By electronic submission

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Washington, DC

U.S. CHAMBER OF COMMERCE

2018 SPECIAL 301 SUBMISSION

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February 8, 2018

Sung Chang
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Office of the U.S. Trade Representative
600 17th Street, NW
Washington, DC 20508

Re: 2018 Special 301 *Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment and Announcement of Public Hearing*, Office of the U.S. Trade Representative

Dear Mr. Chang:

The U.S. Chamber of Commerce's ("U.S. Chamber" or "Chamber") Global Innovation Policy Center (GIPC) is pleased to provide you with our submission for the U.S. Trade Representative's *Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment*. The Chamber has participated in this annual exercise to analyze the global intellectual property (IP) environment for many years and is encouraged that the Office of the U.S. Trade Representative (USTR) has prioritized its commitment to promote property rights as a way to foster development and prosperity. We urge the U.S. government to continue to use all available means to work with our trading partners to address these challenges.

The Chamber is the world's largest business federation representing the interests of more than three million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations. It also houses the largest international staff within any business association, providing global coverage to advance the many policy interests of our members.

Over the past decade, GIPC has worked to foster a global environment that encourages inventors and creators to bring ideas to market and find solutions to the challenges the world faces. GIPC is a leading advocate for strong intellectual property standards that create jobs, save lives, and advance global economic and cultural prosperity.

IP is critical to U.S. economic development and competitiveness. IP-intensive industries directly employ more than 45 million American workers and drive more than $6 trillion worth of total U.S. GDP, and these benefits are not limited to U.S. borders.

The recently released sixth edition of the U.S. Chamber International IP Index, *Create,* shows that economies of all shapes and sizes have a stake in implementing meaningful IP regimes. The Index highlights meaningful and significant correlations between the strength of IP environments and important socioeconomic benefits, such as access to venture capital, biomedical foreign direct investment, high-value job creation, and access to technologies and online content.

Our Special 301 submission seeks to highlight both systemic and country-specific challenges. We take note of the global trends in IP-led innovation and creativity, highlighting both opportunities and challenges; we also include 11 countries and the European Union (EU) in this report, chosen based on factors including market size, geopolitical significance, and specific IP issues posed by that country.

The Special 301 Report is a critical tool that shines a spotlight on inadequate and ineffective IP protection and enforcement in countries around the globe. We encourage the U.S. government to use this blueprint, combined with other available mechanisms, to secure meaningful action by our trading partners to improve their respective IP environments. The Chamber looks forward to working with the U.S. government to ensure that all necessary steps are taken to achieve this goal.

Sincerely,

David Hirschmann
Executive Vice President, U.S. Chamber of Commerce
President and CEO, U.S. Chamber's Global Innovation Policy Center

Myron Brilliant
Executive Vice President
Head of International Affairs, U.S. Chamber of Commerce

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EXECUTIVE SUMMARY

The protection of intellectual property (IP) incentivizes innovation and entrepreneurship in science, technology, and the creative arts, to deliver the latest and greatest products and services to consumers everywhere. Even as we celebrate all that IP does to improve our lives, we urge policymakers to ensure we continue to incentivize more investments in innovation and creativity.

The U.S. Chamber input into the Special 301 process is framed around the sixth edition of the U.S. Chamber International IP Index ("Index")—"Create"—a blueprint for countries seeking to become true knowledge-based economies. Every individual economy represents a blank canvas, with policymakers using broad strokes in the form of IP policy to paint their country's innovative and creative futures.

The metrics captured by "Create" benchmarks 50 economies using 40 indicators in eight categories to capture their 2017 IP landscape. New indicators in the areas of commercialization and systemic efficiency provide a more complete, bottom-to-top picture to recognize the investments countries are making in support of domestic innovation and creativity. The 2018 Index also includes five new economies: Costa Rica, Ireland, Jordan, Morocco, and the Netherlands.

In 2017, both systemic and country-specific issues made global trends in IP-led innovation and creativity. With the ease of e-commerce, many more counterfeits are traveling through small parcels directly to consumers. Illicit streaming devices are paving the way for more homes to access pirated motion picture and television content around the world. Online criminal IP theft is a plague on openness, safety, and freedom on the Internet, and unfortunately profits from the hard work of America's creative industries and the millions they employ.

American IP also faces challenges abroad with regard to fair pricing for innovation and adequate laws to protect creativity. For instance, pricing policies that do not properly value healthcare innovation have the impact of undermining and devaluing IP and access to innovation. Similarly, the rising demand for creative designs in consumer products underscores the need for adequate laws that can protect both consumers and creators to drive competition and differentiation and incentivize new innovations.

Furthermore, instances of inadequate protection of trade secrets and economic espionage have been on the rise, especially as emerging markets increasingly seek innovation-driven investment. We continue to spread the message that in this age of innovation and information, proprietary knowledge and know-how are increasingly valuable assets to a company's ability to compete and succeed. When the information is divulged, its entire value to the owner is lost.

While we take note of the big challenges, some of the U.S.' largest trading partners took small steps in the right direction. New challenges emerged in strategic markets like Colombia, Malaysia, Saudi Arabia, and the United Arab Emirates. Whether as cases of patent infringement, lack of data exclusivity, or compulsory licensing for commercial purposes, such actions continue to undermine the transition to a true innovation-led economic model.

Over in Geneva, business-as-usual continues to hurt innovation. Narrow interests pushed through multilateral institutions are missing the opportunity to talk about real barriers of access to innovative healthcare. New research by the Pugatch Consilium unveiled the top barriers to the availability of essential medicines: lack of healthcare funding, supply chain costs, regulatory burdens, and distribution infrastructure.

However, the United Nations High Level Panel (UNHLP) report—which ultimately recommended diminishing the TRIPS Agreement, calling for automatic compulsory licensing, and putting pharmaceutical R&D in the hands of UN bureaucrats—is driving emerging countries like India, Brazil, and South Africa farther away from their goal of graduating to innovation-driven, knowledge-based economies that could otherwise help to secure their socio-economic future.

In light of these developments and emerging challenges, we believe that the modernization of NAFTA creates an opportunity to strengthen existing IP protection and enforcement mechanisms across the continent. Similarly, agreements that bear the gold-standard for IP protection, like the U.S.-Korea Free Trade Agreement (KORUS), should be effectively implemented to support global creators and innovators.

Global IP standards carry special significance for the U.S. as one of the world's most innovative economies. The U.S. Department of Commerce has found that IP-intensive industries have outsized importance to the U.S. economy, accounting for 45 million U.S. jobs and 38% of gross domestic product. As we take stock of the growing global opportunities and challenges around IP rights issues, the 2018 edition of our Index complements this exercise by country-wise IP-related findings covering over 90% of the world's gross domestic product. This report is attached for your perusal.

We take this a step further and use this opportunity to specifically unpack 12 countries and economic groupings important to U.S. industry based on factors including market size, the geopolitical significance of the market, and specific IP issues posed by that country. This list includes Australia, Brazil, Canada, China, Colombia, India, Indonesia, Malaysia, Russia, South Africa, and Turkey. We intend for this list to be treated as a supplementary synthesis of unique IP trends – opportunities and challenges – and hope that you will find it useful for your purposes.

GLOBAL TRENDS IN IP-LED INNOVATION AND CREATIVITY

Findings from the U.S. Chamber International IP Index

The U.S. Chamber is committed to promoting a global environment that fosters innovation and creativity in the U.S. and abroad. On February 8, 2018, the U.S. Chamber released the sixth edition of the International IP Index (the "Index"), which benchmarks the IP environment in 50 global economies against 40 indicators. The criteria examined in the Index were developed in consultation with industries as factors indicative of robust IP systems.

The 2018 Index reveals a number of trends in global IP protection over the last year. Positive developments in 2018 include:

- **Global IP leaders:** The U.S., UK, and EU economies remain atop the global IP rankings. However, the U.S. and the UK rank so closely together in the 2018 Index that it has become clear the countries stand side-by-side as global leaders in IP protection and enforcement.
- **Positive progress on copyright:** Throughout 2017, courts across the EU, in the UK, and in Australia utilized recent legislative changes to bolster protection for copyrighted content online.
- **Stronger IP foundations:** Many countries – including India, Indonesia, Pakistan, Thailand, and Vietnam – are investing in creating more effective foundations for IP policy through programs to enhance coordination among governments' IP enforcement agencies and initiatives to increase awareness about the importance of IP.
- **Commercialization of IP:** A number of countries, including Malaysia and Saudi Arabia, introduced policies to enable innovators and creators to utilize IP as an economic and commercial asset and encourage legitimate technology transfer.

The Index also demonstrates the ways some countries have taken steps forward in some areas, but regressed in others. For example:

- **Obstacles to patent protection:** Throughout 2017, obstacles to securing effective patent protection for innovative products emerged in a number of key global markets, including through the supplementary protection certificate (SPC) manufacturing exemption in the EU, and insufficient patent enforcement mechanisms in Australia and Saudi Arabia.
- **Undermining fair value for innovation:** Both Malaysia and Colombia used a government-use license and a regulatory proposal, respectively, to circumvent patent protection for innovative, biopharmaceutical products in order to drive down domestic prices.
- **Troubling draft IP policy:** South Africa published a draft IP policy, which includes proposals to weaken patent protection, expand the use of compulsory licensing, replicate

the recommendations of the UNHLP on Access to Medicines Report, and weaken protection for copyright in important ways.

- **Continuing antipathy from Canada:** Despite the Supreme Court ruling overturning the promise doctrine and a strong Federal Court decision on digital rights management, the Canadian government's commitment to IP-led innovation continues to be called into question though its actions in free trade negotiations and the multilateral fora.

The Index also demonstrates how IP-driven innovation and creativity drive global economic competitiveness by examining the relationship between a robust IP framework and different socio-economic indicators. The Index illustrates the strong, positive relationship between the strength of a country's IP framework and innovative and creative outputs, access to venture capital, increased foreign direct investment, and economic competitiveness, among other factors.

We will cite the Index findings throughout our Special 301. Please find attached to this submission the full Index for your reference.

Emerging Issues Online

Through exercises like the U.S. Chamber International IP Index, Measuring the Magnitude, Special 301, and through the practical experience of our member companies, we are able to identify emerging trends—both positive and negative—in the global IP environment.

Influx of Counterfeit Goods Found in Small Parcels: The nature of global counterfeiting has changed. Due to the ease of e-commerce, and consumer preferences, many more counterfeits are traveling through small parcels directly to consumers, requiring increased attention from Global Customs agents and cooperation from e-commerce platforms and shipping providers. Many fraudulent sellers use new cunning techniques to lure unwitting consumers. It is increasingly difficult to determine if products sold online are legitimate. However, it is common practice that the sellers of illegitimate items are not authorized distributors by the original retailer. This is a troubling new trend.

Global Proliferation of Illicit Streaming Devices (ISDs): ISDs are media boxes, set-top boxes or other devices that allow users to stream or download unauthorized content from the Internet. These devices (and corresponding software programs) take many forms, but have common features and have become a significant means through which pirated motion picture and television content is accessed in consumers' homes around the world. China is a hub for the manufacturer of these devices, which are not only distributed domestically but also exported to overseas markets. But, what was once a problem centered mainly in Asian markets has now proliferated worldwide.

ISDs enable many forms of infringement of copyright or other illegal activities, and are often advertised and marketed as such. They facilitate easy and unauthorized access, through apps, to

remote online sources of unauthorized entertainment content including music, music videos, karaoke, motion pictures and television programming (including encrypted content), video games, published materials, and TV dramas. The devices are either pre-installed with apps that facilitate infringement (either prior to shipment or by vendors prior to sale or as an after-sale service), or users themselves are easily able to obtain and install the apps required to access the infringing content. These apps allow the user to connect to a supporting OTT online infrastructure that provides users with instant access to infringing audiovisual content. Many of these piracy apps cross over multiple platforms, including set-top boxes, mobile phones, and computers.

ISDs are part of a sophisticated and integrated online ecosystem facilitating access to pirated audiovisual materials, and enforcement against them presents complex challenges. Under the right fact patterns, the retailer/distributor can be held liable; if the app developer can be identified and located, this may provide another enforcement path. Governments should also take action against key distribution points for devices that are being used illegally. But unless effectively countered with vigorous action against one or more of these ecosystem participants, the impact of ISDs on the legitimate market for digital delivery of copyright materials will be increasingly destructive. In 2017, USTR identified ISDs as an "issue focus" for its 2017 Notorious Markets report.

Internet-Based IP Theft: IP theft is becoming increasingly challenging in a changing online environment. With the dynamic changes to consumer shopping habits and the sophistication of criminal enterprises, the need to ensure that goods are legal, authentic, and trustworthy has never been greater. It is critical that law enforcement authorities have the tools, resources, and will to fight theft in both the online and physical environments. Protecting IP is at least as important on the Internet as it is in the brick-and-mortar world.

In 2016, the Organization for Economic Co-operation and Development (OECD) released a report titled Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact, noting the value of imported fake goods worldwide was $461 billion in 2013, compared with total imports in world trade of 17.9 trillion.[1] This figure is more than double prior estimates in 2005. It is also more than double the 2014 profits of the top ten companies in the world combined.

IP is the foundation of the US economy and supports more than 45 million American jobs in 81 different industries. According to the Department of Commerce, IP-intensive industries make up more than half of all U.S. exports, or $842 billion, and almost 40% of U.S. GDP.[2] America's

[1] Trade in Counterfeit and Pirated Goods, http://www.keepeek.com/Digital-Asset-Management/oecd/governance/trade-in-counterfeit-and-pirated-goods_9789264252653-en.

2 "U.S. Department of Commerce Releases Updated Report Showing IP-Intensive Industries Contribute $6.6 Trillion, 45.5 Million Jobs to U.S. Economy", https://www.commerce.gov/news/press-releases/2016/09/us-department-commerce-releases-updated-report-showing-intellectual.

growth and prosperity is vulnerable. We must be vigilant in the fight against counterfeiting and piracy.

Strong IP protection is the foundation of American innovation and leadership in the world marketplace. For the U.S. to maintain its competitive edge, we must continue to invest in enforcement both in physical marketplaces and in online marketplaces. When IP is undermined through counterfeiting or piracy, it is a direct threat to investment in creativity and innovation, quality products for consumers, enhanced economic growth, and high-paying jobs.

Law enforcement continues to focus on deterrence and disruption. U.S. Immigration and Customs Enforcement (ICE), the National IP Rights Coordination Center, together with International Criminal Police Organization (INTERPOL), created the Illicit Goods and Global Health program designed to emphasize enforcement against trafficking of counterfeit and illicit goods. Similarly, OECD instituted a task force on Countering Illicit Trade to better understand the threats illicit trade poses to our global economy and examine, through quantitative metrics, new solutions to combat transnational criminal networks producing illicit goods. Collaborative global initiatives dedicated to disruption continue to provide new approaches to combat complex risks. We applaud these initiatives.

Enforcement efforts online are complicated by numerous factors. Criminals are very good at hiding their identities and locations; this is even truer in the online ecosystem. The WHOIS data for website registrants often contain entirely fictitious filings. Internet organizations, such as Internet Corporation for Assigned Names and Numbers (ICANN) and the registries and registrars that ICANN accredits, have done far too little to address this reality. Even in the cases where criminals can be accurately identified, they may well be located in (or flee to) countries with inadequate enforcement systems, including jurisdictions that do not cooperate with U.S. law enforcement. Some countries—even some developed countries such as Switzerland—lack or have unclear or inadequate laws, while others may impose impractical standards such as numerical thresholds that stifle enforcement efforts. Additionally, some countries lack the will to bring necessary cases to court, sometimes for political reasons and in other cases for more nefarious reasons.

This collage of international laws and enforcement efforts invites the criminal enterprises behind online counterfeiting and piracy to shop for a forum in which they can evade the law. As a direct result, these enterprises are able to continue to exploit American consumers and businesses. Further, the continued operation of these criminals undermines domestic enforcement efforts by providing alternatives to the illicit operations that we target here. This harm is precisely what has given rise to the widespread recognition of the need for tools to disrupt illegal foreign websites, and to implement strategies to take the money out of online piracy through better and more transparent policies related to ad placement and the provision of financial services to ensure that legitimate enterprises are not unwittingly providing funding to, or otherwise contributing to the operation of, pirate sites.

Rights holders spend hundreds of millions of dollars in this effort annually and the U.S. government has had major victories, such as "Operation In Our Sites," which has successfully acted against criminals using the Internet as their base of operations in over 1,600 instances. In one of the highlights of "Operation In Our Sites," cooperation with certain foreign governments yielded action against criminals offering counterfeit medicine. That action underscores that international cooperation on IP enforcement is possible and, when it occurs, it is highly effective. However, such cooperation remains the exception rather than the rule.

Notorious Markets: Physical markets continue to be significant contributors to piracy and counterfeiting, but fighting illicit Internet actors trafficking in counterfeit and pirated goods is equally important. Online criminal IP theft is a plague on openness, safety, and freedom on the Internet, and unfortunately profits from the hard work of America's creative industries and the millions they employ.

Inclusion in the Special 301: USTR has recognized the problem of these illegal websites and business to consumer and business to business online marketplaces in the context of its Special 301 Out-of-Cycle Reviews of Notorious Markets. We urge USTR to factor the Notorious Market findings into the annual Special 301 review and make action by foreign governments to address any Notorious Markets in their jurisdiction a top priority. When examining notorious markets and online market places we encourage USTR to use objective factors, including the best practices of what platforms already do or could do in terms of proactive and preventive measures.

A Threat to Consumers: It is difficult for consumers to decipher which websites are legitimate. Criminals often design their sites to have the look and feel of legitimate sites. Indicia of legitimacy can be counterfeited on a website, just as it offers counterfeit goods. Logos of payment processors are frequently displayed, even if the site in fact has no business relationship with the processor. Seals from consumer protection groups and federal agencies are frequently imitated. Images may be directly copied from legitimate websites, and some illegal sites even display pictures of the presidents or CEOs of the companies from which they are stealing. Some websites copy the advertisements of well-known companies, again, to feign legitimacy.

IP theft undercuts an IP system that helps provide assurance to consumers that the products they use are authentic, safe, and effective. Consumers can rely on brand names for a level of trust in the safety and quality of the goods they are purchasing. When that system is in danger, consumer confidence is undermined.

National Security Threat from Criminal Enterprises: A report authored by the United Nations Office against Drugs and Crime (UNODC) highlights illegal trafficking of counterfeit goods and cross-border organized crime as a multibillion dollar industry. The opportunity of lower penalties and very high profit margins create an attractive criminal proposition. According to Europol,

criminal networks that traffic in counterfeit goods use similar methods to transport fake goods as they transport other illicit items such as drugs and firearms.

Voluntary Agreements: Beyond the treaties and legal obligations, there is a key role for voluntary agreements among those who recognize that websites that make infringing materials available, or services that facilitate online theft, are destructive to a free, open, and safe Internet. In the U.S., we have seen the rise of voluntary practices and/or guidelines regarding the provision of payment processing services and advertising in the context of rogue sites, though implementation has been uneven. In addition, the copyright alert system was an important step to educate consumers about respect for IP in the online environment.

We believe that these types of voluntary agreements are a critical part of the path forward to reduce online theft of IP. We believe that businesses, governments, and other stakeholders should promote an environment of accountability, recognizing the need for and encouraging legitimate businesses across different sectors of an economy to take reasonable steps to avoid the use of their services by criminals for infringing purposes. "See no evil" is not a responsible business practice in today's sophisticated Internet environment.

Rising Threats to Innovation, Design and Creativity

Pricing and Innovation: Pricing policies that do not properly value innovation have the impact of undermining and devaluing IP and access to innovation. Innovative prices reflect the costs of researching, developing, and testing the new medicine or medical device, as well as others in the company's pipeline – including the costs associated with failed lines of research; while the generic prices need only cover the cost of manufacturing a dose of medicine or product. When countries fail to acknowledge and respect this basic dichotomy, and benchmark innovative prices against generic prices in order to justify the expropriation of IP rights, they pose a real threat to the very innovative pipeline that makes such medicines available to patients in the first instance.

Furthermore, such practices set a harmful global precedent that IP rights will be discretionary when a government no longer wishes to pay the cost previously agreed to with the innovator firms. Expanding their access to new markets require commercial certainty that their products will be protected under the government's regulatory and legal framework. Unilaterally reducing prices in the name of meeting the budgetary constraints of a universal healthcare system undermines industry confidence necessary for the system to work to produce new cures, and sacrifices long term innovation and patient health in the future.

For instance, the Patented Medicines Pricing Review Board (PMPRB) sets maximum prices for patented medicines in Canada. These prices are not the prices that are paid, but a maximum ceiling, which forces American companies to negotiate province by province and often obtain

even lower prices. As another example, in June 2016, the Colombian Government issued a declaration of public interest via Resolution 2475 and committed to unilaterally reducing the price of Glivec by about 45%. This directive, which is discretionary in nature, creates tremendous uncertainty for other innovators in the Colombian market.

In another significant example, reversing the course on successful Japan's Price Maintenance Premium (PMP) has introduced uncertainty into the market. Recent changes to the PMP, as well as considerations of new cost effectiveness programs, and potential changes to the Foreign Average Price Rule for devices, raise the real risk of undoing tremendous progress made to the drug and device lag; increase cost to the broader Japanese healthcare system; and reduce investment in a cutting-edge industry where Japan has become a world leader leading to fewer innovations in the future.

Rising price controls on innovative medical devices in India are also cases in point. An approach that is predicated on certainty, transparency, and respect for American IP, and above all, for the return of fair value for innovation and greater access is vital to the continued development of life-saving medicines and medical devices.

Design Rights: U.S. companies enjoy global reputation for their designs. Companies invest heavily in the research and production of innovative designs and consumers associate specific designs with quality and desirable products. To encourage innovation and incentivize investments, greater clarity and consistency on available IP tools is needed, as well as, an expansion of legal protections for designs across a product's lifecycle. Design drives gross domestic product and economic growth, increases value for both small and large companies, and helps fuel an emerging "makers" movement.

Design rights are also easily visible and recognized by consumers. Increasingly consumers are demanding innovative designs and making purchases based on designs they associate with specific brands. Adequate design laws protect both consumers and creators, and also drives competitors to differentiate themselves and further incentivizes new innovations.

However, in many parts of the world there has been historically little focus on the importance of protecting industrial designs—not just through the patent system or industrial design registration systems, but also through the use of 3D trademarks and copyrights for applied art. For instance, the ability to register trade dress is vital to protecting consumers and brand owners. In particular, iconic product configurations enable businesses to distinguish themselves from competitors and allow consumers to buy products from a trusted source. It is, however, significantly more difficult to register trade dress as European Union Trademarks (EUTMs) than in the U.S. Specifically, the EU IP Office (EUIPO) and the European Court of Justice (ECJ) have set a very high bar for registering trade dress rights.

- *There is a misperception that trade dress cannot be a source identifier*: ECJ and EUIPO routinely find that consumers are "not in the habit" of using trade dress to determine commercial origin. This appears to be largely based on a mistaken belief that consumers do not rely on product configuration marks to identify products. These decisions do not provide any evidence or reasoning for this conclusion.
- *It is almost impossible to show inherent distinctiveness*: For trade dress to be inherently distinctive, it must "depart significantly from the norms or customs of the sector." Although the text of the law indicates that some product configuration marks should be able to meet this test, in actuality, it is rare that a product configuration mark is found to be inherently distinctive.
- *Acquired distinctiveness is expensive and burdensome to demonstrate*: EU case law requires acquired distinctiveness to be proved "throughout" the EU, with limited guidance as to what this standard means. Indeed, it could be interpreted as requiring evidence in all 28 member states. This is contrary to the goal of the EUTM to establish a unitary right, and as a practical matter, it is both burdensome and very costly to demonstrate. In the US, there is no requirement to provide survey evidence of consumer perception of acquired distinctiveness; it is sufficient to show comprehensive evidence of use of the shape or trade dress mark. The lack of clear guidance on what evidence is acceptable for the EU has a chilling effect on these registrations.
- *The shape exclusion is very broad*: The recent revisions to the EU Trademark law expanded what was already a broad shape exclusion to include any other characteristic associated with the goods. This exclusion is substantially broader than the US's functionality restriction and could provide additional grounds for rejecting trade dress registrations in the future.

A series of unfavorable decisions emerging from the European Court of Justice. Many iconic products that are instantly recognizable have been refused registration in the EU. This includes an ECJ decision relating to the Coca-Cola bottle; the Kit Kat four bar shape design; and the reopening of the Louboutin Case (C-163/16), six months after the Advocate General's Opinion.

Protection of Undisclosed Information: Trade Secrets

In this age of innovation and information, proprietary knowledge and know-how are increasingly valuable assets to a company's ability to compete and succeed. These trade secrets often drive inventive activity and are the most valuable assets for many companies today across sectors as diverse as complex manufacturing, climate change technologies, defense, biotech, information technology (IT) services, and food and beverages. Unfortunately, this is a concept that is often not recognized globally.

Many countries fail to offer adequate protection for trade secrets. Even where national laws exist, these regimes do nothing to prevent *government* action that compels the transfer of such information from foreign entities to government agencies or domestic firms as a form of industrial policy. Several different industries have expressed concern for the loss of trade secrets as a condition of doing business in some of the major emerging markets, including companies in the IT, pharmaceutical, chemical, and healthcare sectors.

Moreover, because of the unique nature of trade secrets, any disclosure can effectively destroy the value of the right. The entire economic value of a trade secret stems from the competitive advantage conferred by the confidential nature of the information. By definition, once disclosed, trade secrets cannot be recovered. A trade secret does not give its owner an exclusive right to use the information (in contrast, for example, patents give the owner the right to exclude others from making, using, or selling the invention). As a result, when the information is divulged, its entire value to the owner is lost. The competitive risks created by regulations in emerging markets requiring unnecessarily broad product-related information to obtain government certifications for health, safety, security, or other reasons is compounded by the lack of effective protections requiring those governments to safeguard the information submitted.

The Chamber, further, commends the current Administration for recognizing the significant challenges to innovation presented by trade secret theft and economic espionage and the need for a strategy to more efficiently coordinate the U.S. government's efforts to further address these threats. We further recommend that the U.S. government set up a "Friends of Trade Secrets" working group on the margins of the WTO TRIPS Council in addition to continuing to seek trade secrets protection in all trade agreements being negotiated.

Enforcement Landscape

In order to promote the enforcement of existing international obligations, it is important that the U.S. continue to work with foreign governments. In many cases, there have been significant improvements, such as provisions that ensure greater transparency between rights holders and law enforcement and/or provide ex officio authority to law enforcement and customs officers to seize counterfeit or pirated goods, but in other cases, we have seen considerable setbacks.

Additionally, the Chamber is particularly concerned about the transshipment of illicit goods, including counterfeit products, and the process by which these goods are destroyed once seized.

Transshipment and the Surge of Small Parcels Carrying Counterfeits: Overseas criminals and remote sellers ship counterfeit hard goods into the U.S. often using international express mail services and airmail, such as the China-based express mail service (EMS) of the China Post. These shipments arrive at any of ten international mail facilities with U.S. Customs Service

locations and are inspected for entry by U.S. Customs Border and Protection Service (CBP), before being transferred to the U.S. Postal Service (USPS) for delivery to U.S. consumers.[3] Overseas remote sellers often fraudulently declare small individual mailings to avoid detection of these counterfeit goods by CBP agents. Moreover, depending on the size of the order, many overseas websites will break up shipments into several small packages to avoid seizure or will offer refunds for seized products to attract U.S. consumers. The sheer volume of these small shipments makes it impossible for CBP agents to vigorously screen or x-ray all incoming mail to detect such shipments.[4]

Once admitted undetected, these shipments then enter the U.S. postal mail stream from international mail facilities for delivery to U.S. consumers. The ability of the USPS to detect and inspect these packages is complicated by the fact that materials shipped domestically by first-class, priority, or express mail is closed to inspection without probable cause.[5]

The issue of counterfeit shipments in Express and Mail has continued to increase, as noted by the U.S. Customs and Border Protection, the World Customs Organization[6] and the U.S. IP Enforcement Coordinator.[7] According to Customs and Border Protection, 11 million maritime containers arrive at our seaports. At land borders, another 10 million arrive by truck, and 3 million by rail. Through air travel, an additional quarter billion in cargo, postal, and express consignment packages are transported. Of these shipments, agents seized over $1 billion in counterfeit goods, which unfortunately is estimated to be a small fraction of the counterfeit goods being sent into our country.

Even when counterfeit items are seized and CBP alerts the right holders, many cases never go further than the seizure of the product because of a lack of information. Additional information and processes for better information sharing could help track the real importer, increase enforcement actions, and reduce repeat counterfeit sellers and shippers.

Increased Enforcement: Customs organizations worldwide are battling this very issue. The U.S. has the opportunity to study the successes and best practices from other customs organizations

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[3] *Mailing Standards of the U.S. Postal Service, International Mail Manual*, § 711 (Aug. 11, 2011), incorporated by reference in the *Code of Federal Regulations*, 39 C.F.R. § 20.1.

[4] The Association of Convenience & Petroleum Retailing. *Remote Sales of Tobacco* (Retrieved March 19, 2010). www.nacsonline.com/NACS/Government/Tobacco/Pages/RemoteSalesofTobacco.aspx.

[5] USPS, "*Basic Eligibility Standards for Priority Mail," available at* http://pe.usps.com/text/dmm300/123.htm (November 1, 2010); www.discountcigarettesbox.com (last visited November 17, 2011) ("The parcels are sealed and cannot be opened for postal inspection").

