive local content requirements and sourcing requirements on service providers.

The “wireless broadband decree” requires local content of 30-50 percent in the wireless broadband sector. The “telecommunications decree” requires all service operators to spend 35 percent of their capital expenditures on domestically manufactured equipment. Currently, at least 40 percent of the equipment must be locally sourced, but within the next five years it is expected to increase to 50 percent. These provisions are reiterated in Article 6 of the 2011 decree on the use of the 2.3 GHz Radio Frequency Band (19/PER/M.KOMINFO/09/2011). These restrictions do not appear consistent with Indonesia’s obligations under the WTO Agreement on Trade-Related Investment Measures and may also raise concerns under Article III of the General Agreement on Tariffs and Trade (GATT). USCIB supports the actions taken by USTR in conjunction with the European Union to raise these concerns in the WTO Committee on Trade-Related Investment Measures and urges USTR to continue to press Indonesia to remove these restrictions.[28]

FDI Cap

In addition, current regulations impose a cap (ranging from 49-65 percent) on foreign ownership for telecommunication network and service providers. These foreign ownership caps present significant and often insurmountable barriers for U.S. businesses seeking to enter the Indonesian market from an operational and economic perspective. Service providers are unable to establish operational control, protect their brand, and deliver services in Indonesia that are seamlessly integrated in the service providers global network offerings. The service providers also become a horizontal competitor of the local telecom operator provider, further eroding the value of the investment. USCIB requests that USTR encourage Indonesia to remove this provision and allow foreign companies to offer services with any legally operating telecom entity they find suitable.

E-Commerce Barriers

Another important development is the Indonesian government’s issuance of Government Regulation No. 82 of 2012 on Electronic System and Transaction Operation (“GR 82/2012”), which was stipulated on October 12, 2012 and enacted on October 15, 2012. This Decree creates significant barriers to e-commerce for U.S. firms.

In particular, as USTR noted in the 2015 Section 1377 review, Article 17 of GR 82/2012 requires an Electronic System Operator (“ESO”) for public services to place a data center and disaster recovery center in Indonesia for the purpose of upholding justice, safeguarding, and upholding state sovereignty towards its citizen’s data. While the term “public services” is not defined in the bill, it is defined elsewhere in Public Services Law (Law No. 25 of 2009), despite that this is not clearly mentioned in GR 82/2012. A public services provider can be in the form of a corporation (i.e., company); however, that company must be considered carrying out “public services.” The Public Services Law provides various categories of public services activities, which are all carried out for the benefit of the public and not solely for commercial purposes. Importantly, the government is also reviewing the definition to expand it to include all services provided in Indonesia.

A local data center requirement would prevent providers from leveraging the economies of scale from existing data centers and discourage future investment in Indonesia. Furthermore, such a requirement inhibits the global data flows that are essential to e-commerce transactions. In practice, the increased costs that necessarily accompany a local data center mandate could diminish incentives to offer services in Indonesia.

Other aspects of GR 82/2012 erect significant barriers to entry, including disclosure of encryption used in

[28] *See* WTO, Committee on Trade-Related Investment Measures, Communication from the European Communities and the United States, G/TRIMS/W/61, May 8, 2009.

providing e-services and providing the encryption key to the government.

Local Content Requirements

Several other regulations are also concerning. For example, regulation 68/2015 from the Ministry of Industry imposes local content requirements on the manufacturing and development of mobile phones and communication devices. And a new regulation from the Ministry of Communications and Information Technology, No. 27 of 2015, also provides for local content requirements on LTE based Telecoms Equipment and/or Devices.

OTT

In 2016, Indonesia proposed two new regulations, one governing the provision of over-the-top (OTT) service and the other governing on the provision of e-commerce services. Both proposals contained unnecessary and burdensome data localization requirements in addition to containing provisions imposing content filtering responsibilities on companies, mandating a national payment gateway for online transactions, server localization requirements, and forced cooperation with local telecom operators offering similar services. The compliance and enforcement provisions of the OTT regulation would be difficult, imposing significant costs to both companies and the government that will ultimately hamper the development of Indonesia's digital economy. Indonesia should carefully weigh the broad economic costs of implementing these regulations and engage with industry to find a path forward that promotes growth of its digital economy.

In August 2017, Indonesia's Ministry of Communication and Information Technology (MCIT) released a new draft regulation on OTT services. Some changes have been made to the draft since the 2016 version, but issues remain requiring OTT providers to set up a permanent establishment in Indonesia, offer terms of service in Indonesian language and use Indonesia's national payment gateway.

Law on Food

Indonesia announced in October 2016 major proposed revisions to its Law on Food ("the Law"), including additional restrictions on the use of trademarked brand names, packaging, and symbols, and educational, promotional, and marketing activities for pediatric nutrition products for older infants and young children. The revisions to the Law aim to give full effect in Indonesian law to the WHO Guidance recommendations. We understand implementation of the law is imminent.

The revisions were notified in February 2017 and would impose sweeping new restrictions on the marketing, branding, advertising, labeling, and promotion of U.S. pediatric nutrition products for infants and children up to age three. The proposed restrictions raise serious WTO concerns, as they to appear to violate Indonesia's obligations under the WTO TBT, SPS, and TRIPS Agreements.

The Law would:

- Restrict the use of trademarks, including by restricting the size of master brands; prohibiting the use of trademarked brand names, icons and mascots; and requiring a different look and feel for background designs, icons, and lay-outs for pediatric nutrition products.
- Prohibit marketing and promotional activities for pediatric nutrition and dairy foods products producers by expanding the Law to cover any activities by manufacturers and distributors of such products that

“directly or indirectly” promote the use of pediatric nutrition products through the marketing, promotion, packaging, and branding of non-covered products for toddlers and young children.

- Prohibit the labeling or promotion of any pediatric nutrition products in such a way as to directly or indirectly promote designated products, including activities “to promote or create an association with a designated product.” Thus, marketing with respect to non-designated commercial child nutrition or children’s products could trigger penalties if it somehow creates an “association” with products covered under the Law.
- Prohibit educational activities relating to use and feeding, e.g. demonstrations of how to safely mix and prepare infant formula.

Taxation

Through these regulations, Indonesia has taken steps on taxation that significantly deviate from global norms, bilateral tax treaties, and WTO commitments. These steps include proposed requirements that would compel foreign services to create a permanent establishment in order to do business in Indonesia. For example, Article 4 of the regulation described above would require providers to create a local entity or permanent establishment, as well as undergo a rigorous process of registration, including first with the IT regulator (BRTI) and then with BKPM in order to establish a business entity. This process would require significant resources from online service providers, many of which are small companies that lack the necessary legal and technical resources to comply with such processes, and could have significant tax consequences that conflict with OECD multilateral principles. Furthermore, this requirement would likely violate Indonesia’s WTO commitments to allow computer and other services to be provided on a cross-border basis. USCIB urges USTR to classify these disproportionate taxation measures as market access barriers.

USCIB encourages USTR to encourage Indonesia to adopt approaches that enable cross border data flows, refrain from data localization requirements, remain technology neutral, and enable the use of global standards in a manner that supports an international, interoperable policy framework for the digital economy and that promotes foreign investment and continues promoting the scale and interoperability required for the Digital economy.

Draft Trade Bill

Indonesia’s Trade Ministry released a draft Trade Bill, which in its present state, lacks sufficient clarity and detail and could potentially give a legal basis for barriers to trade not compliant with Indonesia’s international trade commitments, especially the General Agreement on Tariffs and Trade 1994 (GATT). In particular, USCIB has concerns about lack of equal treatment for imported and domestic goods; potential restrictions or prohibitions on trade in goods; licensing, standardization and use of the Indonesian National Standard (SNI) over international standards; and provisions permitting protection of the domestic industry. Use of the draft Trade Bill in sectors such as telecommunications where development and production of equipment and services are global in nature may hinder Indonesia’s national competitiveness.

Spectrum Allocation

Finally, Indonesian regulators have allocated spectrum in a non-internationally harmonized manner to benefit domestic manufacturers. This calls into question Indonesia’s commitment to technology neutrality under the TBT Agreement. Recently, Indonesian regulators have relaxed such rules associated with the 2360 – 2390 MHz band ((19/PER/M.KOMINFO/09/2011).

Media and Entertainment barriers

Indonesia maintains a variety of barriers in its media and entertainment sectors, significantly curtailing the growth potential of this sector and limiting the legal entertainment options of its citizens. Indonesia's film law technically imposes a 60 percent screen quota for Indonesian films – a quota so impractically high that it would cripple Indonesia movie theater sector if it was ever enforced. Other policies seek to limit the import of and market for foreign films – e.g., a prohibition on dubbing imported films into local languages, a local replication requirement that has not been enforced since it is unnecessary and impractical. On the positive side, in May 2016, the Indonesian Government opened up foreign direct investment in film production, distribution, and exhibition, which should help create new opportunities and interest in this sector.

Intellectual Property

Indonesia recently passed a patent law, which contains concerning provisions which will weaken, rather than strengthen, Indonesia's intellectual property system—making the country a less attractive investment destination.

In particular, USCIB remains very concerned about implementation of measures that would:

- Narrow the scope of patentable subject matter;
- Create uncertainty by unnecessarily requiring disclosure of origin of genetic resources or traditional knowledge "related" to inventions;
- Discourage voluntary licensing of technologies;
- Provide for compulsory licensing on vague and arbitrary grounds that are inconsistent with Indonesia's international obligations.

ISRAEL

Nutrition Labeling

Israel notified the WTO in April 2017 of draft measures proposing to impose front of package nutrition labels (a red label for nutrients that exceed set levels for saturated fat, sodium, and sugar content; a green FOP label for foods yet to be determined). The notification states that these proposed requirements were modeled after similar FOP requirements implemented by Chile in June 2016. Extensive comments have been submitted by USCIB members on the above referenced Chilean requirements and remains concerned that such a labeling scheme is not based on science, deviates from international standards, unjustifiably alarms and confuses consumers, denigrates the vast majority of food and beverage products, and is unlikely to contribute meaningful improvements to public health.

JAPAN

Japan's Ministry of Finance (MoF) has proposed that the country's "price-maintenance premium" for patented treatments be eliminated. In addition, Japan's Central Social Insurance Medical Council (Chuikyo) has proposed removing U.S. prices from the foreign price adjustment rule, which uses the average of drug prices in the United States, United Kingdom, Germany, and France to adjust the Japanese reimbursement prices of new drugs. The removal of U.S. prices from the foreign price adjustment rule is expected to remove one element in awarding a higher NHI price for new drugs in Japan, although overall, individual cases will vary depending on which pricing method is used.

KAZAKHSTAN

The Kazakh government imposes a 15% price preference in government tenders for locally produced medicines.

KOREA (Republic of Korea)

Financial Services

In order to implement its commitments related to the transfer of information under KORUS and the Korea-European Union Free Trade Agreement, Korea adopted new regulations in 2013 governing the outsourcing of data and IT facilities to allow financial institutions located in Korea to transfer data to affiliates outside Korea and to allow certain data processing and other functions to be performed in affiliates outside Korea. U.S. stakeholders raised concerns that vague guidelines and a lengthy application review period have hampered Korea's implementation of these data transfer commitments. In order to address these implementation concerns, the United States and Korea meet on a quarterly basis along with industry stakeholders to maintain thorough monitoring of Korea's implementation of the commitment. Stakeholders also raised concerns about strict new rules and enhanced penalties governing data privacy under the May 2014 Act on Promotion of Information and Communications Network Utilization and Information Protection.

