

By electronic submission

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Washington, DC

U.S. CHAMBER OF COMMERCE

2017 SPECIAL 301 SUBMISSION

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February 9, 2017

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Director for Intellectual Property and Innovation
Office of the U.S. Trade Representative
600 17th Street, NW
Washington, DC 20508

Re: 2017 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 United States Trade Representative

Dear Ms. Peterson:

The U.S. Chamber of Commerce's (Chamber) Global Intellectual Property 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 in analyzing the global intellectual property environment for many years and is encouraged that 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 3 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. This year, 2017 marks the 10th anniversary of the creation of the GIPC, which now leads a worldwide effort to champion intellectual property (IP) as vital to creating jobs, saving lives, advancing global economic growth, and generating breakthrough solutions to global challenges.

Intellectual property is critical to U.S. economic development and competitiveness. In 2016, the Department of Commerce found that intellectual property-intensive companies account for over 38 percent of U.S. gross domestic output, drive 52 percent of U.S. exports, and support 45 million American jobs directly and indirectly.

However, the benefits enjoyed by intellectual property-intensive industries are not limited to U.S. borders. As evidenced by the 2017 Chamber International IP Index, *The Roots of Innovation*—released yesterday—economies of all shapes and sizes have a stake in implementing meaningful intellectual property 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 as well as country-specific challenges. In particular, we emphasize growing concerns about the erosion of intellectual property rights, not only in particular countries but also in multilateral settings; deteriorating market access embodied in forced localization requirements; and compulsory licensing increasingly being used for political purposes. We included 11 countries in this report, which were chosen based on factors including market size, the geopolitical significance of the market, and specific intellectual property issues posed by that country.

The Special 301 Report is a critical tool that shines a spotlight on inadequate and ineffective intellectual property 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 intellectual property 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,

A handwritten signature in black ink, appearing to read "David Hirschmann". The signature is fluid and cursive, with a long horizontal stroke at the end.

David Hirschmann
Senior Vice President, U.S. Chamber of Commerce
President and CEO, U.S. Chamber's Global
Intellectual Property Center

A handwritten signature in black ink, appearing to read "Myron Brilliant". The signature is cursive and somewhat stylized, with a long horizontal stroke at the end.

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

TABLE OF CONTENTS

RESEARCHING THE GLOBAL INTELLECTUAL PROPERTY LANDSCAPE.....	5
CHALLENGES TO INTELLECTUAL PROPERTY PROTECTION AND ENFORCEMENT..	8
AUSTRALIA.....	28
BRAZIL.....	32
CANADA.....	39
CHINA.....	45
COLOMBIA.....	74
ECUADOR.....	79
INDIA.....	83
INDONESIA.....	93
RUSSIA.....	98
SOUTH AFRICA.....	103
VENEZUELA.....	109

Researching the Global Intellectual Property Landscape

The U.S. Chamber International IP Index

The Chamber is committed to promoting a global environment that fosters innovation and creativity in the U.S. and abroad. On February 8, 2017, the U.S. Chamber released the fifth edition of the International IP Index, *The Roots of Innovation* (the “Index”), which provides a roadmap for countries seeking to create jobs, promote economic growth and investment, and build innovative and creative economies. In the Index, economies are scored against 35 indicators in six categories of IP protection – patents, copyrights, trademarks, trade secrets and market access, enforcement, and ratification of international treaties. This cross-disciplinary, empirical assessment of intellectual property protection and enforcement in 45 economies provides a snapshot of what countries are doing well and what they can be doing better.

These economies are: Algeria, Argentina, Australia, Brazil, Brunei, Canada, Chile, China, Colombia, Ecuador, *Egypt*, France, Germany, *Hungary*, India, Indonesia, Israel, Italy, Japan, *Kenya*, Malaysia, Mexico, New Zealand, Nigeria, *Pakistan*, Peru, *Philippines*, Poland, Russia, *Saudi Arabia*, Singapore, *Spain*, South Africa, South Korea, Sweden, Switzerland, Taiwan, Thailand, Turkey, Ukraine, United Arab Emirates, the United Kingdom, the United States, Venezuela, and Vietnam (*italics* indicate new countries added for 2017 edition). Together, these countries constitute over 90% of estimated world gross domestic product.

The Index is not intended to be an industry version of the Special 301 Report and, as such, not all countries ranked in the Index are included in the Chamber’s Special 301 submission. Rather, our 301 submission serves to further highlight markets whose policies and practices have special significance for the global IP environment facing U.S. innovators.