[6] Illicit Trade Report 2013, World Customs Organization, Page 68, accessed at http://www.wcoomd.org/en/topics/enforcement-and-compliance/activities-and-programmes/~/media/WCO/Public/Global/PDF/Topics/Enforcement%20and%20Compliance/Activities%20and%20Programmes/Illicit%20Trade%20Report%202012/ILLICIT%202013%20-%20EN_LR2.ashx

[7] 2013 Joint Strategic Plan on IP Enforcement, U.S. IPEC, June 2013, Pg. 35, accessed at http://www.whitehouse.gov/sites/default/files/omb/IPEC/2013-us-ipec-joint-strategic-plan.pdf

globally to make progress against this pressing issue. For example, Her Majesty's Revenue and Customs (HRMC) organization in the U.K. has made significant progress against the issue of express and mail shipments for many years now. The HMRC has strategically redeployed additional HMRC staff to postal depots in the form of tactical Anti-Illicit Trade Teams. This approach continues to show sustained enforcement success.[8] Working closely with commercial stakeholders, HMRC staff made use of postal depot technical equipment to increase throughput and x-ray examination of parcels, enabling them to target high-risk locations and significantly improve seizure rates. We are also working with CBP and the U.S. Postal Service to improve our efforts domestically. We ask USTR to urge our trading partners to do their part.

CBP's limited resources can be maximized effectively. Through some technological targeting solutions, we can make steady improvements to the operational efficiencies within CBP's time consuming seizure process. The Chamber urges the U.S. government to work with its trading partners to ensure customs agents have the authority to confiscate, seize, and destroy goods that are determined to be illicit, without undue requirements placed on right holders to prove the seized goods are counterfeit and that all seized counterfeit goods, materials, and related manufacturing equipment pieces are swiftly and completely destroyed. Effective destruction procedures are essential to prevent both counterfeit goods from returning to legitimate trade channels and manufacturing equipment from returning to illicit factories. If we are going to be credible in our requests for our trading partners to employ best practices for the enforcement of IP, we must set the right example.

Enforcing Baseline Protections: There are accepted baseline standards concerning minimum protection for and enforcement of IP, which all countries should meet. These baselines include elements specifically intended to address the digital and online environments.

Many of these standards have been accepted globally as part of major trade and IP agreements and treaties. Some of the leading instruments include the TRIPS Agreement of the WTO, and the WIPO Copyright Treaty and Performances and Phonograms Treaty (commonly known as the WIPO Internet treaties). Other examples reflect widespread and/or regional standards, such as the provisions of the IP chapters of the U.S.' Free Trade Agreements (FTAs). These modern standards have been accepted on five continents and have been a model for IP protection and enforcement to FTA partners and non-FTA partners, alike.

Full and complete implementation of these baseline standards is essential to begin to address the forum shopping and flight from jurisdiction-to-jurisdiction that we have seen repeatedly in the fight against criminals engaged in online IP theft. We urge the USTR to continue to make this a top priority and that where our trading partners fail to meet these standards they be held accountable through all the tools at USTR's disposal.

[8] HM Revenue & Customs. *www.**hmrc**.gov.uk.*

Regional Challenges

Strategic Markets: In 2017, both Saudi Arabia and UAE – two high-income economies that have historically had a strong record of accomplishment on IP protection in the region – took steps to undermine patent protection. While Saudi Arabia introduced a patent linkage system in 2013, the Saudi Food and Drug Authority (SFDA) effectively overrode Saudi Arabia's linkage regime by approving a follow-on product to Daclatasvir, a medicine under a registered patent held by BMS. This negative development in Saudi Arabia runs counter to their own country goals and general principles to develop an innovation ecosystem outlined in the *Vision 2030* and *National Transformation Program 2020* and risks undermining continued foreign investment needed to achieve these goals.

Similarly, in the UAE, under the Ministry of Health Decree 404, the Ministry will deny marketing approval for a product that infringes on a patent existing either in the UAE or in the market from which the product has been imported. However, recently the UAE government approved two generic versions of a pharmaceutical product that remain patent-protected in the country of origin. This development seriously undermines the life sciences IP environment in the UAE since patents on the majority of pharmaceutical products are not protected in the UAE, but rather protection is based on foreign patents. U.S. industry looks to Saudi Arabia and UAE to lead on IP protection in the region, and we encourage the U.S. government to continue to highlight our concern with these two troubling policy developments in your ongoing bilateral conversations with both governments.

EU Supplementary Protection Certificates: In what could be major step backwards for IP protection, the European Union is currently considering changing the nature of its regime for Supplementary Protection Certificates (SPCs) by implementing a waiver for manufacture and export. SPCs are an essential IP right recognized in the U.S. as patent term restoration, which ensures the right holder of any product compensation for lost patent term during the development and regulatory process. Any suggested waiver would damage the EU and its member state's ability to incentivize medical innovation and would set the wrong precedent for third countries. Studies have found, furthermore, that the adoption of a manufacturing and export waiver could cost Europe thousands of jobs and reduce investment in R&D.[9]

[9] Pugatch, Meir and Torstensson, David P and Laufer, Ma'ayan, *Unintended Consequences: How Introducing a Manufacturing and Export Exemption to Supplementary Protection Certificates Would Weaken Global Standards of IP Protection and Result in Direct Losses to Europe's Research-Based Biopharmaceutical Industry* (October 2, 2017). Available at SSRN: https://ssrn.com/abstract=3051545

Standard-Setting through Bilateral and Regional FTAs

NAFTA Modernization: The U.S. Chamber believes that the modernization of the North American Free Trade Agreement (NAFTA) creates an opportunity to strengthen existing IP protection and enforcement mechanisms across the U.S., Mexico, and Canada. The harmonization of North American IP standards can significantly increase U.S. exports and realize a vision of North America as the world's innovative and creative engine. Historically, U.S. IP laws have been the most effective in the world at delivering new, innovative, and creative products, services, and technologies to market. However, the full potential of these industries will not be realized until IP rights are fully protected and respected under law around the world. This begins with America's closest neighbors, Canada and Mexico, who also stand to gain exponentially from a regional strengthening of IP laws and enforcement.

The U.S. Chamber supports the following elements of a 21st century IP infrastructure for North America:

- **Providing for National Treatment:** The agreement should include a commitment to full national treatment without carve outs.
- **Establishing Terms of Protection:** The agreement should contain a re-commitment to strong base terms of protection for patents, copyrights and related rights, trademarks, and designs, and establishment of a statutory commitment to protect trade secrets. Notably, the U.S. Chamber supports bringing Canada's term of protection for creative works in line with the OECD consensus and growing global norm of life-plus 70 for all forms of creative, copyrighted works.
- **Defining Exclusive Rights:** The agreement should define exclusive rights for all forms of IP – regardless of business model – including exclusive rights to distribution/"making available" and communication of copyrighted material and proprietary IP licensing rights.
- **Providing Trade Secrets and Regulatory Data Protection:** The agreement should include a requirement for statutory protection for proprietary information and establishment of criminal penalties for trade secrets theft, including by means of a computer system. The U.S. Chamber specifically supports:
    - Providing a civil and criminal cause of action and penalties for trade secret theft;
    - Requiring minimum terms of statutory protection of regulatory test data submitted for marketing approval of both small molecule and biologic medicines, including 12 years for biologics, 5 years for small molecules and for combination products containing at least one new active ingredient, and 3 years for new formulations, indications, and administrations.
- **Determining Eligibility:** The agreements should contain a guarantee of technology-neutral patent eligibility for all industry sectors strictly based on the international norm of novelty, usefulness, and non-obviousness. The U.S. Chamber specifically supports:

    - Including comprehensive patent subject matter eligibility;
    - Prohibiting additional or heightened criteria (beyond 3-step test),
    - Including codification of elimination of patent utility "Promise" doctrine.
    - Including text that builds on the principles enshrined in TRIPS Article 27.1, by adding language to NAFTA clarifying that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology, the method of exploitation, and whether products are imported or locally produced."
- **Regulating Exceptions and Limitations:** The agreement should include transparent, predictable, and carefully-defined rules for exceptions to rights across all forms of IP. The U.S. Chamber specifically supports:
    - Maintaining clean recitation of the Berne three-step test applied to exceptions and limitations;
    - Requiring appropriate safeguards to ensure quantities of ingredients of patented pharmaceuticals that are imported to conduct local testing to secure marketing approval are strictly limited to research activities and therefore do not conflict with the legitimate interests of patent owners.
- **Ensuring Rule of Law and Due Process:** The agreement should contain rule of law mechanisms that enable IP owners to maintain, commercialize, and defend their rights. The U.S. Chamber specifically supports:
    - Prohibiting forced transfer of IP rights and government interference in commercial technology agreements;
    - Including strong legal protections against circumvention of technological protection measures for the digital marketplace, with appropriately limited exceptions;
    - Including provisions to penalize aiding and abetting of criminal copyright offenses;
    - Creating effective early resolution mechanisms that enable bio-pharmaceutical innovators to resolve patent disputes before potentially infringing products enter the market;
    - Ensuring full patent rights are made available during the period of patent term adjustment and restoration to compensate for patent life lost due to patent office delays, a portion of the period required to obtain regulatory approval, and delayed reimbursement decisions;
    - Including provisions requiring predictable and transparent biopharmaceutical pricing and reimbursement rules and procedures and timely pricing and reimbursement decisions that appropriately recognize and reward the value of new medicines;
    - Ensuring right holders are allowed to freely transfer and exercise rights; and
    - Ensuring fully effective injunctive relief.

- **Enacting Infringement Penalties:** The agreement should contain deterrent-level civil and criminal remedies in law and mechanisms to enhance enforcement efforts. The U.S. Chamber specifically supports:
    - Including criminalization of camcording;
    - Including civil and criminal remedies for both satellite and cable signal theft;
    - Including *ex officio* authority w/seizure and destruction capabilities for IP-infringing goods and extending this authority to goods in-transit;
    - Including deterrent-level enforcement resources for digital piracy;
    - Including criminal liability for commercial-scale infringement without a requirement of for-profit basis;
    - Including statutory damages for commercial and non-commercial copyright and trademark infringement.
- **Committing to Multilateral Cooperation:** The agreement should include provisions to ensure North American IP interests are protected through the implementation of relevant international IP agreements in domestic law, such as the WIPO Internet Treaties, UPOV 1991 (plant varieties), and the Budapest Convention on Cybercrime.
- **Ensuring Value for Innovation**: The agreement should include provisions that impose disciplines on pricing and reimbursement systems for medicines and medical devices that ensures transparency, predictability, and market-based value for IP.

The U.S. Chamber looks forward to working with USTR to ensure the above elements are included in the modernized NAFTA agreement.

Suspension of IP Chapter in TPP: Following the U.S. withdrawal from the Trans-Pacific Partnership Agreement (TPP), in late fall 2017, the 11 remaining economies decided to go forth with the trade pact, making a few significant changes. The first of which was cosmetic, with the TPP now being referred to as the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). The second of which was substantive, with the Canadian delegation nearly holding the agreement hostage under the demand of suspending the IP chapter- a wish eventually granted by the remaining 10 participants.

The TPP, with its flaws and all, provided an important first step for plurilaterally updating the rules of the road on IP rights globally, which are still ever-so reliant on the 20-plus year old WTO TRIPS agreement. The suspension of the IP chapter in CPTPP represents a sucker punch for the innovators and creators around the world.

It also makes it even more important and clearer that it is incumbent on the U.S. and our trade negotiators to make the case for IP protection through trade agreements. Though many CPTPP economies already ratified and introduced/passed implementing language for the IP standards they had agreed to under the TPP, it is unclear if these nations will scrap these developments wholesale. We urge USTR and the U.S. government to advise and assist in any way possible to ensure that these countries don't roll back the clock on IP rights.

KORUS Review: As the Administration continues to review existing trade agreements, we urge the U.S. government to give particular attention to implementation of such agreements. Most notably, the U.S.-Korea Free Trade Agreement (KORUS) was seen as having the gold-standard for IP protection in U.S. trade agreements. Unfortunately, Korea has much to be desired in its full implementation of the chapter.

Notably, industry reports implementation concerns in Korea with regard to criteria for patentability, discrimination based on field of technology, patent linkage, pricing and reimbursement transparency for pharmaceuticals, and government legalization of software. A detailed examination of such concerns can be found in 2015 GIPC study "Trading Up." We urge the U.S. government to use renewed KORUS negotiations as platform to address these gaps in implementation and support U.S. creators and innovators with this important trading partner.

Norm-Setting Multilateral Environment

Specialized agencies that operate within the framework of the United Nations (UN) continue to play an important role in the evolution and administration of global IP rights. As previously discussed, the World Trade Organization's (WTO) Trade Related Aspects of IP Rights (TRIPS) Agreement sets the baseline standard for IP rights internationally. However, special interest groups and certain countries—many of which are profiled in the GIPC's 2018 Special 301 submission—are continuing to advance negative policies, including a suite of exceptions and limitations to what is generally accepted as rudimentary benchmarks for the creator's and inventor's rights the TRIPS Agreement establishes.

Furthermore, these same countries are using documents, doctrines, and resolutions developed in multilateral fora to provide cover for their misguided policies at home. For instance, in November 2017, the local Delhi office of the World Health Organization (WHO) organized "The First World Conference on Access to Medical Products and International Laws for Trade and Health." Despite their promise to "take the agenda forward," the conference and its participants instead continued the same old debate that's been hashed out for decades.

Unfortunately, the implementation of the UN High Level Panel on Access to Medicines (UNHLP) recommendations from 2016—which the U.S. government provided sharp criticisms of—was the primary focus of the conference and has given these activists another thread to hold onto in the hopes of unraveling IP rights globally. This is despite the fact that the UNHLP was completed entirely outside of member state purview and the UN General Assembly rightfully did not approve of the UNHLP report.

Even though over a year has passed since the report was published and a new Secretary General has taken the helm of the UN, activists within multilateral organizations and activist countries

continue to venue-shop the report throughout Geneva and international organizations. Their hope is that despite member state rejections of the UNHLP, they can selectively insert UNHLP recommendations by reference throughout UN bodies. We've seen such efforts in the WTO, World IP Organization (WIPO), UN Human Rights Council, UN Conference on Trade and Development, and Organization for Economic Cooperation and Development (OECD).

Most notably, however, we are seeing a concerted effort to resurrect the ashes of the UNHLP report again in the WHO. This effort appears to have direct links to the aforementioned Delhi conference and again attempts to circumvent member states by imposing UNHLP recommendations. We urge the U.S. government to continue to take a holistic approach that acknowledges the many complex factors that impede access to medicines, reject all attempts to incorporate the divisive and deleterious UNHLP into official agendas and resolutions, work with other member states to reassert their leadership over these processes, and not allow secretariats a free pass to shape the conversation and agenda.

This is just one case of the vicious cycle for diminishing IP protections in multilateral organizations. Member states push these misguided agendas to provide international cover for their less-than savory policies at home before exporting these policies back to Geneva. South Africa's draft IP laws seem to take a page from the UNHLP; also in Indonesia where UNDP is said to have a hand in crafting their troublesome patent law; and in Colombia, where the WHO Secretariat sought to unilaterally interpret the TRIPS Agreement to provide cover for a potential compulsory license.

It is essential that American leadership in multilateral organizations create—and in many cases, maintain—a global environment which rejects these negative policies and instead supports creativity, innovation, and access to new technologies through strong IP rights.

At WIPO, there is a continued push to focus on exceptions and limitations to copyrights in a misguided effort to further the "development agenda" and facilitate cross-border uses in the digital environment. The underlying assumption is that strict copyright rules and enforcement impede development, an assumption contrary to the data found in the Chamber's International IP Index on the positive correlations between strength of IP environments and important socioeconomic indicators. There is a similar effort to weaken biomedical innovation, with several countries pushing for a standalone treaty on genetic resources. It is not uncommon for the same countries to challenge the link between innovation and IP, and push back efforts to improve the patent backlog such as via work-sharing, unfortunately rejecting them as an affront to sovereignty. While WIPO could engage in efforts to enhance the functioning of IP systems—such as, through the WIPO Match program or helping member states implement their existing digital treaty programs—those laudable endeavors are regularly thwarted by the countries that could benefit most from their implementation.

We also have concerns over the direction of the OECD's Directorate for Science, Technology, and Innovation, which despite lacking technical expertise, continues to assert that copyright is an impediment to digital commerce even though the U.S. and European experiences demonstrate the exact opposite. More comprehensively, the Chamber's International IP Index Annexes provide evidence that stronger copyright legal protections are correlated with more robust digital sectors.

In addition, we see a number of countries seeking to accede to OECD membership without a willingness to satisfy the high standards of OECD members, particularly with respect to IP laws. Allowing accession on substandard terms weakens the entire organization.

The Chamber will continue to engage on these emerging issues within international organizations. In the coming weeks and months, future discussions of the UN, WHO, UNHLP, WTO, WIPO, OECD and other issues or negotiations taken up by international organizations will only be able to successfully address areas such as promoting innovation, development, and access to medicines if our U.S. delegation is appropriately staffed and prepared. This means ensuring that all relevant U.S. government agencies are aligned and making sure that the delegation includes USG officials with adequate IP expertise.

Endemic Challenges to U.S. Patent System

No portrayal of the global IP landscape would be complete or accurate without describing the reduced confidence of rights holders and end-users in the U.S. patent system. Three factors are principally at work:

1) *Patent Eligibility*: A series of Supreme Court rulings[10] between 2012 and 2014 had the effect of limiting patent eligibility for cutting-edge sectors of the U.S. economy, particularly bio-pharmaceuticals and information technology (software).
2) *Legal Uncertainty*: Many rights-holders have expressed concerns that the post-grant opposition proceedings implemented since 2011[11] diminished the due process, clear and convincing standard for challenges, and long-standing presumption of validity previously afforded patent holders by the courts, resulting in unprecedented rates of patent invalidations and creating uncertainty that extends throughout the life of a patent.
3) *Litigation Burden*: Mounting costs of enforcing and defending patents – as well, conversely, as defending against spurious infringement allegations – have effectively denied small inventors and businesses the enjoyment of their private property rights vested in patents.

[10] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566_(2012); Association for Molecular Pathology v. Myriad Genetics, 569 US_(2013); Alice Corporation v. CLS Bank International, 573 US_(2014)
[11] ''Leahy-Smith America Invents Act' 125 STAT. 284 PUBLIC LAW 112–29—SEPT. 16, 2011

Many economists, academics, rights holders and investors have stated that the net effect of these developments has been to dampen the economic incentive for long-term, capital-intensive, or high-risk research and development undertakings in cutting-edge sectors by undermining the durability of the patent as a reliable basis for investment. Coupled with advances in IP protection in other global markets, U.S. leadership and competitiveness in key innovative sectors has suffered. Consequently, the U.S. is currently ranked 12th globally in strength of patent rights on the U.S. Chamber International IP Index.[12]

There are a number of steps that can be taken to address concerns about the current state of the U.S. patent system: Subsequent U.S. court rulings have incrementally mitigated the narrowed scope of patent eligibility that was a legacy of the Mayo, Myriad, and Alice decisions; nevertheless, much of U.S. IP-intensive industry has pointed to a need for a more thorough and permanent fix through amendment of Section 101 of the U.S. Patent Code. The current administration has an opportunity to address legal uncertainty created by adverse patent opposition proceedings either through legislation or administrative reform from within the U.S. Patent and Trademark Office. Finally, measures to strengthen patent rights through reforms to patent eligibility and opposition proceedings will have a salutary effect on court costs by reducing the perverse incentive that currently induces end-users to litigate patents rather than seek to license rights on commercial terms; in conjunction with such steps, exorbitant litigation costs can be addressed through targeted legislation to punish extortionary patent assertion practices.

Resourcing U.S. IP Leadership

Global IP standards carry special significance for the U.S. as one of the world's most innovative economies. The U.S. Department of Commerce has found that IP-intensive industries have outsized importance to the U.S. economy, accounting for 45 million U.S. jobs and 38% of gross domestic product. Nevertheless, aside from free trade agreements negotiated by the U.S. with a relative handful of countries, IP standards have advanced little since the World Trade Organization's Agreement on Trade-Related Aspects of IP Rights (TRIPS) entered into force in 1995. On the contrary, the minimum standards reflected in the TRIPS agreement have been under near constant attack from countries seeking to circumvent commitments to respect IP rights.

Multilateral organizations including the World IP Organization (WIPO), the World Trade Organization (WTO), and the World Health Organization (WHO), have a whole or partial member-state mandate to discuss and address IP matters under their remit; in others, such as the UN Development Program, UNAIDS, the UN Forum on Climate Change, and many more, activists have promoted an anti-IP agenda under the rubric of addressing broader, often wholly

[12] U.S. Chamber International IP Index: http://theglobalipcenter.com/IPIndex

unrelated, social ills. The effect of this multilateral mission creep is to put IP policy in the hands of non-elected staff who lack either the requisite expertise or authority to make decisions with critical implications for the global knowledge economy.

In this environment, U.S. government leadership has been critical to holding the line on TRIPS standards and promoting a data-driven, evidence-based dialogue in multilateral organizations about the importance of IP. The Statistical Annex to the U.S. Chamber International IP Index illustrates the stakes: Countries scoring above the median of the Index enjoyed greater access to innovation-related economic inputs (e.g., research and development expenditures, skilled researchers, access to venture capital, foreign direct investment), as well as enhanced levels of economic outputs (e.g., growth of high-tech sectors, software creation, online creativity, and clinical trials).

Working with a small cadre of like-minded nations, U.S. officials from across the federal government have been able to monitor and respond in timely and effective fashion to wide-ranging proposals to eviscerate global IP standards in a host of multilateral organizations. The contributions of many agencies deserve credit for the good work that has been done by the U.S. government, yet special recognition is due to the coordination role played by the Office of Policy and International Affairs (OPIA) at the U.S. Patent and Trademark Office.

Uniquely among U.S. government offices, OPIA has the breadth, depth, and institutional memory under one umbrella to recognize and respond to policy challenges to IP in all its forms. The private property rights associated with patents, trademarks, copyrights, and trade secrets are each regulated by specialized statutes defining rights and remedies, as well as appropriate exceptions. Yet an attack on one form of IP is an attack on the institution as a whole, and the singular capability of OPIA to see the entire field and marshal resources from across the inter-agency suite must be respected, protected, and preserved.

COUNTRY-SPECIFIC TRENDS

Australia

Overview: Innovative and creative companies continue to face challenges to adequately protect their IP in Australia, the highest-income country included in the U.S. Chamber's 2018 Special 301 submission. As the 2016 Productivity Commission report states, Australia continues to view itself as a net-importer of IP-intensive goods and services, and thus has avoided embracing stronger IP laws. Yet, a more effective IP framework, which incentivizes innovation and creativity, will be critical to fostering innovation, attracting foreign investment, and stimulating long-term economic growth and global competitiveness.

Australia's overall score rose from 77% of the total possible score (with a score of 27.07 out of 35) in the fifth edition of the Index to 80% (32.11 out of 40) in the sixth edition. This mainly reflects strong performance on the new indicators.

The U.S. Chamber looks forward to working with the U.S. government to address the below IP-related concerns.

Australian Productivity Commission: Over the last 10 years, the Australian government has undertaken a number of IP policy reviews. In December 2016, the Productivity Commission released its final report of IP Arrangements, which included many negative recommendations that would jeopardize the strength of Australia's IP system. In August 2017, the Australian Government issued a response to the Productivity Commission recommendations, consulted further by launching a public comment period, and announced its intention to move forward with legislation on others. In relation to patents, the Government supports the Commission's recommendations to align patent standards with the European Patent Office and announced it would not implement the report's recommendations on patent term extension. In relation to copyrights, the Government did not respond to the recommendation to violate TRIPS and other international obligations by reducing the term of copyright and said it will review and consult on the need for new exceptions for TPMs and introduction of a fair use exception to copyright. The U.S. Chamber appreciates the Australian Government's thoughtful review of the report's recommendations and supports the government's decision to reject the proposals that will undermine Australia's existing IP framework. However, the ongoing IP policy reviews over the last 10 years create an unstable policy environment in Australia as the effectiveness of the government's IP policy is consistently being reviewed. The U.S. Chamber looks forward to working with the U.S. and Australian governments to ensure that all IP policy reviews help to create greater legal certainty for innovative and creative industries operating in Australia.

Patents and Related Rights

Market-Size Damages and Patent Notification Period: In Australia, an innovative company receives no advance notification when the Therapeutic Goods Administration (TGA) approves a competing generic medicine and lists on the Pharmaceutical Benefits Scheme (PBS). The PBS imposes automatic and irreversible price cuts on medicines as soon as competing versions enter the market. If the innovative company tries to defend their patent in court and loses, the Australian Department of Health seeks damages from biopharmaceutical innovators to compensate the PBS for any higher price paid for a patented medicine during the period of patent enforcement. Yet, the policy does not include a mechanism to compensate innovators for losses incurred if an infringing product enters the market prematurely. These market-size damages undermine the use of provisional enforcement measures and unfairly penalize innovators. Further, the policy creates an inherent conflict of interest by allowing the same government which granted the patent to seek damages if the patent is later invalidated. The policy sends a troubling signal that the Australian government will circumvent IP protection in an effort to drive down pharmaceutical prices, which will undermine Australia's attractiveness for biomedical foreign direct investment and discourage the investment in new, life-saving cures.

The continued application of market-sized damages appears to be inconsistent with the Australia-U.S. Free Trade Agreement (AUSFTA). Article 17.10.4(a) of the AUSFTA states that Australia is obligated to "provide for the patent owner to be notified" of the identity of a third person requesting marketing approval during the term of a patent, and to "provide measures in its marketing approval process to prevent" third persons from marketing a product during the term of the patent without consent of the patent owner. In January 2005, the Australian government amended the Therapeutic Goods Act (TGA) to bring the law into compliance with the terms of the AUSFTA. However, amendments to the TGA under sections 26B(1)(a), 26C, and 26D allowed the government to seek these market-sized damages to reimburse the PBS when a company pursues unsuccessful patent claims. In a letter from then-USTR Robert Zoellick to Australian Trade Minister Mark Vaile in 2004, USTR states that the "U.S. reserves its rights to challenge the consistency of these amendments with such obligations." Given that these amendments appear to be inconsistent with the letter of the AUSFTA, the U.S. Chamber requests that USTR utilize their rights under the AUSFTA to challenge the legitimacy of the amendments and work with Australian government to identify a legislative fix which will prohibit the government from pursuing these damages. At a minimum, the U.S. Chamber believes the introduction of a 12 month notification period as an amendment to the TGA would bring Australia into compliance with its AUSFTA obligations and reduce the need for legal action over patents. The U.S. Chamber encourages USTR to prioritize the market-size damages policy and the need for an appropriate notification period to ensure a fair and predictable market for biopharmaceutical investors in Australia.

Patentability Requirements: The Australian Patent Office released new guidance on patentability of genetic material in light of the High Court's 2015 decision in D'Arcy v. Myriad Genetics. The guidelines maintain that genetic material remains patentable, with exceptions for certain claims that focus on naturally occurring material. Recent court and patent office decisions, such as Cargill Incorporated v. Dow AgroSciences LLC and Arrowhead Research Corporation (2016) APO 70, confirm that isolated nucleic acids are patentable as long as they have been modified. In addition, 2016 case law, notably Central Ltd v. Commissioner of Patents and Research Affiliates LLC v. Commissioner of Patents, provides further clarity concerning the patenting of business methods and software claims: broadly speaking, they are considered patentable subject matter as long as they produce a new and useful physical effect on a computer. The U.S. Chamber appreciates the court decisions which support the patentability of biotechnology and business method and software patents and looks forward to working with the Australian government to ensure these patentability requirements are adequately applied.

Regulatory Data Protection: Current Australian law allows only five years of regulatory data protection for biologic medicines—drugs made up of living matter that are incredibly expensive and risky to produce. The current five-year standard represents an exclusivity level far below the U.S.-standard of 12 years and is a significant roadblock for innovative companies that are stimulating research and development in treatments for some of the riskiest and most complex issues facing human health. As such, the Chamber would like to suggest that enhanced data exclusivity protection for biologic medicines would be in Australia's interest and strongly in line with the Government's stated industrial policy objectives with respect to pharmaceuticals.

Market Access Concerns: The Pharmaceutical Benefits Advisory Committee (PBAC) in Australia compares new products to the "lowest cost" comparator, which creates a barrier to patient access due to the comparisons being made to cheaper, off-patent medicines that have undergone several rounds of competitive price reductions through price disclosure. As the price-disclosure measure has expanded and matured, creating downward pressure on prices in the multi-brand, competitive market for off-patent medicines, comparators are increasingly being drawn from very low cost drugs. This practice acts as a disincentive to bringing innovative medicines to Australia.

Copyrights and Related Rights

Copyright Amendment (Service Providers) Bill 2017: In December 2017, the Australian Government introduced the *Copyright Amendment (Service Providers) Bill 2017*. The bill amends the *Copyright Act 1968* to expand the definition of "service provider" and to extend safe harbor provisions to educational institutions, libraries, archives, cultural institutions, and organizations assisting the disabled. The U.S. Chamber appreciates that the proposed amendments did not expand the definition of service provider to include online service providers. However, in its response to the Productivity Commission report, the Australian Government stated that it "supported in principle" the report's recommendations to expand safe harbor

protections to “all providers of online services.” The U.S. Chamber remains concerned that in further review of the Copyright Act amendments, the Australian government could propose such an expansion. As the amendments are further considered within the Australian government, we hope USTR will help ensure that the safe harbor provisions are not expanded further to all online service providers as such an expansion would undermine Australia’s current copyright system.