Further strides were made by Korea in 2015 to address the concerns of the USG and private sector. A new regulation improved the environment to offshore and process data, however, implementation is still underway and is not yet fully compliant with the KORUS obligation. The United States must continue to monitor Korea's implementation of the new regulation and continue to work to ensure that KORUS commitments are fully implemented in practice.

Media and Entertainment

Korea maintains regulatory restrictions on local advertising and local language dubbing for retransmitted foreign channels, and prohibits foreign retransmitted channels from carrying ads for the Korean market. These provisions unnecessarily interfere with foreign access to Korea's television market.

Cloud Computing

The Cloud Computing Promotion Act was passed in 2015 but significant blockers still exist to the adoption of public cloud services, especially those that are provided from offshore locations. Under government procurement policies, all public-sector agencies are required: (a) to ensure that server, network, security equipment they procure are physically separated from cloud computing services consumed by general users; and (b) ensure that only specific encryption algorithms that are recognized locally are used in IT products that incorporate encryption technology. These government policies effectively favor local IT providers to the detriment of foreign service providers. Furthermore, in the healthcare sector, medical records must remain onshore and backup systems need to be physically segregated from other systems that process patient data.

Patent Enforcement

In September 2016, the Korean Intellectual Property Trial and Appeal Board issued a decision, affirmed by the Korean Patent Court, related to the scope of patent term extensions which has the potential to undermine patent term extensions because they can now be circumvented by companies introducing follow-on products containing a slightly modified active ingredients during the PTE Period rendered on September 2016 and Patent

Court Decision. These decisions may discourage bringing innovative medicines to Korea and create disharmony with the Korea-US FTA and the Korea-EU FTA.

Drug Pricing & Reimbursement

Since the Positive Listing System (PLS) was introduced in 2007, the reimbursement prices of new drugs have reached new lows, less than half of the average OECD price for new drugs. In turn, these unsustainably low prices for existing drug prices are referenced in setting prices for new medicines in Korea. Moreover, it is difficult for a new drug to be listed under Korea's pharmaco- economic (PE) evaluation given the current comparator selection criteria, which inappropriately reference generics. As a consequence, the ratio of medicines listed under PE evaluation has been significantly lower in recent years; out of 209 submissions, only 14% achieved a price premium and 31% failed to be listed after the price negotiation.

LATIN AMERICA

Signal Theft

The unauthorized use of encrypted television signals is a widespread practice in Latin America. Such practice distorts competition, affects existing U.S. investments in the region and restrains new entrants from accessing the market.

Pay-TV operators in Latin America have to compete against illegal or informal providers that offer services at predatory prices or even for free. Such providers do not pay taxes, do not comply with regulatory licensing regimes and requirements, do not pay for the content they illegally retransmit and do not offer installation, support or warranty services. Therefore, any revenue derived from the business represents positive margins, which are a significant competitive advantage and permits them to set artificial low prices that a law-abiding operator could never match.

Governments in Latin America are well aware of the problem, yet they fail to take measures that effectively stabilize competition and regulate informal service providers. This creates a barrier to market access and harms U.S. investment in the region.

Signal theft equipment (which are the devices used to decrypt encrypted pay-TV signals) cost between US$80-130 and are sold online or in large retail stores. Once such equipment is acquired, the user is able to access an average of 200 pay-TV signals illegally and no longer needs to pay a monthly subscription fee[29]. Most Latin American countries have laws prohibiting the commercialization of equipment that decrypts encrypted signals, yet the practice is generally tolerated and insufficiently enforced by the local governments.

The Organization of American States (OAS), through its telecommunications advisory body (CITEL), recently acknowledged that "subscription satellite television has been negatively affected" by the widespread use of signal theft devices "to the extent of putting its future development at risk". CITEL has urged its member states to "set forth provisions to prevent importation, marketing and use" of such signal theft devices.[30]

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[29] See, for example, Decos Chile's webpage, available at http://www.decoschile.com/, last accessed August 27, 2015. Decos Chile offers and sells online signal theft devices in Chile at an average price of US$100 and announces that customers do not need to pay any monthly fees, will not be attached to subscriber agreements and can access more than 200 pay-TV signals.
[30] Available at: https://www.citel.oas.org/en/SiteAssets/PCCII/Final-Reports/P2!R-3857r1_i.pdf.

DIRECTV Latin America, a subsidiary of AT&T, has urged USTR[31] in the past to particularly engage the governments of Brazil, Colombia, Chile, Ecuador, and Paraguay to enact legislation that would specifically prohibit the theft of pay-TV signals, and to better enforce the laws already in force.

In the case of Brazil, despite important efforts made by customs to stop signal theft devices from entering into Brazil's territory, it has not yet adopted specific legislation to combat signal theft.

Colombia has not made material progress in better enforcing its own laws or implementing its trade agreement obligations to combat signal theft. Many local community cable television operators retransmit pay-TV signals without authorization. Although Colombia's television regulator has initiated a variety of enforcement actions against community cable operators, the vast majority of them continue infringing rights of content owners.

In Chile, signal theft remains a competitive threat to pay-TV operations, which lose numerous subscribers every year to "free" decoders used to steal pay-TV satellite signals. Under the U.S.-Chile FTA (2003), Chile is committed to adopt measures to sanction signal theft[32]. In compliance with such commitment, the Chilean Government proposed measures in 2013 to criminalize the sale, importation, distribution, and installation of illegal satellite devices, however, the proposal has yet to be approved by the Chilean Congress.

Paraguay continues to be the leader of legal importation of satellite decoders with pay-TV signals decryption capabilities, in South America. Such devices have also been openly available throughout the Paraguayan territory, in particular in Ciudad del Este city. Paraguay is yet to make progress in better enforcing current legislation to combat signal theft.

In Ecuador, the Intellectual Property Law from 1998 that criminalized the violation of copyright and related rights was repealed. As of February 10, 2014, with the new Criminal Integral Code, the intellectual property crime, ceased to be a typical, unlawful and culpable conduct, therefore leaving copyright owners with just administrative and civil remedies. However, the Code was amended in 2015 to ensure consistency with TRIPS.[33]

USCIB remains concerned that signal theft constrains the growth of the telecommunications and media industry in Latin America, and diminishes investment in technology and innovation across the region. USCIB urges USTR to engage Latin American countries (including Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Puerto Rico, Uruguay and Venezuela) to take the following actions:

- Enact robust laws to prohibit the importation, commercialization and use of signal theft equipment,
- Increase regulatory oversight and monitoring, strengthen civil and criminal enforcement, and
- Consider the impact of signal theft when conducting regulatory market analysis.

Delivery of Online Video Content

Traditional Pay-TV providers in Latin America, particularly in Brazil, Mexico, Argentina and Colombia, are increasingly facing competition from entities that provide or facilitate the delivery of video content via the Internet (Online Video Content service providers). Such entities typically deliver movies, television and video programming over broadband Internet connections through a customer's own device and at a lower monthly fee

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[31] See, United States Trade Representative's Special 301 Review, 2013, 2014 and 2015 submissions made by DIRECTV Latin America LLC.

[32] United States-Chile Free Trade Agreement, U.S.-Chile, art. 17.8, June 6, 2003, 42 I.L.M. 1026, available at http://www.ustr.gov/trade-agreements/free-trade-agreements/chile-fta/final-text ("U.S.-Chile FTA")

[33] http://www.wipo.int/wipolex/en/text.jsp?file_id=430857

than traditional cable and satellite Pay-TV providers do. In addition, the providers of Online Video Content services are often not subject to the same licensing and regulatory or tax regimes that historically have been imposed on traditional entertainment services providers. The costs of licensing, regulations, and taxes can impact the underlying cost of services that different competitors are able to offer to consumers.

While it is of the utmost importance for regulators to restrain from putting unnecessary restrictions on the entrance and penetration of new services that benefit consumers, it is also equally relevant to assure that traditional providers can fairly compete. Given the evolution of competition in the video content market, it would be prudent for policymakers to evaluate which of their regulations, fees, and taxes remain necessary in the contemporary competitive marketplace, and whether those necessary policies are being applied in an appropriate and consistent manner. USCIB urges USTR to encourage the governments of Brazil, Mexico, Argentina and Colombia to eliminate the unnecessary regulatory burdens imposed on traditional Pay-TV providers that are not mandated for Online Video Content service providers in order to create a fair competitive marketplace.

Performance Rights Organizations (PRO)

In most of Latin-American countries (Brazil, Argentina, Colombia, Chile, Ecuador, Peru and Uruguay particularly included) Pay-TV providers face significant pressure from performance rights societies seeking to charge certain royalties for performance rights fees allegedly due to composers and performers of musical compositions, and also, to producers, actors, directors, musicians and others whose audiovisual works are supposedly embedded in the content that Pay-TV providers offer to subscribers. The legal regimes and grounds for such fees are less well established than in the United States and it is most of the times uncertain whether or not such societies have the right to request a compensation, which are the rights they represent, and how fees are assessed in order to be reasonable, transparent and non-discriminatory. Furthermore, those entities are exempt from any control or supervision, and because of this, their compliance with the law is at least doubtful.

These entities are a significant concern for Pay-TV providers since they have been significantly growing in number without effective regulation and control and, more relevant, because a majority of them claim excessively high fees, which threatens to increase the cost of doing business in countries where they operate. For example, according to industry estimates, total contingency of PROs' claims in a country like Argentina could amount to approximately 3% of a Pay-TV provider gross income; an unreasonable burden under market standards. Taking advantage of the lack of regulation of their market activities and the fact that they have monopoly power over the rights that they say to represent, PROs are setting prices for performance rights in an arbitrary and capricious way. In Colombia, for example, the PRO SAYCO charges fees that are up to 4 times higher than those charged by comparable PROs for similar rights in the same market.

Moreover, most PROs have failed to prove which rights and right holders they represent, whether Pay-TV providers have in fact made use of the allegedly represented works and, even worse, what is the reasonableness and proportionality of the fees they expect to collect.

In Colombia, Peru, Uruguay, and Ecuador, for example, the PRO EGEDA is reluctant to disclose the authorizations it is supposed to have from right holders to pursue royalties and is not committed to deal under transparent, reasonable and non-discriminatory pricing. Fees claimed by EGEDA vary from country to country and from provider to provider in the same jurisdiction.

USCIB urges USTR to request the governments of Brazil, Argentina, Colombia, Chile, Ecuador, Peru and Uruguay to subject PROs to strict regulation and supervision, requesting them to clarify the list of right holders

and works they allegedly represent, together with the corresponding authorizations to do so and to set market-based, transparent and non-discriminatory fees for all Pay-TV providers.

MALAYSIA

Financial Services

In 2013, Malaysia adopted a screening mechanism for the financial sector. The screen, known as the Best Interests of Malaysia test, gives the Malaysian financial services regulator, Bank Negara Malaysia unfettered and unchallengeable discretion to restrict or add conditions on U.S. investments in the Malaysian financial services sector. The "Best Interests of Malaysia" test, is highly subjective and applies to all investments in the financial services sector (e.g., banking and insurance). The criteria for evaluation under the "Best Interests" screen are vague, and not subject to review. Moreover, the 2013 Act provides the Malaysian financial services sector regulator (Bank Negara Malaysia, BNM) unfettered authority to impose whatever limitations BNM sees fit pursuant to the Best Interests screen, including equity caps.