In addition to the country rankings, the fifth edition includes an analysis of the standards included in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement and the final text of the Trans-Pacific Partnership (TPP) Agreement relative to the benchmarks included in the Index. This analysis shows that trade agreements have progressively raised the bar for IP standards in a 21st century global marketplace and will be further discussed below under the section entitled “Importance of Bilateral and Regional Free Trade Agreements.”

The Index also notably includes statistical evidence of the direct link between the relative strength of IP environments and important socioeconomic indicators. The Fifth Edition of the Index focused on 21 such socioeconomic outcomes, finding direct positive correlations between IPR strength and a host of benefits, including: R&D expenditures, high-value job growth, access to venture capital, biotechnology innovation, and access to creative content and advanced technologies just to name a few.

We are pleased to provide a copy of the Index with our Special 301 submission to provide additional evidence to support the issues raised throughout.

Global Measure of Physical Counterfeiting

The continued growth of the global counterfeiting industry is a major cause for concern. Fueled by the surge of online shopping and social media platforms, the magnitude of global physical counterfeiting is estimated to have increased significantly since the beginning of this century. As part of the 2016 International IP Index, the U.S. Chamber updated the global counterfeiting measure in its study “*Measuring the Magnitude of Global Counterfeiting: Creation of a Contemporary Global Measure of Physical Counterfeiting.*”

Based on new modeling of an economy’s propensity for counterfeiting, the purpose of this study is twofold: 1) to provide a deep-dive analysis of trade-related physical counterfeiting on a comparative level, and 2) to provide a breakdown of the share of the global rate of physical counterfeiting (as both a percentage and with a USD figure) for the 38 economies included in the fourth edition of the U.S. Chamber of Commerce’s International IP Index.

The study makes the following key findings:

1. China alone is estimated to be the source for more than 70% of global physical trade-related counterfeiting, amounting to more than 285 billion USD. Physical counterfeiting accounts for the equivalent of 12.5% of China’s exports of goods and over 1.5% of its GDP. China and Hong Kong together are estimated as the source for 86% of global physical counterfeiting, which translates into 396.5 billion USD worth of counterfeit goods each year.

2. Despite China and Hong Kong's dominant share of global counterfeiting, a considerable amount of physical counterfeiting activity as share of world trade can be attributed to other economies as well. Indeed, the level of counterfeiting activity attributed to some economies is substantial and bears significant economic and public health implications, both locally and internationally.
3. In addition to the modeled estimates of rates of global physical counterfeiting and percentage attributed to each economy, this report has also examined the value of seized counterfeit goods in the 38 economies sampled and the World Customs Organization (WCO). The value of counterfeit goods seized and reported by customs authorities from our sample of 38 economies (\$5.2 billion) represents slightly less than 2.5% of the global measure of physical counterfeiting of \$461 billion dollars. This suggests that though customs authorities' activities yield results and their efforts are highly laudable, the extent of their successes still represents "a drop in an ocean." This does not mean to say that economies should not continue to step up efforts to combat counterfeiting. Recent actions taken by economies include enhancing customs authorities' scope of action and strengthening IP protection are expected to increase economies' ability to limit counterfeiting activities both domestically and globally over time.
4. Our analysis of seizure data from customs authorities shows that the dearth of seizure data is acute. Of the 38 economies examined in this study, only a third of the customs authorities publish data. Moreover, only a small proportion of these publish reliable, consistent, and detailed seizure statistics. Additionally, the data are often focused on intermittent seizures of varying scope and so do not necessarily reflect systematic efforts against counterfeiting.

We are pleased to attach a copy of *Measuring the Magnitude* in our Special 301 Submission for further detail on the global counterfeiting landscape.

Challenges to Intellectual Property Protection and Enforcement

The Chamber is a strong advocate for the fundamental right of innovators and creators to protect the economic and cultural benefits resulting from their scientific, literary, or artistic works; and, for the right of all businesses to protect and promote their products through established names and marks.

Emerging Trends

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.

Key positive developments include:

Enhanced protection for trade secrets- 2016 proved to be a hallmark year for trade secrets, with both the United States and European Union passing and signing into law sweeping protections against trade secrets theft. Further, the Trans-Pacific Partnership (TPP) Agreement established a benchmark for criminal penalties for trade secrets theft on a plurilateral level, while the ministers at the Asia Pacific Economic Cooperation (APEC) endorsed a set of best practices aimed at strengthening enforcement against trade secrets misappropriation.