Brazil

Overview: Though much work remains to be done, both the Brazilian government and private sector are increasingly recognizing the fundamental link between IP and innovation in Brazil in recent years. The U.S. Chamber is encouraged by the work undertaken under the National Institute of Industrial Property (INPI) to improve Brazil's IP system. In addition, local pharmaceutical associations are now working with the industry to develop a stronger IP framework. We believe that introducing incremental changes to strengthen Brazil's overall IP system will help assure investors that their innovations will be adequately safeguarded in the market, which presents a tremendous long-term investment opportunity.

The U.S. Chamber is pleased to note that the U.S. Patent and Trademark Office (USPTO) is in discussions with INPI on renewing and expanding the Patent Prosecution Highway (PPH) Pilot Program that was launched in January 2016. We encourage the U.S. government to ensure that the PPH becomes a permanent agreement beyond the oil and gas sector as it will provide a critical mechanism to expedite the patent approval process for all IP-intensive industries.

Brazil's overall score on the U.S. Chamber IP Index has increased from 38% (13.23 out of 35) in the fifth edition to 39% (15.72 out of 40) in the sixth edition. This increase in score mainly reflects a relatively strong performance in the new indicators added and the removal of administrative barriers to licensing and commercialization of IP assets.

In order to further support efforts in Brazil to improve the IP regime and to further reiterate the importance of robust IP protections to the growing bilateral relationship, we encourage the U.S. government to pursue the following policy priorities with its counterparts in Brazilian government.

Patents and Related Rights

Patent Review Delays: While U.S. industry reported extensive patent and trademark approval delays in 2016-17, new initiatives and structural reforms within INPI are steps in the right direction to help reduce the backlog. In 2016, INPI hired an additional 70 patent examiners. Later in 2016, the Official Gazette published Ordinance No. 357, which gave INPI the authority to hire an additional 30 new examiners and 40 new IP "technologists," adding a total of 70 examiners and technologists in January 2017. Currently, INPI is estimated to have a total of 326

patent examiners and 147 technologists.[13] Additionally, Resolution 76/2013 created an accelerated patent examination mechanism for priority patent fields.[14]

In addition, INPI introduced reforms to automate and digitize internal procedures in order to reduce the time taken for administrative processes, and in turn, reduce the time taken to examine patents. For instance, of the total number of patents filed in 2017, 92% used the electronic submission method.[15] INPI's new telework program is reportedly growing in popularity among INPI staff, with prospective and current teleworkers given higher production goals per staff than those examiners who work in the office.[16] INPI's new initiatives have led to a "downward trend" in the patent backlog by 6.6% in October 2017 compared to the same term in 2016.[17] At the same time, 2017 ended with 28,667 new patent applications, a number that reflects a 7.6% decrease in comparison with the previous year and lower than 31,020 filed in the same period in 2016. The Chamber supports the recent INPI initiatives and looks forward to collaborating with the U.S. government and INPI on further programs to address the patent backlog. In addition to the reported improvements, the ratification of Madrid Protocol has been advancing in the Brazilian Congress, which could help further reduce backlogs.

Patent term adjustment for mailbox patents: Brazil provides 20 years of patent protection from the date of filing or a minimum of ten years from the date of patent grant. However, in September 2013, INPI issued a binding opinion followed by the filing of related lawsuits to invalidate or limit the term of approximately 240 so-called "mailbox patents", which are patents related to biopharmaceutical products or agrochemical compounds that were filed after Brazil acceded to the World Trade Organization (WTO) on January 1, 1995, but before the Patent Law went into effect on May 14, 1997. These lawsuits, primarily affecting pharmaceutical patents, are currently proceeding through the legal system including the Court of Appeals, but most decisions have upheld INPI's retrospective decision to no longer provide a minimum ten years of post-grant patent protection. The Chamber and its members would benefit from additional clarity on this matter.

[13] Mayer Brown LLP, BPTO Backlog: The Proposal to Fast-Track Patent Applications in Brazil, November 27, 2017. Accessed on January 10, 2018; INPI, Industrial Property: Brands Panel," Ministry of Industry, Foreign Trade, and Services, Accessed on January 10, 2018. http://www.inpi.gov.br/menu-servicos/marcas/painel-de-marcas

[14] Federation of the Industries of the State of São Paulo, National Confederation of Industry—Brazil, and Brazil Industries Coalition. 2016 Special 301. Pg. 8.

[15] INPI, "Boletim Mensal de Propriedade Industrial – January 2018." Accessed January 8, 2018 at http://www.inpi.gov.br/sobre/estatisticas/arquivos/publicacoes/boletim-jan_2018.pdf.

[16] "Segunda fase do trabalho remoto amplia número de vagas," Ministry of Industry, Foreign Trade and Services. Accessed January 10, 2018 at http://www.inpi.gov.br/noticias/com-mais-40-vagas-segunda-fase-do-trabalho-remoto-comeca-em-breve.

[17] "INPI receberá R$ 20 milhões em 2018 para melhoria de processos e TI," Ministry of Industry, Foreign Trade and Services. Accessed January 10, 2018 at http://www.inpi.gov.br/noticias/inpi-recebera-r-20-milhoes-em-2018-para-melhoria-de-processos-e-ti.

Patentability and Dual Examination: There were a number of efforts taken by the Brazilian authorities in 2017 affecting the patenting environment. In a positive step the Brazilian Patent Office (INPI) announced in July that it would introduce a simplified procedure for the granting of patent applications. The new draft procedure would allow for the processing and issuing of patents within a 90-day window. Any efforts to reduce INPI's backlog are welcome as this long-standing problem presents a significant curtailment and barrier to rights-holders' exploitation of their IP. The current backlogs range from 10-13 years depending on the field of technology with applications in the biopharmaceutical and ICT fields traditionally being the worst affected. And these efforts build on international patent prosecution efforts from 2016 and 2017 with the U.S., Japan and other offices aimed at streamlining and expediting the prosecution process albeit for a select few technologies.

Unfortunately, the draft procedure has from the outset excluded biopharmaceutical patents which have historically suffered significant delays in patent prosecution. On the other hand, a new interagency ordinance clarifies and institutionalizes the Brazilian Health Regulatory Agency's (ANVISA) role in evaluating biopharmaceutical patent applications. As noted in previous editions of the IP Index, ANVISA has traditionally had the right to provide prior consent to biopharmaceutical patents that are being examined by INPI. Consequently, decisions on whether to grant a patent have been based on examination not solely by patent specialists and officials at INPI, but also by ANVISA. This has in effect meant a requirement of dual examination, in turn violating the TRIPS Agreement. The exact meaning and nature of ANVISA's right to prior consent has never been fully defined and frequently been questioned in court.

As a step in the right direction, the publication of the Interagency Ordinance in April 2017 clarified the relationship and interaction between ANVISA and INPI in the patent review process. Following INPI's notification, Article 2 of the Ordinance moves ANVISA's role to earlier stages in the patent application to initiate the procedure for prior consent. Next, ANVISA will analyze applications in light of public health, and opinions regarding patentability may be binding on INPI only in cases where ANVISA concludes that there is a severe public health risk as prescribed under Article 4 of the regulation. Article 5 further mentions drugs "of interest to the drug policies and pharmaceutical assistance of the Public Healthcare System (SUS)." The new rules attempt to clarify, with caveats, the extent of ANVISA's role in providing opinions on patentability, with INPI leading the rest of the examination. Eventually, Article 9 of the Ordinance calls for the establishment of an "Interagency Policy Group" between ANVISA and the INPI for the "harmonization of understandings between the agencies". It remains to be seen whether this interaction will further facilitate or restrict the biopharmaceutical patentability process.

Regulatory Data Protection: Brazilian law 10.603/2002 currently provides regulatory data protection for veterinary products, fertilizers, and agrochemicals, but does not extend this protection to pharmaceuticals made for human use. Regulatory data protection, which protects

innovative companies against the unfair commercial use of their data by a third party during the marketing approval process, allows a biopharmaceutical company to recoup the significant investment needed to generate the data required for the marketing approval of a new drug. The lack of regulatory data protection for human use innovations has created challenges for biotechnology companies operating in Brazil. The Chamber encourages the U.S. government to work with the Brazilian government and ANVISA to ensure equivalent and equitable regulatory data protection for human-applied innovations.

Technology Transfer and Commercialization of IP Assets: Brazil has a number of policies and regulations in place to promote the transfer of technology and commercialization of IP. For instance, one of the key tenets of the 2004 Innovation Law was to encourage the transfer and commercialization of technologies through incubation services for public researchers and greater encouragement of start-up activities. The law provides incentives including royalty guarantees to inventors. There are also special R&D tax incentives in place which reward the commercialization and protection of IP. These include a potential 60% deduction on corporation tax liability and social contributions, which can also increase if there is a year-on-year cumulative increase in R&D spending. An additional 20% deduction becomes available once an invention has been patented.

However, these initiatives are in many respects undermined by an administrative and regulatory framework which can be both burdensome and inefficient. For example, the practical availability of the additional 20% R&D deduction for patented inventions is very limited given patent backlogs at INPI. Despite these positive incentives, regulatory and formal requirements can limit the attractiveness of licensing IP assets in Brazil. Technology transfer agreements must be registered with INPI. During the registration process the INPI has sought to modify the terms of these freely negotiated contracts. Typical modifications include limits on confidentiality clauses and royalties. INPI's interference can also put trade secrets at risk by generally refusing to require the return of confidential information at the close of a contract's term as well as limiting the time period for these agreements. These policies discourage collaboration, ultimately slowing down technology transfer rather than encouraging it.

The year 2017 saw a positive change of direction in Brazil's environment with respect to the commercialization of IP assets. Traditionally, significant regulatory and formal requirements were in place limiting the attractiveness of licensing and widespread technology transfer. For example, to become effective and binding on third parties, licensing agreements were required to be published in the INPI's Official Gazette. Agreements were also required to be approved by INPI with limitations on fees and payments between the contracting parties. Exclusive licensing agreements were subject to more onerous publication requirements than non-exclusive licenses making this process more time-consuming.

This changed in 2017 with the INPI announcing through Rule 70 that INPI will no longer take an active role in the framing and approval of licensing agreements. Instead, the new Rule suggests that the agency will merely operate as an agency for recording those registrations. The U.S. Chamber applauds this change to Brazil's IP framework addressing long-standing concerns highlighted in the U.S. Chamber's 2017 Special 301 submission. By clarifying the role of the National Health Surveillance Agency in the patent review process and restricting the scope of review by the Brazilian Patent Office of technology transfer contracts, the government has taken positive action to remove bureaucratic barriers to innovators in Brazil. If this is implemented and, in fact, the net effect of the rule is positive, it would represent a significant improvement in the technology transfer environment in Brazil. As a result of this new change Brazil's score on this indicator of the IP Index has increased.

Copyrights and Related Rights

Online and Hard Goods Piracy: Both online and hard goods piracy remains pervasive in Brazil, greatly limiting economic and cultural opportunities for Brazilian and American creative industries alike. Because increased broadband use has accelerated the expansion of pirated works online, steps must be taken to develop a legitimate online marketplace which adequately protects copyrighted works. Of note, in 2017, a new important player has gained force in the Brazilian piracy ecosystem: illegal streaming devices, such as the HTV box, which offers the entire grid of live TV paid channels, as well as a VoD service with movies and TV shows, illegally sourced. Furthermore, industry reports that over 50% of the products on the main Brazilian e-commerce platform, Mercadolivre.com.br, are counterfeit. The U.S. Chamber looks forward to engaging in meaningful conversations with Mercado in order to adequately combat the sale of counterfeit goods through the online marketplace. Further, the U.S. Chamber encourages the U.S. government to urge their Brazilian counterparts to institute effective and timely mechanisms to combat online copyright infringement, most notably expanding the availability of injunctive relief to prevent access to infringing materials, and ensuring that implementation of the Marco Civil Internet law and related decrees and legislation do not interfere with voluntary notice and takedown efforts or other constructive and cooperative agreements to combat online piracy.

Additionally, an increasing number of counterfeit goods are being manufactured in Brazil. In Nova Serrana city and in Minas Gerais State, industry reports that counterfeit factories outnumber legitimate factories. The Brazilian government created the National Council Against Piracy and IP Crimes (CNCP), which included a number of programs – including the "City Free of Piracy Initiative" – to combat hard goods piracy. While the CNCP continued to implement a number of educational programs to create greater awareness about the implications of online piracy, industry reports suggest that other CNCP initiatives have largely stalled over the last three years. According to the CNI-BIC-ICC report cited earlier, in Rio de Janeiro, the work of the border control law enforcement, has resulted in the seizing of 60 tons of counterfeit goods since the start of the Fiscal Barrier program in 2010.

Despite these positive initiatives, IP holders face challenges utilizing the legal system to enforce against IP theft. For example, in the Judiciary of the State of São Paulo, IP owners report issues obtaining injunctions to seize counterfeit products. The U.S. Chamber strongly encourages the U.S. government to encourage the Brazilian government to place a priority on strengthening IP enforcement efforts and address legal barriers which prevent IP rights holders from utilizing the judicial system to protect their IP. Additionally, the U.S. Chamber recommends that the U.S. government collaborate with Brazilian government colleagues to ensure that previously successful initiatives, like those of the CNCP, have the resources and local government support to more effectively combat all forms of copyright piracy throughout Brazil. Furthermore, we encourage Brazil to enact: pending legislation authorizing court orders requiring Internet service providers (ISPs) to block access to offshore websites dedicated to criminal activity, including criminal copyright infringement and pending legislation to criminalize signal theft in the home entertainment sector.

In recent years, Brazil introduced several initiatives, like the Brazilian National Forum Against Piracy and Illegality's "click original" campaign – to educate consumers about the importance of accessing legitimate content online. This public initiative provides rights holders the opportunity to submit information on potential infringement of their brand and gives the public at large and consumers a source of evidence and statistics on the scale of online piracy. Additionally, in October 2016, under *Operação Barba Negra*, the Brazilian Federal Police successfully took down a total of 30 websites containing pirated materials. Furthermore, we are encouraged by the Brazilian Ministry of Culture's anti-piracy initiatives through working groups on awareness and education.

However, in order to operate effectively, industry reports that both the education initiatives and enforcement efforts need sustained and increased resources, including dedicated personnel with a clear and defined mandate. The U.S. Chamber supports U.S. government engagement with the Brazilian government to help bolster the resources needed to ensure the continued success of these initiatives.

Local Content/Forced Localization: Brazilian law includes a number of local content requirements, which impact a number of IP-intensive sectors including the movie and music industry and ICT sectors. The forced localization policies limit the legitimate content that Brazilian consumers can access, which could force users to seek out the content on illegitimate sites. The local content requirements also disrupt the existing supply chain and inhibit the growth of new technologies. The U.S. Chamber encourages the U.S. Government to work with the Brazilian government to introduce policies that help stimulate innovation and creativity across the content sectors – through industry training programs and tax incentives – rather than local content requirement policies.

Unlicensed Software Use: The rate of software piracy in Brazil has decreased over the last five years, placing the use of unlicensed software in Brazil below the mean for Latin American countries. CNI reported that the Brazilian Association of Software Companies (ABES) led several successful initiatives to combat the use of pirated software. Of note, ABES removed 70,476 advertisements, links, or websites which hosted copyright-infringing software content.[18] The U.S. Chamber recommends that the U.S. government collaborate with the Brazilian government to introduce additional mechanisms to combat software piracy in Brazil.

Camcording: The unauthorized camcording of films in theaters continues to present a problem for copyright-intensive industries and further fuels online piracy in Brazil. The International IP Alliance (IIPA) reported that 90% of all pirated films in Brazil originated from camcording in theaters.[19] From January 2015 through November 2017, the Motion Picture Association of America (MPAA) detected at least 7844 illegal recordings – image, sound, or both – originating in Brazilian theaters. As a result, the MPAA recently created an industry coalition, the Cinema Against Camcording (4C), which is comprised of six studios. The coalition seeks to increase information sharing between studios operating in Brazil and foster support for legislation to address camcording. The U.S. Chamber endorses pending legislation providing criminal penalties for unauthorized camcording without mandating proof of the infringer's intent to distribute and profit from the camcorded film. Likewise, we encourage the U.S. Government to work with the Brazilian government to implement measures criminalizing camcording in order to provide greater protection for copyrighted content in Brazil.

Trademarks

Fast-track for Trademark Registrations and Industrial Design: In 2012, as part of its agreement to host the 2013 FIFA Confederation Cup and 2014 World Cup, Brazil enacted the "World Cup Law" providing special protections (including recognition as famous marks) for FIFA–and World Cup–related trademarks, as well as fast-track procedures for INPI to process and register FIFA-related applications. Similarly, ahead of the 2016 Olympic Games, the Brazilian Patent and Trademark Office (BRPTO) allowed fast-track examination of industrial design applications for sporting goods. The U.S. Chamber applauds both the expedited industrial design application process and the Olympics Act, which provided critical protection for innovative companies operating in Brazil. We look forward to further clarity on the proposal for a special, temporary fast tracking procedure for patent applications and balancing this with patent quality considerations.

[18] Federation of Industries of The State of São Paulo and National Confederation of Industry. 2015 Special 301 submission, February 2016, pg. 15.
[19] International IP Alliance (IIPA). 2016 Special 301 Report on Copyright Protection and Enforcement. February 2016, pg. 4.

INPI's new initiatives to restructure and address trademark application backlogs are steps in the right direction. According to INPI's Painel de Marcas, in October 2017, there were 372,686 unexamined trademark applications, 56,697 fewer compared to October 2016.[20] The Painel also indicates that INPI was examining applications without oppositions from September 2015 in mid-November, with a 25-26 month backlog at that time.[21] New trademark applications increased by 11.9% in 2017 compared to 2016 with a total of 186,103 registrations.[22] We are also encouraged by Brazil's renewed effort to join the Madrid Protocol, as announced by Brazil's Minister of Industry, Foreign Trade and Services in 2016, whereby INPI is working to reduce the backlog to 18 months or less. INPI expects to accede to and adopt the Madrid Protocol in late 2018 or early 2019. The U.S. Chamber welcomes a speedy accession.

[20] INPI, "Industrial Property – Painel de marcas," November 29, 2017. Accessed January 10, 2018 at http://www.inpi.gov.br/menu-servicos/marcas/painel-de-marcas.
[21] INPI, "Industrial Property – Painel de marcas," November 29, 2017. Accessed January 10, 2018 at http://www.inpi.gov.br/menu-servicos/marcas/painel-de-marcas.
[22] INPI, "Boletim Mensal de Propriedade Industrial – January 2018." Accessed January 8, 2018 at http://www.inpi.gov.br/sobre/estatisticas/arquivos/publicacoes/boletim-jan_2018.pdf.

Canada

Overview: A unified North American IP framework will be critical to furthering global economic competitiveness for the Canada, Mexico, and the U.S. alike. Through the NAFTA modernization, the Canadian government can strengthen its existing IP framework, which can significantly increase U.S. exports and help realize a vision of North America as the world's innovative and creative engine. In 2017, the Canadian government passed a number of legislative reforms and handed down judicial decisions that took steps towards improving Canada's IP framework. Most notably, the Supreme Court decision to overturn the patent utility standard and the Federal Court ruling on technological protection measures (TPMs) helped provide greater certainty that the Canadian government will better protect innovative and creative companies' IP in Canada.

Yet, the Canadian government's action in multilateral fora and through free trade agreement negotiations continue to call into question the Canadian government's commitment to embracing more effective IP policies. Specifically, the Canadian government's insistence on suspending many of the IP provisions in the CPTPP among the 11 member countries and the final implementing regulations for the Comprehensive Economic and Trade Agreement (CETA) with the EU illustrate how the Canadian government continues to weaken IP protection because the country is a "net-importer" of IP. The U.S. Chamber hopes the U.S. government will leverage the NAFTA modernization process to address the below concerns to create a more effective IP framework in Canada in order to strengthen North American competitiveness.

Canada's overall score has increased substantially from 61.3% (21.44 out of 35) in the fifth edition to 66% (26.5 out of 40) in the sixth edition of the Index. This reflects a strong performance on the new indicators added to the sixth edition and a number of precedent-setting court judgments relating to patentability and copyright enforcement.

Patents and Related Rights

Patent Utility: From 2005-2017, Canadian courts applied a heightened standard for patent utility by imposing a subjective and inequitable patentability test on inventions, which represents a significant erosion of patent rights. This test was accompanied by a heightened and often unreasonable evidentiary burden, requiring innovators to demonstrate the effectiveness of a pharmaceutical in light of a subjectively construed "promise." In November 2016, the Supreme Court of Canada heard oral arguments in the long running case *AstraZeneca Canada Inc. v. Apotex Inc.* over the utility of AstraZeneca's patent for Nexium. Previously, the Court of Appeal had ruled that the "promise" of utility made in the original patent "was neither demonstrated nor soundly predicted at the time the patent was filed." In June 2017, the Court handed down the final judgment rejecting the promise doctrine. The judgment stated that the promise doctrine "is unsound," "antagonistic to the bargain on which patent law is based wherein we ask inventors to

give fulsome disclosure in exchange for a limited monopoly" and that "promises are not the yardstick against which utility is to be measured." The watershed decision in Canadian pharmaceutical patent jurisprudence should reverse what has been a decade and a half long negative trend. The U.S. Chamber applauded the Supreme Court decision as a first-step towards restoring much-needed clarity and confidence that biopharmaceutical IP protections will be equally protected under the law in Canada. The U.S. Chamber hopes that the Supreme Court's judgment will be a critical turning point towards realigning Canada's requirement with international standards.

Patent Enforcement and Resolution Mechanism: Under the Canada-EU Economic and Trade Agreement (CETA), the Canadian government committed to implementing a two year patent right of appeal term for patent holders. Previously, the PM (NOC) regulations allowed a generic company to appeal a decision in a Notice and Compliance proceeding. The CETA implementing regulations sought to address this imbalance by creating a similar right of appeal for biopharmaceutical innovators. However, the changes made to the PM (NOC) through CETA created a new pharmaceutical litigation regime, which further dilute innovative companies' rights in the process. While the purpose of eliminating the dual litigation procedure and creating a single, combined regime was to create a more efficient system, in practice, the new policy will create greater legal uncertainty for innovators and likely increase the amount of IP litigation. The ongoing NAFTA negotiations create an opportunity to address this imbalance through the further modification of the PM (NOC) regulations to introduce a full and effective right of appeal. The U.S. Chamber recommends that the U.S. government continue to highlight the importance of an adequate patent enforcement and resolution mechanism through the ongoing NAFTA renegotiation process.

We were also pleased that the Canadian government engaged in a helpful manner to secure amendments to the PM (NOC) regulations in 2015, which clarified that single medicinal ingredient patents can be listed in relation to combination products. The amendments were introduced following two Federal Court decisions which were inconsistent with paragraph 4(2)(a) of the PM(NOC) regulations. The clarifying regulations help to ensure that the patent holders have an effective patent enforcement mechanism for these important products.

Patent Term Restoration: Canada's IP environment could also improve significantly with the proper implementation of patent term restoration (PTR), which provides additional patent life to compensate for the time lost during clinical trials and regulatory approval process. Following the implementation of CETA, Canada has now introduced a new regulatory scheme allowing for some compensation for delays in obtaining marketing approval for biopharmaceutical products. The relevant amendments made to the *Patent Act* (sections 106-134) and implementing regulations published in the Canada Gazette provide a maximum restoration period of two years through a Certificate of Supplementary Protection (CSP) mechanism. While overall this is a positive step and an improvement in Canada's biopharmaceutical IP environment there remain

significant areas of concern. To begin with, under section 116(4) the Canadian Government retains the right to reduce the term of protection at its discretion. Specifically, this sub-section states "the Minister may, if he or she is of the opinion that that person's [the rights-holder's] failure to act resulted in a period of unjustified delay in the process of obtaining the authorization for sale, reduce the term of the certificate when issuing it by the amount of that period." No further definition of what constitutes an "unjustified delay" has been provided in any of the relevant regulations, which leaves a broad scope for interpretation with the Canadian Government. Moreover, the implementing regulations contain a 'Timely Submission Requirement' which sets a timeline for the submission of CSP applications based on the regulatory status of a given product in a set of 'prescribed economies'. The net effect is that the availability of a CSP is made contingent on early market entry. Equally troublingly, the law also contains an export claw-out with section 115(2) effectively exempting the infringement of CSP protection if the activity is for the purposes of exports. It is unfortunate that the law has undermined a positive and necessary incentive by limiting the actual protection afforded with these additional requirements and exemptions. In order to fulfill the fundamental purpose of restoring patent term lost due to marketing approval delays, the patent term restoration term must confer the full extent or rights contained in the underlying 20-year patent term. The NAFTA negotiations create an opportunity to address problematic aspects of the CSP in order to create an effective PTR mechanism, including the elimination of this "manufacture for export" exception. The U.S. Chamber encourages the U.S. government to work with the Canadian government to implement a PTR system that is consistent with other frameworks implemented by developed economies.

Disclosure of Confidential Business Information: Canada amended its Food and Drugs Act in November 2014 through Bill C-17 to include broad provisions that would allow the Health Minister to disclose confidential business information submitted to Health Canada as part of the regulatory approval process for pharmaceutical and medical device products. In 2015, the Canadian government released the guidelines with respect to how it would administer this law. These guidelines have maintained the broad and sweeping powers of the legislation. Specifically, section 21.1.2 includes the power to disclose confidential business information (including data submitted as part of an application for market and regulatory approval of medicines and medical technologies) to any person without notifying the owner of that information in cases where the Health Minister believes there is a "serious risk of injury to human health." Questions remain under what circumstances information will be disclosed, despite Health Canada guidelines that reference Canada's international treaty obligations to protect trade secrets (specifically TRIPS and NAFTA). The Chamber recommends that the U.S. government work with the Canadian government to ensure that Health Canada puts in place adequate safeguards to limit and control the release of clinical trial data.

Patented Medicines Prices Review Board (PMPRB): The Patented Medicines Pricing Review Board (PMPRB) sets maximum prices for patented medicines in Canada. These prices are not

the prices that are paid, but a maximum ceiling, which forces American companies to negotiate province by province and often obtain even lower prices. For many years, the PMPRB's decisions have diminished the value of American IP and innovation. Proposed regulations recently published by the Canadian Government to amend Canada's Patented Medicines Regulations will greatly exacerbate this problem and discriminate against U.S. innovators in an attempt to reduce the cost of innovative medicines in Canada at the expense of U.S. healthcare consumers and future innovation. Notably, the proposal removes the U.S. and Switzerland from the basket of comparator countries that the PMPRB uses to set drug prices, adding instead seven new countries with weaker IP systems, including Australia and South Korea. Additionally, the proposal would require patentees to report price and revenues, net of all price adjustments (e.g., confidential rebates). Finally, the proposal includes three new excessive price regulation factors that PMPRB must consider: "pharmacoeconomic value"; market size; and GDP measures. Canada's recent disregard for the rights of IP owners continues to be reflected in the proposed Patented Medicines Regulations. As mutual respect for IP is critical to the U.S.-Canada relationship, the U.S. Chamber recommends that the U.S. government leverage ongoing NAFTA negotiations as a means to ensure Canada is sufficiently respecting the rights of American IP owners through their domestic pricing policies.

Copyrights and Related Rights

Copyright Modernization Act Review: In December 2017, the House of Commons launched the five-year review of the Copyright Modernization Act. We believe this provides a critical opportunity to modernize copyright protection in Canada. Specifically, the Chamber would support the following changes: bringing Canada's term for all copyrighted works in line with the rest of North America, the OECD consensus, and the growing international norm of 70 years; tightening the limitations on statutory damages in the 2012 amendments so that they more clearly apply solely to infringements of a personal nature, and that the $5,000 cap applies to each individual act of infringement rather than creating an effective blanket license for all acts of infringement by a particular actor; applying national treatment to U.S. rights holders without exception; creating a more balanced and effective intermediary liability/safe harbor regime including notice and takedown; and providing more effective incentives for legitimate Internet intermediaries to cooperate with right holders to combat online infringement. The U.S. Chamber encourages the U.S. government to continue to raise the importance of these reforms through their ongoing bilateral dialogue with Canada.

Illicit Streaming Devices: Canadian consumers increasingly use illicit streaming devices (ISDs), such as the Android TV boxes, to access copyright-infringing content in Canada. A 2017 study by an Ontario-based networking solutions company, Sandvine, found that more than seven % of Canadian households – or more than one million users – use ISDs to stream pirated content

at home.[23] In 2016, three major cable service providers, Bell, Rogers, and Vidéotron, won a temporary injunction in Federal Court prohibiting 45 Canadian companies from selling Android TV boxes. While Federal Court ruling was a positive step, the continued use of ISDs in Canada not only undermines protection of copyrighted content but also deprives the economy of revenue, which creative companies provide. The Sandvine study estimated that if all North American users who currently utilizes ISDs were to access the same content legally, it would add $4.2 billion in revenue each year.[24] The U.S. Chamber urges the U.S. government to work with their Canadian government counterparts to limit the availability of ISDs both in the U.S. and Canada in order to better protect copyrighted content.