Media and Entertainment Services

Malaysia undertook a number of important market-opening commitments in TPP. Once that agreement is in full effect, Malaysia's media and entertainment market will be largely open to providers from TPP countries. Until Malaysia makes the changes necessary to implement TPP, however, it maintains a variety of laws and regulations that limit the size of this sector and discriminate against foreign providers. Malaysia maintains a quota on free over-the-air broadcast TV of 70-80 percent local content, including no foreign content during primetime. Malaysia's cinema entertainment tax is at an effective rate of up to 31 percent, among the highest in the world, limiting the growth of the theatrical industry. Malaysia imposes limits on foreign investment in a variety of media and entertainment sectors, limiting capital inflows and business opportunities in these sectors.

Cross Border Dataflows

The government requires medical records to be kept within the premises of local healthcare institutions, which effectively amounts to a data localization policy.

Intellectual Property

In a move to increase access to Gilead's hepatitis C treatment, the Malaysian Ministry of Health issued a press release on September 20, 2017 stating that the Cabinet has approved the use of Rights of Government under the Patent Act by exploiting the patented invention of sofosbuvir (Sovaldi). This decision undermines the incentives provided by the IP system and is not a sustainable solution to the access problem or the healthcare challenges faced in Malaysia.

MEXICO

On July 18, 2016, President Peña Nieto enacted legislation that includes several reforms to the National Anticorruption System. The central purpose of these reforms is to tackle one of the most criticized issues of the current administration, through transparency, accountability, property and financial background checks.

As part of the reforms, Mexico has approved the General Law of Administrative Responsibilities ("GLAR"). This law establishes that serious administrative offenses derived from private party activities will include:

bribery, illegal participation in administrative procedures, use of false information, conspiracy, wrongful use of public resources, and wrongful recruitment of ex-public servants. The reforms also establish obligations for public officers to fully disclose their asset declaration, and compels private companies to establish internal "integrity" policies.

The GLAR also establishes coordination mechanisms at the three government levels, for prevention, investigation and corruption activities. A Civil Committee will be created to oversee policy proposals, methodologies, indicators and evaluation of the National Anticorruption System.

Drug Registries announcements

On June 19th, the Mexican Federal Commission for the Protection Against Sanitary Risk (COFEPRIS) announced measures to streamline the process for securing marketing authorization for medicines, starting in September 2016. One of the initiatives entails the partial acceptance of dossiers in English in order to facilitate the marketing process for international firms. The exemption will apply to three of the five sections included in the dossier, related to pre-clinical and clinical trials.

From July 22, 2016, COFEPRIS agreed to recognize foreign Good Manufacturing Practices (GMP) from authorized sanitary authorities valid for foreign manufactured drugs, and for registry renewals. Approved foreign sanitary authorities include: FDA (US), Health Canada, TGA (Australia), EMA (UE), Swissmedic (Switzerland), ANVISA (Brazil), MHLW (Japan), and MFDS (KOREA). As a part of the announcement, COFEPRIS proposed a new strategy for extending renewals of drug registries. The proposal allows for modifications and two 5-year term extensions for registries. It also simplifies the process and promises review within 45 days after the extension renewal is submitted.

Drug Patent Enforcement

There have been concerning developments regarding Mexico's regulatory agency, COFEPRIS, granting marketing authorization for entry of products for which a valid patent exists. This undermines company confidence in the IP system in Mexico and impedes companies' ability to do business in Mexico.

Special Economic Zones

On July 2, 2016, the Federal Government enacted new regulations for the Federal Law of Economic Special Zones, which creates a new Federal Authority for the Development of Special Economic Zones (SEZ), with the capacity and competence to declare a SEZ. These new SEZ swill have administrative, financial, tax and customs benefits and advantages for industrial investments.

Telecommunications

Telecommunications reform has brought about new investments and improved services and reduced prices for consumers in Mexico. However, these developments are threatened by the still very high participation of the preponderant economic agent in the telecommunications sector, which remains well above 60 percent. The participation of this agent only in mobile services remains very high at levels of 70.1 per cent in mobile telephony and of 66.9 in mobile broadband. Accordingly, it is necessary to maintain and reinforce the asymmetric measures to the preponderant economic agent to promote effective competition conditions in the sector, allow the development of competitors and provide more and better services to consumers.

An important development in the last year, August 2017, has been the decision of the Supreme Court to grant the preponderant economic agent an injunction against the Federal Law of Telecommunications and Broadcasting (LFTR) voted by Congress. Article 131 of the Law establishes that competitors would not pay termination interconnection rates, in both mobile and fixed services, to the preponderant economic agent while it retains such status. The Supreme Court ruled that the power to define interconnection rates corresponds to the autonomous Federal Institute of Telecommunications (IFT) and not to Congress. The decision is not retroactive and the IFT will be defining the asymmetric interconnection rates for 2018.

The LFRT had defined a clear regulatory policy of asymmetrical interconnection rates as an essential tool to improve competition conditions in the telecommunication sector and to foster competitiveness of service providers in telecommunications for the benefit of consumers. Appropriately determined interconnection rates in a market such as Mexico's provide powerful market-based incentives, which boost competition in the short and medium terms, enhance static efficiency, and provide carrier inducements to increase tele-density.

The decision of the Supreme Court introduces a degree of legal uncertainty to the operation of the non-preponderant economic agents in the telecommunications sector since it leaves in the air perhaps the single most important provision of the regulation that explains the significant inflows of investment into the sector. These changes could affect both, businesses and customers, since the conditions under which the business models of the operators competing with the preponderant economic agent were changed. It is important to maintain the clarity and legal certainty of the structural reforms to reinforce investors' trust in Mexico and to continue attracting investment.

USCIB urges USTR to request the Mexican regulator to consider the potential negative effects on competitiveness and customer welfare when defining a new asymmetrical interconnection regime, that is unlike the one previously defined by LFTR.

Also, as explained in the previous report, contrary to the spirit of the reform, difficulties persist in the efficient deployment of the telecommunications infrastructure necessary to provide comprehensive and quality services. In particular, permits to install infrastructure such as cell sites must be obtained at a municipal level and the criteria to obtain these permits vary greatly among local governments. The IFT continues to develop a voluntary national framework for the issuing of these permits.

USTR should actively monitor the ongoing development of the national framework for the issuing permits and urge the Mexican authorities to implement it in order to secure better services for the public and new investors for the economy.

Technical Barriers to Trade

Mexico's National Commission on Efficient Energy Use (CONUEE) will be publishing NOM-029-2016 soon, and this standard, like others related to energy consumption limits, requires certain testing methods, labeling for electronic and electrical equipment that are unique for the country, and yearly verification of the certificate. International labeling imposes less burdens on international products, ensures early access to consumers, creates a certificate valid as long as the product remains the same, and eliminates an unnecessary burden to the producers and importers.
The Secretary of Economy has published a project that modifies the General Rules and Criteria on Foreign Trade, specifically number 10 of Annex 2.4.1, which considers the elimination of the exceptions for standards for electric and electronic safety, telecommunications and energy efficiency. This change applies even for products that are not destined for commercialization. This change creates a trade barrier, as it will require the

certificates to comply with the NOM even when the products are new and are being imported for the process of testing and certification, or for service parts that are never sold separately. This change will affect market entry and consumer service.

Administrative Procedures and Customs Practices

Mexico's tax authority, the *Servicio de Administración Tributaria* (SAT) issued an amended version of the Customs Law Rules (reglamento de la ley aduanera) on April 20, 2015, ostensibly to harmonize its terminology and regulatory definitions with the Customs Law, while including new documentary requirements. The most significant change resides in Article 81, which establishes the "requirement for an Importer of Record to provide documented support on the valuation of imported merchandise to the Mexican customs broker." Documents must be available at the time of importation to be provided to customs upon request. As written, the article makes importing cumbersome, and sometimes impossible, as it asks for documents that are usually issued after the article is imported, or are confidential, or non-existent. The enforcement of this requirement has been delayed five times.

The SAT's practice of creating regulations without private sector input, by relying on a provision of Mexican law that does not require public comment on fiscal-related regulations, has led to several regulations that cannot be applied because they are impossible to implement, and are following the same path as the aforementioned Article 81.

Currently, there is a project to change rule 3.7.3 and include a new rule 3.7.35 of foreign trade. These proposed changes would increase the VAT and duty for express shipments, in addition to several new requirements, such as reporting the HS code of every product contained in an express shipment and monthly reports listing tax IDs for customers and shipment invoices. This would eliminate the possibility to import via courier with the "simplified import" figure and apply to every import where the package comes from a company to an individual or another company.

This would mean that all imports will need a Custom agent and a formal classification of merchandise, and undergo the normal import procedure for large cargo. It would apply even when the cost is minimal or there is no declared value a specific import. While the SAT maintains this is necessary to avoid technical smuggling via courier from e-commerce sites, the enforcement of this requirement would (1) create additional burdens both in time and money for all types of companies, (2) run counter to what the Mexican Government has been negotiating within the North American region on facilitating e-commerce, and (3) not address its purported objective of eliminating technical smuggling.

Maintaining a simplified imports model not only helps fuel the growth of a new sector of the Mexican economy, but also brings consumer benefits by allowing wider selection of products at the best possible prices. Mexican customs authorities should 1) ensure compliance with its national and international commitments regarding foreign trade facilitation, as expressed in the TPP and the TFA—to which Mexico recently adhered; and 2) evaluate the alternate rule proposed by courier companies. Industry requests the U.S. government include this issue in the NTE 2017 and immediately oppose these changes.

Regulation without comment or due process

The Mexican Fiscal Authority continues to regulate via instruction guidelines for the new electronic invoice system, changing the requirements and the procedures for the companies and persons subjects to them in each new version. This increases costs and procedural burdens on companies for the simple act of creating an

invoice.

MIDDLE EAST AND AFRICA

Restrictions on Voice of Internet Protocol (VoIP)

Government policies around the world that restrict or prohibit voice over Internet protocol (VoIP) and other forms of Internet telephony create obstacles to continued Internet innovation and have a negative impact on trade and investment. Since VoIP is a key application that drives broadband deployment, such prohibitions on VoIP can easily deter cross-border service deployment and negatively impact a broad range of other information flows. VoIP restrictions also effectively limit access to, and distribution of, video applications, such as video conferencing, that incorporate real-time voice traffic.

Requirements to separately engineer service deployments in line with national rules, and/or comply with *sui generis* national licensing requirements, are costly and greatly impede, deployment of VoIP and Internet telephony services to a given market.

Please consider the following country-specific examples:

- Saudi Arabia[34] policies restrict the use of VoIP by non-basic service licensees to closed user groups (CUGs) that do not allow for origination or termination of IP phone calls on the PSTN.
- Other governments restrict the provision of VoIP to a licensed operator and sometimes one that is state-owned, require VoIP providers to partner with the licensed operator, or impose onerous or restrictive licensing regimes which unnecessarily constrain trade and investment. Examples of jurisdictions with restrictions include Egypt,[35] Qatar,[36] United Arab Emirates,[37] Uzbekistan,[38] and Vietnam.[39]
- In UAE, Morocco, Saudi Arabia, and Oman, nationally controlled telecom services have consistently throttled foreign VoIP and communications services, creating significant market access barriers for US-

[34]International VoIP services are permitted to a limited extent in Saudi Arabia, and are restricted to closed user groups that may not interconnect to the PSTN. Note: Saudi Arabia confirmed on in March that it was seeking to regulate local use of popular Internet-based services such as Skype and Whatsapp, and threatened "suitable measures" if the providers of the services failed to comply with the kingdom's demands. See http://www.marketwatch.com/story/saudi-arabia-seeks-to-regulate-skype-web-services-2013-03-31

[35]There is no specific legislation for the provision of VoIP, but VoIP providers are required to have a license. Class A Internet Service Provider (ISP) licensees may offer VoIP services within closed user groups, either within a company or via virtual private networks (VPNs), and only on a PC-PC basis..