Strengthening judicial expertise on IP- Over the last few years we have witnessed significant developments in the establishment and utilization of specialized IP courts. Most notable is China's work starting in 2015 to establish three specialized courts to oversee IP adjudication. Progress on specialized IP courts can also be witnessed in Pakistan, the United Arab Emirates, and Sweden.

Accelerating patent examinations- Economies recognized the value of leveraging international partnerships through the Patent Prosecution Highways (PPH). The PPH aims to accelerate patent examinations by allowing for communication between countries that may be processing corresponding patent applications. Countries that signed PPH

agreements in 2016 include: Argentina, Chile, Colombia, Mexico, Peru, the Philippines, and Vietnam. Additionally, countries such as India and Indonesia signaled efforts to streamline IP administration as part of broader national strategies to leverage IP to enhance the environment for domestic innovation.

Unfortunately, IP rights holders also faced many challenges in the global economy in 2016. Key challenges include:

Deteriorating market access- When operating abroad, industry is encountering government discrimination against foreign content—measures that would drive consumers to infringing websites. Furthermore, companies are experiencing more and onerous requirements for local production, procurement, and manufacturing. In 2016, Ecuador, Indonesia, Russia, and South Africa all introduced new forced localization requirements. Canada is considering discriminatory measures as part of its cultural policy review. Meanwhile, Nigeria is pushing to implement its 2015 localization guidelines, which targets multinational IT companies and could impose exacting local content requirements for IT software, hardware, and services for government procurement in addition to forcing technology transfer and require the disclosure of sensitive IP data.

Inappropriate use of compulsory licensing - Certain governments have taken or are pursuing actions that use or promote the use of compulsory licensing in a manner that is inconsistent with global rules and norms. Indonesia's new Patent Law enables the use of compulsory licensing to discriminate against manufacturers in the United States and other overseas markets. It makes particular patents subject to compulsory licensing if the patent holder does not manufacture the product for which the patent was granted in Indonesia within three years. Colombia and Russia inappropriately use compulsory licenses as a bargaining tool in negotiations with suppliers in the United States and elsewhere. Furthermore, in many cases, multilateral institutions have directly promoted the inappropriate use of compulsory licensing.

Global Proliferation of Illicit Streaming Devices (ISDs) - ISDs are media boxes, set-top boxes or other devices that allow users, through the use of piracy applications (apps), to stream, download, or otherwise access unauthorized content from the Internet. These

devices have emerged as a significant means through which pirated motion picture and television content is accessed on televisions in homes around the world. China is a hub for the manufacture of ISDs. The devices are often promoted and/or advertised as enabling infringement of copyright or other illegal activities. ISDs are part of a sophisticated and integrated online ecosystem facilitating access to pirated audiovisual materials. Governments must increase enforcement efforts, including cracking down on piracy apps and on vendors who preload the devices with apps that facilitate infringement. Moreover, governments should take action against key distribution points for devices that are being used illegally.

Multilateral mission-creep impacting IP- Together with increasing awareness of the economic impacts of IP has come a growing desire on the part of a wide range of multilateral institutions to set, influence, or curtail global IP standards. Some of these institutions lack the background, competency, or mandate to make IP policy, leading to a confused policy environment and an often misinformed global dialogue. Notably, the UN Secretary General's High Level Panel on Access to Medicines took a controversial premise not based in fact and administered recommendations which cut at the heart of the global IP system. Further, the UN Development Program this past year issued "Guidelines for the Examination of Patent Applications relating to Pharmaceuticals," which reportedly informed policy decisions in Indonesia and South Africa. Discussion of international IP standards should appropriately be the jurisdiction of those organizations with the established member-state mandate, including the World Trade Organization (WTO), World Intellectual Property Organization (WIPO), and to limited extent the World Health Organization (WHO).

Many of these trends will be discussed further and in more detail in the individual country sections.

Importance of Bilateral and Regional Free Trade Agreements

The World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is now more than 20 years old, yet implementation of many aspects of the agreement has been delayed repeatedly for a significant portion of the WTO's membership.

As previously mentioned, the 2017 U.S. Chamber International IP Index assessed the commitments in the TRIPS Agreement and the concluded text of the TPP in order to understand how they compare to actual standards and practices in place in various countries. Unsurprisingly, the TRIPS Agreement was found to represent under one-half of the total Index score, demonstrating that for the most innovative economies TRIPS is a minimum standard—a floor, not a ceiling. Meanwhile, intellectual property dialogues at multilateral institutions are increasingly mired in global development politics that effectively prevent substantive progress on a norm-setting agenda, such as would enable more economies to achieve a policy environment supportive of innovative activity and access to innovative products and services.