Trademarks

Trade-Marks Act Amendments: In June 2014, the Canadian Parliament passed amendments to the Trade-Marks Act, which would enable Canada to accede to the Madrid Protocol, the Nice Agreement, and the Singapore Treaty on the Law of Trademarks. The signing, ratification, and accession to these international treaties would be a positive and important step in aligning Canada's trademark environment with international best practices. However, the IP Canada Report 2016, released by the Canadian IP Office, (CIPO) indicated that Canada is still preparing to comply with the treaties.[25] The Chamber recommends that the U.S. government work with the Canadian government to swiftly accede to the treaties in order to strengthen trademark protection in Canada.

Enforcement

Goods In-Transit: The Combatting Counterfeit Products Act, or Bill C-8, provides Canadian border services officers with the *ex officio* authority to seek and detain shipments suspected of containing trademark counterfeit or copyright pirated goods. Allowing rights holders to filed Requests for Assistance will better allow border service officers to exchange information with the IP owner in order to begin the process of dealing with the offending goods in court. The full introduction of *ex officio* authority and actual use by Canada's customs authorities is a significant step forward for Canada's IP rights enforcement environment, bringing it in line with international best practices. However, the final text of Bill C-8 failed to include provisions prohibiting the shipment of in-transit goods. The omission of such provisions jeopardizes efforts to facilitate trade, enhance bilateral cooperation, and strengthen border security in order to prevent the shipment of hazardous counterfeit goods to the U.S. The Chamber recommends that

[23] http://www.cbc.ca/news/business/piracy-android-box-free-tv-1.4098249
[24] https://arstechnica.com/information-technology/2017/11/pirate-tv-services-are-taking-a-bite-out-of-cable-company-revenue/
[25] Canadian IP Office. *IP Canada Report 2016.* https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/IP_Canada_Report_2016_en.pdf/$file/IP_Canada_Report_2016_en.pdf

the U.S. government utilize the NAFTA modernization process to ensure that American consumers are protected from the threat of in-transit counterfeit goods.

China

Overview: The Chamber and its member companies have long been and remain committed to mutually-beneficial U.S.-China economic and commercial relations. We continue to work closely with the Government of the People's Republic of China on a full suite of issues, including improving the protection and enforcement of intellectual property rights (IPR) across a broad range of IP policy concerns on behalf of our diverse membership.

Over the years, the Chinese government has acknowledged a need to bolster its protection of IPR and made efforts to implement reforms. As a recent example, the China Food and Drug Administration's (CFDA) proposed reforms in Circulars 52-55 to strengthen China's regulatory data protection term, enhance patent enforcement, improve regulatory review, and establish a list of approved drugs in China, and on October 8, 2017, the General Office of the CPC Central Committee and the General Office of the State Council issued a joint opinion codifying these encouraging reforms and calling for their implementation. Moreover, we recognize Chinese IP judges' efforts to increase damage awards and implement various judiciary reforms, including setting up more specialized IP courts such as the fourth IP court in Shenzhen. China's continued efforts aimed at accepting amicus type submissions, developing a case database system, and curating its guiding case system are all positive signs for the judicial protection of IP rights in China.

However, counterfeiting and piracy in China remain at epidemic levels, particularly in the online environment, as shown by the fact that USTR has re-integrated Taobao.com on the Notorious Market List. Enforcement efforts continue at a similar pace in the last few years, yet counterfeits sourced in China doubled over the last five years. Physical counterfeiting accounts for the equivalent of 12.5% of China's exports of goods and over 1.5% of its GPD.[26] Consequently, it is estimated that 72% of counterfeit goods in circulation in three of the world's largest markets for such products, namely the EU, Japan, and the United States, have been exported from China.[27] No genuine efforts to restructure the counterfeit manufacturing sector in China have been offered. The benefits of such efforts would protect consumers and stimulate long term economic growth in China and around the world.

At the same time, a lack of sufficient IP protection has remained a barrier for foreign companies operating in China. According to the American Chamber of Commerce 2017 Business Climate Survey, nearly half of respondents said insufficient IP safeguards were a barrier to increasing

[26] "Measuring the Magnitude of Global Counterfeiting: Creation of a Contemporary Global Measure of Physical Counterfeiting," U.S. Chamber of Commerce (2016) http://www.theglobalipcenter.com/wp-content/themes/gipc/map-index/assets/pdf/2016/GlobalCounterfeiting_Report.pdf

[27] *Id.*

innovation in China. The same survey also found that while companies say IP enforcement is improving, the majority of respondents still find IP enforcement largely ineffective.

In addition to the challenges posed by IP laws and enforcement, foreign companies must navigate an overall regulatory environment that is increasingly shaped by industrial policy priorities. These issues are long-standing, and the Chamber, in particular the Chamber's China Center, has been forthright in expressing our serious concerns regarding a range of Chinese government policies and practices that restrict access to its market, condition participation in the market on technology transfer, and broadly seek to undermine the value of IP held by American companies.

The Chamber further recognizes that as it receives input on the Special 301, USTR is concurrently investigating China's technology transfer, IP, and innovation acts, policies, and practices under Section 301 of the Trade Act of 1974. The Chamber filed a comprehensive submission (please see here) to USTR in October 2017. As USTR and the broader U.S. government deliberate and conclude the Section 301 investigation, we recommend that any finding form part of a comprehensive strategy so that the United States can continue to make progress on the full panoply of issues, including those related to IP, in our bilateral relations over time.

China's overall score rose from 42% (with a score of 14.83 out of 35) in the fifth edition to 48.5% (19.44 out of 40) in the sixth edition of the Index. This is mainly due to a strong performance on most of the new indicators as well as enhancing key IP protections for the life sciences.

Innovation and Industrial Policy

Notwithstanding incremental positive steps in select areas, China's regulatory environment is increasingly emphasizing industrial policy outcomes that are raising the costs, risks, and uncertainties for many U.S. companies in China. Over the past year, Chinese central government agencies have made a concerted effort to erect a legal and regulatory framework to advance the senior leadership's objective to create national—and even global—champions with cutting-edge technology and IP in key industries. The Chamber China Center has comprehensively documented many of these efforts in two recent reports—"Preventing Deglobalization: An Economic and Security Argument for the Free Trade and Investment in ICT" and "Made in China 2025: Global Ambitions Built on Local Protections." Moreover, the Chamber China Center's IT and Data Working Group has been closely tracking discreet policy developments and advocating on behalf of its membership.

In the proceeding sections, our submission highlights the non-IP specific laws, regulations, and policies that are of particular concern to American industry in China.

Cybersecurity and National Security

China Cybersecurity Review Regime: The Cybersecurity Law (CSL), adopted on June 1, 2017, codifies China's Cybersecurity Review Regime, which is one of the most critical mechanisms that China employs to deny adequate IP protection through forced technology disclosure or transfer. According to the Cybersecurity Law, all critical information infrastructure (CII) operators—which may cover a large swath of commercial industries[28]—buying communications networking products and services are required to undergo a security review.[29] The potentially broad scope of this requirement and the intrusive aspects of the review—including the possible required disclosure of source code, algorithms, and other sensitive IP—may result in U.S. companies being either marginalized from the market or forced to disclose valuable, proprietary information.[30]

> *TC 260 Secure and Controllable Standards*: As part of China's Cybersecurity review regime, Technical Committee 260 is developing a set of secure and controllable standards. Although never formally defined, regulations and guidelines using the term secure and controllable indicate that companies' information communications products would not be able to meet the standard unless they surrender key technologies, such as source code and encryption algorithms, to Chinese authorities.[31] In recent draft standards issued by the Chinese TC 260 committee on CPUs, operating systems, and office suites, the "secure and controllable" score is linked directly to IP disclosure (i.e., the more IP an applicant disclosed the higher its score).[32]

Catalogue of Network Critical Equipment and Cybersecurity Specific Products: To implement Article 23 of the CSL, China's Cyberspace Administration of China (CAC) issued the *Key Network and Specialized Equipment Security Products Catalogue*, which requires products in the Catalogue to undergo an unspecified government security-examination or obtain a security

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[28] The U.S. Chamber of Commerce, the American Chamber of Commerce in China, and the American Chamber of Commerce in Shanghai Joint Submission to the Cyberspace Administration of China on the Draft Critical Information Infrastructure Protection Regulations (August 2017)

[29] The U.S. Chamber of Commerce, the American Chamber of Commerce in China, the American Chamber of Commerce in Shanghai, and the American Chamber of Commerce South China Joint Submission on the National People's Congress Cybersecurity Law (second draft) (August 2016)

[30] *Id*.

[31]中国银监会办公厅、工业和信息化部办公厅关于印发 银行业应用安全可控信息技术推进指南（2014-2015年度）的通知 [Notice of the China Banking Regulatory Commission and the Ministry of Industry and Information Technology on Issuing the Promotion Guidelines for the Application of Secure and Controllable Information Technologies in the Banking Sector (2014 – 2015)] (China Banking Regulatory Commission and the Ministry of Industry and Information Technology, effective Dec. 26, 2015)

[32] U.S. Chamber of Commerce and American Chamber of Commerce in China Joint Submission on the TC 260 Secure and Control Standards for CPU, Operating Systems, and Office Suites (December 2016)

certification to be sold in the commercial market.[33] The Ministry of Public Security and CAC, among other agencies, are responsible for certifying the testing laboratories. Companies with products going through the testing may be required to either meet subjective criteria or disclose an excessive and burdensome amount of sensitive information that is unnecessary for its stated objective.[34]

Cryptography Law: The draft Cryptography Law explores a "cryptography test and certification system," but does not provide details for how this system would be implemented.[35] Furthermore, the draft Cryptography Law gives encryption management departments of the State Cryptography Administration law enforcement capabilities, which could be overly burdensome to company operations and put sensitive company information at risk of inappropriate disclosure. Moreover, the Cryptography Law limits participation by foreign companies to one of the three categories of encryption and only under strict regulation.

Multi-Level Protection Scheme: First issued in 2007, the Multi-Level Protection Scheme (MLPS) is a rating system aimed at promoting indigenous innovation by mandating certain products used in Chinese information networks be developed and produced by entities invested by Chinese citizens or controlled by the State. MLPS imposes significant restrictions on procurement that unjustifiably restrict foreign companies from accessing the market. More recently, companies report that the scope of MLPS is broadening and the requirements are becoming more onerous. MLPS mandates that a broad spectrum of advanced IP-intensive systems, including commercial insurance, cloud computing, big data, mobile Internet of Things, and industrial controls, that go well beyond national security, contain not only indigenous innovation but indigenous IP. As a result, companies face a stark choice between transferring their core IP or losing market access.

Data Localization and Cross Border Data Flow: While data are already core to technological innovation, their importance will grow exponentially over the coming years as advancements are made in artificial intelligence and machine learning. Data not only contribute to short-term growth and profitability, but are also integral to long-term competiveness. Chinese efforts to exert greater control over where commercial data is stored and how it is transferred are skewing the decision-making process for foreign companies that must decide where products are made and innovation takes place. If a company is forced to localize a valuable set of data or information in China, and it faces legal uncertainties about its ability to adequately protect that

[33] 网络关键设备安全专用产品目录（第一批） [Key Network and Specialized Equipment Security Products Catalogue (First Batch) (CAC, June 9, 2017)
http://www.miit.gov.cn/n1146290/n4388791/c5679459/content.html

[34] American Chamber of Commerce in China and U.S. Chamber of Commerce Joint Submission on the Cyberspace Administration of China's Draft Measures on Network Product and Service Security Review (March 2017)

[35] The U.S. Chamber of Commerce and the American Chamber of Commerce in China Joint Comments to the Office of the State Commercial Cryptography Administration on the Draft Cryptography Law (Draft Law) (May 2017)

data or information tied to a lack of rule of law, then the company assumes a significant amount of risk that its data may be misappropriated or misused. Moreover, Chinese laws, such as the National Security, Cybersecurity, and National Intelligence Laws, give authorities expansive latitude to gain access to companies' physical facilities and digital information. As a result, data residency requirements, combined with broad investigatory powers and a legal regime with limited IP protections are becoming a considerable risk for many across U.S. industry.

Industrial Policy and Patent Licensing

Anti-Monopoly Law: The Chamber has a long history of robust engagement with Chinese authorities on all aspects of the implementation of China's Anti-Monopoly Law (AML). In September 2014, the Chamber commissioned a report providing detailed analysis on China's application of its AML.[36]

As part of our ongoing work to track China's implementation of the AML and provide input to the Chinese government regarding U.S. practices in the field, the Chamber has provided detailed comments on a number of regulations, rules, and guidelines, including:

IP Abuse Rules

- In May 2013 and April 2014, respectively, on SAIC's draft *Rules on the Prohibition of Abuses of intellectual property Rights for the Purposes of Eliminating or Restricting Competition* (draft rules).[37]

IP Abuse Guidelines

- In December 2012 on SAIC's unofficial draft of its *Intellectual Property Rights Enforcement Guidelines under the Anti-Monopoly Law* (draft guidelines) and
- In September 2015, on the National Development Reform Commission's Questionnaire on the proposed *Antitrust Guidelines against Abuse of Intellectual Property*.
- In February 2016 on National Development Reform Commission draft *Antitrust Guidelines against Abuse of Intellectual Property*.
- In February 2016 on SAIC's draft *Antitrust Guidelines against Abuse of Intellectual Property*.
- In April 2017 on the State Council Antimonopoly Commission (AMC) draft *Antimonopoly Guidelines on the Abuse of Intellectual Property Rights*.

[36] Competing Interests in China's Competition Law Enforcement: China's Anti-Monopoly Law Application and the Role of Industrial Policy https://www.uschamber.com/sites/default/files/aml_final_090814_final_locked.pdf

[37] The U.S. Chamber of Commerce submitted comments to SAIC on the draft Guidelines on Anti-Monopoly Law Enforcement of IPR: http://image.uschamber.com/lib/feed13797d6c06/m/1/Chamber+Comments+on+SAIC+AML+IP+Abuse+Nov++2012_CH+EN.pdf

The AMC of the State Council is taking the lead to consolidate the various versions of the guidelines prepared by NDRC, SAIC, MOFCOM and SIPO. The multiple editions of the drafts, many of which were made public to the local and global legal community, attracted rounds of discussions and submissions among professional groups and government agencies. The most recent AMC draft guidelines continued to raise serious concern among industry regarding provisions that would impose antimonopoly sanctions on refusal to license and excessive pricing, as well as provisions that provide for an expansive "essential facilities doctrine."

It is critical that competition law authorities view intellectual property rights as complementary to the end goal of promoting consumer welfare, not a threat to it, requiring special treatment under the Anti-Monopoly Law. The Chamber hopes that the antimonopoly enforcement agencies will agree with this universally held view among leading competition enforcement agencies and abandon plans to incorporate an "essential facilities doctrine" for intellectual property rights and other concerns from members of the Chamber, and we urge USTR to track this process closely.

The Chamber also looks forward to engaging the Chinese government on upcoming revisions to China's Anti-Monopoly Law. We understand that the Chinese government has already begun exploratory research on the revisions and held discussions with select stakeholders.

Import-Export Rules: China's Technology Import Export Regulation (TIER) includes provisions that mandate burdensome and inflexible terms for the licensing of Chinese companies by foreign technology owners. These terms create barriers, including indemnification and ownership of technology improvements, which restrict the ability of foreign companies to negotiate licensing and technology contracts on market terms and to fully commercialize their technology in China.

> *Indemnities*: Article 24 of TIERs mandates that foreign technology owners indemnify their Chinese licensees for unforeseen infringement risks. This provision is mandatory and results in a lack of freedom to contract that discriminates against overseas licensors and could be viewed as a non-tariff technical barrier. By comparison, licensors of Chinese technology are not subject to any explicit indemnification requirement. Moreover, this requirement is generally unaligned with international best practices for technology licensing. Other open source models, such as the Apache license, have no such indemnification requirement.
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> *Ownership of Improvements*: According to Article 27 of the TIERs, any achievement made in improving the licensed technology belongs to the party making the improvement. As a result, a Chinese licensee has the potential to own any and all of the improvements it makes to a technology it is licensed. In essence, a foreign technology licensor risks creating a competitor through this mandatory provision, in the form of a legalized forced technology transfer. These terms of ownership contradict market principles and inhibit trade. In contrast, U.S. law has no similar requirement.

It is worth noting that China's Contract Law (Articles 353 and 354) does allow freedom of contract and the ability to negotiate technology transfer and licensing terms. TIERs, however, ultimately overrides the Contract Law via Articles 123 and 355.

Compulsory Licensing: Compulsory licensing is not a new concept within China's legal and regulatory frameworks. A provision in SAIC's IP enforcement rule promulgated under the AML could be used in some cases to force U.S. companies to license their essential technologies to Chinese companies. Furthermore, China's Patent Law includes a provision on compulsory licensing that may, if applied broadly, impose an unreasonable obligation for patentees to provide their technology to Chinese competitors.

China is also exploring tying compulsory licensing to state funding. The State Council issued in July 2017 a Guiding Opinion that discusses compulsory licensing of patents that are obtained with funding from the state.[38] This approach raises significant concerns for companies that would choose to accept public money to conduct R&D in China, including under industrial plans such as Made in China 2025 and Strategic Emerging Industries, as they could be forced to license their IP to the Chinese government. This policy, if implemented, would undermine innovation and diverge from the spirit of comments made by Minster Miao Wei that Made in China 2025 would not compel a technology transfer.[39]

Moreover, China's draft Export Control Law—which includes factors such as economic development and industrial competitiveness in determining control lists—is creating uncertainty about whether technology developed by foreign companies in China-based R&D centers can be exported, thereby creating a non-market restraint on a companies' ability to commercialize their technology.[40]

Standardization Law: The latest revision to the Standardization Law expands on a public disclosure requirement that is both unique to China and potentially damaging to all market participants, and would add unnecessary costs and risks for all enterprises in China.[41] Furthermore, a newly added and deeply concerning article stipulates state endorsement of

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[38] 关于强化实施创新驱动发展战略进一步推进大众创业万众创新深入发展的意见 [Opinion on Strengthening the Implementation of the Innovation-Driven Development Strategy and Further Promoting the Developing of Mass Innovation] (State Council, July 27, 2017)
http://www.gov.cn/zhengce/content/2017-07/27/content_5213735.htm

[39] Press Conference for the Fifth Session of the 12th National People's Congress
http://www.xinhuanet.com/politics/2017lh/live/20170311a/index.htm#wzsl

[40] The U.S. Chamber of Commerce, the American Chamber of Commerce in China, and the American Chamber of Commerce in Shanghai Joint Submission to the Ministry of Commerce on the Export Control Law of the People's Republic of China (Draft for Comments) (July 2017)

[41] The U.S. Chamber of Commerce and the American Chamber of Commerce in China Joint Comments to the National People's Congress on the Draft Revisions on the Standardization Law (September 2017)

incorporating indigenously innovated technology into industry and social standards.[42] Combined with other implementation documents and public statements that allow social standards to be transposed to become national and industry standards, the inclusion by the state of a preference for indigenous innovation (i.e. domestic Chinese IP) seems to create a trade barrier that would conflict with the WTO Technical Barriers to Trade.

Other Policies and Trends that Impact IP and Innovation

Made in China 2025: The Made in China 2025 plan is a 10-year blueprint to improve China's manufacturing competiveness and an example of China's efforts to support indigenous innovation, domestic production, and Chinese IP. In "Made in China 2025: Global Ambitions Built on Local Protections," the U.S. Chamber comprehensively documented the legal and regulatory environment as well as the specific implementing measures of the Made in China 2025 plan that are adversely impacting American industry. Since publication of the report, Chinese government ministries are continuing to implement near term plans, including the *Additive Manufacturing Development Action Plan (2017-2020)* and *Three-Year Action Plan (2018-2020) on Strengthening the Manufacturing Industries' Core Competiveness*, that, among other things, aim to strengthen indigenous innovation, IP, and brands.

Cloud Computing: While U.S. cloud service providers have been at the forefront of the movement to the cloud in virtually every country in the world, China has imposed onerous regulations on foreign cloud service providers—effectively barring them from operating or competing fairly in China.[43] Chinese laws and regulations on non-Chinese cloud service providers force U.S. cloud service providers to transfer valuable intellectual property, surrender use of their brand names, and hand over operation and control of their business to a Chinese company in order to sell in the Chinese market.

Patenting in Strategic Technologies: In addition to the difficulties of protecting and enforcing legal claims on IP in China, U.S. companies have been hindered in even obtaining patents—potentially for discriminatory reasons. New research finds that foreign patent applicants in technical fields that are of strategic importance to China are less likely to be approved than local applicants.[44] This finding indicates that Chinese industrial policies permeate the decision-

[42] National People's Congress, Draft Revisions to the Standardization Law (September 2017), Article 19
http://www.npc.gov.cn/npc/flcazqyj/2017-09/04/content_2028318.htm

[43] The American Chamber of Commerce in China, BSA | The Software Alliance, the US-China Business Council, the U.S. Chamber of Commerce and the United States Information Technology Office Joint Comments to the Ministry of Industry and Information Technology on the draft Notice on Regulating Business Behaviors in the Cloud Service Market (December 2016)

[44] "Technology Protectionism and the Patent System: Strategic Technologies in China," Gaetan de Rassenfosse and Emilio Raiteri (July 1, 2016)
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2803379

making processes throughout China's regulatory system and suggests a potential violation of national treatment principles.

13th Five Year Plan (FYP) on IP Protection and Application: In January 2017, the State Council issued the 13th FYP on the Protection and Application of IPR. Although the plan has many positive initiatives to improve China's legal environment and enhance the value of IP, it contains aspects that may exacerbate longstanding challenges. For instance, the FYP includes quantitative metrics to assess China's IP prowess, which in the past has put greater focus on quantity over quality of patents and resulted in the proliferation of low-quality (i.e. junk) patents.

Remuneration: SIPO's draft service invention regulations (SIRs) continue to be a concern to industry in China. The draft regulations include provisions on the ownership of inventions, the employment relationship, and the companies' commercialization of inventions. In partnership with the American Chamber of Commerce in China (Beijing), the Chamber provided detailed comments to SIPO on the measures in December 2012, August 2014, and May 2015.[45]

If implemented as drafted, the provisions in the draft regulations will negatively affect the ability of U.S. companies to make choices about how to commercialize intellectual property assets derived from their employees in China and will increase legal and financial risks. For example, under Article 19.2, the draft regulations could take away an employer's ability to contract around SIPO's default rules and replace the current autonomy that an employer has with extremely onerous regulations. Employers are also required to make a decision about how best to protect an asset very quickly, even if an invention has not been fully conceptualized by the inventor. Although the Chamber is pleased to see that technical secrets included in previous iterations of Article 4 of the draft SIRs has been deleted. We note, however, that "know-how" is still referenced in article 24 of the latest draft. If the draft regulation applies to "know-how" it will greatly disadvantage the trade secret owner, should there be any disputes between the inventor and the trade secret owner. We were somewhat encouraged by a Shanghai court's promulgation of guidelines in June 2013, which were meant to clarify and improve elements of the draft regulation, but believe the further development of this policy merits close ongoing scrutiny.

More broadly, the draft regulations would have an adverse impact on China's innovation. In our comments to SIPO, the Chamber recommended a number of changes to the text of the Draft Regulations. In Chamber meetings with SIPO, we have received assurances that the regulations will only be applied to companies that currently lack an inventor compensation policy, but our members would appreciate having this caveat made explicit in the final regulations. We urge USTR to closely follow this process.

[45] The U.S. Chamber of Commerce and the American Chamber of Commerce in China comments on SIPO proposed Service Invention Regulations:
http://image.uschamber.com/lib/feed13797d6c06/m/1/Joint+USCC+AmCham+Comments+on+SIPO.pdf

Market Access Restrictions: China maintains a host of market access restrictions to U.S. copyright-protected content – an artificially low revenue share with film distributors, a cap of 34 (20 +14) revenue sharing films, release date and theatrical run restrictions, extensive measures that largely exclude foreign content from China's broadcast and payTV sectors, an opaque and uncertain censorship regime, and limits (legal and practical) on import and distribution, among other measures. For television series, China's content review process requires submission and review of the entire season before any episode can be approved. As a result, consumers in China turn to illegal pirated copies of the latest episodes online. Collectively, these policies make China one of the most closed markets in the world for foreign content. One bright spot had been the "Over the Top" (OTT, or Internet-delivered) sector, which had seen significant growth in market access in the years prior to 2014, when China announced new limits on the use of foreign content by OTT services, including a new 30% max quota and prior approval and censorship review, implemented through a fixed semi-annual process, rather than on a rolling basis.. The new regulations effectively limited access to the market, added substantial uncertainty and required significant changes to the structure of existing deals. Further, they penalize legal service providers to the benefit of China's vast illegal online marketplace. The Chamber urges China to address concerns that have been raised.

Rule of Law

Latest Judicial Reform Efforts: The Chamber welcomed details from China's Fourth Plenum of the 18th CCP Central Committee in 2014 that aimed to adopt ideas from a rule of law system. At the Fourth Plenum, China vowed to support the value of the laws and make it harder for officials to make arbitrary decisions and intervene in judicial cases. Following up on these pledges, the CCP Central Committee and the State Council jointly issued a set of regulations to prevent official interference in judicial cases. The *Regulations on Recording, Notification and Accountability of Intervening into Judicial Activities and in Handling of Specific Cases by Officials*, set out five types of illegal conduct for officials in an effort to increase judicial independence and deter local protectionism. Although too early to judge its impact, these regulations are a positive step for China in creating an independent court system..

At the Fifth Plenum, China announced its policy of placing innovation as its highest policy priority. The Chamber hopes that all the proposed reforms will greatly enhance the Chinese courts' ability to enforce IP rights, especially in hotbed areas, and develop a deep level of intellectual property expertise and sophistication to foster innovation. The Chamber has noted the challenges that China has faced implementing such institutional reforms at judicial levels, e.g., losing mid-level IP judges to private practice due to reduced openings for judicial appointments. The Chamber will closely monitor the progress and find out if the reforms have real benefits to intellectual property protection.

China held the 19th CPC Central Committee meeting in 2017. The Chamber has taken note of the decision released at the Congress to set up a special rule of law leadership team at the highest level designed to exercise unified leadership to judiciary authorities across China. A special agency in charge of "rule of law" affairs at the CPC leadership level shows some interesting institutional changes. Increasing political leadership of the CPC over judiciary affairs may likely undermine the technocratic style of government that has been developing in recent decades.

Intellectual Property Courts: The establishment of four specialized intellectual property courts in Beijing, Shanghai, Guangzhou, and Shenzhen and 10 IP tribunals in Suzhou, Nanjing, Wuhan, Chengdu, Hangzhou, Ningbo, Hefei, Fuzhou, Jinan and Qingdao has been encouraging to the Chamber and its members. We have identified various improvements and reform measures at these IP courts. For example, the Beijing IP court has been developing new mechanisms to publish guiding cases and citing precedents from the judgments. The Beijing IP Court has started using en banc trials in trademark administrative cases, which helps in establishing standing precedents. Also, the Beijing IP Court sought outside opinions from several research institutes on a trademark issue in January of 2016, which could be seen as a Chinese version of an "amicus brief." Similar practice was seen in another case related to copyrightability of live sports broadcast. We also note that hiring technical assessors by the Beijing IP Court may help in adjudicating complex patent cases although more time will be needed to evaluate the efficacy of the technical assessors and whether litigants have opportunities to cross examine the technical assessors' opinion. The Chamber also welcomes the IP courts' efforts to increase transparency through the disclosure of the courts' decision making process and trial details to the public.

The Chamber also notes that the court has a fast growing caseload, especially those of non-patent cases. The very purpose of the intellectual property court may be somehow compromised as these courts at the intermediate level have no power to render final judgments in high-stake cases, including those judicial reviews of the Patent Review Board (PRB) and the Trademark Review and Adjudication Board (TRAB) decisions. We have heard that there are discussions about elevating the IP courts to national appellate level courts, which is confirmed in the *Opinion of Giving Full Play to the Functions of Trials and Effectively Enhancing Judicial Protection on Property* issued by the Supreme People's Court in December of 2016. The Chamber will continue fostering such discussions or other constructive experiments through its U.S.- China IP Cooperation Dialogue and monitoring the real impact of the new intellectual property courts.

Trademarks

Trademark Law: The long-awaited Supreme Court's Trademark Judicial Interpretation has also been approved in December of 2016 and is expected to be published soon. The Chamber submitted comments to address the outstanding challenges and issues in relation to trademark registry and trademark enforcement. These remaining challenges include bad faith trademark registrations; well-known marks; elimination of opposition appeals; lack of default decisions;

deadlines that are particularly onerous on foreign rights holders; non-use cancellations; coverage for retail service marks and assignment and licensing procedures.[46]

Damages: While the increased cap of statutory damages in the amended Trademark Law gives some hopes of better enforcement, the actual outcome is mixed. The courts have been handing down higher amount of damages in anti-counterfeiting cases. The Supreme People's Court is also encouraging local courts to be more progressive in awarding damages. The Supreme People's Court issued a special report in October 2013 announcing a number of representative cases as examples of improvement of remedies in intellectual property rights cases.[47] The cases involved reduction of the burden of proof on intellectual property owners to prove damages and significant increase in the amount of compensation in civil cases. The Beijing IP Court also awarded the record breaking 10 million RMB (around 1.44 million USD) damage in a trademark case in November of 2016. However, the average damage award for IP cases is still low. The Chamber will keep monitoring developments in this area.