[36] VoIP is permitted in Qatar; however, it may only be provided through the two existing licensees, Ooredoo Qatar (formerly Otel) and Vodafone Qatar.

[37] VoIP is permitted in the United Arab Emirates; however, it may only be provided by, or in partnership with, the four licensed operators: Etisalat, Du and satellite companies Thuraya and Yahsat. Licensees are allowed to block unlicensed VoIP traffic on their networks.

[38] VoIP is permitted in Uzbekistan: however, services are strictly controlled by the state-owned operator Uzbektelekom (UT). There are four ISP providers offering VoIP services in the country and all are directly or indirectly owned by the UT, and UT sets high VoIP tariffs. Consequently, it is unlikely that foreign operators would be able to provide a new VoIP service in Uzbekistan under the current regulatory and market conditions. CUG VoIP would be categorized as a data transmission network service and would not be exempted from licensing requirements.

[39] VoIP is permitted in Vietnam; however, foreign companies are prohibited from providing such services. The Vietnamese Government recently passed a new Telecommunications Law which clarifies that VoIP services, including those offered on a CUG basis, are considered Internet Telephony services and categorized as a Telecommunications Value-Added Service (Telecom VAS). Pursuant to Vietnam's WTO commitment, foreign companies are not permitted to obtain a license to provide such services. Instead, foreign companies are required to enter into a joint venture with a locally licensed telecommunications service provider and cannot receive more than 65 percent of the total revenues flowing from the joint venture.

based Internet services and apps. Regulators have generally condoned these blocks. We urge USTR to classify this issue as a market access barrier and to engage directly with UAE and other countries in resolving these barriers.

- Moreover, in some instances, regulations are ambiguous or subject to government caprice. This is the case in jurisdictions such as Kuwait and Ethiopia[40] where the status of VoIP has fluctuated, but it is not generally considered to be legal.

USTR should encourage governments to permit the unrestricted use of VoIP to enable U.S. companies to gain the economies and efficiencies of global platforms, reduce the cost of doing business in foreign countries, and promote investment and vigorous information flows.

Free Trade Zones (FTZs)

According to the International Chamber of Commerce, in which USCIB serves as the U.S. National Committee, there is a great need for greater regulation and oversight of Free Trade Zones. They are especially vulnerable to facilitating counterfeiting and illicit trade. According to the ICC, "FTZs provide significant opportunities for legitimate business and play a critical role in global trade. However, the by-product of their proliferation brings increased vulnerability for abuses by criminal actors who take advantage of relaxed oversight, softened Customs controls and lack of transparency. Free Trade Zone management, in some instances, fails to enforce intellectual property rights (IPRs), thereby enabling laundering, distribution of counterfeit goods and consumer purchases of potentially unsafe products."[41]

Recent cases in the United Arab Emirates, such as Case No. 15873 of the 2006 penal and Criminal Circuit Misdemeanor Case No. 1614/2009, as well as the Kardo Case in Turkey, provide examples of the challenges that are often associated with the regulation and oversight of FTZs. We encourage USTR to look more deeply into this phenomenon and develop with its interagency colleagues, a government-wide effort to encourage trading partners to control the FTZs.

<u>Saudi Arabia</u>

- **Gulf Council Cooperation (GCC) pricing policies**

Pricing for new registrations is decided on the lowest price among a basket of 30 countries. In the last months, the Saudi FDA pricing committee went beyond this rule, requesting a further reduction. This lack of a clear price mechanism makes the market unpredictable for innovative breakthrough medicines.

- **Regulatory data protection (RDP)**

The submission of confidential test or other data for the marketing authorization of innovator drugs are protected for at least five years from the approval date. However, Saudi Arabia has not complied with its own regulation and WTO commitments. It demonstrates a lack of effective RDP in Saudi Arabia.

- **Cancellation of quantities for awarded tenders**

On January 28, 2016, the Saudi Ministry of Health issued a circular related to 2015 and 2016 tender awards. The government canceled 30 percent of the quantities that were awarded in 2015 tenders and planned to be delivered in February, and 50 percent of the quantities of the tenders of 2016 (the government has the right to increase or decrease the quantities by 30 percent). Key concerns with this issue are the predictability of the decision, as well as the unilateral move without consultation with the industry.

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[40] The legal status of VoIP is unclear and has fluctuated several times in recent years as the government simultaneously tried to limit VoIP's negative impact on the Ministry of Communications' (MoC) international call revenues, while acknowledging VoIP's value in driving Internet use.

[41] http://www.iccwbo.org/advocacy-codes-and-rules/bascap/international-engagement-and-advocacy/free-trade-zones/

- **Offset requirement condition**

Saudi Arabia inserted a new requirement called "offset requirement" in one of the most important national tenders in January 2016. For all Saudi pharmaceutical tenders equal to or greater than SAR 400 million,[42] the winning bidder must invest a minimum of 40 percent of the total value of the bid in Saudi Arabia. This requirement is detrimental to attracting innovative pharmaceutical investment to Saudi Arabia.

- **Drug Patent Enforcement**

The Saudi government has granted approval to a local generic manufacturer to produce a product while a valid patent is in place and the Saudi FDA has also granted marketing approval for a local generic product during the regulatory data protection term of an innovative product in reliance on the innovator's data.

Jordan

- **Local preference in government tenders**

The government is not willing to sign the Government Procurement Agreement, resulting in the preferential treatment to locally-produced generic products and affecting MNCs in government tenders.

- **Burdensome regulatory and pricing policies**

The implementation of regulatory policies, bureaucratic procedures and frequent price revision has a negative impact on the registration of novel products and limits the availability of registered products.

- **Innovative industry representation in the Higher Council for Drugs**

The request for representation aims to improve policy dialogue on best practices with the government.

- **Regulatory Data Protection (RDP)**

Health authorities have consciously taken steps to weaken their RDP regime, and continue to deny RDP to new indications. Jordan requires the MA application of a new medicine to be filed within 18 months from the first worldwide regulatory approval in order to be considered as a "new chemical entity" and, thus, eligible for RDP. If it is not so filed, a generic version of that medicine can be approved. Meeting the 18-month deadline is complicated by a series of regulatory requirements established by the JFDA.

- **Drug Pricing & Reimbursement**

In April 2017, the JFDA decreased the prices of 639 drugs 2016 by 10% bringing total price decreases since 2016 to 81%. The price cuts targeted medicines in therapeutic areas including hypertension, diabetes, antibiotics, and mental health. Some of the price reductions were triggered by a decrease in prices in reference countries or nations of origin. Jordan has about 16 reference countries used for pricing drugs. Jordanian law obliges pharma companies to announce any changes to drug prices in the country of origin. The country is also one of the leading exporters of pharmaceuticals in the Middle East. About 80% of Jordan's pharmaceutical production is exported, with an estimated value of USD670 million.

Iran

- **Localization**

In Iran, there is a strong government preference for in-country manufacturers for tenders which effectively closes out MNC participation.

Iraq

- **Counterfeit Pharmaceuticals**

The situation of counterfeits worsened via parallel trade, which is not clearly or transparently regulated.

- **Pharmaceutical product licensing**

The registration process is non-transparent, and guidelines on assessing new submissions are ambiguous. Pharmaceutical companies receive irrational and excessive requests for documentation, beyond the international

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[42] 1 SAR, Saudi Riyal = 0.27 USD

norms, making the registration process long. Also, the law requires the molecule to be listed in the national formulary, in order to be considered for registration. However, the formulary listing has no clarity on criteria.

Algeria

- **Pharmaceutical Pricing**

The process for setting prices is not transparent and does not provide for any specific appeal system. Algeria has implemented policies to control prices: (1) products that have corresponding generics on the Algerian market are subject to reference pricing for reimbursement; (2) some patented products with no generic equivalent on the market have been referenced against generics deemed to be in the same therapeutic class; and (3) imported, patented products are subject to international reference pricing. This poses new issues to pharmaceutical companies. Due to delays in pricing approvals, combined with new international pricing benchmark, the pricing review for products is often delayed. Additionally, a 25% preferential price is afforded to domestic bidders in public procurement contracts.

- **Regulatory delays**

The registration process is slow and additional, burdensome requirements for obtaining registration to market pharmaceutical innovative products have been implemented. Also, local manufacturers receive preferred treatment, affecting patient access to innovative medicines.

- **Intellectual property**

Algeria has inadequate patent protection, ineffective mechanisms to enforce patents, and does not grant RDP. A generic copy of a product covered by an Algerian patent may be granted MA while the patent on the original product is still in effect. This puts the originator in an unfair position with no possibility to defend its rights.

Morocco

- **Discriminatory pharmaceutical pricing policies**

The price for a drug is picked based on the lowest price out of 7 reference countries: France, Portugal, Spain, Belgium, Saudi Arabia, Turkey and the country of origin (COO). Since Morocco doesn't have the same sales or medical coverage as in these countries, it is not possible to compensate for the low price.

- **Marketing authorization (MA)**

MA is granted only to companies that have a manufacturing site in Morocco. This law is problematic for many MNCs as they do not hold all the rights to their products (the MA is owned by a third party, in general a local manufacturer). This means that if a MNC wants to do business in Morocco but does not have a manufacturing plant in the country, it needs to make an agreement with a local company.

- **Lack of regulatory data protection**

Morocco does not provide effective RDP. A new Decree on MA, requiring the Office of Drug and Pharmacy at the Health Ministry to implement effective RDP in Morocco, is therefore needed.

Tunisia

- **Government pricing restrictions**

A price for a pharmaceutical product is based on prices of the registered product in the COO; and prices of other products deemed to be in the same therapeutic class. In addition, health authorities impose a discount of a minimum of 12.5 percent compared to the price in the COO. In some cases, the authorities are requesting additional price reductions of up to 50 percent. The criteria for these requests are not clear nor based in legislation, creating a highly unpredictable environment for the marketing of new medicines.

- **Lack of regulatory data protection (RDP)**

Tunisia has not complied with its own law and international obligations to provide RDP for pharmaceutical product marketing approval, except for products that are already protected in their COO and when their companies have already submitted a request to protect the patent in Tunisia.

Egypt

- **Pharmaceutical Pricing**

Government pricing is not clear, fair nor transparent. There is a need for pricing policies that enhance timely access to treatment, based on transparency and predictability and consistent with international trade agreements.

- **Intellectual property**

Egypt does not have patent linkage system allowing the Ministry of Health to grant regulatory approval for copies of innovator products that still have a valid patent. Egypt also lacks RDP and effective patent enforcement. This allows local manufacturers to obtain MA for generic products prior to the expiration of the patent of the originator. Accordingly, there is a need for stronger IP protection.

THE NETHERLANDS

In December 2016, VWS published an amendment to its existing "lock" system whereby high-cost medicines would be identified through horizon scanning and defined as those (a) over €40 million per year or (b) over €50,000 per treatment and over €10 million per year. A drug placed in the "lock" would be temporarily ineligible for reimbursement pending positive economic assessment and successful price negotiation with the manufacturer – although its manufacturer would be able to opt to provide the drug free-of-charge to patients during the lock period. Since its inception, the mechanism has been applied to about 19 "high-cost" medicine products (including five in 2016) across various indications. The amendments likely mean that more medicines will be subjected to this procedure in future, thereby subjecting patients to delayed access.