Further analysis of the TPP Agreement in comparison to the Chamber International IP Index and the TRIPS Agreement demonstrates how important trade agreements are for raising and establishing standards more in line with the global economy of 2017. Benchmarking the TPP against the Chamber Index, the concluded agreement represents 73% of the total possible score, a large improvement from TRIPS but still allowing for room for improvement. Accordingly, bilateral and plurilateral trade agreements are, and will likely continue to be, important vehicles for building consensus around policy commitments to strengthen intellectual property standards internationally.

Plurilateral agreements such as the TPP can have special significance due to their enlarged country scope, with its implied precedential value. The agreed upon TPP text, along with other FTAs that include high-standard TPP chapters, is a benchmark against which IP chapters in future trade agreements of all countries will be assessed. It is critical to optimize the outcomes from these rare opportunities to win meaningful international commitments to strengthen IP.

At the same time, notwithstanding the generally strong overall provisions of the TPP's intellectual property chapter, certain omissions, such as the absence of a commitment for a stronger term of regulatory data protection for biologics, for instance, suggest an advantage for bilateral agreements in setting the highest possible standards.

Going forward, it should be a priority of both industry and government to proactively identify other potential trade policy vehicles for raising global IP standards, so that the broad benefits to innovative output and access can be enjoyed by a much broader global constituency.

The 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 intellectual property rights. As previously discussed, the World Trade Organization's (WTO) Trade Related Aspects of Intellectual Property 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 2017 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. American leadership in multilateral organizations is essential to creating—and in many cases, maintaining—a global environment which rejects these negative policies and instead supports creativity, innovation, and access to new technologies through strong IP rights.

The U.S. demonstrated this leadership in its outright rejection of the UN Secretary General's High Level Panel on Access to Medicines (UNHLP). The UNHLP proved to be a direct attack on the very basic principle of intellectual property rights since the Panel's scope remained altogether overly narrow in looking only at how to “remedy the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies” (a premise of “incoherence” moreover that we reject as fundamentally flawed).

While our member companies welcome a discussion on health technology and access to care, they believe the UNHLP should have provided an opportunity for an informed, balanced and inclusive dialogue. The U.S. government, along with many other UN member-states, rightly recognizes that the access to medicines debate encompasses aspects far beyond intellectual property rights. The ability of patients to obtain quality care depends on many factors – including healthcare infrastructure government policies, adequacy of funding, availability of trained healthcare providers, health literacy, and stigma. Moreover, as opposed to a barrier, IP rights are a critical incentive to the development of new medicines and the dissemination of these medicines to the patients that need them. Addressing the barriers to access requires collaborative

efforts and solutions presented by a broad range of stakeholders— not a misguided and limited ideological debate.

The Chamber is concerned that the UNHLP report lends a false legitimacy to diminished IP policies on the multilateral level and to be adopted within national frameworks. We would echo the sentiment of the newly minted Secretary General António Guterres who stated in his opening speech at the UN that it is “about restoring human rights as a fundamental value that must be defended as such, not for other political purposes.” The Chamber urges the U.S. government and other governments to continue to reject the UNHLP and its recommendations as well as work towards a more constructive, holistic discussion around the true barriers to access.

Similar anti-business issues continue to plague the World Health Organization (WHO). Most notably is the passage of the Framework for Engagement with Non-State Actors (FENSA). Implementation of this text would exclude engagement with industry and other non-state actors ad hoc and would devastate the WHO and its mission to direct and coordinate international health initiatives. The Chamber is concerned that the WHO is shutting out the very source of the implementation of these programs and generator of the majority of R&D spending- the private sector. This would amount to significant repercussions for the innovation community who are on the frontlines of solving these public health challenges.

At WIPO, there is a continued push to focus on exceptions and limitations to copyrights in an 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. There is a similar effort to weaken patent rights, with several countries pushing for the development of a manual to guide countries in setting aside intellectual property rights. It is not uncommon for the same countries to challenge the link between innovation and intellectual property, and push back efforts to improve the patent backlog such as via worksharing, 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 members states implement their existing digital treaty programs—those laudable endeavors are regularly thwarted by the countries that could benefit most from their implementation.