Bad Faith Trademark Registrations: China's amendments to its *Trademark Law* increase the risk that brand owners will be held hostage to pirates registering marks in bad faith. For example, under the amended law, if a brand owner opposes a preliminary approved mark and loses, the mark will be immediately registered; only a cancellation proceeding before TRAB can invalidate it. As a result, a bad-faith registrant may freely use a mark for years while waiting for a TRAB decision without infringing on the brand owner's rights. While waiting for a TRAB decision, the bad faith registrant can build up years of use. This problem is exacerbated by a Chinese judicial policy that allows marks that are confusingly similar to co-exist after a certain period of use. To add insult to injury, a bad faith registrant may also be able to take enforcement action against the brand owner's own use of the trademark. It is hoped that the Chinese courts will continue such practice and take a firm position against bad faith registrants. Trademark filings rose 55.7% in 2017, bringing China's total filings to more than 27 million this year. Almost 15 million of those trademarks were found to be valid. Although filing fees and the government's average time to review trademark filings has been reduced, we are concerned that the record numbers of filings will likely make it easier for bad-faith trademarks to be registered and approved. In turn, it could increase costs for legitimate businesses to oppose these filings. The Chamber has taken note of the recent initiatives of the China Trademark Office (CTMO) which include having a centralized review at the early stage of trademark registration and opposition, putting together a white list of prominent trademarks for special protection as well as building a black list of notorious trademark squatters. The Chamber and its members are looking forward to seeing tangible results of these measures. The Chamber also encourages the CTMO to explore additional tools to deter

[46] Approaches for Implementing China's New Trademark Law can be found at http://www.theglobalipcenter.com/wp-content/uploads/2013/01/GIPC-Comment-Trademark-Law-10-18-13-FINALweb.pdf

[47] See the transcript of the press conference of the Supreme People's Court and video broadcast at http://www.chinacourt.org/article/subjectdetail/id/MzAwNEhKN4ABAA%3D%3D.shtml.

bad faith trademark filers, for example the CTMO could consider instituting a similar rule to the European Union trade mark regulation (Section 2, Article 85), which requires a losing party to bear the opposition's cost if a trademark is found invalid.

Quality Examination Practices: China's Trademark Office is the busiest in the world and the rate of increased applications combined with strict timelines for review have put pressure on the resources of the office. A new division was created and contract workers have been hired to deal with the demand. The quality of the examination is at risk with this expansive growth. Efforts are underway to improve the training and management of these workers as this will directly affect the quality of the trademarks issued in China.

Counterfeit Economy in China

Restructuring the Counterfeit Economy in China: It is clear that the current enforcement regime alone will not turn the tide on the flood of counterfeits made in China and sent around the world. Now is the time for China's leadership to address this sector of their economy by calling for its restructuring in China's next five year plan. Setting long term restructuring goals will motivate and empower central and local level officials as well as important market players to end economic dependence on illicit trade. In creating and protecting a legitimate marketplace in China, positive benefits will come to small and medium-sized Chinese businesses and the economy and protect consumers around the world. The U.S. Chamber has launched a research project to analyze the benefits to brand owners of this restructuring and explore methods to accomplish it in consultation with experts in China and around the world.

Size of the Problem and the Next Phase of OECD's Counterfeiting Study: Two studies were released in 2016 which make clear that counterfeiting is a global epidemic and China remains the largest source of such illicit products. In April 2016, OECD's *Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact* revealed that counterfeiting levels have doubled since 2005, totaling $461 billion of global trade.[48] For the study, OECD collected data from custom offices in the EU and United States, and the research team is ready to continue to mine the data to map the cross-border flows. The U.S. government should support and provide funding for the next phase of OECD's counterfeiting study. This additional analysis is integral to devising effective anti-counterfeiting enforcement programs in the United States, in China and in countries around the world.

Counterfeiting and piracy in China remain at epidemic levels, particularly in the online environment. In another study, *Measuring the Magnitude of Global Counterfeiting*, among the 38 economies studied, China and Hong Kong are responsible for 86% of the global supply of

[48] The OECD's report, based on 2013 trade figures, estimate that international trade in counterfeit and pirated goods make up 2.5% of global trade, representing $461 billion. This represents a value over double the OECD's previous estimate of $200 billion based on 2005 trade flows.

counterfeit goods, with the next largest supplier at less than 1%. China and Hong Kong produce an estimated $396.5 billion of counterfeit goods each year.

Enforcement Efforts: There are three categories of enforcement: Online Enforcement, In-Country Enforcement and Cross-Border Enforcement. Countries around the world are struggling to address such an onslaught of counterfeit goods, to protect legitimate marketplaces and to keep consumers safe. The U.S. Chamber's International IP Index,[49] which maps the IP environment in economies around the world, found the vast majority failed to reach 1/3 of the maximum available score on enforcement against intellectual property theft and forgery.

China appears to have maintained a similar level of active enforcement efforts against counterfeiters in 2017.[50] According to a report on the website of State Administration of Industry and Commerce (SAIC), in the second half of 2017, a total of 25,000 IP infringement and counterfeit cases were handled, among which 22,000 cases were completed. The National Copyright Administration of China (NCAC) claimed closure of 1,655 websites in its national campaign named "Jianwang 2017." China also announced a special IPR campaign between September and December 2017, targeting the protection of foreign IPR.[51] No official statistics of the final outcome of this campaign are available yet. Despite these efforts, however, the scope and scale of the problem is getting worse. Below are some procedural concerns and changes that could be made to improve China's enforcement system.

In-Country Enforcement: The Chamber is concerned that Article 60 of the new Trademark Law dealing with reseller's infringement liability may have suppressed enforcement efforts. Art. 60 paragraph 2 has been interpreted by Administration of Industry and Commerce (AIC) nationwide to prevent AIC authorities from seizing counterfeits from or penalizing resellers who claim no knowledge about the sold items and prove the legitimacy of transactions with details about the sources. This provision has dramatically blocked the brand owners and the AIC authorities from going after counterfeit resellers. The Chamber strongly recommends USTR urge China to amend this particular provision or otherwise interpret the provisions differently.

The Chamber suggests that the national and local police keep investing in more dedicated police officers in the intellectual property crime unit. Apart from the food and drug field, the police need to deliver more deterrence in the areas of consumer goods, high-tech, auto parts, and machinery.

[49] http://www.theglobalipcenter.com/gipcindex/

[50] Complete data for 2017 is not available as of this writing. The available data is noticeably more limited than previous years. In 2016, China reported that a total of 15,000 individuals were convicted in 170,000 cases. Such data is similar to what happened in 2015, where 12,741 suspects were convicted. http://legal.china.com.cn/2017-01/17/content_40117407.htm

[51] See http://www.gov.cn/xinwen/2017-09/18/content_5225999.htm

The number of criminal transfers seems to remain low.[52] The Chamber highly encourages USTR to underscore to China the need for more innovative measures to promote cooperation between administrative authorities and the public security bureaus (PSBs) in the course of investigations. Brand owners report that low rates of transfers result in part from a lack of a special budget for warehousing counterfeits and investigations and a reluctance of AIC to transfer if it can collect large amount of fines from counterfeiters. Governments around the world must deal aggressively with repeat offenders by closely monitoring them and referring a greater number of these cases to authorities for investigation.

Local protectionism is still a concern even if some improvements have been made: brand owners are facing many challenges in Guangdong, Zhejiang and Fujian Province. The Chamber is particularly eager to see a substantial increase in the number of referrals of cases—large and small—to authorities in Guangzhou, China, one of the primary locations where online traders and manufacturers of fakes are located. Court orders to seal funds in counterfeiters' accounts at online payment service providers should be explored, as well as ways to hold parties responsible for aiding and abetting the sale of counterfeit and pirated goods, whether through advertisement or sale of these items or otherwise. The Chamber urges USTR to increase attention and focus on improving the online environment and press for effective policy changes.

Brand owners have also raised concern about the increasing costs for warehousing and destruction of their brands seized by the Chinese enforcement authorities, especially, in view of environmental concerns that are being raised with the traditional destruction methods of burning or burying the counterfeit goods. The Chamber recommends the development of national standards on the storage and destruction of counterfeit goods. In parallel, the Chinese government should explore ways to reduce the financial burden on brand owners.

Online Counterfeiting: Online counterfeiting remains a significant challenge. The explosive growth of online transactions in China has fueled online sales of counterfeit goods as well as the upstream manufacturing and distribution of these goods. In 2015, a report to Chinese lawmakers found that more than 40% of goods sold online in China were either counterfeits or of bad quality.[53]

The State Administration for Industry and Commerce (SAIC) issued *Measures for Online Trading and Related Services* ("Online Trading Measures") in 2014, which seems to give high priority to consumer protection and intend to address unfair competition. But the Online Trading

[52]The official report of SIPO states that in 2016, only 203 cases were transferred to criminal procedure out of nearly 49,000 cases that SAIC opened up for investigation in China. NCAC transferred 33 cases to criminal procedure out of 514 administrative investigation cases. The Ministry of Agriculture transferred 121 cases among 24,000 cases. http://www.sipo.gov.cn/gk/zscqbps/201704/P020170425580002993482.pdf

[53] "Shoddy, counterfeit goods in 40 pct China online deals: report," Xinhua (November 3, 2017) http://www.xinhuanet.com/english/2015-11/03/c_134776510.htm

Measures lack sufficient deterrence against both individual vendors involving counterfeit transactions and online trading platforms.

Reportedly some online platforms have taken a very cooperative approach with courts nationwide, including collaborating on court orders for evidence preservation and providing vendors' mailing addresses to the courts. All such measures are welcomed by the Chamber.

However, massive amounts of counterfeit goods continue to be distributed online, indicating the need to do significantly more. China must deal aggressively with repeat offenders by closely monitoring them and referring a greater number of these cases to Chinese authorities for investigation. The Chamber is particularly eager to see a substantial increase in the number of referrals of cases—large and small—to authorities in Guangzhou, one of the primary locations where online traders in fakes are located. Court orders to seal funds in counterfeiters' accounts at online payment service providers are a process worth exploring. We urge USTR to increase attention and focus on improving the online environment and press for effective policy changes.

The online sale of counterfeits remains a significant challenge. Massive amounts of counterfeit goods continue to be distributed online, indicating the need to do much more. The explosive growth of online transactions in China has fueled the sale of counterfeit goods online as well as the upstream manufacturing and distribution of these goods. Online platforms can take stronger steps to respond to this epidemic, including simplifying processes for rights holders to register and request enforcement action, giving rights holders access to information about sellers accused of infringement, implementing policies that prevent sellers from hiding behind multiple accounts, reducing timelines for takedowns, adopting rating systems allowing the public to assess whether a seller has any history of IP violations and issuing penalties for sellers of counterfeit goods.

Concerning IPR enforcement online, China released the second draft E-Commerce Law for comment. The Chamber welcomes some changes made in the second draft, such as the counter-notice process, which requires the vendor to provide evidence of non-infringement. However, some key concerns remain unresolved. For example, the law must be able to address the ability of counterfeiters to escape prosecution by maintaining anonymity. The Chamber hopes such significant problems will be addressed in the next revision or final version.

Border Enforcement: Cross-border anti-counterfeiting efforts and collaboration between the U.S. and Chinese customs should be a priority for both countries. As mentioned earlier, funding of the OECD phase-two study on counterfeiting that intends to map out illicit trade flows will provide the necessary data for countries to enforce at the borders and therefore should be supported by both the United States and China.

Dealing with counterfeits in small parcel packages has increasingly become a focus of anti-counterfeiting enforcement campaign. This is particularly true as global e-commerce activities

are growing substantially. China's General Administration of Customs (GAC) has taken some initiatives to stop counterfeits in transit at airports and other international express deliveries. As part of the national IPR campaign starting from September 2017, local State Post Bureaus (SPB) have been asked to launch campaigns and put in place safety check mechanisms targeting infringed goods, which require pickup check, real name mailing and scanner safety check.[54] But the success is inconsistent, and the practical difficulties are significant. On the other hand, the regulator of the China Post's express mail delivery service (EMS) and other EMS service providers – the State Post Bureau (SPB) – have been trying to regulate the entire sector for years through industry standards and new ministerial rules, some of which touch on the legal duty of inspection for counterfeits. However, most of the SPB's efforts are related to market access, and the SPB has not prioritized this issue and rarely holds EMS liable for assisting counterfeiters.

Some of our members report a decrease in self- initiated inspections conducted by customs in 2016. Furthermore, customs cases are not transferred to the Public Security Bureau for criminal investigations despite having an easy transfer process in place, so cases are not pursued criminally.

Pharmaceutical Counterfeiting: The Chamber applauds the achievements made by the Ministry of Public Security (MPS) and local PSBs in cracking down on drug counterfeits over the years. The positive changes in the PRC Criminal Code and establishment of a special police force dedicated to food and drug safety in local areas have resulted in a sharp increase of successful criminal prosecutions. Chinese police reported progress in going after online sales of counterfeit medicines. The Chamber is encouraged by the special campaign initiated by the China Food and Drug Administration (CFDA) targeting the online sale of counterfeit medicines and is pleased that Chinese officials reported that the campaign will continue in future years.

The Chamber was encouraged by the agreement that China and the U.S. government have made through the Sixth Meeting of the Strategic and Economic Dialogue with respect to counterfeit active pharmaceutical ingredients (API), but possible reforms of the Criminal Code and Drug Administration Law to deal with illegal bulk chemical factories have not been implemented. Enforcement staff of major pharmaceutical companies reported that Chinese police often found it challenging to trace suppliers of raw materials used for making counterfeit medicines as well as taking other regulatory measures to combat illegal API problems. The Chamber hopes that the U.S. government will closely engage China on this particular area.

Patents and Related Rights

Patent Linkage: The Chamber applauds China, namely the China Food and Drug Administration (CFDA), for its recent major breakthrough in calling for adoption of a patent linkage system. The Chamber has been making substantial efforts to promote the economic

[54] See http://www.spb.gov.cn/xw/dtxx_15079/201710/t20171031_1404190.html

benefits of a patent linkage system in the past few years, and we are pleased that China is moving toward establishment of such a regime via the May 2017 CDFA circulars and the October 2017 joint State Council/CPCC opinion. On October 8, 2017, the General Office of the CPC Central Committee and the General Office of the State Council jointly proposed exploring the patent linkage system, carrying out a pilot program for patent term extension and improving regulatory data protection system. In May 2017, CFDA published *Policies On Encouraging The Innovation Of Drug Medical Devices To Protect Innovators' Rights* (Circular No. 55) proposing the establishment of a patent linkage system. According to the Circular, a drug applicant should disclose relevant patent information that the applicant knows or should know about when filing an application for drug registration, and the applicant shall notify the patentee within 20 days if the drug applicant is going to challenge the innovative drug's patents. If the patentee believes that its patent is infringed, it shall file a patent infringement lawsuit within 20 days from receiving the notice, and the CFDA may set a stay period of up to 24 months to stay the drug approval. Once the settlement is reached or an effective decision is made by the court within the stay period, CFDA may approve or disapprove the drug registration. Otherwise, CFDA may approve the drug registration once the stay period expires. We are supportive of the intensifying efforts of CFDA and various other ministries in setting up the patent linkage system. It will be in the best interest of China and U.S. industries if China closely consults with the innovative pharmaceutical industries and experts with sufficient expertise in formulating the rules.

Data Supplementation for Patent Applications in China: SIPO had been criticized for years for not accepting post-filing data after the patent applications are filed. In 2013, both during Vice President Biden's trip to China and at the U.S.-China Joint Commission on Commerce and Trade (JCCT), China agreed to consider post-filing data and explicitly agreed that any of its newer versions of the patent examination guidelines will not have retroactive effects. On April 1, 2017, SIPO released the amendment of the Patent Examination Guidelines. A paragraph related to the data supplementation was included in the new Guidelines: *The experimental data submitted after the application date shall be examined by the examiners. The technical effects to be evidenced by the supplementary experimental data shall be those that a person skilled in the art can get from the disclosed content of the patent application*.

The amendments provide that an applicant can supplement data to further strengthen the technical effects that have already been proved by the data in the specification. However, for the asserted technical effects in the application, the post-filing supplemented data may still not be accepted. The Chamber encourages the U.S. government to push China to revise the guidelines to accept more data supplementation.

Regulatory Data Protection (RDP): Though formally China provides a six-year term of RDP for small molecule medicines, the scope of RDP remains at once ambiguous and narrow. On the one hand, both the Drug Administration Law and the Drug Registration Regulation lack a clear definition of a new chemical ingredient and what constitutes unfair commercial use of clinical

data. China's recent steps announcing an intention to increase these standards in May 2017 (Circular 55) has provided positive momentum. For example, the Circular proposes longer terms of data protection, including six years of data protection for biologics, orphan drugs, and pediatric drugs. While the Chamber applauds the Chinese government for these proposed improvements, it is critical that China move forward to implement this proposal. More importantly, it is critical that these proposals be implemented in such a way that values innovation and does not discriminate against U.S. companies. Proposals to limit these new protections to products that are "new to the world" rather than "new to China" would discriminate against U.S. companies and dramatically limit the benefit of proposed IP protections.

Patent Protection and Enforcement: The latest proposed amendment to the Patent Law issued by the State Council at the end of 2015 is still pending. The Chamber submitted joint comments on SIPO's draft Amendments to the Patent Law with the American Chamber of Commerce in China. The primary concern in the draft pertains to the expansion of the remedial powers of local administrative agencies. The local intellectual property offices may be empowered to impose injunctive relief, damages, fines and penalties for patent infringement, powers previously limited to the more experienced judicial authorities. We believe the courts—and not the patent administration agencies—are the best vehicle for the efficient and effective adjudication of patent disputes. The Chamber urges continued close monitoring by USTR in this regard. This proposed dual system of enforcement will increase litigation, costs, and produce conflicts with judicial actions. In addition, there is potential for increased assertion of low or no-quality patents by domestic entities to disrupt foreign-owned patent holders and options for such entities to forum shop for the most attractive venue. This will greatly increase the potential for abuse by patent holders that seek not just appropriate compensation, but to harass and burden competitors and impede their competitiveness and innovation capabilities in China.

Patent Quality and Utility Model Patents: There are signs that SIPO is putting its focus back on the growth of patent filings at the cost of quality. It is therefore essential that the U.S. government continues to engage with China in this particular area to encourage the filing of high quality patents and to mitigate the damage caused by the abuse of the utility model patent system in China.

In the *Patent Examination Guidelines* of March 2013, SIPO officially permitted patent examiners to conduct patent searches to examine novelty of utility model application and design patent applications.[55] The change of practice reportedly has led to numerous rejections issued by SIPO against utility model filings.

However, China seems to keep emphasizing the number of filings in its recent work plan to implement the national IP strategy in 2015-2020. One of the new quantitative measures is

[55] The official decision is at http://www.sipo.gov.cn/zwgg/jl/201311/t20131106_876947.html

invention patents per 10,000 people, which is aimed to increase from 4 in 2013 to 14 by 2020; another measure is Patent Cooperation Treaty (PCT) filings, increasing from 22,000 applications in 2013 to 75,000 in 2020.[56] All these measures tie to filings without accounting for the quality of the patents. This raises a strong concern that the national or local governments may continue using subsidies to incentivize large numbers of, but not necessarily quality, patent filings.

Again, the Chamber urges the Chinese government to reduce or eliminate government subsidies for design patent filings and mandate substantive examination of utility model and design patents prior to initiating litigation.[57] The Chamber also recommends that the inventiveness criteria for utility model patents be raised to the same level as invention patents. Currently, utility model patents have no substantial examination, and they are difficult to be invalidated due to the low inventiveness criteria. Due to the low inventiveness threshold for utility model patents, there remain a significant number of utility model patent applications and patents.

In addition to requiring substantive examination, China's patent system should further allow recourse to civil litigation for patent infringement to the exclusion of any administrative enforcement remedies, which can be subject to local protectionism and discriminate against foreign rights holders. Doing this would help rights holders who can actually demonstrate the innovative nature of their patent or other rights to address, inter alia, the problem of low or no-quality patents before competent (and less political) adjudicators and courts. Finally, China's patent system should be reformed to ensure that infringement litigation that is based on unexamined rights cannot proceed until the validity of the utility model and design involved is finally determined through the PRB's examination and judicial review.

Design Patents: The Chamber noted that the amendments to the 2016 *Patent Examination Guidelines* have not addressed the patentability of partial designs, which is also a critical subject matter to many of our members. But the Chamber was very delighted to see that the latest proposed amendment to the *Patent Law* seems to adopt the idea of partial designs, although the grace period in the draft is too narrowly defined and the time period should be extended. The Chamber hopes that USTR will encourage the Chinese legislature to approve such changes in the final text of *Patent Law*.

Trade Secret Protection

The protection of trade secrets in China remains quite challenging.

Anti-Unfair Competition Law Amendments: The amendment to Anti-Unfair Competition Law (AUCL) was believed to provide a great opportunity to enhance trade secret protection, but the

[56] See http://www.gov.cn/zhengce/content/2015-01/04/content_9375.htm.
[57] U.S. Chamber of Commerce publishes "China's Utility Model Patent System: Innovation Driver or Deterrent" in November 2012: http://www.uschamber.com/sites/default/files/reports/1211_china_patent_paper.pdf

final text as approved in November 2017 failed to deliver that promise. The relevant amendments concerning trade secrets are fairly limited, although the improvements are arguably beneficial. The improvements include a broadened definition of trade secret. One of the criteria for trade secret protection in the past was that the protected technical and business information must bring economic benefits and have practical utility. The new definition removes the requirements of practical utility. The new law has direct implication on current or former employees who conduct trade secret theft, which may arguably give more opportunities for trade secret owners to go after infringers. The Chamber is encouraged that the new law specifically requires local authorities to keep confidential trade secrets discovered during an investigation. It appears the law relies upon a newly added statutory damages provision (RMB 3 million ~$450,000 USD) to increase the deterrence for trade secret infringement cases.

The amendments are positive, but far from enough. Some of the proposed amendments in the draft were deleted, such as shifting the burden of proof to the defendants in trade secret cases.

The ultimate use of the trade secret and the venue where relief is pursued affect the ability to recover. For example, it is unclear whether cyber-attacks, such as hacking, constitute misappropriation.[58] Even if a trade secret misappropriation is actionable, proving it is extremely difficult. There is no discovery available and oral testimony carries little weight. Original written evidence is critical but difficult to obtain. Often the best way to secure evidence is through criminal prosecution, though trade secret owners have little sway in the decision to pursue a criminal case. In addition to proving the misappropriation itself, many courts require the trade secret owner to prove that the trade secret was not in the public domain. Not only is proving a negative exceptionally difficult, it generally requires the use of external experts who must submit a written document detailing the trade secret.

In criminal cases theft is determined not by the conduct itself but by the consequences of the loss. Article 219 of the Criminal Law and relevant judicial opinions as well as economic crime prosecution guidelines require a loss by the trade secret owner or illegal profit by the misappropriator valuing at least RMB 500,000 (~$75,000 USD).[59] Providing the required proof to initiate a criminal investigation can be difficult, if not impossible. Even if an investigation is successful, the misappropriator is generally imprisoned for less than three years, a punishment which provides limited deterrence.[60]

Unfortunately, China's courts still lack effective measures to prevent the leakage of evidence presented during civil enforcement. Therefore, the act of seeking relief can actually exacerbate

[58] The crime of theft and civil as well as administrative violation of trade secret through the conduct of "theft" referred to under Article 219 of the criminal law and Article 10 of the AUCL respectively are defined by Article 264 of the Criminal Law and only applies to tangible assets.
[59] Bankruptcybankruptcy by the trade secret owner is also sufficient.
[60] Losses great than ¥2.5M (~$375k USD) qualify for longer prison terms.

the damage, and plaintiffs are often forced to withdraw their civil cases.[61] Even if it makes sense to pursue civil enforcement, the damage may continue until the case is finally adjudicated. Preliminary injunctions to bar use of the trade secret, while available, are extremely rare.[62] In part, the limited availability is due to the tremendously high burden of proof discussed above.

In November 2016, the Asia Pacific Economic Cooperation (APEC), whose membership includes China, endorsed a set of best practices aimed at strengthening enforcement against trade secrets misappropriation. The U.S. should hold China accountable to upgrade its trade secret regime in line with the identified best practices.

Copyrights and Related Rights

Online Piracy: With respect to online piracy, there has been some progress in recent years in government enforcement against distribution of infringing content. Chinese enforcement authorities have begun to crack down on illegal distribution of content, and rights holders have successfully sued websites engaged in brazen infringement, in some cases supported by the National Copyright Administration of China (NCAC).[63] Not surprisingly, the legitimate market has responded positively to this crackdown on illegal activity. However, China still lacks effective tools to encourage cooperation of Internet intermediaries, ensure rapid takedown of infringing content, take action against repeat infringers, and provide proactive measures to address piracy. The NCAC national campaign, pushing ahead the third amendment of the Copyright Law, and the new NCAC guidelines for cloud services have been good steps in the right direction, but much more still needs to be done. Increased criminal actions against online infringers and additional measures against Internet service providers and online platforms that knowingly host infringing content should be a priority in the coming year.

There is an additional type of piracy that has become rampant throughout Asia—illicit streaming devices such as media boxes, set-top boxes, or other devices that allow users, through the use of piracy apps, to stream, download, or otherwise access unauthorized content from the Internet. ISDs are part of a sophisticated and integrated online ecosystem facilitating access to pirated audiovisual materials. These devices have emerged as a significant means through which pirated motion picture and television content is accessed on televisions in homes in China. China is a hub for the manufacture of these devices. The devices may be promoted and/or advertised to enable infringement of copyright or other illegal activities. Chief among these activities are: (1)

[61] See discussion above considering service inventions where trade secret owners may be forced into court by employees seeking greater levels of compensation by their employers.

[62] Less than 1% of all intellectually property cases in China get a preliminary injunction. This is even more difficult to achieve in trade secret cases.

[63] In March 2017 NCAC enforcement brigade investigated Beijing OrangeVR Co. Ltd.at the request of MPAA for unauthorized distributing its products including Ant-Man, The Fast & Furious, and San Andreas. NCAC imposed a fine of 30, 000 RMB (USD4,500). It was the first case in China involving VR technology subject to administrative penalty. http://ent.sina.com.cn/m/c/2017-11-03/doc-ifynnnsc4222799.shtml

enabling users to access unauthorized decrypted motion pictures or television programming; (2) facilitating easy access, through apps, to remote online sources of unauthorized entertainment content including music, music videos, karaoke, motion pictures and television programming, video games, and published materials; and (3) pre-loading the devices with infringing apps that provide access to hundreds of high definition (HD) motion pictures prior to shipment or allowing vendors to load content upon import and prior to sale, or as an "after sale" service. The Chamber notes that the Beijing Intellectual Property Court held a set top box manufacturer liable for streaming unauthorized content under secondary liability theory in 2015. The Chamber is hopeful that China will take a firm stand against this type of infringing activity and take enforcement efforts to eradicate the problem, including against exports.

The issue of online journal piracy continues in China and appears to be worsening. Unauthorized services sell online access to, or copies of, journal articles without the authorization of—or payment of compensation to—publishers. These unauthorized services undermine the investment that international (and Chinese) publishers make in journal publishing, which helps to deliver high quality journals that are critical to the advancement of science, technology and medicine within China and globally. Timely enforcement and effective deterrence is critically important. China's failure to conclude the investigation of the case against KJ Med illustrates the remaining enforcement challenges that allow such an entity to continue its operations.

Publishers also continue to be concerned about "sharing services," which are open online platforms where users can upload and share documents. These services, such as Baidu Wenku, Sina, and Docin, employ "digital coin" systems, whereby coins earned through uploading documents may be used to "purchase" English language and Chinese translations of trade books, textbooks, and journals for download. These sharing services have ineffective notice and takedown processes for reporting and addressing infringements. Other online entities sell login credentials that are used to gain unauthorized access to proprietary online journal databases.

Camcording: Illegal camcording of feature films is a significant problem in China. Given the explosive growth of China's movie theaters, it is a problem that is likely to grow. SAPPRFT acknowledged the problem through notices in 2015 recognizing the threat camcording poses to the film industry, calling for Chinese movie theaters to be aware of and take steps to address the problem, and requiring availability of digital watermarking. While these are positive developments, experience has shown that a critical step is enacting an effective criminal law against the act of camcording. An effective law does not require a showing of intent to distribute, which significantly complicates enforcement and is unnecessary since there is no legitimate reason to camcord a film.

Copyright Law Amendments: China is considering a significant set of amendments to its Copyright Law. The Chamber appreciated the work of the NCAC on earlier versions of these amendments and was pleased to have the opportunity to submit comments on those drafts. These

amendments are an important opportunity for China to modernize and streamline its copyright system. Given the importance of the legislation, the Chamber encourages China to place the Copyright Law on tier one of the legislative agenda. It is critically important that China's copyright law move forward in solving the problems of administration and enforcement that have been identified by domestic and foreign rights holders alike. This is especially true in the online environment, where China has made significant strides in recent years.