NEW ZEALAND

Encryption

The government recently relaxed its policy on the use of office productivity policy cloud services hosted outside of New Zealand. However, they are now considering imposing a condition that, in order to use such services, government agencies must "*ensure that data is encrypted both in transit and at rest, and that agencies have sole control over the associated cryptographic key*"[43] This condition, if adopted, would appear to be inconsistent with New Zealand's future TPP obligations.

Drug Pricing & Reimbursement

Though not explicitly stated, PHARMAC's reimbursement decisions suggest a pharmaceutical must achieve a cost per QALY (quality adjusted life year) of less than NZ$10,000 to NZ$15,000 to be considered cost effective. This is despite public spending in other areas of health proceeding at up to NZ$100,000 per QALY. This approach, combined with the need to stay within a capped budget, means that many of the most effective medicines are not available to New Zealand's patients. A recent study found that between 2009-2014, 88% of new medicines available in Australia were not available in New Zealand. Almost 10% of these medicines are for diseases with no current treatment available in New Zealand. In 2014, Australia listed 17 new medicines on the Pharmaceutical Benefit Scheme (PBS), and New Zealand listed just one. The data also showed that the timeliness of the listing in New Zealand was slower than in Australia, taking two years longer, on average, for PHARMAC to fund the same medicines compared to Australia

[43] See Cabinet paper: Accelerating the adoption of public cloud services, June 2016 (copy available at https://www.ict.govt.nz/guidance-and-resources/information-management/requirements-for-cloud-computing/)

NIGERIA

In December 2013, the Nigerian Ministry of Communication Technology issued *Guidelines for Nigerian Content Development in Information and Communications Technology (*the Guidelines). The Guidelines contain highly problematic provisions that will undermine the ability of U.S. ICT companies to compete in Nigeria's telecommunications sector, as well as other sectors of the economy that rely on telecommunications products. Among many problematic provisions, the Guidelines contain onerous local content requirements, applicable for both government and private sector procurements, for hardware, software, services and data. Moreover, the Guidelines state that failure to meet these local content requirements will result in criminal penalties for executives of multinational companies. The Guidelines run counter to Nigeria's WTO commitments.

We urge USTR to press the Nigerian government to rescind these guidelines. U.S. ICT companies stand ready to work with the Nigerian government to develop Guidelines that are based on international best practices, rely on positive incentive policies to attract investment, and do not deviate from fundamental WTO obligations.

NORWAY

Despite being the third wealthiest nation in Europe in terms of GDP per capita, patented-medicine prices are low by European standards, largely due to the impact of the international reference pricing system and other high-pressured cost containment policies. Where IRP is concerned, Norway's prices are pegged at the average of the lowest prices in three of the nine reference countries (Austria, Belgium, Denmark, Finland, Germany, Ireland, the Netherlands, Sweden and the UK). Additionally, specialty medicines are part of the LIS tendering process that are increasingly based on therapeutic tender including 'winner-takes-all' awards.

Moreover, all new medicines must now undergo HTA evaluation before inclusion in the hospital formulary. Drugs undergoing assessment at national level will not be administered in hospitals until they are recommended for reimbursement by the RHA forum and reviews are reported to take 8-12 months. With recent measures taken to strengthen the evaluation process, only the most cost-effective products will gain reimbursement and products rejected on the basis of lack of cost-effectiveness can be re-evaluated if the products in question are discounted to a level that make them acceptably cost-effective to the Norwegian government.

PERU

Price controls in the provision of Decoders for Pay TV Services

A price control attempt might be hidden under a possible new regulation on the use of Integrated Receive Decoders (IRDs) for Pay-TV services. According to the president of the Peruvian regulator, "OSIPTEL," no charge can be applied to the provision of an IRD by the pay-tv provider, or if it does, such IRD should have the ability to be integrated to the platform of another pay-tv provider.

As well as in many other businesses, in the Pay-TV market charges are applied on a consumption basis. In Pay-TV postpaid services, no charges are applied to the provision of the first IRD. However, if the subscriber has more than a single TV, he/she may want to be provided with more than a single IRD, in which case he/she will be required to pay a minimum monthly rental fee for each additional IRD that compensates its cost.

The prohibition to apply a rental fee for additional IRDs not only would negatively impact Pay-TV providers' cost structure, but would also trigger an increase on the Pay-TV service fees.

Furthermore, the prohibition of applying any sort of charge in connection with the use of an IRD may have a negative impact on the prepaid service. DIRECTV Argentina, a subsidiary of AT&T, is the only provider of satellite TV in Peru offering a prepaid service under which an eligible subscriber may purchase an IRD at almost any retail store of Peru. The prepaid service let subscribers pay by the day, without being charged monthly fees, which has turn Pay-TV more affordable for all segments of the market. USCIB urges USTR to request OSIPTEL to reconsider its proposal due to the significant costs it would impose on Pay-TV providers, the paramount consequences it will have on piracy and intellectual property rights and because it is ineffective to improve consumers' welfare.

GMO Labeling

Peru has notified the WTO of a Draft Regulation on the Labelling of Genetically Modified Foods. The draft regulation addresses "genetically modified foods" whereas USCIB members have noted the application of the term "genetically modified" may not apply to finished processed food products themselves. Finished processed foods may be derived from a genetically modified organism (GMO), contain a GMO, or contain ingredients derived from GMOs, but are not genetically modified themselves. Therefore, the definition as proposed would be potentially misleading to consumers and should be revised so that it does not give a false impression that the final food or individual ingredients are genetically modified themselves.

The proposed regulation does not establish a threshold for allowance of incidental or adventitious presence of genetically modified material (e.g., resulting from transportation and/or storage). The regulation appears to require testing to a zero threshold (e.g., to the limit of detection), which creates significant challenges and poses an undue restriction since the limit of detection is affected by testing method, type of food or ingredient, sampling process, sample size, calibration of equipment, and may even vary from laboratory to laboratory where other variables are identical.

USCIB members submitted comments urging Peru to reconsider appropriate definitions and revise the draft regulation to establish a threshold of GMO content above which products must be labeled, particularly taking into account that highly refined ingredients cannot be said to "contain" detectable GM material. Peru should establish definitions, disclosure language, and thresholds that are truthful and not misleading while establishing clear, enforceable, and effective controls. However, such controls must not overly restrict trade when products contain highly refined ingredients, have low amounts of GM material, and/or have very low levels of unintentional, adventitious genetic contamination. Given the comments in item four above, USCIB members do not believe the proposed 180-day compliance period is sufficient for manufacturers and distributors to comply with the draft regulation.

Nutrition Labeling

In May 2014, Peru notified draft regulations (G/TBT/N/PER/59) to the WTO TBT Committee which established criteria for added sugar, sodium, and saturated fat in processed food and beverages by which these products would be considered "high in" these nutrients. Multiple WTO member states and other stakeholders submitted comments requesting, among other things, more information on how the government of Peru developed these nutrient limits and justification for the departure from existing international standards, like Codex, that set guidelines for nutrient intakes in the context of an individual's total diet.

The government of Peru did not respond to these and other questions, and instead, in April 2015, issued a new regulation establishing even stricter nutrient criteria than those originally notified to the WTO. These criteria, though publicly issued by Peru's Ministry of Health, were not ultimately implemented and enforced however,

and in September 2016 the Ministry issued yet another set of criteria for added sugar, sodium and saturated fat in processed food and beverages. These criteria were notified to the WTO as a TBT measure, but once again no supporting technical information, risk assessment or other scientific justification was offered demonstrating why this latest iteration of criteria depart from international standards or how they are applicable to the Peruvian population.

Since the definition of processed foods in this latest regulation is so broad, and the nutrition criteria so strict, many pre-packaged foods offered in Peru will likely be considered “high in” added sugar, sodium and/or saturated fat and therefore subject to additional provisions including warning labels occupying at least 10 percent of the front-of-package, and restrictions on the marketing and advertising of these products.

Specifically, the warning label must state: “High in (Sugar and/or Sodium and/or Saturated Fat): Avoid Excessive consumption.”

The WTO TBT Agreement calls on member states to ensure that technical regulations be “no more trade restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create.” WTO Members are required to assess those risks on the basis of “available scientific and technical information.” Peru provides no scientific support for the criteria proposed in the regulation, and no justification for the departure from existing Codex standards, including Codex General Guidelines on Claims (CAC/GL 1-1979) which prohibits claims on labels which “could arouse or exploit fear in the consumer,” and Codex Guidelines for Nutrition and Health Claims (CAC/GL 23-1997) stating “health claims must be based on current relevant scientific substantiation and the level of proof must be sufficient to substantiate the type of claimed effect and the relationship to health as recognized by generally accepted scientific review of the data and the scientific substantiation should be reviewed as new knowledge becomes available.”

In August 2017, the Ministry of Health in Peru published its draft “warnings” manual (in Spanish only) to implement its 2013 Healthy Eating Law, opening a 90-day consultation period. It appears that these proposed regulations are adopting the Chilean-style stop sign approach, while also requiring warning labels on all corresponding product advertisements. USCIB members request that Peru notify this warning manual to the WTO.

In August 2016, some members of Peru’s Congress sought to renew a compulsory licensing petition through legislation (Bill 275/2016). The bill did not demonstrate a legitimate public interest in issuing a compulsory license.

PHILIPPINES

Local Ownership Requirements

Pursuant to the Philippine Constitution and Foreign Investments Act, telecom operators in the Philippines must be at least 60 percent Filipino-owned. These regulations result in significant barriers to entry for foreign telecom services wishing to do business in the Philippines.

Similarly, Philippines prohibits foreign investment in mass media, including the payTV and broadcasting sectors. These restrictions impede capital inflows, limit the choices available to Philippine consumers, and inhibit the growth of these sectors in the Philippines.

Government Procurement Restrictions on Cloud Services

In September 2014, the government released a draft administrative order that appears to require government agencies to procure cloud services from the Government cloud, and only where this is not possible will they be permitted to purchase commercial cloud services. Such restrictions could prevent Philippine government agencies from accessing best-in-class cloud services. This is further aggravated by government procurement preferences that generally favor local companies and locally produced materials and supplies

Licensing Restrictions on Cloud Services

Telecommunications regulators have sometimes interpreted existing regulations to mean that cloud service providers are required to obtain a Valued Added Telecom Services license, which is open only to Filipino companies. The requirement has not been consistently enforced, but if it were, it could severely limit overseas companies' ability to provide cloud services in the Philippines.

Financial Services

The Philippines continues to require mandatory lending to the agricultural and agrarian reform sectors under the Republic Act No. 10000, which requires banks to lend 25 percent of their loanable funds to the agricultural and agrarian reform sectors. Mandated lending should be eliminated in the Philippines as has been done in Indonesia and Thailand. Foreign banks face difficulties in complying with the law due access to these sectors, and infrastructure (e.g. limits on branching capability). The practice of mandated lending has been abandoned in Indonesia and Thailand.

Taxation

The Philippines maintains an array of taxes on film distribution, which collectively make for an oppressive tax regime curtailing economic activity in the film distribution sector – including 30 percent income tax on net profits, 5 percent withholding tax on net receipts, 10 percent tax on distributor's share of box office, duties on prints and trailer imports, tax on advertising materials, tax on royalty remittances.

ROMANIA

Romania has introduced new draft pricing legislation (the 3rd in only 6 months), which includes that the marketing authorization holder should submit a statement for each product indicating the patent expiry dates of the compound patents and use patents covering approved indications together with the price dossier.

RUSSIA

Data Storage Requirements

On September 1, 2015, Russian Federal Law No. 242-FZ went into effect and threatens to have serious consequences on trade and investment. This law requires any company collecting personal data of Russian citizens through automated/computerized means to store and process the data on Russian territory. The law would impact a broad range of industries. Based on the first guidance that came from the regulator, non-Russian companies would be allowed to send data outside the country as long as it was collected with the use of local infrastructure in Russia and remains stored and processed on that infrastructure. That obligation means that, in practice, companies operating in Russia and dealing with individuals will be forced to place their servers within

Russia if they plan to continue doing business in the market. In the case that a company does not comply, Roskomnadzor will require carriers to restrict access to those services following a court decision establishing the violation. In case of a restrictive interpretation of the law, current frameworks on cross-border data transfers would be under scrutiny with a huge impact on companies doing business in Russia and their customers and users.

On July 6, 2016, Federal Law No 374-FZ was signed into law and, like the above law, also is likely to have a significant impact on investment and trade in Russia. This law provides certain Russian authorities with information access rights. It also requires (i) Communication Providers and (ii) Internet Organizers to retain, in Russia, "metadata" as well "contents of a communication" sent through their services. The Law further requires Internet Organizers to provide the Russian authorities decoding information necessary to decrypt Internet communications.

Companies will be required to store huge quantities of data to comply with this new law. Furthermore, the process of retaining such data and complying with the decryption requirement will likely be complex. Accordingly, these obligations will likely impose significant cost and resource burdens on Communication Providers and Internet Organizers, which will likely discourage trade and investment in Russia

Pharmaceuticals

The Russian government has instituted a ban on imported medicines for government tenders if two or more products with the same INN are available from local manufacturers. There is also up to a 25% price preference for locally produced medicines in government tenders.

On December 5, 2016, the Ministry of Health put forward draft regulations to restrict identifying criteria for medicines in the state procurement process; dosage form, treatment method or other characteristics would no longer determine eligibility, only INN. This would further undermine incentives to innovate and the quality, safety and efficacy of treatments available to patients.

According to a May 26, 2016 Supreme Court ruling, Article 18.6 of the Law on the Circulation of Medicines, there are possibilities for generic companies to by-pass the legal right of originators to protect its data by relying on clinical data published abroad before the originator seeks local registration in Russia. As a result of this ruling, in late October 2016, the Ministry of Health proposed amendments to Article 18 of the Law on the Circulation of Medicines that would enshrine the court ruling. Additionally, beginning in 2016, a registration application is allowed for follow-on medicines four years after the granting of marketing authorization for a reference small molecule drug and three years after marketing authorization of a reference biologic medicine. Currently compulsory licensing is only technically permitted under article 1362 of the Civil Code, but this can only be done in the interest of national defense. Despite this, the FAS is seeking expanded compulsory licensing provisions in the interests of the nation's health, which would mean pharmaceutical companies losing their exclusive rights to certain products. A test case was filed by Russian firm Nativ, for the local production of generic versions of an innovator multiple myeloma drug.

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Regulatory Data Protection

Beginning in 2016, a registration application is allowed for follow-on medicines four years after the granting of marketing authorization for a reference small molecule drug and three years after marketing authorization of a reference biologic medicine.

SINGAPORE

There is a need for Government-industry collaboration and feedback with regards to HTA implementation in Singapore; open and transparent HTA framework with criteria/requirements well defined. The Singapore Government started HTA implementation in Singapore with focus on recommending the lowest-priced drugs available. There is no published schedule of disease review and no published information on the members of the review committee. It is therefore important for collaboration between government and industry to ensure there is consistent information being shared with regards to HTA implementation in Singapore, especially regarding criteria and requirements.

Singapore should also update patent term extension policies to compensate for clinical testing and marketing approval processes that are integral to the development of innovative medicines. Clinical trials represent an integral and indispensable part of the marketing approval process in Singapore. Many developed countries' intellectual property regimes include clinical trials when calculating patent term extension periods (e.g. European Economic Area, Switzerland, Australia, Japan USA, South Korea). It is therefore important to update patent term extension policies to compensate for clinical testing and marketing approval processes that are integral to the development of innovative medicines.

Cybersecurity

A Draft Cybersecurity Bill was issued by Singapore's Ministry of Communications and Information (MCI) and the Cyber Security Agency (CSA) in July 2017 that will be onerous and impractical for US Companies (and their employees) providing such security services at a distance in Singapore.
The proposed new licensing regime will prejudice US entities providing services in Singapore by requiring them to obtain licenses in Singapore, ensure that their employees and vendors are licensed under the new regime and add to an existing compliance burden in Singapore. The licensing regime is a violation of Article 8.8 of the Singapore FTA, which prohibits qualification requirements and procedures, technical standards and licensing requirements that constitute unnecessary barriers to trade in services. Singapore should instead pursue performance based policies that utilize existing international standards such as ISO and are proportionate to risk.

SOUTH AFRICA

Intellectual property – potential changes to legal framework for IP protection

South Africa is reviewing draft changes to its intellectual property policy. It is important that any such changes advance a strong and balanced intellectual property framework for information and communication technologies that fosters innovation and growth.

Following the publication of the Intellectual Property (IP) Consultative Framework in 2016, a draft IP Policy has since been developed by the Department of Trade and Industry (DTI) in partnership with the inter-Ministerial Committee on Intellectual Property (IMCIP). Guidelines will be introduced (including legal process

for government use) to facilitate access through compulsory licensing. USCIB encourages the South African government to ensure a balanced IP Policy that promotes innovation across all sectors and results in an enabling environment for technology transfer and investment.

Local content requirements

South Africa's Black Economic Empowerment (BEE) policies include "Equity Equivalent" provisions by which multinational companies can contribute to advancement of minority groups in lieu of explicit share set-asides. These rules include local content and manufacturing provisions that are inconsistently interpreted and applied, hindering availability of best-in-class ICT products and services in South Africa.

Media and Entertainment Sector

South Africa imposes content quotas on broadcast and pay TV sectors that limit access of its consumers to foreign TV content. At the same time, South Africa has seen a significant growth in sales of set top boxes used to bypass encryption on pay TV or to access pirated content, with little to no enforcement against this activity. These policies substantially interfere with the growth of the legitimate market in South Africa.

SPAIN

In January 2017, the Spanish Hospital Pharmacy Association (SEFH) presented a guide for the economic evaluation and budget impact of medicines in which it recommends a cost-effectiveness threshold of EUR21,000 (USD22,537) per QALY. The new threshold is substantially lower than the EUR30,000 commonly considered to be in use until now.

Spain and Portugal are both discussing the potential of jointly purchasing medicines. The objective of joint purchases would be to achieve lower prices for innovative medicines and other medicines that have a large financial impact. Categories that are under particular scrutiny include oncology, antiviral, and orphan drugs.

THAILAND

Thailand's National Broadcasting and Telecommunications Commission (the NBTC) has committed to finalizing by 2018 a governing policy on the classification of owners and operators of OTT services, which to date have been allowed to operate without a license. The intention of the policy is to have owners and operators of onshore and offshore OTT services to be subject to the same or similar regulations as traditional broadcasters and telecommunications companies, including requirements to obtain and pay for operating licenses, pay a value added tax, and be subject to stringent checks on illegal content. USCIB urges USTR to raise concerns with Thailand's moves to regulate OTT services, which often are delivered without a local presence and, should be treated with a flexible and light touch framework.

In December 2007, Thailand brought its domestic telecommunications regulatory regime, Telecommunications Business Act (TBA), into compliance with its 1997 GATS Schedule of Commitments, including a new licensing framework. The National Broadcast and Telecommunications Commission (NBTC) was created to oversee implementation of the regulations. Despite these positive steps, the new licensing framework offers limited market opportunities for U.S. telecommunications services providers in Thailand.

The existing licensing regulations provide for three types of telecommunications licenses. The Type I license is

for non-facilities-based telecommunications services and is subject to no foreign ownership restrictions. However, types of business in this category are very limited as set forth in the Telecommunications Business Act. Type II and Type III licenses restrict foreign ownership to less than half of registered capital (i.e. 49.99 percent) in companies seeking to provide advanced telecommunications services, whether facilities-based or non-facilities-based, to businesses (Closed User Groups) and consumers. At present, no large-scale telecommunications service operator in the Thai telecommunications market is wholly owned by a foreign investor.

In 2010, the NBTC has released a draft notification on business takeover by a non-Thai person. The Notification prohibits any "business takeover" of a Thai telecommunications business by a "foreigner," which is defined as allowing non-Thai persons or entities to exercise controlling power or influence, whether directly or indirectly, to formulate policy, and/or to manage or administrate important business that may affect a telecommunication business's management or operation. Under existing law, non-Thai persons and entities are already prohibited from holding a majority of shares in such a business. If this draft becomes effective, the Thai telecommunications market would be less attractive to foreign investments compared with the current regulatory regime.

In 2011, the NBTC published a Notification on August 30, 2011, in the Royal Thai Government Gazette that restricts "foreign domination" of the country's telecommunications businesses.[44] The Notification applies to all current and future telecommunications licensees and severely restricts foreign investments in Thailand's telecommunications sector. It came into full force on July 23, 2012. In particular, NBTC prohibits the following acts by non-Thai persons and entities:

- Direct or indirect shareholding by foreigners or foreigners' agents;
- Use of apparent agents;
- Holding of shares with special voting rights;
- Participation in appointing or having control over the board of directors or senior officers of the licensee;
- Any financial relationship such as having a corporate guarantee or a loan with a lower-than-market interest rate;
- Licensing or franchising;
- Management or procurement contracts;
- Joint investments (by a licensee and foreigners);
- Transactions involving transfer pricing; and
- Any other behavior which provides direct or indirect control to a foreigner over a licensee.

In October 2012, Thailand's 2100MHz 3G mobile license auction was approved by the NBTC, giving local concessions to AIS, DTAC and True. The approval was endorsed in November 2012, despite a petition made by a group of senators to the Administrative Court, alleging that the auction is illegal. Although adding 3G to the mobile market can be considered a positive step in opening up more competition, there is no change on controls imposed on foreign investors.

USTR should urge Thailand to further broaden the list of telecommunications services that can be provided by foreign carriers and eliminate the restriction on foreign ownership of telecommunications businesses. Expanding

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[44] Wendy Zeldin, Thailand: Notification Restricting Foreign Takeovers of Telecom Businesses, Library of Congress Global Legal Monitor, http://www.loc.gov/lawweb/servlet/lloc_news?disp3_l205402837_text.

market access would increase competition and stimulate new investment in the Thai telecommunications market. As is the case with China, restrictions on FDI are a significant disincentive to investment by U.S. service providers seeking to provide seamless, global services to their multinational enterprise customers.

At the 2007 ASEAN Summit, the leading countries in the region declared their strong commitment to accelerate the establishment of an ASEAN Economic Community (AEC) by 2015. The main purpose of the AEC is to make ASEAN a more dynamic and competitive economic force by making it a single market and production base by applying the principles of an open, outward-looking, inclusive, and market-driven economy. As envisioned, the single market would be based on five core elements: (1) free flow of goods; (2) free flow of services; (3) free flow of investment; (4) freer flow of capital; and (5) free flow of skilled labor.