In particular, while the amendment process is pending, we urge China to use the Supreme Court's advisory opinions and official records of the legislature to document the consensus on some of the areas worthy of special attention, e.g., the copyrightability of live broadcasts of sports programming. China is now giving significant priority to sports industry development as part of its new round of economic reform. The government is deregulating the industry and is also trying to give more policy incentives to encourage more investment from the private sector. The lack of strong IP protection in this sector must be addressed urgently. At present, the exact ways live broadcasts should be protected in China are unclear among policy makers, courts, and legal professionals. Some judges and scholars disapprove or doubt the copyrightability of live sports programming, or believe it should be protected under the general legal principles of unfair competition law, while some scholars argue that live sports programming should be protected as "cinematographic works and works created by means similar to cinematography." The Chamber is now concerned that the highly regarded decision made by the Chaoyang District Court in Beijing—which recognized the copyrightability of live sports broadcasts in a ruling relating to the Chinese soccer league—will be overturned by the Beijing IP Court. What is more disturbing is that it appears that more scholars and judges are speaking out against the copyrightablity of live sports broadcasts while China itself is going to host 2022 Winter Olympics.

Notably, the draft amendment of the Copyright Law proposes a new category of audio-visual works, which raises some hopes for the future. However, proposed legislative changes do not make any immediate impact.

The Chamber urges the U.S. government to closely engage China in addressing the legal protection of live broadcasts through various channels.

Criminal Code Revision: The recent rounds of amendments to the Criminal Code led by the National People's Congress Standing Committee in the last few years completely ignored intellectual property issues. This is very disappointing.

China must realize the importance of clarifying a number of issues in the current code, which include the use of pirated business software that can be deemed a criminal offence; the "for profit" requirement to pursue criminal liability against distributors of pirated works; reducing thresholds for criminal liability; and the application to online infringements, in which context the evidence needed to prove a certain threshold of violation is difficult, if not impossible, to obtain.

Pre-installation of pirated software on PCs has been a major reason for the rampant piracy of business software in China. Chinese authorities are generally under the impression that the for-profit requirement is not met where software is installed for no additional cost. Pending amendment of the Criminal Code, the Chamber urges the SPC and SPP to clarify that any pre-installation of pirated software by vendors of hardware may be deemed a criminal violation.

Liability Thresholds: The unclear schedule for work towards the intellectual property amendment of the PRC Criminal Code's provisions has frustrated the vast majority of police investigations into intellectual property theft, and functions as an enormous loophole which is routinely exploited by infringers. A critical step in changing the intellectual property environment in China is dependent upon amending the law to reduce liability thresholds for counterfeiting and piracy.

Colombia

Overview: The Colombian government has an opportunity to create one of the leading IP and innovation frameworks in the region. Out of the Latin American and Caribbean economies benchmarked in the Index, Colombia ranks just behind Costa Rica and Mexico. Yet, in recent years, the Colombian government has taken a number of troubling steps to weaken Colombia's overall IP framework, signaling to investors that Colombia does not aspire to be a regional leader on IP, despite the many positive benefits that a robust IP system would provide for the Colombian economy. Further, while the U.S. and Colombia signed the Trade Promotion Agreement (TPA) over five years ago, Colombia has yet to pass legislation bringing its domestic laws in line with the IP chapter of the agreement. As Colombia looks to become a member of the Organization for Economic Cooperation and Development (OECD), the Colombian government must signal that it will address the below IP concerns in order to bring its IP framework in line with other OECD member countries.

Colombia's overall score rose slightly from 43% of the total possible score in the fifth edition (with a score of 15.22 out of 35) to 45.5% (18.27 out of 40) in the sixth edition of the Index. This mainly reflects a strong performance in many of the new indicators in the sixth edition.

The Chamber looks forward to working with the U.S. government to seek the following changes to Colombia's IP system.

Patents and Related Rights

Declarations of Public Interest: In June 2016, the Colombian Government issued a declaration of public interest (DPI) via Resolution 2475 and committed to unilaterally reducing the price of Glivec by about 45%. The issuance of the DPI, which is discretionary in nature, creates tremendous uncertainty for other innovators in the Colombian market. On November 22, 2016, the National Commission of Prices of Medicines and Medical Devices (Comisión Nacional de Precios de Medicamentos y Dispositivos Médicos) issued Circular 03 of 2016, which defines the general pricing methodology applicable to all drugs under a public interest declaration. In contrast to the existing price setting methodology – whereby the average price is calculated from a basket of 17 economies – public interest medicines are subjected to the lowest price available, including prices of follow-on products. In effect, this practice all but nullifies any existing IP protection and is highly questionable under Colombia's obligations under TRIPS and the U.S.-Colombia Trade Promotion Agreement. Shortly after the issuance of Circular No. 3, in December 2016 the National Pricing Commission issued Circular No. 4 of 2016 which sets the price of Glivec at ~44% of its former price. Subsequently in April 2017 the Colombian Government issued Decree No. 670, which regulates the use of the public interest measure. This requires that any declaration of public interest will be issued by an inter-institutional technical committee composed of representatives from the Ministry of Commerce, Industry and Tourism

and from the National Planning Department in addition to representatives from the Ministry of Health.

Further, in December 2017, the Ministry of Health and Social Protection issued Resolution No. 005246 to begin consideration on whether the government should declare nine Hepatitis C medicines in the public interest as well. Following the DPI on Glivec, the Ministry agreed that DPIs would only be issued following a multi-agency review. Yet, the Ministry has begun the process to issue the declaration on Hepatitis C medicines without such a consultation. Further, industry is particularly concerned by the Colombian government's consideration because the Hepatitis C medicines were pool-procured prior to their introduction in the Colombia market. Thus, the biopharmaceutical companies who invested in the research and development of these medicines have already negotiated a price reduction with the Colombia government. The U.S. Chamber fully acknowledges the budgetary challenges that a universal healthcare system can create for a government, however undermining the IP of the innovative companies who invest in the development of life-saving medicines should not be a means to address the healthcare system's fiscal challenges. The issuance of an additional declaration for the Hepatitis C medicines will set a harmful global precedent that IP rights will be discretionary when a government no longer wishes to pay the cost previously agreed to with the innovative company. Innovator firms seeking to expand access to new markets require commercial certainty that their products will be protected under the government's regulatory and legal framework. Unilaterally reducing prices in the name of meeting the budgetary constraints of a universal healthcare system undermines the investor confidence necessary for the system to work to produce new cures. As such, the U.S. Chamber urges USTR to convey to the Colombian government that the further DPIs would undermine Colombia's IP framework and likely hinder the availability of new medicines in the market. Moreover, such a measure – particularly if broadly applied to Hepatitis C medicines – would appear to be inconsistent with the international obligations undertaken by Colombia, including under the TRIPS Agreement.

Patentability: In 2015, the Colombian Government introduced its National Development Plan (NDP), which includes questionable provisions that may be out of step with Colombia's international treaty obligations. While Colombian law provides for a basic patentability framework, Article 70 combined with Article 69 of the NDP gives the Ministry of Health the ability to review patent applications directed to health products, similar to the prior consent mechanism currently in place in Brazil. The policy reflected in Article 70 whereby the patent applications of only one industrial sector are singled out for additional scrutiny through a second government agency may be inconsistent with Colombia's obligations under TRIPS.

Further, Articles 69 and 70 allow for the broad review by the Ministry of Health of all patented health technologies, which can be subject to a compulsory license. The open-ended standard for the use of compulsory licenses is likely in violation of TRIPS Article 31(a), which mandates that compulsory license request must be reviewed on an individual basis. The U.S. Chamber supports

efforts to both ensure that medicines are safe for consumers and that patients around the world have access to life-saving technology; however, we believe that the health and safety review and compulsory licensing provisions should be in line with Colombia's existing treaty obligations.

Additionally, a recent Plenary Chamber of Colombia's Constitutional Court decision confirmed the Ministry's ability 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 further enables the Ministry to intervene in medicine pricing in Colombia, a policy that has already had negative implications for the country's innovative pharmaceutical industry. Thus far, the measure has brought more than 500 additional medicines under price control. Similar to the DPIs, this authority undermines IP as a means for the government to regulate pharmaceutical prices. The U.S. Chamber urges the U.S. government to recommend to the Colombian government that the provisions of the NDP also both fulfill Colombia's obligations under the TRIPS Agreement and adequately protect the IP of innovative and creative companies operating in the market.

Finally, while patent office guidelines (Guía para examen de Solicitudes de Patente de Invención y modelo de Utilidad) provide criteria for software patent approval, based on having a technical application directed toward a hardware or process operated by a computer, legal analysis indicates that as of 2015, in the large majority of cases, the patent office denies software patents. The U.S. Chamber encourages the U.S. government to work with the Colombian government to introduce gold-standard guidelines to ensure adequate patent protection for software in Colombia.

Patent Enforcement: Colombian law could also be further strengthened by the introduction of a more robust patent enforcement resolution mechanism. While INVIMA introduced a process to notify the patent holder when their patent could be infringed upon by a company seeking market authorization, key gaps in Colombia's civil and administrative framework make this mechanism difficult to utilize in a timely manner. As such, the U.S. Chamber recommends that the U.S. government encourage the Colombian government to provide a transparent and effective pathway for the adjudication of patent validity and infringing issues before the marketing of a generic or biosimilar product.

Second Use Patents: The Andean Court of Justice (ACJ) issued several legal opinions (89-AI-2000, 01-AI-2001 and 34-AI-2001) forcing Andean Community members to refuse recognition of patents for second uses. This is contrary to long-standing precedents and inconsistent with TRIPS Article 27.1. Andean Community member countries, including Colombia, have either been compelled by the ACJ not to grant second medical use patents or have chosen to honor Andean Community obligations, while ignoring their TRIPS obligations. The failure to provide patents for second medical uses adversely affects members who dedicate many of their research investments to evaluating additional therapeutic benefits of known molecules (second uses) in order to provide more effective solutions for unsatisfied medical needs. The ACJ position is

dispositive on the issue and no further domestic appeals or remedies are possible. The U.S. Chamber of Commerce recommends that the U.S. government support efforts by the Colombian government to bring the patentability standards in line with Colombia's obligations under TRIPS.

Third Pathway for Biologics: In 2014, Colombia issued Decree 1782, which established the marketing approval evaluation requirements for all biologic medicines. As part of the Decree, Colombia established an unprecedented abbreviated pathway for registration of non-comparable products, which is inconsistent with World Health Organization (WHO) or U.S. Food and Drug Administration (FDA) standards and could result in the approval of medicines that are not safe and/or effective. In contrast to the Full Dossier Route (for originators) and the Comparability pathway (pathway for biosimilars) found in WHO guidelines, the "Abbreviated Comparability Pathway" allows for summary approval of non-comparable products and does not provide adequate controls or any clarity regarding how the safety or efficacy of a product approved via this pathway will be evaluated and assured. Furthermore, per the Decree, a product approved via the "Abbreviated Comparability Pathway" will use the same non-proprietary name as the innovator, despite the fact that the proposed similar biologic product is not the "same" as the innovative product. Assigning identical non-proprietary names to products that are not the same could result in inadvertent substitution of the products, and would make it difficult to quickly trace and attribute adverse events to the correct product. The Chamber recommends that the U.S. government work with the Colombian government to encourage the development of implementing guidelines to guarantee that safety and efficacy are compliant with international standards since by definition an abbreviated third pathway does not comply with international standards, as recognized by the WHO and FDA.

Copyrights and Related Rights

Copyright Law Review: In 2016, the Colombian government began to review the 1982 Copyright Law, which would allow Colombia to partially comply with commitments made in the TPA. Among other elements, the draft extends civil liability to circumvention of TPMs as well as to production and sales of circumvention devices, and allows destruction of circumvention devices and infringing materials. In addition, the draft expands certain exclusive rights to authors and phonogram producers. At the same time, the text also seeks to update copyright exceptions by adding exceptions for library and research use and for temporary electronic copies not involving commercial gain, among others. Moreover, it introduces statutory damages for copyright infringement (although the actual amounts must be decided by decree) and would increase copyright protection to 70 years for works for hire as well as for phonograms and broadcasts. However, it falls short of addressing other key gaps in the online copyright regime, including in relation to ISP liability and assistance in takedown of infringing content online. While Colombia's commitments go ignored, levels of piracy there continue to grow, increasingly online. There is no serious effort on the part of Colombian law enforcement to prosecute

administrators and owners of websites, blogs, and "hubs" involved in the distribution of illegal files. From January to November 2017, nine U.S. feature films were illegally camcorded in Colombian theaters, roughly on par with the same period in 2016. The Chamber urges the U.S. government to prioritize its dialogue with Colombia and encourage this vital trading partner to fulfill its obligations under the TPA and to demonstrate the will to protect creative sectors by combating the high levels of piracy that persist throughout the country.

Trade Secrets and Market Access

Regulatory and administrative barriers to the commercialization of IP assets: A number of barriers to licensing of IP assets exist in Colombia. Colombian public sector researchers and university faculty are not allowed a second salaried income, limiting incentives for setting up new businesses through spin-offs or start-ups. Looking at outputs, relatively few universities derive significant forms of income from commercialization and commercial research services. In addition, Colombian law prohibits any non-profit organization, including private universities, from engaging in commercial activities. Andean Community legislation also adds significant restrictions on agreements with foreign licensors, requiring registration and evaluation of licenses by national authorities on the basis of subjective criteria regarding the so-called value of imported technologies. The U.S. Chamber recommends that the Colombian government introduce licensing policies that encourage technology transfer to enable new, innovative and creative technologies to be commercialized in Colombia.

European Union

The United States and European Union (EU) have traditionally been the global leaders in protecting and promoting intellectual property rights. The U.S. Chamber is proud to have been a co-host of the Transatlantic IPR Working Group Stakeholder Consultation for over ten years. From the December 2017 meeting, it is clear that there are still many areas in which the U.S. and EU can collaborate on enhancing and protecting IPR internationally. But it is also clear that there is a concerted push within the EU to erect barriers and potentially diminish IP rights, which presents some enormous challenges for U.S. businesses.

The lion-share of European nations rank towards the top of the Chamber's International IP Index, and out-rank the United States in some respects. However, this momentum will halt or even backslide if certain IP-degrading initiatives are fully realized.

Patents and Related Rights

Supplementary Protection Certificates: In October 2015, the European Commission released its report "Upgrading the Single Market: More Opportunities for People and Business," which details the overarching initiative to reform and deepen the single market with the purpose of spurring economic growth and job creation and reducing administrative burdens. One key challenge identified in the report was the need to address the ambiguity formed with the ongoing process for the creation of an EU-wide unitary patent system and the lack of a conforming mechanism for Supplementary Protection Certificates (SPCs). While emphasizing the benefits of a unitary SPC title, the EC also announced its intentions to explore options for recalibrating certain elements of this IP right. One such option put forth by the EC is to provide European manufacturers of generic drugs and biosimilars with an SPC manufacturing exemption, which would "create thousands of high-tech jobs in the EU and many new companies."

Regrettably, the EC appears to have lost sight of the fact that IP incentives, such as SPC protection, have been central to the success of Europe's research-based biopharmaceutical industry. In 2016, industry estimates suggest that this sector generated some 745,000 direct jobs (with over 113,000 employed directly in innovative R&D) – a growth of 33% since 2000. Furthermore, over EUR 238 billion in pharmaceutical production were generated by the European research-based biopharmaceutical industry in 2015, as well as investments of some EUR 33.5 billion in R&D activities across the EU.

There are many troubling assumptions underlying the Commission's proposal. One running assumption about the potential gains to European generic manufacturers is that there is an actual market and demand for their products. Yet looking at this from a more practical standpoint it is not at all clear what this market is or where the demand for generic medicines produced in Europe would come from. The markets that per definition will be targeted by European generic manufacturers under an SPC exemption are markets that do not provide IP protection and exclusivity for products under SPC protection in the EU for which the SPC exemption would

apply. It would follow that in all likelihood generic follow-on products are already on the market in many of these countries and, critically, being produced by local manufacturers who are often preferred partners in local drug procurement. And for those markets where equivalent protection mechanisms are in place, it is highly unlikely that an SPC exemption would grant the European generic and biosimilar manufacturers an exclusive status for early market entry of their products across the globe. In fact, the obvious response to an EU SPC exemption is other countries asking themselves: "If the European Union is weakening IP standards to benefit their domestic industries why shouldn't we?" And so instead of benefiting the European generics industry, it is much more likely that other countries would emulate Europe, triggering a race to the bottom in weakening global IP standards.

In January 2017, American Chambers of Commerce (AmCham) from Bulgaria, the EU, Germany, Gibraltar, Ireland, Italy, The Netherlands, Norway Slovakia, Spain, and Sweden sent a letter to the European Commission expressing concern over the EU's consideration of the manufacture for export waiver to the SPCs. The U.S. Chamber similarly encourages the EC to reject the waiver and preserve the EU's position as a global leader in IP.

Copyrights and Related Rights

General Data Protection Regulation: The EU's General Data Protection Regulation (GDPR), which goes into effect in May 2018, will significantly impact American companies of all sizes and sectors operating in the European market. American companies have spent the last two years coming into compliance with this new regulation, yet uncertainty in its implementation remains. Even still, beginning May 25, companies could face tough penalties if determined to not adequately protect the personal data of European data subjects.

In particular, this regulation will affect the WHOIS database maintained by ICANN, which is a vital resource used by law enforcement, cybersecurity professionals, intellectual property professionals, businesses and others to investigate and enforce against crimes, cyberthreats, infringement, fraud, and other malfeasance. The GDPR will severely limit the personal information that domain name registries and registrars can provide in order to be compliant with GDPR's heightened level of privacy by default. This effectively requires them to change their delivery of public WHOIS or face stiff fines and possible litigation.

The WHOIS database provides valuable information on registrants of most top-level domains and serves as an essential tool used to investigate online violations and abuses. If registrars put this data behind a privacy firewall because of the GDPR, law enforcement, cyber security professionals, brand protection representatives and others may not have continued access to this key resource. Ensuring that legitimate players have continued access to this data in order to protect consumers and to protect against illegal activity online is critical.

India

Overview: While Chamber members observed some positive developments in 2017, overall there were mixed policy signals from India, which continue to stall the overall IP and innovation landscape for industry. While the U.S.-India commercial relationship poses significant opportunities for bilateral trade, India remains a challenging market for IP-intensive investment.

The level and frequency of engagement between the U.S. and Indian governments in 2017 continued to be a source of hope for the future, marked by ongoing dialogue on a broad range of IP rights issues between the U.S. and India under the Trade Policy Forum and the Commercial Dialogue. We are encouraged that both sides exchanged thoughts on a range of market access barriers in India, including the protection and enforcement of IP rights, and committed to further engagement in an effort to achieve concrete outcomes leading up to the 2018 dialogue and beyond. The decrease in the U.S. trade deficit in goods with India over the past year is a testament to the actions and policies of both governments to benefit American workers and jobs. We strongly hope that continued discussion will ensure a return of fair value to innovators and greater access to innovation for Indians. We look forward to continuing our efforts to help strengthen India's IPR policy with a view to drive bilateral trade ties with an innovation-led agenda.

In 2017, the Government of India (GOI) took some administrative steps in the right direction toward transitioning the long-awaited National IPR Policy ("Policy") of 2016 to the next level from its mere aspirational status. This includes unveiling an action plan for the "Scheme for IPR Awareness." The GOI has taken steps to expedite patent approval processes to reduce pendency rates, implement training programs for police officials on enforcement, encourage state-level competition on innovation, and simplify procedures for trademark filing.

The Policy continues to be inclined to improve IP administration, with an implicit recognition of the importance of IP to domestic innovation, and further contemplates efforts to educate Indian businesses about IP rights and facilitation initiatives to leverage IP rights in support of domestic innovative activity. The Policy addresses a number of important gaps in India's national IP environment, including the need for stronger enforcement of existing IP rights through the building of new state-level IP cells and investing of more resources in existing enforcement agencies; strengthening administrative capacities at India's IP offices, including reducing processing times for patent and trademark applications; as well as the need for introducing a legislative framework for the protection of trade secrets. Comprehensive reform and execution in these areas would mark a notable improvement to India's national IP environment. As initial steps in the right direction, 459 additional technically competent patent examiners have been appointed to clear the patent application backlog, resolution of trademark pendency has been reduced to just 1 month from 13 months, and eased procedures for trademark filing have been

implemented. The U.S. Chamber looks forward to further opportunities to support IP technical capacity building efforts with GOI.

However, the Policy does not do enough to strengthen the generation of IPR, enhance their reliability, facilitate commercialization, and provide deterrent-level enforcement. For example, it would be helpful to clarify implementation of the Policy, including outlining steps toward attaining "strong and effective IPR laws," such as by reviewing existing Indian IP laws to update and improve them or to remove anomalies and inconsistencies, in consultation with stakeholders. This could include, for example, coordination of more focused dialogue on Section 3(d) of India's IP laws to remove the existing anomalies and inconsistencies in the examination of pharmaceutical patents. Under Section 3(d), there is no clear guidance to specifically define the term "enhanced therapeutic efficacy," nor is there any consistency in how Patent Examiners in India apply Section 3(d) in analyzing patent applications.

We are concerned about the new Draft Pharmaceutical Policy proposed by India's Department of Pharmaceuticals. On the one hand, it is forward-looking in its approach: It recognizes the high risks and high costs of entry to the bio-pharmaceutical sector at the firm level and suggests the need for sufficient economic incentives, combined with a high degree of legal certainty, to make the risks sustainable over the long life-cycle that connects R&D to financing to product development and commercialization.

On the other hand, while patented medicines are excluded from price controls, the draft policy explicitly reserves the right to issue compulsory licenses. An active compulsory licensing mechanism and a government bias toward its use is the most extreme option; it signals to innovative investors that patent rights are discretionary, largely undermining the critical forward-looking aspects of this draft policy. Furthermore, pricing that does not properly value innovation has the impact of undermining and devaluing IP and access to innovation. We would welcome an approach that is predicated on consistency, transparency, predictability, and return of fair value for innovation.

Ultimately, the year was characterized by policy initiatives that brought India two steps forward and one step back: The new July 2017 revised "Guidelines for Examination of Computer Related Inventions (CRIs)" significantly improves the patenting environment for computer-implemented inventions (CIIs) in India. Unlike previous drafts of the guidelines there is no requirement for hardware innovation. We are also encouraged by the GOI's intention to make use of the WIPO Centralized Access to Search and Examination (CASE) system as a potential remedy to ease notification procedures on foreign patent application per Section 8 of the Patents Act. India's Department of Industrial Policy and Promotion (DIPP) also launched a three year national awareness campaign with the Cell for IPR Promotion and Management (CIPAM) to spearhead its implementation. Some key features include IP awareness workshops and seminars in collaboration with industry organizations, academic institutions, and other stakeholders;

technical training and capacity-building with key enforcement agencies; and a broad public awareness raising campaign reaching out all the way to school-aged children on the ill effects of counterfeiting and piracy.

However, despite this positive IP narrative, India also championed the weakening of IP rights in multilateral organizations, including WIPO and the WHO. On November 21-23, India's Ministry of Health and Family Welfare, Indian Society of International Law along with the WHO convened the "1st World Conference on Access to Medical Products and International Laws for Trade and Health, in the Context of the 2030 Agenda for Sustainable Development." The UNHLP Report on Access to Medicines formed the basis of the conversation with other emerging economies like Brazil and South Africa. The discussions questioned the link between IP, innovation, and access to health technologies.

Overall, India's score on the U.S. Chamber IP Index increased from 25% (8.75 out of 35) in the fifth edition to 30% (12.03 out of 40) in the sixth edition. This reflects a relatively strong performance in the new indicators added as well as positive reform efforts on patentability of CIIs and registration procedures for well-known marks.

Patents and Related Rights

Patent Opposition: Section 25 of the Patents Act outlines the procedures and requirements to initiate opposition proceedings. The law provides for both pre- and post-grant oppositions. The procedures are similar with the key difference being that pre-grant opposition can be initiated by "any person" whereas post-grant opposition must be initiated by an interested party. The pre-grant opposition mechanism has long been criticized for adding significantly to the already lengthy patent prosecution timelines in India. In particular, local legal opinion suggests that pre-grant opposition and the right by the applicant to, for example, request a hearing causes undue delays. The most recent statistics suggest that 98% of patents granted in India in 2015 were for applications over five years old. In one case it took 19 years to prosecute and grant a patent.

Patentability Requirements:

Bio-Pharmaceutical Inventions: Indian patent law has in place an additional requirement to patentability that goes beyond the internationally recognized requirements of novelty, inventive step, and industrial applicability. Under Section 3(d) of the Indian Patent Act, there is an additional "fourth hurdle" with regard to inventive step and enhanced efficacy that limits patentability for certain types of pharmaceutical inventions and chemical compounds. This approach to patentability requirements is inconsistent with the TRIPS Agreement, which specifies three basic patentability requirements, and importantly deters investment in developing new applications for existing pharmaceutical molecules—especially the hundreds of thousands of such molecules that are already off-patent.

Specifically, as per the Supreme Court of India's ruling on April 1, 2013, in the Novartis Glivec case, Section 3(d) can only be fulfilled if the patent applicant can show that the subject matter of the patent application has a better therapeutic efficacy compared with the structurally closest compound as published before the patent application had been filed (regardless of whether or not a patent application on the earlier compound was filed in India). The Supreme Court also found in that same case that it was not in the interest of India to provide patentees with protection that goes substantially beyond what was specifically disclosed in the patent application; compounds that fall within a chemical formula of a claimed group of compounds in a patent application but that are not specifically disclosed in the patent could be regarded as not protected.

The 2015 Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals do not address these challenges of interpreting Section 3(d) adequately. The U.S. Chamber urges the USTR to work with the GOI in ways that can help India clearly identify "patentable" incremental innovation by first recognizing that there are valid incremental innovations and that Indian entrepreneurs and the general public clearly stand to benefit from such incremental innovations. This could possibly serve as the basis for clarifying and interpreting Section 3(d) of the Patents Act.

The Indian Patents Act also imposes unique disclosure requirements for inventions using biological materials. Applicants are required to identify the source and geographical origin of biological materials and provide evidence that they have received permission from the National Biodiversity Authority (NBA) to file for IP protection on an invention using biological materials from India. This often places an undue burden on the applicant as it may be not be possible to ascertain the source and geographical origin of a particular material, especially if it has been procured from a commercial institution or depository or obtained from a public collection. Obtaining NBA approval has proved problematic and has resulted in the delay in the grant of patents. Delays in obtaining patent protection can compromise the commercial potential of useful inventions. Again, we would encourage the GOI to examine this issue and work towards a solution, which will clarify an applicant's obligation under the law and reduce delays in granting patents.

Computer-Related (Software) Inventions: We are encouraged by the recently re-issued guidelines on computer-related inventions (CRIs) as an important step towards recognizing the principle of comprehensive patentability with non-discrimination across technology sector, including patentability of all forms of software technology in an emerging, digital age. While the guidelines deleted the novel hardware requirement of the prior guidelines, the business community hopes to receive further guidance on what will be considered patentable under the new rules. Further clarity around the guidelines that recognizes the importance of CRIs to India's future will be critical to fostering technological innovation across India and ensuring India can unleash the benefits provided by a more effective IP regime.

Notification Procedures on Foreign Patents: Patent applicants are required to provide significant detail concerning the prosecution of counterpart and possibly other related patent applications outside of India. This requirement was instituted based on recommendations of the Ayyangar Committee Report on Patents in 1959. While at the time the information provided may have been accessible only to the patent applicant, in the more than 50 years that have passed many patent offices around the world have digitized their records. While we agree that having access to rejections in other similar cases may be useful to examiners, the administrative burden on the Indian Patent Office to catalogue information already available to their examiners drains precious patent office resources and potentially contributes to their growing examination backlog.

In a positive development, we are encouraged that the GOI intends to make use of the WIPO CASE system as a potential remedy to ease notification procedures on foreign patent application per Section 8 of the Patents Act. However, the Indian Patent Office has yet to issue guidelines or rules clarifying how information accessed through WIPO CASE will impact current disclosure requirements under Section 8 of the Patents Act.

Patent Term Restoration: Indian law does not provide patent term restoration for pharmaceutical products.

Regulatory Data Protection: Indian law does not currently provide a term of regulatory data protection. Data protection is a regulatory mechanism, which, for a pre-determined period of time, prevents competitors from relying on an innovator's safety and efficacy data to apply for marketing approvals for generic versions of the innovative product. TRIPS Article 39.3 requires parties to provide protection for certain pharmaceutical test and other data, but India has not yet done so. Data protection provides an economic incentive for innovative companies to test drugs, seek marketing approval, and introduce new drugs to the Indian market. After this fixed time period, generic manufacturers can obtain approval of generic versions of the drug and begin marketing their products. The ability of generic companies to rely on the innovator's safety and efficacy data provides significant commercial and economic benefits for generic companies. It permits them to obtain approval to market their products for a small fraction of the cost, and with none of the risk of failure that the innovator must face to gain approval. By preventing the authorization of third party products that rely on an innovator's data for a defined period of time, data protection ensures that an innovator's data is not subject to unfair commercial use. GIPC encourages GOI to take steps to implement its TRIPS Article 39.3 regulatory data protection commitment and prevent authorization of third party products that rely on an innovator's data for a defined period of time.

Legislative Criteria and Compulsory Licensing: Industry continues to be concerned by the potential threat of compulsory licensing. Statements by Indian officials at international organizations in support of the findings of the UN High Level Panel on Access to Medicines,

which called for broad use of "TRIPS flexibilities" to support routine use of compulsory licenses in non-emergency situations, are highly concerning. India takes similar positions in the policy bodies of the WIPO, WTO, and other fora.