Regarding the free flow of services, it is notable that the ASEAN member countries have so far negotiated eight packages of commitments under the ASEAN Framework Agreement on Services (AFAS). The "free flow of services" covers the liberalization of:

- Business services
- Professional services
- Construction
- Distribution
- Education
- Environmental services
- Healthcare
- Maritime transport
- Telecommunications
- Tourism

Thailand has entered into the 7th package of the AFAS, pledging commitment to allow for higher foreign equity ownership, but has not ratified the protocol itself. Regardless of whether the ratification is yet done by Thailand or not, USTR may not be directly benefited by the AFAS because this aims to make it opened for ASEAN members only. However, entering into the Thai market through other ASEAN countries may enable investors from outside ASEAN to indirectly get involved in Thailand's telecommunication businesses, if the laws of such other ASEAN countries are less restrictive.

Thailand's market entry restrictions are a significant disincentive to investment by U.S. service providers seeking to provide seamless, global services to their multinational enterprise customers. USCIB therefore urges USTR to encourage Thailand to broaden the list of telecommunications services that can be provided by foreign carriers.

Financial Services

Thailand continues to restrict foreign participation in the banking sector. Banks are limited in the number of licenses for bank branches and subsidiaries. In practice, discretion by the Bank of Thailand means little access for foreign banks. For example, foreign banks typically must acquire an existing bank to participate in the market and is limited to 25 percent ownership. The Bank of Thailand has discretion to raise the equity participation by the foreign bank. Thailand maintains restrictions on the maximum numbers of branches allowed and a subsidiary may open only 20 branches and 20 off-premise ATMs across Thailand. Thailand also restricts the number of ATMs a foreign bank branch may open to three.

Food Marketing

In November 2014, Thailand opened up for public consultation the Draft National Act on Control of Marketing of Food for Infants and Young Children and Related Products ("the Act"). Thailand finalized the act in April 2017, and it went into effect June 2017. USCIB members have serious concerns with the Act's restrictions on formula and milk products for children up to three years of age, expanding previous restrictions on formula for infants under twelve months. The Act would expand existing restrictions to cover a much broader range of promotional, advertising, educational, labeling and branding activities involving products that provide important nutrition for young children. The Act also adds criminal penalties such as imprisonment for non-compliance and establishes a committee of government and non-government representatives with non-transparent oversight and enforcement powers.

The law raises serious trade and public health concerns, as it:

- Discriminates against imported products by targeting them for these restrictions while exempting local products commonly consumed by older infants and young children;
- Ignores less trade-restrictive alternative policy measures that would better achieve Thailand's stated goal of increased breastfeeding rates; and
- Restricts the use of trademarked brand names, logos, symbols and packaging, thereby denying consumers access to important information to identify reputable products that are safe and effective and increasing the risk that counterfeit products could enter the supply chain.

The draft law diverges without scientific justification from relevant international standards, specifically those of the Codex Alimentarius, and from the World Health Organization Code of Marketing of Breast-Milk Substitutes, and it has generated concerns by leading medical societies in Thailand, including the Royal College of Pediatricians. The Act is inconsistent with Thailand's obligations under the WTO TBT and TRIPS Agreements and would deny Thai consumers and healthcare providers access to important information that would enable them to identify reputable, safe products and to make informed decisions about nutrition for young children.

TONGA

Although the Tongan government has removed its former requirement that all international traffic must pay a minimum rate of US$ 0.30, that country's major supplier, Tonga Communications Corporation ("TCC"), refuses to negotiate cost-oriented and reasonable termination rates and continues to block the circuits of U.S. carriers that refuse to accede to its unreasonable rate demands. Tonga thus continues to act in blatant violation of its recently-made WTO Reference Paper and Annex commitments to ensure that termination rates are both cost-oriented and reasonable. Additionally, Tonga's failure to prevent TCC's disruption of U.S. carrier circuits violates Tonga's Annex commitment to "ensure that service suppliers of any other WTO Member have access to and use of any public telecommunications transport network or service offered within or across the border of Tonga."[45]

Tonga joined the WTO on July 27, 2007 pursuant to commitments that it would, among other things, ensure that interconnection rates for the termination of international traffic with TCC, its major supplier carrier, are both "cost-oriented," as required by the WTO Reference Paper, and "reasonable," as required by the WTO Annex on Telecommunications.[46] Tonga also made the further Annex commitment described above that to ensure that

[45] Annex on Telecommunications, Sect. 5(b).

[46] WTO, *Report of the Working Party on the Accession of Tonga*, T/ACC/TON/17/Add.2, Dec. 13-18 2005.

carriers from WTO member countries would have access to and use of its cross-border circuits. At that time, U.S. carriers terminated international calls with TCC at rates of approximately US$ 0.13 per minute. Subsequently, under one U.S. carrier's most recent agreement with TCC, international termination rates were further reduced to approximately US$ 0.09 per minute for the period July 1, 2008 through August 31, 2008.

Notwithstanding its recent WTO commitments, the Tongan government issued a ruling on August 11, 2008 requiring all international traffic terminated in Tonga to pay a minimum rate of US$ 0.30.[47] The ruling provided no explanation or justification for the rate increase, which raised rates to more than three times the previously-negotiated level. Tonga has therefore provided no evidence that the rate increase reflects increased costs, as required by its WTO obligations. Indeed, the near-contemporaneous agreement of Tonga's major supplier, TCC, to the rate of US$ 0.09 per minute for the period July 1, 2008 through August 31, 2008 is compelling evidence that there is *no* cost justification supporting this increase.

Furthermore, on June 15, 2009, the FCC issued the Settlements Stop Payment Order on the U.S.-Tonga Route which found that the actions taken by TCC to disrupt the U.S. international networks of AT&T and Verizon, for purposes of trying to force these carriers to agree to higher termination rates, are anticompetitive and require action to protect U.S. consumers in accordance with FCC policy and precedent. The FCC Order requires that all U.S. carriers with FCC authorizations permitting the provision of facilities-based international switched voice services on the U.S.-Tonga route to suspend immediately all U.S. carriers' payments for termination services to TCC. Neither TCC nor the Tongan government have responded favorably to the FCC Order and have refused to modify the rates and exchange traffic directly with U.S. carriers. On November 16, 2009, the Federal Communications Commission extended its stop payment order to include all U.S. carrier payments for termination services to Digicel Tonga Limited. The Order remains in effect as of November 2012.

Also, as USTR reported in prior Section 1377 reports, the government of Tonga has instituted a new requirement that its carriers must pay the government US$0.051 for each minute of international incoming calls, which will maintain termination rates above cost-based levels. USCIB supports continued action by USTR to strongly press Tonga to take immediate action to ensure that TCC negotiates cost-oriented and reasonable rates in compliance with Tonga's WTO commitments and to require TCC to restore all U.S. carrier circuits.

TURKEY

As of September 2014, Article 51 of the Social Security Institute Law has been amended. According to the new wording, the Institute is entitled to demand a fee for the application to the reimbursement list and remain in the list and for any kind of amendment to the list, also it maybe charge an agreement fee, and all these fees differ between importing or local groups. Additionally, following an announcement by the Ministry of Health on July 17, 2014, imported pharmaceuticals must renew their GMP inspections every three years. The same condition does not apply to locally produced pharmaceuticals, and the GMP inspection has to be conducted by the Ministry of Health. This process generally takes a minimum of 2 years.

Data localization

Existing or draft regulations applicable to several sectors, including financial and telecommunications services, impose restrictions on the transfer or storage of data outside Turkey. This has led entities in other sectors to insist on their data being kept in-country. Such measures may disrupt entities wishing to offer or utilize cloud services from offering innovative, cloud-based services in Turkey.

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[47] Tonga Government Gazette, Aug. 11, 2008.

Protectionist measures to foster local manufacturing

The Turkish government is considering safeguard duties on ICT hardware, including tablets and mobile phones, despite the fact that the conditions required under WTO rules to use such safeguards do not appear to be present. The proposed safeguards appear to be part of a broader push to use protectionist measures to foster local manufacturing.

Pharmaceutical

In February 2017, the Social Security Institute (SSI) announced the first wave of delisting of 54 imported medicines from the reimbursement list. As over 90% of products sold in Turkey are sold through the SSI reimbursement list, exclusion from the list means effectively being excluded from operating and selling products in the Turkish market.

Additionally, the public tender law was revised to provide a mandatory 15% pricing advantage for local medium and high technology industrial products that are specified by the Ministry of Science, Industry and Technology in Turkey.

UGANDA

Uganda enacted legislation in 2013 imposing a tax of US$ 0.09 on inbound international calls. FCC international traffic reports show that U.S. carriers paid average rates to terminate international traffic in Uganda of $0.062 in 2012 and $0.075 in 2011.[48] Press reports indicate that the new tax was enacted as part of a package of measures to address the country's budget deficit.[49] The new tax is contrary to Uganda's WTO commitments under the Annex on Telecommunications requiring the provision of access to telecommunications networks and services in Uganda on reasonable terms and conditions. The tax also is contrary to Uganda's commitments under the WTO Reference Paper requiring, for the types of international services covered by Section 2.2, the provision of interconnection with major supplier carriers at cost-oriented rates.[50] The tax substantially increases international termination rates without any demonstration of increased costs and fails to provide the reasonable terms for access and use required by the Annex. USTR noted these concerns in the 2015 Section 1377 Review and USCIB encourages USTR to continue to press this issue.

UNITED ARAB EMIRATES

The United Arab Emirates' (UAE) transitioned halal oversight from the Ministry of Climate Change and Environment (MOCCAE) to the Emirates Authority for Standardization and Metrology (ESMA) June 1, 2017. At that time, ESMA had approved only one halal certifying body in the United States (Halal Transactions of Omaha). Many U.S. food manufacturers use other certifying bodies currently recognized by the UAE but not by ESMA (e.g., the Islamic Food and Nutrition Council of America, IFANCA). None of these products are able to enter the UAE after the transition to ESMA authority. In July 2017, ESMA approved an additional U.S. certifier (RACS Quality Certificates Issuing Services) but is still in the process of reviewing IFANCA for approval.

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[48] *See* FCC International Traffic Reports for 2011 & 2012 , Table A1.
[49] *See* Uganda Radio Network, Sep. 20, 2013, http://ugandaradionetwork.com/a/story.php?s=56524. S*ee also, Uganda Hikes Mobile Taxes in Wake of Corruption Scandal*, Jun. 18, 2013, http://reason.com/blog/2013/06/18/uganda-hikes-mobile-taxes-in-wake-of-cor.
[50] WTO, Uganda, Schedule of Specific Commitments, Supplement 1, GATS/SC/89/Suppl.1/Rev.1, Nov. 29, 1999.

UNITED KINGDOM

The National Institute for Health and Care Excellence (NICE) said in draft guidance that although an oncology treatment was likely to offer some improvement in overall survival, this could not be quantified from clinical trials. As such, NICE's offer was equivalent to the cost of chemotherapy 25 years ago.

In Scotland, the SMC is responsible for assessing the clinical and cost-effectiveness of new drugs and its decisions supersede those of NICE decisions. In Scotland, if a product is not expected to be cost effective under SMC's more stringent evaluation system at the UK price set by NICE then manufacturers can opt to accept a "not recommended" decision, and thereby enter into patient access schemes and other negotiations. Around 15% of medicines (154 of 1,136) have opted to accept this status.

URUGUAY

Article 56 of the new Audiovisual Media Services Law (the "Media Law") prohibits pay-TV service providers from offering any other telecommunications service (including Internet). Such line-of-business restriction does not apply to the state-owned telecommunications and IPTV provider, ANTEL, which is exempted article 1 of the Media Law.

The restriction was subsequently challenged under constitutional grounds by different industry actors, including DIRECTV Uruguay, a U.S. company and a subsidiary of AT&T. Even though all constitutional claims against such provision are based on the same legal grounds (i.e. violation of the constitutional right to Free Enterprise), the Constitutional Court surprisingly decided to uphold the prohibition in the case of DIRECTV, but overrule it in the case of two local cable providers; Montecable and Nuevo Siglo (i.e. Constitutional rulings in Uruguay are "in personam", for the benefit of plaintiffs only).

Lines-of-business limitations that are discriminatorily imposed are contrary to the national treatment, performance-requirement, and fair and equitable treatment requirements of the United States-Uruguay Bilateral Investment Treaty. The Constitutional Court decision has the effect of targeting a single provider in Uruguay.

Measures that single-out and seek to limit a specific provider are part of a general approach towards limiting foreign investors' participation in the Uruguayan telecommunications market and restricting competitive opportunities. In line with that approach, the Uruguayan government revoked America Movil's license to provide pay-TV services in the country twice already and also included a provision in the Media Law (article 106) which states that new audiovisual service licensees can no longer be an affiliate of a foreign company. DIRECTV Uruguay has been grandfathered because it has been in Uruguay for over 10 years.

USCIB urges USTR to encourage Uruguayan authorities to revoke the existing line-of-business restrictions, such as the prohibition on DIRECTV Uruguay providers to offer other telecommunications services.

Nutrition Labeling

Uruguay notified the WTO in June 2017 of draft measures proposing to impose front of package stop sign labels on foods exceeding set levels for fat, saturated fat, sodium, and sugar content. These stop sign labels are modeled on Chile's stop sign labels, about which serious concerns have been raised as they are unjustified warning statements that fail to consider total dietary intake or the amount and frequency of the food's consumption.

USCIB remains concerned that such a labeling scheme is not based on sound science, deviates from international standards, unjustifiably alarms and confuses consumers, denigrates the vast majority of food and beverage products, and is unlikely to contribute meaningful improvements to public health.

National Regulations Related to the World Health Organization's (WHO) Technical "Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children"

In May 2016, the World Health Assembly (WHA) considered but did not endorse the Guidance on Ending Inappropriate Promotion of Foods for Infants and Young Children ("the Guidance"), a "technical" report issued by the WHO Secretariat in 2016. USCIB has previously expressed concerns with the non-transparent process through which the WHO Secretariat prepared the guidance, its divergence from relevant international standards, and the lack of scientific evidence to support its recommendations.

Member governments at the WHA agreed the guidance does not represent an international standard, recognized the Codex Alimentarius as the relevant standard-setting body, and emphasized that any national implementation should be conducted in accordance with national context. Nevertheless, several countries are poised to implement or have already implemented all or parts of the Guidance, without evidence it will improve nutrition for infants and young children. The Guidance contradicts long-standing dietary guidance issued by the WHO, the UN Food and Agriculture Organization (FAO), and national governments recommending that milk, yogurt, cheese, formula milks, and other dairy products can contribute to a healthy, balanced diet for older infants and young children.

The Guidance's overly broad restrictions on marketing, branding, labeling, and promotional measures, and restrictions on the use of trademarks, interactions with health care providers, educational materials, and health care facilities for imported dairy, formulated milks, and complementary foods will not achieve the intended public health objective and are inconsistent with World Trade Organization (WTO) rules, including GATT Article III:4 and Article 2.1 of the WTO Agreement on Technical Barriers to Trade ("TBT Agreement").

VIETNAM

Foreign Investment Restrictions

In April 2011, Vietnam's Ministry of Communications issued Decree No.25/2011/ND-CP implementing the new telecommunications law to comply with its WTO commitments. While the new law purportedly complies with Vietnam's minimum WTO commitments, it still fails to allow full competition in the Vietnam market.

In particular, Decree No. 25 limits foreign investment to 49 percent for providing telecom network service, and 65 percent for value added services. USCIB applauds Vietnam for its efforts in implementing its WTO commitments, including seeking comments from the private sector, but urges USTR to encourage Vietnam to eliminate all barriers to entry, including the FDI restrictions.

OTT Services

In 2014 and 2015, Vietnam's government released two draft regulations appearing to target foreign providers of Internet services. In October 2014, the Ministry of Information and Communications released a draft "Circular on Managing the Provision and Use of Internet-based Voice and Text Services," proposing unreasonable regulatory restrictions on Over-The-Top (OTT) services. These services are VoIP and Internet Based Text Services provided over IP broadband connections, either fixed or mobile through or over the Internet. These

restrictions include requiring that foreign providers of OTT services must either install a local server to store data or enter into a commercial agreement with a Vietnam licensed telecommunications company. They also include allowing foreign providers of OTT services to place a server in Vietnam only if they cooperate with Vietnam's telecommunications companies who are licensed to provide telecommunications services in the form of OTT services in accordance with international commitments and foreign investment regulations as stipulated in the Law on Telecommunications. These restrictions are major barriers to market access for foreign OTTs that effectively prevent foreign competitors from viable entry into the supply of Internet-based services in Vietnam.

In April 2015, the Authority on Broadcasting and Electronic Information released a draft circular "On detailed regulation of cross border provision of public information." This regulation specifically targets overseas providers of some Internet services and imposes forced localization requirements, including the appointment of a "local legal representative."

Both of these draft regulations raise major concerns regarding Vietnam's compliance with its WTO commitments. They are trade-distortive and encourage anti-competitive behavior. The provisions requiring commercial agreements with a Vietnam licensed telecommunication's company and the requirement to install a local server violate several commitments Vietnam made in joining the WTO. As the provision of OTT services does not require an interconnection arrangement with a telecommunications operator, the imposition of a "commercial arrangement" with a local telecommunications service provider is unnecessary and on its face violates GATS Article VI requiring that "all measures of general application affecting trade in services are administered in a reasonable, objective and impartial manner." These provisions also violate GATS Article XIV requiring that "[s]ubject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where like conditions prevail, or a disguised restriction on trade in services." Indeed, there is no reason to require a commercial agreement between OTT providers and local telecommunications providers other than to raise costs of rivals providing service in Vietnam.

These draft regulations also are more restrictive than those listed in Vietnam's GATS schedule in 2007. While Vietnam's schedule for Internet Access Services states only that "service must be offered through commercial arrangements with an entity established in Viet Nam," the draft Circular requires foreign providers of chargeable OTT services to locate a server in Vietnam or to enter into a specified commercial agreement with a Vietnamese telecommunications company. To the extent that these restrictions represent "GATS-minus" commitments, or restrictions above and beyond those stated in Vietnam's GATS schedule only eight years ago, they are inappropriate limitations. These restrictions also have an even more burdensome impact than they would have had in 2007, given the continued development of cloud computing and other telecommunications/Internet services.

The proposed OTT Circular also violates Vietnam's commitment to provide National Treatment to foreign suppliers. These requirements specifically state that "foreign providers" without a local server shall enter into a commercial arrangement with a local telecommunications provider in order to provide service. This treatment of foreign OTT providers on its face is discriminatory as it does not apply to domestic OTT providers. Similarly, requiring a foreign OTT provider to locate a server in Vietnam in order to avoid the "commercial arrangement" with a local telecom provider is likewise discriminatory and also violates the National Treatment commitment. There is no reasonable basis to require such local servers except to raise the cost of service to a foreign competitor.

As USTR stated in the 2015 Section 1377 Review, Vietnam should reconsider the Circular and instead promote policies to encourage greater growth and competition in ICT services. USCIB urges USTR to continue to press these concerns.

Data Localization

The 2013 Decree on Internet Content ("Decree 72") requires companies that provide online gaming, social network and general website services to locate servers inside Vietnam. The rules are ambiguous with regard to other online services; implementing circulars will be required to clarify the Decree's scope.

Draft Decree on Business Licensing Requirements for Information Security Products and Services

Vietnam has issued a draft decree proposing licensing requirements for entities engaged in providing information security products and services. Given that information security services can be supplied remotely and on a global basis, it is important that Vietnam's eventual policy does not contain trade barriers that require localization requirements, either for data or local presence. We also note that these provisions would appear to contradict the commitments made by Vietnam in the Trans Pacific Partnership, specifically with respect to local presence requirements in the delivery of cross-border services and for data flows/computer facilities in the E-Commerce Chapter. Vietnam should consider aligning its approach to cybersecurity along the lines of international best practice, which creates a flexible and market driven approach based on risk management. Excessive government regulation of these services may make ultimately make it harder for Vietnam's economy to benefit from the latest cybersecurity products and services. USCIB urges USTR to monitor developments and seek clarification from Vietnam that the Decree does not apply to foreign entities without a local permanent entity or branch office in Vietnam.

In June 2007, Vietnam's Ministry of Information and Communications (MIC) agreed to delay implementation of import licensing requirements for cyber information security (CIS) products under the Law on Network Information Security (LONIS), which were set to go into effect in June 2017. However, MIC has created a list of products that are covered by the draft Circular "*Detailing the Procedures and Documents for Granting Import Licenses for Cyber Information Security (CIS) Products*." The list is organized by HS code, commodity description, and core function. Products and Services corresponding to the HS codes on the list could come under import licensing requirements.

Media and Entertainment Services

When TPP is fully implemented in Vietnam, it will result in some improvements in access to Vietnam's media and entertainment services market. Vietnam maintains a variety of discriminatory and distortive policies – including a screen quota of 20 percent (with a proposal to increase it to a TPP-inconsistent 35 percent); a broadcast quota of 50 percent, an outright prohibition on foreign content during prime time, and a requirement that 30 percent of air time be devoted to Vietnamese feature films; restrictions on foreign investment; an opaque and uncertain censorship review process; 30 percent of total channels limit on foreign channels for pay TV providers; discriminatory requirements on advertisements on pay TV channels; local agent requirements for pay TV.

Cybersecurity Bill

Vietnam's Ministry of Public Security (MPS) issued a Draft Law on Cybersecurity in June 2017.
The draft law tasks MPS with a range of responsibilities, including maintenance of cyber infrastructure,

development of national standards on cybersecurity, issuance of business licenses, and response to network incidents/cyber-attacks.

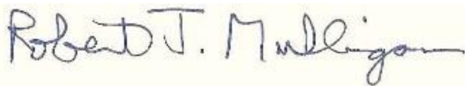
Among its wide-ranging provisions, the Law:

- Requires that foreign enterprises providing "telecommunication and/or internet services" to obtain business licenses, establish representative offices, and locate all servers "in which Vietnamese users data are administered" within Vietnam's borders;
- Establishes a business licensing regime for entities offering “cybersecurity assurance services”;
- Obliges telecommunications and internet service providers to deny service to any user failing to provide “authentic personal information”; and
- Sets a broad definition of cybersecurity, including not only national security issues but also public order and social interest, allowing for the suspension or withdrawal of the operating license for any website hosting content “contrary to the morality or the fine customs and practices.”

Following industry advocacy efforts, MPS issued an updated version of the draft law in August 2017, removing the criminal liability section and the licensing requirements for "cybersecurity assurance services" (though certification requirements may still apply to entities providing products/services to state bodies and critical information systems).

The updated draft law however, still maintains the provisions on data localization, content restrictions, and other key issues including the ones highlighted above. The ability to effectuate cross-border data transfers is essential to the global digital economy. USTR should encourage Vietnam to adopt policies that ensure that transfer mechanisms are predictable and interoperable by creating an environment for service providers to follow industry best practices and guidelines regarding the cross-border use and protection of personal data, while providing appropriate accountability mechanisms for those who wish to challenge data management practices. Agreements such as the APEC Cross-Border Privacy Rules Framework, Privacy Shield, and the EU-US Principles for ICT Services are positive examples.

Sincerely,



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