Compulsory licensing is rarely the best policy option to promote access to medicines. They are not a suitable tool to deal with the long-term healthcare issues confronting countries – health infrastructure and financing mechanisms. These issues need to be addressed in partnership with all stakeholders, including the innovative biopharmaceutical industry. Compulsory licensing should not be used to support industrial policy objectives aimed at favoring domestic industries or as a routine cost containment measure when national resources and financial reserves are adequate and other alternatives are available.

While no additional compulsory licenses for biopharmaceuticals were issued by Indian authorities in 2017, the GOI continues to examine potential compulsory licenses under Section 92, and Indian companies continued to seek compulsory licenses under Section 84. We continue to urge the Modi government to repudiate the use of compulsory licenses as a commercial tool.

Copyrights and Related Rights

The decision by the GOI to move jurisdiction over copyright policy to the Department of Industrial Policy and Promotion ("DIPP") was viewed by the industry as an important positive step, putting copyright in the hands of regulators with specialized expertise related to IP.

India has enforced website blocking injunctions, which is a more advanced approach to online enforcement than in most countries. That said, the civil litigation route is not capable of addressing the piracy problem in India given the backlog of IP infringement cases. India needs stronger measures to encourage cooperation and meaningful engagement between rights holders and users of materials, such as clear third party liability for inducing infringement, and more effective notice and takedown procedures. Much more also needs to be done to coordinate and improve India's fractured system of state-level enforcement to address online copyright piracy as well as the hard copy piracy that still plagues some copyright sectors. Effective administrative and criminal enforcement are essential, in light of the massive backlog of cases awaiting a hearing before Indian courts. Measures, including a judicial reform, should also be taken to speed up the processing of court cases.

Piracy: Despite high levels of software piracy, music piracy, and counterfeit goods, Indian law remains unclear about the availability and requirements of a notice and takedown system to combat online piracy. Studies have shown that 60% of software in India is pirated, creating an enormous cyber-security risk for Indian businesses and consumers.

However, in what is otherwise a challenging copyright environment in India, a positive trend has emerged over the past few years with rights-holders increasingly being able to defend and

enforce their copyrights through injunctive relief. Since 2012 there have been a number of cases whereby access to websites offering pirated and infringing content has been disabled through court orders, including notorious international sites like The Pirate Bay. Injunctions have been issued by both the High Court of Delhi and High Court of Bombay with the Department of Telecommunications instructing Indian Internet Service Providers to carry out the order. While the case law and procedures are still evolving (particularly with regards to disabling access to only specific URLs versus entire websites), we hope that this development will act as a strong deterrent against online piracy in India.

To combat movie camcording, India should enact the Cinematograph Bill to make it unlawful to possess an audiovisual recording device to transmit or make a copy, in whole or in part, of a motion picture from a performance of such work in a motion picture exhibition facility.

Digital Rights Management Legislation: While the 2012 Copyright Act includes DRM measures, the measures allow for broad exceptions that do not cover the import and distribution of circumvention equipment. We look forward to engagement with the Government of India to close these loopholes.

Trademarks

Protection of well-known marks: Like in many jurisdictions, rights-holders in India have long struggled with the lack of clarity on the protection for well-known marks, with case law offering sometimes conflicting judgments. To provide more clarity the Office of the Controller General of Patents, Designs and Trade Marks (CGPDTM) has since 2003 compiled a list of marks that they recognize as being well-known. This list includes international brand names such as Philips, Intel, Pepsi, Toshiba, Honda, Mars and others. In total the list has grown to close to 100 marks. Unfortunately, this list is not exhaustive, and there are many marks that by any reasonable standard would be considered well-known that are not included. Recognizing this, the Controller in May 2017 issued a new set of Trade Mark Rules. Rule 124 allows individuals and entities to apply directly to the Registrar to receive official recognition for their marks as being 'well-known.' These are positive steps in the right direction, but the associated guidelines would benefit from further clarity on what constitutes supporting evidence.

Specifically, it would seem that a determining factor for the Registrar would be the availability of court judgments in India recognizing the applying mark as well-known. This would be a rather narrow basis on which a determination could be made, as the majority of well-known marks globally have yet to be determined to be well-known in an Indian court of law. It is hoped that during the course of 2018 and the actual application of this Rule that it will be clarified that an Indian court judgment is not a prerequisite or determining factor for receiving recognition as a well-known mark. On this basis India's IP Index score for this indicator has increased. We are encouraged to note that the CGPDTM has reduced trademark pendency to one month and eased the procedure for filing applications with the number of forms brought down from 74 to 8.

Trade Secrets and Market Access

India lacks an effective trade secret protection regime in law, though courts have in practice provided some protection. The most reliable tool innovators have in this regard is contract law, which has significant limits, particularly given the high mobility of workers and the amount of sub-contracting taking place within the countries. In many cases, if confidential business information is stolen, the innovator will have no avenue for relief. Industry was encouraged by emergent dialogue on this issue in 2016, which gave some indication that progress on this issue is recognized as an area of non-controversial, mutual interest. We are encouraged by the intention of the GOI to upgrade their legislative framework to offer meaningful trade secret protection and look forward to working with the U.S. government to continue to interact with the GOI this year to follow up from the 2016 dialogue.

India also has in place a number of policies making market access contingent on the sharing or divulging of IP. For example, through its 2012 decision in the Nexavar compulsory licensing case, the Controller General of Patents, Designs and Trademarks set a precedent of requiring foreign innovators to manufacture in India as a condition of "working the patent" in order to avoid forced licensing of their inventions to third parties. U.S industry in the information and communications technology sector have stated that in-country testing requirements and data- and server-localization requirements limit market access in India and compromise their IP and trade secrets. Industry remains committed to working with the GOI to resolve this issue.

Telecommunications Network Security: U.S. industry remains concerned about security testing requirements for ICT equipment that will enter into force later this year. These requirements, issued by India's Department of Telecommunications (DoT), appear to deviate from global practices. However, DoT has yet to issue any specific details about the scope and coverage of these requirements. GIPC members require significant lead time to adjust complex global supply chains to meet these types of requirements.

Of most concern are potential requirements for U.S. ICT companies to provide source code, IP, and other sensitive design elements to private or Indian government labs. The original 2011 Telecom License Amendments, which created the in-country security testing requirement, mandated the transfer of technology from foreign equipment manufacturers to domestic ones and the escrow source code and other sensitive design elements as a condition of market entry. This extremely sensitive and proprietary information is at the core of U.S. ICT companies' products, and the compromise of such information would severely harm their continued commercial viability.

Not only do India's new telecommunications security requirements raise potential WTO compliance concerns, but if they remain unchallenged, other governments may use them to justify their own elaborate information security regimes. In other words, India's approach is

establishing a dangerous precedent for governments that may be inclined to use national security claims in a way that is detrimental to global ICT trade.

USTR should urge the GOI to continue to work closely with all stakeholders, including global telecommunications service providers and equipment vendors, to ensure that implementation of the telecommunications security provisions do not undermine basic IP protection, nor create obligations outside of global norms that inhibit market access.

Pay-TV Market Access Issues: The Indian government should eliminate "must provide" rules in the pay-TV sector and price caps for pay-TV channels.

Enforcement

Enforcement Capacity: Consistent with implementation of the National IPR Policy, we encourage the establishment of positions for cybercrime law enforcement officers in State police stations and a centralized IP crime unit under CBI Cyber Crime Detective Unit to focus on IP crimes as a means to enhance India's institutional enforcement capacity.

India's Customs authorities lack the necessary training and resources to enforce IP rights at the border. Customs should substantially simplify the process and reduce the cost necessary for rights holders to register copyrights with Customs and to confirm that a shipment contains infringing products. Customs officers at all levels should be empowered and trained to combat infringing trade through authorization and use of risk-management targeting. Customs should be authorized to seize goods based on confirmation from the rights holders of the counterfeit status (currently, the rights holder must file a civil action to complete the seizure process if the importer does not voluntarily abandon the infringing goods).

We welcome the launch of the "IPR Enforcement Toolkit for Policy" in January 2017 by the DIPP's Cell for IPR Promotion and Management (CIPAM), which is being made available to all state police departments across the country to assist them in dealing with the cases relating to trademarks and copyrights infringements. According to CIPAM, "This toolkit will be a ready reckoner for police officials across the country in dealing with IP crimes, specifically Trade Marks counterfeiting and Copyrights piracy. In addition to details of offences under various laws, it provides for checklists for registering a complaint and conducting search and seizures. It also lays down general guidelines for search and seizure in case of IP crimes."

Intermediary Liability: Many of the websites exposing Indians to pirated content are hosted outside of India; nevertheless, they are supported by online advertising originating in India and targeting Indian consumers. A concerted effort by the government to pressure the online advertising industry in India to stop funding piracy through online ads could significantly reduce revenue to these criminal enterprises. We are encouraged by recent discussions on this as part of the U.S.-India Trade Policy Forum.

We urge the GOI to amend Article 69A of the IT Act to make copyright infringement a predicate offense and to cover linking and other sites that are central parts of the piracy ecosystem but do not themselves host content. This would provide an efficient administrative injunctive relief remedy against structurally infringing sites.

Compulsory Licensing: It would be helpful if the GOI can ensure that compulsory/statutory licenses comply with Berne Convention and TRIPS, and statutory license options for broadcasters of non-Indian repertoire should be eliminated. In the meantime, creation of the Copyright Board with authority to set reasonable royalty rates must be a priority.

Camcording: India continues to have the unfortunate status of being a major source of illicit camcords. The domestic industry is a principal victim of this form of copyright infringement, leading domestic constituents, such as the Andhra Pradesh Film Chamber of Commerce, to be outspoken on the issue.

Digital Rights Management/Technological Protection Measures: The Indian Copyright Act should be amended to ensure adequate protection against circumvention of Technological Protection Measures, including access controls and trafficking.

State-level Patent Enforcement: State drug regulatory authorities in India are permitted to grant marketing approval to generic versions of medicines four years after the innovator product is approved and without considering the remaining term of the patent granted by the Indian Patent Office. Lack of transparency around these decisions forces companies to enforce their patents through India's court system, oftentimes resulting in decisions after the infringing product is already on the market.

Membership and Ratification of International Treaties

India is not a contracting party to many well-established international treaties, including among others the WIPO Copyright Treaty; the WIPO Performances and Phonograms Treaty; and the Singapore Treaty on the Law of Trademarks.

Indonesia

Overview: In 2016, the Indonesian Parliament (People's Representative Council) passed a wide-ranging patent law (Law 13 2016), with IP-restrictive provisions that sent a chilling message to the innovative and creative content sectors. However, the government has taken a deliberative approach to implementing regulations in a process marked by regular consultation with stakeholders; consequently, key measures remain pending implementation. The U.S. Chamber and its members are encouraged by signals that the Indonesian government appears willing to engage with industry to shape its patent law consistent with international standards. The future direction of Indonesia's IP policies will become clearer as key implementation decisions are taken, especially in areas such as local working requirements, patent eligibility, and compulsory licensing that can serve either to enhance or undermine legal certainty for investors in the innovative and creative investment.

Indonesia's overall score on the U.S. Chamber International IP Index has increased from 27.5% (9.64 out of 35) in the fifth edition to 30% (12.14 out of 40) in the sixth edition. This increase is due to the presence of a patent prosecution highway with Japan, the availability of administrative relief for copyrighted content online, and the existence of a cross-ministerial group to enhance Indonesian government coordination on enforcement of IP rights. The U.S. Chamber hopes the Indonesian government can build upon this positive momentum to address the following concerns of innovative and creative industries operating in Indonesia.

Patents and Related Rights

Membership in Patent Prosecution Highways (PPHs): Although Indonesia is not a member of either the Global Patent Prosecution Highway or the IP5 PPH, the Directorate General of Intellectual Property Rights (DGIPR) and Japan Patent Office (JPO) have in place a patent prosecution highway. The initiative began in 2016 for a three-year trial period. This is a positive feature of Indonesia's national IP environment and is commended. The U.S. Chamber recommends that the U.S. government encourage the Indonesian government to consider entering other PPH agreements in order to expedite the patent review process in Indonesia.

Restrictive Patentability Criteria: Article 4 of the new patent law denies patent protection to a wide range of biopharmaceutical inventions. Specifically, it prohibits, *per se*, the patenting of new uses and new forms of existing products. Such a narrow interpretation may have the unintended effect of diverting research and development activity in affected sectors away from Indonesia. This is an additional requirement that does not apply to any other types of inventions and is therefore discriminatory by nature. Article 27.1 of the TRIPS Agreement provides that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." The U.S. Chamber recommends that the U.S. government work closely with the Indonesian

government to ensure that the implementing regulations provide greater clarity for inventors in Indonesia and elsewhere.

Parallel Importation: Article 167of the new patent law allows the parallel importation of follow-on products under patent protection in Indonesia but approved for consumption in other markets. The law explains that this importation is to target the cost of medicines and in particular where prices in Indonesia are judged to be higher than the "international market." No details are provided as to what constitutes a "higher price" or the "international market." The U.S. Chamber encourages the U.S. government to seek clarity from the Indonesian government on the scope of the parallel importation policy proposed under Article 167 in order to ensure that the implementing regulations do not undermine innovative biopharmaceutical companies' IP in Indonesia, as well as address the added risk of counterfeits entering the market.

Forced Localization: Article 20 of the new patent law mandates that all patent rights-holders "make" the patented product or process within Indonesia. Subsection (2) of this article states that this production should support Indonesia's industrial and development policies, specifically the "transfer of technology, investment absorption and / or employment." No further details are provided as to the meaning or legal definition of "make" in this context, although efforts to provide substantive guidance through regulation have been evident in consultations with stakeholders. Indonesia has had in place a number of localization requirements targeting certain industrial sectors (most notably the biopharmaceutical sector), but it would seem that this new requirement has broadened this mandatory localization to any patented technology. On its face, this provision contravenes obligations under the TRIPS Agreement, which prohibits WTO members from discriminating based on whether products are imported or locally produced. The U.S. Chamber encourages the U.S. government to clarify with the Indonesian government how this requirement will be interpreted in practice and to enable inventors abroad to continue to serve the Indonesian market.

Software Patentability: The new patent law allows a limited form of patenting of CIIs. The explanation to Article 4(3) seems to suggest that patents will be allowed when they fulfill a technical effect or problem solving requirement. The U.S. Chamber encourages the U.S. government to work with the Indonesian government to expand the scope of Article 4(3) of software patentability to ensure that all forms of software are patentable in Indonesia.

Compulsory Licensing: Since the mid-2000s, the Indonesian government has issued nine "government use" licenses overriding existing pharmaceutical patents primarily for hepatitis and HIV drugs. These licenses allow the government to exploit existing patent-protected products in the event of threats to national security or an urgent public need. The manner in which these licenses were issued appears to be in contradiction of Article 31 of the TRIPS Agreement. First, the issuing of these licenses took place without engaging the relevant rights holders on an alternative solution or obtaining their authorization. Second, the issuing of the licenses was

conducted on a group basis as opposed to an individual basis as required by TRIPS. Finally, there does not appear to be any specific recourse mechanism available that would allow a rights holder to appeal the issuing of these licenses, with the Government's decision, as stated by the relevant articles in the patent law, being defined as final. No new licenses were issued in 2017, but the legal framework for compulsory licensing – including so-called government use licenses – was retained and expanded in the new patent law. For example, Article 82 of the new law makes patented products subject to compulsory licensing if patent holders do not manufacture such products in Indonesia within three years after the patent is granted. Furthermore, the recently amended patent law also creates uncertainty by discouraging voluntary licensing agreements between private parties and by promoting compulsory licensing on grounds that are vague or appear to be inconsistent with Indonesia's international obligations. In particular, the patent law unnecessarily requires disclosure of private licensing agreements and allows compulsory licensing if a patented product is not being manufactured in Indonesia. The U.S. Chamber urges the U.S. government to work with the Indonesian government to make clear that compulsory licenses should only be used under extraordinary circumstances and as a measure of last resort, rather than a means to try to address unmet healthcare needs. The U.S. Chamber welcomes the opportunity to work with the U.S. and Indonesian governments to find a solution that supports the needs of Indonesian patients while at the same time promoting IP protection, which continues to be critical to the development of new and innovative medicines.

Regulatory Data Protection: At present, Indonesia does not provide regulatory data protection for biologic medicines. The U.S. standard of data exclusivity is 12 years, and Indonesia's lack of data protection is a significant roadblock for innovative companies that are stimulating research and development in treatments for some of the riskiest and most complex issues facing human health. The U.S. Chamber recommends that Indonesia adopt a policy to provide regulatory data protection for biologic medicines.

Annuity Payments: The Indonesian Patent Office is currently issuing invoices for past annuity payments on previously abandoned patents that were not expressly withdrawn from the patent office. Annuity payments represent the renewal fees companies pay to maintain a granted patent. The invoices received from the Indonesian Patent Office represent up to 3 years of annuities as well as back taxes if due. The amounts are significant, and if companies do not pay, they have been threatened with property seizure. This practice is not in line with that of major patent offices worldwide.

Copyrights and Related Rights

Availability of Injunctive Relief: The 2014 Copyright Act introduced a new ministerial notification system on online infringement granting the Ministry of Communication and Informatics the power to disable access to infringing websites. While these powers had been in existence since the late 2000s, it was unclear the extent to which they applied to potential online

acts of copyright infringement. The Directorate General of IP operates an online notification system whereby rights-holders can file a notice of infringement and request the disabling of access to suspected websites. Since implementation in 2015, the system has been widely used by both local and international rights-holders. Local press reports and industry sources suggest that access to between 250 to 300 infringing websites has been effectively disabled. While the scale of copyright piracy (both physical and online) remains an immense challenge to rights-holders in Indonesia, together with other initiatives – including the 2017 launch of an "Infringing Website List" in a partnership between the Indonesian Government and private sector rights-holders – these legislative and regulatory steps taken by the Indonesian authorities and their continued enforcement and application is a significant achievement and step in the right direction. The U.S. Chamber hopes the U.S. government will work with the Indonesian government to ensure that the government continues to put in place initiatives that help deter online copyright infringement.

Frameworks for Cooperation to Prevent Piracy: Indonesia has made meaningful improvements over the past year, though significantly more needs to be done given the scale and scope of piracy in Indonesia's market. The 2014 Act provided new tools to combat online infringement and the circumvention of technological protection measures (TPMs). Regulations implementing the law (Regulations No. 14 and 26) were enacted in July 2015, providing new administrative remedies in response to websites that facilitate infringement by disabling access to primarily infringing websites. Additionally, the Creative Economy Agency established an anti-piracy task force in the second half of the year. These new tools have already proven useful and suggest new dedication to anti-piracy efforts within Indonesia.

While recognizing these important developments, we also must note the significant challenges the creative community continues to confront in Indonesia. Piracy is persistent and enforcement is wholly insufficient. Courts are mostly ineffective. Developments in 2015 were positive, but a significant and continued investment of resources and training for enforcement entities and courts and high-level political commitment is needed.

Additionally, Indonesia maintains a number of protectionist policies, some of which are not enforced in practice, which keep out legitimate content, including a proposed 60% local content screen quota, onerous pre-production content review requirements, a prohibition on dubbing imported films, local replication requirement, foreign investment limitations, and other restrictions on the audiovisual industry. The U.S. Chamber recommends that the U.S. government collaborate with its Indonesian government counterparts to build on the positive momentum of the 2014 Act to work towards addressing the outstanding concerns of the creative community in Indonesia.

PayTV Piracy: PayTV signal theft is a major problem in Indonesia. Some payTV channels are devoted almost entirely to playing pirated content. The U.S. Chamber strongly urges the government to crack down on these pirate channels, as well as those engaged in the unauthorized

trafficking, dissemination, decryption, or receipt of pay-TV, and support the growth of legitimate pay-TV services.

Illicit Streaming Devices: ISDs are a prevalent problem in Indonesia. The U.S. Chamber recommends that the U.S. government help the Indonesian Government to increase enforcement efforts, including cracking down on piracy apps and on device manufacturers who preload the devices with apps that facilitate infringement. Moreover, the Government should take action against key distribution points for devices that are being used illegally.

Trademarks

In October 2016, a new Trademark and Geographic Indications law was passed. While primarily focusing on expanding the realm of protection for trademarks to non-traditional trademarks (including sound holograms and 3-D marks) and improving the speed and administration of trademark applications, the law also strengthened existing enforcement mechanisms. Specifically, article 100 strengthens existing criminal sanctions against trademark infringement. Fines have been increased to a maximum of IDR 2-5 billion (approximately USD 150,000-380,000) and prison sentences to between 4-10 years. The higher fines and sentences are applicable only in cases in which the infringing goods have led to public health issues, death or environmental damage. Given the relatively high level of counterfeit medicines in Indonesia, this is a positive development. Unfortunately, there were also a number of negative developments, increasing the already high level of uncertainty with regards to the protection of well-known marks. Two decisions by the Supreme Court of Indonesia entrench the difficulties that rights-holders face in protecting their registered and well-known marks from rival and potential bad-faith registrations and subsequent use. In September 2016, the Court rejected the claims of designer Pierre Cardin that a local company was infringing its trademark. The local company had filed a similar trademark in the late 1970s incorporating the Pierre Cardin name whereas the French designer had only registered its trademark in Indonesia in 2009. In a different case the Supreme Court held that Swedish furniture giant IKEA's locally registered trademarks were not valid as they had not been used for a period of three years. The challenge of non-use came from a local furniture company wishing to file its own trademark acronym "IKEA" which is short for "Intan Khatulistiwa Esa Abadi." The U.S. Chamber encourages the U.S. government to collaborate with the Indonesian government to strengthen the legal protection for well-known marks in order to ensure that brand owners' goods are adequately protected in Indonesia.

Malaysia

Overview: On September 20, 2017, Malaysia issued a government-use license, a public form of a compulsory license, for Sofosbuvir, a new breakthrough medicine to treat Hepatitis C. Malaysia last issued a compulsory license in 2004 for the importation of generic ARV medicines. In an accompanying statement to the decision, the Ministry of Health made clear that the decision to issue the license was driven primarily by the cost of the medicine. In contrast, Article 31 and the Doha Declaration suggests that compulsory licensing, or in this case, government-use licensing, represents a measure of last resort, intended primarily for public health and humanitarian emergencies such as pandemics, and should be used only after all other options for negotiating pricing and supply have been exhausted. Malaysia has had a long stated national ambition of continuing to transform its economy with a focus on high-tech industries and innovation, including the innovative biopharmaceutical sector. It is unlikely that the issuing of a compulsory license as a basis for price negotiation with a research-based manufacturer will help advance these ambitions.

In light of this, Malaysia's overall score has decreased from 49.1% (17.19 out of 35) in the fifth edition to 48.7% (19.47 out of 40) in the sixth edition of the International IP Index. This reflects a mixed performance in the new indicators added, the suspension of the IP provisions of the TPP treaty, and uncertainty over the IP chapter, if any, in the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). Moreover, the issuing of a government-use license in 2017 has greatly damaged Malaysia's national IP environment and risks undermining much of the progress made since 2004 and the last time the Government issued a similar license.

Patents and Related Rights

Compulsory Licensing: A statement issued by the Ministry of Health referring to the September 2017 issuance of the Sofosbuvir government-use license said, "The decision to initiate the Rights of Government was made after the MOH efforts to be included in the Medicine Patent Pool (MPP) and price negotiations with patent holder were unsuccessful [sic]. Through the implementation of The Rights of Government, the cost of treatment will be lower and more patients can be treated."

However, cost is not a relevant justification or basis for government-use or compulsory licensing. Furthermore, as noted recently by the Pharmaceutical Association of Malaysia (PHAMA), compulsory licensing or government-use license "does not result in lower prices for medicines compared with international procurement programs and other alternatives. They are not suitable tools to deal with the long-term healthcare issues confronting developing countries – health infrastructure and financing mechanisms. These issues need to be addressed in partnership with all stakeholders, including the innovative biopharmaceutical industry. . . . An active compulsory/government-use licensing policy will not be helpful in promoting such a

partnership." It may also have a long lasting impact on the future of trade and investment in Malaysia by multinational companies, including those in other industries that rely heavily on intellectual property rights protection. "The pharmaceutical industry flourished on predictable, reliable and strong intellectual property regime which is an enabler for innovation. Government-use license particularly impacts upon innovative bio-pharmaceutical companies, which reinvest profits back into R&D, including clinical research to discover and develop the next generation of medicines."[64] The U.S. Chamber supports PHAMA's recommendation of a more holistic and sustainable approach to ensure that patients have access to medicines and quality healthcare. We are committed to contributing towards a stronger healthcare infrastructure as a key part of this long-term solution.

Membership in Patent Prosecution Highways (PPHs): Although Malaysia is not a member of either the Global Patent Prosecution Highway or the IP5 PPH, the IP Corporation of Malaysia (MyIPO) does have PPH agreements in place with both the EPO and JPO. Launched in 2014, the PPH program between the MyIPO and the JPO is the older of the two pilot programs. In 2016 the EPO and MyIPO announced their intention of launching a comprehensive PPH pilot program. The program came into effect in July 2017.

Patent Term Restoration: Malaysia does not currently allow patent term restoration for pharmaceutical products. Industry sources suggest that discussions on reforming the Patent Act to include a term of restoration have taken place, but at the time of research no official legislation had been introduced. The agreed text of the TPP (of which Malaysia is a negotiating party) released in November 2015 contains very clear requirements that contracting parties make available a term of patent restoration for unreasonable delays. However, upon finalization of negotiations in early October 2015, the Malaysian Deputy Health Minister Datuk Seri Dr Hilmi Yahaya was quoted by local news sources as saying: "The Health Ministry has announced that we do not agree on the extension of the duration of patency of the medicines as it will burden the people." Subsequent to the publication of this report, the Ministry of Health released a statement by Yahaya clarifying this remark arguing that regulatory delays in Malaysia were within international norms, thus precluding the need for any restoration period. Providing biopharmaceutical innovators a full term of patent exclusivity in line with international best practices and standards is an essential component of incentivizing R&D and investment in new medical technologies. Introducing a term of patent restoration for any delays caused through the regulatory review process would be a positive step in strengthening Malaysia's IP environment as it relates to the life sciences.

Regulatory Data Protection: Malaysia introduced a 5-year term of regulatory data protection in 2011. While this is a positive achievement, challenges remain. Specifically, the full term of protection is not offered to new products introduced in Malaysia. Instead, the term of protection

[64] PHAMA letter to YB Dato Sri Mustapa Mohamed, Minister of International Trade and Industry, regarding industry concerns on the decision to invoke government-use licensing for Hepatitis C, dated November 3, 2017.

begins whenever a product was introduced globally. This significantly weakens the actual exclusivity and incentive being offered to pharmaceutical innovators through regulatory data protection. Recent academic research published in the *Journal of IP Rights* shows the negative impact of this measure by quantifying the actual length of the term of protection provided. Since its introduction in 2011, the average effective term of protection has been just over 43 months (i.e., about 3.5 years for the 10 products that have been granted data exclusivity). This is considerably lower than the statutory term of 5 years. Regulatory data protection is an essential IP right for the life sciences sector—in particular for biologics—providing a tangible incentive to the investment and research required to develop new drugs and medical technologies.

Commercialization of IP Assets: Malaysian policymakers are increasingly recognizing IP as an economic asset to be used and developed. Successive national innovation plans and strategies have identified the need to further build and encourage the commercial use and dissemination of IP as an asset. For instance, the 11th five-year plan (2015-2020) pledged to create a Research Management Agency and to "encourage local and international collaborations for technology transfer, including strategic alliances between MNCs and SMEs." MyIPO runs an "IP Academy" with a range of training programs and capacity building activities. Other government departments have IP training programs in place.

For example, in 2013 MyIPO and the Multimedia Development Corporation of Malaysia (MDec) developed an IP valuation training program targeting SMEs. The purpose of the program is to provide real-world training on IP valuation, contract negotiation, managing of IP assets, and related commercialization activities. Malaysia does not have in place a specific technology transfer law akin to the U.S. Bayh-Dole framework. Instead, technology transfer at universities and public research institutions are guided by internal guidelines (often developed together with the main funder of the program, the Malaysian Government) and two Government regulations: the 1999 Government Circular and the 2009 IP Policy. While the former by and large retains IP ownership with the Malaysian Government, the latter policy vests ownership with the recipient of the relevant funding. As a result, under this policy publicly funded innovators and creators are able to retain ownership of their creations. There is some evidence to suggest that patenting rates by Malaysian universities and PROs has increased since the introduction of the 2009 IP Policy.

Membership and Ratification of International Treaties

While Malaysia is not a contracting party to the Patent Law Treaty or the Singapore Treaty on the Law of Trademarks, it acceded to the WIPO Internet Treaties in 2014. It is also one of the negotiating parties to the TPP. With the withdrawal by the U.S. as a contracting party to the TPP in early 2017 there has been considerable uncertainty as to the future of the agreement. In November 2017 in an inter-ministerial statement the remaining contracting parties – Malaysia included – confirmed that the TPP was being substantively renegotiated as the CPTPP. While some elements of the previously agreed and ratified TPP have been kept, the majority of the IP

chapter has been suspended. As the text of the CTPP is still being negotiated, Malaysia's score has decreased on indicator 40.

Russia

Overview: Though Russia leads the BRICS economies in relative strength of IP rights in the 2018 Chamber International IP Index, its IP environment scores below half the available amount desired to provide confidence in its market. We are encouraged to see Russia taking steps to better enforce against online copyright infringement, but the Chamber continues to remain concerned about many aspects of Russia's IP rights regime.

Russia's overall score has decreased from 44.4% (15.53 out of 35) in the fifth edition to 43.2% (17.29 out of 40) in the sixth edition of the Index. This reflects a relatively weak performance on the new indicators added.

Patents and Related Rights

Regulatory Data Protection: Under its WTO commitments and the 2010 Law of Medicines, Russia has committed to implementing a regulatory data protection term of six years. This was a positive step and has significantly strengthened the existing framework and protection mechanisms for pharmaceutical innovation.

However, there remains a lack of progress in implementing this commitment and developing a fully functioning form of regulatory data protection. This lack of direction has been compounded by uncertainty in the interpretation of the existing legal framework by the Russian judiciary. For example, in a case hinging on whether or not a local generic manufacturer (BioIntegrator) relied on clinical data submitted by an innovator (Novartis), the latter initially lost its case of exclusivity infringement in the spring of 2015. This decision was later reversed by an Arbitration Court and then again partially revised in December 2015 by the relatively newly established IP Court in Moscow. The Court upheld the reasoning by the Arbitration Court that Novartis was entitled to protection for its submitted clinical research data. However, the Court also argued that not all data was statutorily protected. Specifically, data that was not protected was information that had been published in specialized journals and was viewed as being in the public domain. Such an interpretation is inconsistent with established international principles of data protection and trade secrets. As such, this judgment creates further uncertainty for what is already a challenging situation for rights-holders in Russia.

Furthermore, legislative amendments to the Law of Medicines that regulate the time period for the submission of follow-on product applications took effect in 2016. These amendments allow follow-on applicants to submit their applications for market approval four years after market approval for small molecule products and three years for biologic (large molecule) products. Given the existing uncertainties in the Russian market with respect to the approval of follow-on products within a current term of exclusivity, there is a clear risk that these amendments will further undermine the practical availability of regulatory data protection in Russia.

Industry will continue to advocate for the introduction and application of full coverage of protection for regulatory data in Russia.

Patent Enforcement: Russia does not provide for a resolution process which enables patent holders to resolve patent conflicts before the authorization of follow-on product marketing. Furthermore, Russian courts rarely, if ever, grant preliminary injunctions in patent cases. This has led to the approval and marketing of follow-on products, despite the fact that a patent for the original drug is still in force. The Russian regulation is then compounding this injury by permitting prematurely launched generics to participate in state procurement tenders. The U.S. Chamber urges the Russian government to put in place meaningful patent resolution and enforcement mechanisms.

Compulsory Licensing: The Federal Antimonopoly Service (FAS) has proposed to amend the Civil Code to allow for the greater use of compulsory licensing for biopharmaceutical products. In July the head of the FAS, Igor Artemyev, stated it was only a matter of time before the Government would formally begin to use this tool. The underlying reason behind much of this effort is to reduce public expenditure on drugs and increase domestic Russian manufacturing capacity. Yet neither the cost of medicines nor domestic industrial policy is a relevant justification or basis for compulsory licensing under the TRIPS agreement. In addition, Article 31 and the Doha Declaration suggests that compulsory licensing represents a measure of last resort, intended primarily for public health and humanitarian emergencies such as pandemics, and should be used only after all other options for negotiating pricing and supply have been exhausted. Furthermore, the language used in the "Competition Development Plan" announced last December is quite broad, including a proposal for the government to use patents without the consent of a patent owner whenever in the interest of national security and health protection. This reinforces the deteriorating IP environment for the innovative pharmaceutical industry

Copyrights and Related Rights

Online Piracy: Although online piracy remains a serious problem in Russia, the Government has taken a number of important steps to provide new tools to address the issue. In 2013 and 2014, the Russian Federation signed into law amendments to the Civil Code Part IV, which included notice and takedown obligations to intermediaries upon notice of infringement by a rights holder and allows for disabling access to infringing sites in the event of repeat infringement. With regards to the application and enforcement of the 2013 and 2014 amendments, reports from the Russian government suggest that traffic onto websites with legitimate content was increasing as a result of the law; however, in other areas enforcement challenges persist. For example, online piracy rates continue to remain high in Russia. VK.com remains one of the most visited websites in the world and is included in USTR's Notorious Markets Report.

In 2017 further legislative changes were introduced to strengthen rights-holders ability to request the disabling of access to infringing material online. Specifically, there were a number of important amendments to the "Law on Information, Information Technologies and Information Protection." These amendments include the ability of the court to extend injunctive relief against so-called mirror sites that infringe copyrighted content. In addition, rights-holders now have the option of notifying the Ministry of Communications, which has two days to order the hosting provider to disable access to the site. Furthermore, Internet mediators (including search engines) are now obliged to remove links to sites that have been found to host illegal content. These are positive developments and show how Russian authorities are actively seeking to address the immense challenge of online piracy.

Unlicensed Software Use: According to BSA, the Software Alliance, Russia ranks among the top in the world of unlicensed software use. As of 2015, Russia's unlicensed rate amounted to 64%.

Collective Management Organizations: Currently, Russia's state-accredited collecting societies are replete with governance and transparency issues, which continue to concern the copyright community. Russia should, consistent with its WTO commitments, resolve the confusion surrounding the operation of collecting societies by confirming that rights holders have the legal and practical ability to determine how to exercise their rights, including by allowing them to choose whether to entrust licensing to any collective, and if so, to which entity and for which rights.

Enforcement

Adjudication: Industry reports that despite some mild improvements in the legal infrastructure with updated IP legislation and the creation of IP specialized courts, court proceedings are very long and judges are still reluctant to award damages. Furthermore, industry reports that enforcement bodies (mainly Police and Customs) are not very active in fighting counterfeiting.

Online Enforcement: The Russian e-commerce market is worth over 9 billion Euros in 2015, and sporting goods, clothing and footwear are the fastest growing categories. It is advisable to establish a dialogue with government and enforcement bodies to develop and implement a better strategy to fight against counterfeiting over the Internet. Industry reports having experienced non-cooperation from Internet service providers when required to block access to infringers. Better cooperation and collaboration between government authorities, platforms, and rights holders could address the current inefficiencies and help clean the local marketplaces and address websites with global visibility.

Trade Secrets and Market Access

Trade Secrets Protection: The Russian legal system offers poor protection of trade secrets. The law itself creates barriers—namely, overly prescriptive requirements that businesses must meet before commercial information is eligible for protection as a trade secret. Further, even when information qualifies as a trade secret, enforcement is weak and unpredictable, meaning there is little deterrent for would-be infringers. Industry reports that Russian courts generally do not impose meaningful penalties for trade secrets breaches, despite the fact that Russian law provides for the full suite of civil and criminal remedies.

As a result of the challenges in protecting trade secrets under Russian law, doing business in Russia is difficult for foreign companies in knowledge-rich industries.

Currently, Industry reports that Russian law is insufficient in its application of TRIPS Article 39, which requires a three-step test to be met in order to protect information as a trade secret. While Russian law is not dissimilar to Articles 39(2)(a) and (b) of TRIPS (requiring trade secrets to not be readily accessible and to have commercial value as a result of their secrecy), the major departure from TRIPS in Russian law comes in relation to Article 39(2)(c) -- the "reasonable steps" requirement. This appears in the Russian law as the requirement to introduce a "regime of commercial secrecy" in respect of the information to be protected. The Russian law places significant bureaucratic requirements on trade secret holders to meet the "regime of commercial secrecy" requirement. In contrast to many countries that have incorporated the flexible "reasonable steps" standard from TRIPS almost verbatim, Russian law is highly prescriptive and onerous.

In November 2016, the Asia Pacific Economic Cooperation (APEC), whose membership includes Russia, endorsed a set of best practices aimed at strengthening enforcement against trade secrets misappropriation. The U.S. should hold Russia accountable to upgrade its trade secret regime in line with the identified best practices. The U.S. Chamber recommends that the U.S. government work with its Russian counterparts to bring trade secrets law more into compliance with the TRIPS standards and make protection less onerous on rights holders.

Trade Secrets Enforcement: Russian law provides for various remedies for trade secrets breaches, in both the criminal law and the civil law. Despite the seemingly favorable remedies landscape for trade secret holders provided by Russian law, the reality of enforcement is very different. Industry reports that in various trade secret cases where misappropriation has been found, the consequences for defendants have been relatively trivial.

Preliminary remedies such as injunctions and seizures are theoretically available. There is little publicly available evidence on the grant of injunctions in Russia. However, both experience and some historical information indicates that injunctions are only rarely used, if at all.

Criminal penalties also tend to be rarely used in IP cases, including in cases of trade secrets theft. For example, in one case where there was a proven loss of two million dollars, the defendant was

sentenced to undertake “corrective works” (similar to a community service penalty). In June 2015, the criminal law was amended to increase the potential penalties for trade secret theft, but (the very limited and largely unreported) experience with actual cases does not yet reflect any notable change in imposed penalties.

The U.S. Chamber recommends that the Russian Government adequately use all the tools at its disposal to administer effective and reasonable deterrent penalties for trade secrets misappropriation.

Forced Localization Policies: In its efforts to diversify and modernize its economy, the Russian Government has increasingly focused on erecting localization barriers and mandatory localization requirements for foreign entities to access the Russian market. A number of industries and sectors (in particular biopharmaceuticals and other high technology industries) have been targeted with requirements and preferences for local production and manufacturing. These efforts intensified in 2017.

Furthermore, the “New Digital Society Strategy 2017-2030” approved in May 2017 contains a number of localization policies including the location of databases and data within Russia and online payments to be made through Russian payment systems. Further restrictions have also been put in place for foreign ownership of online content providers.

Together these localization policies create a significant market access barrier for rights-holders, in effect conditioning access to Russia’s healthcare market on fulfilling the localization of production and development.

South Africa

Overview: In 2017, South Africa's Department of Trade and Industry (DTI) published the "Draft IP Policy of the Republic of South Africa Phase I" ("Draft Policy") following the 2016 release of the "IP Consultative Framework" ("Framework"). This is the first document of what is to be a series of policy documents addressing all major IP laws in South Africa. This Phase I document focuses on patents (primarily for biopharmaceuticals) and related IP rights. It is a positive step that the Government of South Africa recognizes the need for reform to its national IP environment and the value of consulting all stakeholders in that process.

However, much like the Framework document, the Draft IP Policy focuses on ways in which South Africa could better access existing and developed forms of IP rather than on the means by which IP can be created, commercialized, and become an industrial asset in South Africa. For all economies – emerging and developed alike – what drives innovation, technological advances, and ultimately economic development and growth is the creation of new forms of intangible assets and IP. Yet the Draft is silent on this. Instead it focuses on the expansion of the use of compulsory licensing as a public policy tool to, one, "progressively realize the right to have access to health care services" in South Africa, and two, as a basis for South African manufacturing and exports to Africa.

TRIPS Article 31, including the amendments introduced in the 2001 Doha Ministerial Declaration, and the subsequent General Council decision allowing the export of medicines produced under a compulsory license (outlined in Paragraph 6), form the legal grounds for compulsory licensing for medicines. The Chairman's statement accompanying the General Council decision (concerning Paragraph 6 of the Doha Declaration) underscores that these provisions are not in any way intended for industrial or commercial objectives, and if used, it is expected that they would solely be aimed at protecting public health. In addition, Article 31 and the Doha Declaration suggests that compulsory licensing represents a "measure of last resort," intended primarily for public health and humanitarian emergencies such as pandemics, and should be used only after all other options for negotiating pricing and supply have been exhausted.

The Draft also proposes to introduce heightened standards of patentability, the use of parallel importation, and the introduction of a pre- and post-grant opposition mechanism – making it more difficult to invest, innovate, and create new products and technologies in South Africa. In this vein, it is unlikely that any of these policies – independently or in aggregate – will help South Africa "transition towards a knowledge economy" as the Draft hopes.

It is interesting to note that China's State Council endorsed a set of measures similar in function to those outlined above. Meanwhile, India's Department of Pharmaceuticals issued a forward-looking draft policy that said, "There [has been] disproportionate focus on generic formulations

to the point of exclusion of lack of adequate R&D." Brazil, too, over the last year has advanced a set of reforms aimed at streamlining patent registration and licensing.

Several studies point to the direct correlation between a strong IP framework and economic competitiveness. For instance, the *Scientific American Worldview Scorecard* clearly demonstrates the close correlation between high IP standards and a country's ability to climb into the global top 20 countries that attract 80% of annual investment. Furthermore, the 2017 *Biopharmaceutical Competitiveness and Investment* (BCI) Report surveys 36 country investors, highlighting that concerns about IP risks are weighing down South Africa's performance, and in turn, its investment attractiveness. South Africa continues to stand in the lower-third of the U.S. Chamber International IP Index, behind Kenya, Ukraine, and Brazil.

South Africa's overall score has decreased from 36% (12.7 out of 35) in the fifth edition to 34% (13.71 out of 40) in the sixth edition of the Index. This reflects a weak performance on the new indicators added.

Patents and Related Rights

Substantive Search and Examination: The U.S. Chamber welcomes the Framework's and Draft Policy's proposal to move towards a Substantive Search and Examination (SSE) system. We believe the introduction of an SSE system will help increase the quality of patents granted and create greater certainty for the patentee and third parties alike. Additionally, we support the Companies and IP Commission's ("CIPC") interest in working with "highly efficient" global patent offices, such as the UK and Singapore. The Chamber believes that through coordination, work sharing, and the adoption of best practices with these offices, South Africa will move towards a high quality, robust patent system under the SSE framework.

However, while we broadly support the introduction of SSE, we recognize that the use of SSE in lieu of a depository system could result in an examination backlog. South Africa should consider the lessons learned from the Brazilian government's move to a SSE system. Technological and resource constraints in Brazil created an estimated 10 year patent examination backlog since the government implemented the SSE framework. As such, the U.S. Chamber recommends that the South African government introduce mechanisms to protect against undue delays in examination, including patent term restoration provisions to account for the time lost during the patent examination process.

The U.S. Chamber stands ready to work with the South African government to offer support, as needed, towards implementing a highly efficient and robust patent examination process through the SSE model.

Patent Opposition: Section 4.1.3 of the Framework and Section 7.1.3 of the Draft Policy sets out a high-level desire to allow for third-party opposition procedures as a cheaper alternative to

revocation hearings. It provides for multiple layers of administrative patent opposition, both pre- and post-grant. In the proposed system, at no time from the grant of a patent through its expiration would either an innovative or a generic producer have a reasonable degree of legal certainty regarding the likely patent life applicable to any given product. It is difficult to ascertain whether introducing third-party opposition will be beneficial to the South African patent system without further details on how such a proposal would be implemented. In fact, countries like Thailand, Turkey and Israel – whose scores have increased on the 2018 IP Index – are either in the process of reviewing or eliminating their pre-grant opposition procedures. The U.S. Chamber looks forward to working with the South African government as it considers alternative patent opposition measures.

Patentability Criteria: As the South African government looks to international best practice to strengthen its patentability criteria — as section 4.1.4 of the Framework — and implement a more fulsome examination process, the U.S. Chamber recommends taking a broad approach to patentability that embraces both the development of new technologies and the refinement of existing discoveries — the latter being a ripe area for developing country activity.

Section 7.1.4 of the Draft Policy suggests that the criteria of the WTO TRIPS Agreement's three-step test for patent eligibility may be re-interpreted, despite the fact that the ordinary meaning of these terms in the context of the TRIPS Agreement and international law is well-defined. By seeking to re-define these criteria in favor of a more restrictive standard, the draft policy unduly limits the scope of innovation that can take place in South Africa, putting a lid on the future growth prospects of any bio-pharmaceutical investment in South Africa.

In that spirit, the U.S. Chamber recommends that South Africa take steps to ensure the availability of patent protection for emerging technologies like computer-implemented inventions (CIIs). In an era where software innovation cuts across all industries — from medical technology to electronic manufacturing to digital communication — patenting of CIIs is critical to stimulating new innovations and future technological growth.

Adequate IP protection for CIIs will create a platform for South African innovators to bring their products and services to global markets in a much more efficient, comprehensive fashion. Indeed, since the passage of the TRIPS agreement, patentability of CIIs has become a de facto best practice, and as such, the Chamber recommends that the South African government include robust patent protection for CIIs as it reviews patentability requirements. Likewise, by taking steps to ensure patentability of incremental innovation, South Africa will give its domestic entrepreneurs a foothold by which to enter the technological innovation space.

Patent Term Extension: Section 4.1.7 of the Framework and Section 7.1.7.1 address the Bolar exemption, which the U.S. Chamber believes provides a critical mechanism for generic companies to conduct pre-market testing prior to an innovative company's patent expiration. The exemption allows for earlier development and approval of new generic medicines,

stimulating competition in the marketplace. This, in turn, drives down the cost of medicines and helps to provide a variety of medical innovations in a given market. However, the U.S. Chamber believes that the Bolar exemption must be paired with other measures that promote patent rights, such as patent term extension.

In the U.S., the Hatch-Waxman Act included the Bolar exemption alongside provisions for patent term extension. Patent term extension enables innovative companies to recover the patent life lost during the regulatory approval process. The balance struck between patent term extension and the Bolar exemption helps to ensure that the innovative company's rights are adequately protected while promoting the growth of new generics. As the South African government evaluates the efficacy of the Bolar exception under the 2002 Patents Act, the U.S. Chamber encourages the government to include a mechanism similar to patent term extension in order to support the entry of generics into the marketplace while also creating a system which supports the innovator's patent rights.

Fundamentally, we view patent term extension as a rule of law mechanism that protects the base IP incentive represented by the 20-year patent term from inappropriate erosion due to bureaucratic or political delay.

Policies That Encourage the Use of IP Flexibilities: Section 4.1.9 of the Framework and Sections 7.1.7 and 7.1.9 denote that compulsory licenses are one of the most important tools to ensure that IPRs do not unduly restrict access to essential innovations. By contrast, the U.S. Chamber believes that a stable, predictable IP system facilitates — rather than inhibits — the dissemination of new technology. Recent studies have shown that stronger IP protection results in faster access to new medicines in developing countries. In addition, robust IP protection results in the introduction of many medicines in developing countries that would not otherwise be available to patients in those markets.

Given the importance of IP to increasing the availability of new technologies, including innovative medicines, the U.S. Chamber recommends that the South African government embrace a policy that ensures that compulsory licenses and other forms of IP expropriation are only used as a tool of last resort, such as public health emergencies. An expansive use of compulsory licensing as a discretionary policy or fiscal tool runs the risk of diminishing the value of all IP in South Africa and consequently reducing all economic activity that relies upon IP, from basic research, to product development and testing, to access by the end-user.

Instituting greater flexibilities with respect to IP creates uncertainty for investors, which jeopardizes the potential for growth of the industry and deprives the local economy of the benefits that robust IP systems provide.

Copyrights and Related Rights

South Africa is currently engaged in reforming its copyright law. Draft Copyright Act amendments were published in 2015 and made open to public consultations. These amendments have now been revised, and a new set of amendments were published by the DTI in May 2017.

On the positive side, these amendments would strengthen and reinforce important aspects of South Africa's legal framework, including the protection for DRM and TPMs. There is no current provision in the existing Copyright Act with regard to DRM or TPMs. However, Chapter 12 of the Electronic Communications and Transactions Act (ECTA) does contain a number of provisions that could be interpreted as pertaining to TPMs. Specifically, Section 86 prohibits the "production, sale, design, distribution or possession of any device, including a computer program or a component, which is designed primarily to overcome security measures for the protection of data."

The proposed 2017 amendments contain a fairly robust set of draft sections corresponding with those already contained in ECTA. However, there are a number of areas which are still marked by uncertainty. Specifically, the proposed amendments would introduce a system of "fair use" exceptions to copyright. There has for many years been a lack of clarity in South Africa on what constitutes infringement of copyright and what is fair reproduction and use with no relevant full definition in the current Copyright Act.

While this is a positive step, many of the proposed exceptions are quite broad. There are also issues relating to state ownership of copyright. Under the proposed amendments the South African Government would retain copyright "on every work which is eligible for copyright and which is made by, funded by or under the direction or control of the state." It is unclear how this proposed section would interact with, for example, publicly funded academic research or state commissioned cultural programming. It begs the question: Would the academic researcher or creator of a work retain any rights or would all rights automatically vest with the state funding entity?

Market Access

Forced Localization: The South African Government has for many years focused on developing its domestic economy through a range of localization policies. These policies are both general as well as industry and sector specific. For example, South Africa has long-standing local content requirements for certain sectors including broadcasting. Within public procurement, significant local content requirements have been in place since 2011 for a host of specially designated sectors ranging from automotive (buses), set-top boxes, clothing, and furniture. Local content requirements range from 10-100% depending on the industry.

Specifically, the DTI is strengthening cross-governmental enforcement activities and ensuring greater compliance and application of these localization requirements. Furthermore, South Africa's industrial policies place a heavy emphasis on the transfer of technologies from

international rights holders to local companies. Conditioning market access and access to opportunities for public procurement on local partnering requirements and the sharing or divulging of proprietary technologies with local partners presents a significant barrier to trade and impediment to investment.

Separately, as South Africa considers adopting universal health coverage under the National Health Insurance system, it would benefit from a fulsome, sustainable approach in terms of access to healthcare. Such an approach would be remiss if it did not account for non-IP related factors that impede access to medicines, including "the distribution system within a community or country, the quality of the healthcare system, general infrastructure, access to insurance, and policies on import tariffs and taxes," as noted in the 2017 submission of the Innovative Pharmaceuticals Association of South Africa (IPASA) in response to the release of the Draft Policy. Furthermore, alternatives should be considered to the use of compulsory licensing as South Africa moves toward this path, including options such as voluntary licensing and non-assert declarations.

Turkey

Overview: The new Industrial Property Law (No.6769) was passed by the Turkish Parliament in late 2016. The Law consolidates measures on the enforcement of major IP rights (excluding copyrights and related rights) into one law and under one agency, the new Turkish Patent and Trademark Institution (TPPT). The new law involves a number of positive steps and new measures that strengthen the IP system and harmonize it with EU standards. This includes the introduction of a post-grant patent opposition system. Under the new system, an opposition may be filed within six months of the grant of a patent. Remaining issues that are expected to be resolved as the new system is implemented (and will be monitored for the next edition of the Index) include the ability to amend claims and the timing/coordination of invalidation and opposition proceedings. In addition, the new IP law expands protection available to well-known trademarks. Specifically, it provides for both absolute and relative grounds for refusal of registrations in relation to an unregistered, well-known mark.

The former was provided under the previous law (and addresses same or similar marks), but the addition of relative grounds represents an enhanced level of protection, particularly for marks involving likelihood of confusion or risk of dilution. The law also enhances the ability to protect against unused trademarks, enabling applicants for a trademark to request proof of use of conflicting marks within the past five years, and expands trademark offenses to include acts such as providing services, importing or exporting, and distributing (beyond simply manufacturing and selling). In relation to design rights, the new IP law aligns a number of aspects of Turkish law on designs protection with the EU Community Designs Regulation, including adding a three year term of protection for unregistered designs (applicants) and specifying the scope of protection be limited to visible parts of a product.

Finally, the new IP law strengthens the technology transfer framework in Turkey. Under the law, assets developed by researchers at universities are owned by the university, with one third of proceeds directed to inventors for publicly funded projects. The ability to better leverage university resources for patent applications is expected to support an increase in the rate of licensing of IP in Turkey as well as income from licensing going to universities. Nevertheless, in one negative development the IP law, article 29 broadens the basis for issuing compulsory licenses to cases in which a third party claims that the patented invention is not meeting the needs of the national market. The language lacks details or definition of what needs of the market are, and risks being interpreted overly widely, creating a great deal of uncertainty for patent holders.

Turkey's overall score has increased from 45% of the total possible score (15.8 out of 35) in the fifth edition to 47% (18.86 out of 40) in the sixth edition of the Index. This is mainly a result of the introduction of the new IP law, affecting scores in the areas of Patents, Trademarks, Designs

and Commercialization of IP Assets, as well as a relatively strong performance on some of the new indicators.

Patents & Related Rights

Compulsory Licensing: Compulsory licensing is rarely the best policy option to promote access to medicines. It is not a suitable tool to deal with the long-term healthcare issues confronting countries – health infrastructure and financing mechanisms. These issues need to be addressed in partnership with all stakeholders, including the innovative biopharmaceutical industry. The inclusion of a compulsory licensing framework under Article 130 and Article 132(2) falls short of all necessary due process protections. Both "national market's need" and "public interest" are pre-conditions for a compulsory license to be requested. Industry has voiced concerns that the patent holder is not allotted sufficient time to express opinion in both of these cases. It has been recommended that either the patentee be given an opportunity to seek an extension of time to respond with just cause, or that the time to respond should be revised to give the patentee at least 90 days. Compulsory licensing should not be used to support industrial policy objectives aimed at favoring domestic industries or as a routine cost containment measure when national resources and financial reserves are adequate and other alternatives are available.

Regulatory Data Protection: The Turkish Government took steps to establish a six year period of RDP for innovative pharmaceuticals in 2005. Turkey now provides RDP for a period of six years for products starting from first registration in the European Customs Union (ECU), limited by the patent protection period of the product. Industry is concerned that the period of RDP begins on the first date of marketing authorization in any country of the ECU. Considering the extended regulatory approval times and delays stemming from the Good Manufacturing Practices certification approval period, current estimates are that it could take 2-3 years (approximately 500 days for registration, and 235 days for reimbursement approval) to register and reimburse a new medicine in Turkey. As such, new products will receive, in practice, no more than one to two years of RDP, undermining incentives needed for innovators to undertake risky and expensive research and testing.

In addition, industry is concerned that legislation governing RDP is inconsistent with EU standards as it does not recognize RDP for combination products, unless the combination product introduces a new indication. Furthermore, Turkey does not provide RDP for biologic medicines. RDP is essential for all medicines, and particularly critical for biologic therapies.

Copyrights and Related Rights

Turkish copyright law lacks a clear obligation for ISPs to expeditiously cooperate with rights holders when they have knowledge of infringement without an official order from a prosecutor's

office or court. However, a basic notice and takedown mechanism, whereby rights holders may notify ISPs and if there is no response pursue a takedown through the courts, as well as requirement for ISPs to respond to a court's order, is present in Additional Article 4 of the Copyright Law. In addition, the Internet Law (No.5651) provides for the takedown or disabling of access to websites for matters of "national security, restoration of public order and prevention of crimes," which can include copyright and trademark infringement.

Under the law, courts may issue orders for service or hosting providers to disable access to sites infringing the law. Law 5651 also established a central body of ISPs (Association of Access Providers), which is required to respond to courts' orders and may also receive notices of violation from the private sector. Industry reports suggest that having such a "one-stop shop" for submitting notices or directing orders has aided in growth in responsiveness by ISPs in the past year, including notices from copyrights holders. As a result the score for indicator 12 rises by 0.25. In addition, some sites, such as the The Pirate Bay, have been disabled under court order in the past.

Nevertheless, the Association of Access Providers and the Internet Law more widely tend to be used more frequently for political-related site disabling. Copyright amendments introduced in 2016 and under discussion in 2017 would establish, among other elements, a new Center for Combating Digital Violations within the Ministry of Tourism and Culture. The new Center, if implemented, is intended to become a copyright-focused body for handling rights holder notices.

Market Access

U.S. manufacturers are concerned about Turkey's decision in late 2016 to impose new tariffs of as much as 25% on hundreds of manufacturing products, and other decisions over the years to increase tariffs on hundreds more manufacturing products by as much as 50%. These tariffs add new barriers to the many barriers that manufacturers in the United States encounter in Turkey, undermining the ability of manufacturers in the United States to compete in the Turkish market.

Delisting of Products: Beginning in February 2017, companies began receiving notices that their products would be delisted within 12 months unless sufficient localization plans are put in place. These notices followed implementation of provisions in Article 46 of the 64th Government Action Plan (released on December 10, 2015), which called for the delisting of imported products from the reimbursement list and providing preferential reimbursement arrangements for healthcare products produced domestically. GIPC members are concerned that these actions by the Turkish government are inconsistent with Turkey's national treatment obligations under the World Trade Organization (WTO) Agreements. The second wave of product delisting notifications, impacting 176 products, was announced in May 2017, while the third and fourth wave notifications are also underway. In the case of the full five phases being implemented, it is expected to impact up to 75% of the market.

Using Turkey's reimbursement system to implement forced localization policies discriminates against imported medicines in order to reach local manufacturing targets.

To ensure Turkish patients have access to the best medicines, vaccines, and medical devices, we recommend that Turkey keep all approved medicines on its reimbursement list and align practices with its international obligations under the General Agreement on Tariffs and Trade 1994 (GATT), and World Trade Organization (WTO) Agreements.

Market access challenges are present in both goods and services, especially as they concern the digital economy. Global companies increasingly rely on modern communication networks and data flows to deliver services to customers, run internal operations, optimize manufacturing, and manage global supply chains. Restrictions on the ability of companies to move data across borders, including through data and server localization requirements, will undermine Turkey's economic growth and impede Turkey's ambition to become a regional financial center. Recent communiques published in December 2017 and January 2018 by Turkey's Data Protection Authority and Capital Markets Board governing data controllers' registry and information systems management, respectively, may disrupt cross-border data flows with requirements to have data stored on local servers. These measures follow similar legislation from Turkey's Banking and Regulatory Supervision Agency Law No. 6493 governing, "Payment and Security Settlement Systems, Payment Services and Electronic Money Institutions."