Furthermore, a byproduct of this push to degrade IP rights includes venue-shopping by activists and activist countries. The WTO, WIPO, and to some extent the WHO have traditionally had jurisdiction on multilateral discussions surrounding IP, which is especially prominent when they join forces every year to convene the Trilateral Symposium. However, 2016 was marked by a concerted effort by other UN agencies that lack expertise in IP to attempt to set standards and policies, as evidenced by the UNHLP, UNDP's patent examination guidelines, and UNITAID's call for suggestions on "overcoming intellectual property barriers." Similarly, despite lacking technical intellectual property expertise, the OECD's Directorate for Science, Technology and Innovation continues to assert that copyright is an impediment to digital commerce even though the U.S. and European experiences demonstrate the exact opposite. What all of these examples demonstrate is that after having found resistance to these deleterious ideas in mature decision-making venues like the WTO, WIPO, and WHO, activists and activist countries are searching for less mature or under-the-radar venues to incrementally cement anti-IP policies.

The Chamber will continue to engage on these emerging issues within the UN framework. In the coming weeks and months, future discussions of the WHO, UNHLP, WTO, UN Framework Convention on Climate Change (UNFCCC), WIPO and other issues or negotiations taken up by UN agencies will only be able to successfully address issues 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.

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 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, to a patent). 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.

Many of the countries highlighted in the Chamber's Special 301 submission pose a risk to protecting trade secrets globally. It's worthwhile to note that the protection of trade secrets isn't limited to developing economies. For example, though not covered in the Chamber's country-specific section of our 301 submission, Austria's trade secrets regime remains a concern for innovative businesses. While Austria offers protection for trade secrets, gaps in the system make it unlikely that confidential information will be safe from bad actors. For instance, if a party trusted with a "non-technical" secret, such as a go-to-market strategy or a list of customers, discloses it, there is no criminal liability.¹ Similarly, a competitor can make use of confidential information it receives, as long as the party providing it originally received it legitimately.² It is immaterial as to whether the disclosing party was providing details in contravention to a non-disclosure agreement. Such a state of affairs makes it harder to work in Austria, with suppliers, customers, and other partners that could provide access to critical intelligence or technology.

¹ See Austria's Act Against Unfair Competition (UWG), Section 12

² See UWG Section 11

Unfortunately, the lack of protection in the first instance is not the only shortcoming for businesses in need of protecting confidential information. In some cases and jurisdictions, the criminal penalties for misappropriation lack value as a deterrent. Under Austria's Act Against Unfair Competition, three months incarceration is the maximum penalty for the most heinous conduct. These penalties are low by Austria's standards for similar crimes. Another bar to punishing trade secret theft is the challenge in gathering evidence. Public prosecutors lack the authority to prosecute trade secret cases crimes. Even at times when a case can be brought before Austria's courts, the venue where they are adjudicated is far from ideal. Criminal prosecutions of trade secrets are heard by District Courts that generally handle low-value criminal matters. Unlike these minor offenses, establishing whether a wrongdoing has occurred requires a sophisticated understanding of technical and commercial concerns. Trade secret cases are therefore better off handled by judges more experienced in commercial matters, such as those in Regional Courts. We ask the U.S. Government to work with the Austrian government to fix these loopholes and guarantee the fair, unfettered protection of trade secrets.

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. In addition, we are pleased to see the U.S. Congress and European Parliament independently pass legislation in 2016 that further protect against trade secrets misappropriation.

Internet-Based Intellectual Property Theft

The problem of online theft of intellectual property is massive and growing. Intellectual property-based companies, like all companies, seek to maximize business and commerce with their customers online. However, just as consumers and legitimate businesses have embraced the internet, unfortunately so have those who engage in irresponsible practices in the online ecosystem. These irresponsible practices directly harm innovators, creators, and other IP owners, and are a public policy problem because of the considerable role intellectual property plays in a healthy economy. Finally, Internet-based piracy is particularly harmful because a single pirated file on online piracy platforms can be the source of literally millions of perfect copies—meaning massive, ongoing theft of creativity.

When intellectual property 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. Protecting intellectual property means protecting America's economic, creative, and innovative achievements across our economy. With the rise and volume of intellectual property-intensive goods being distributed online, the need to ensure that those 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 intellectual property is at least as important on the internet as it is in the brick-and-mortar world.

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 intellectual property 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 intellectual property theft on the internet is imperative. Criminals operating websites and internet-based services dedicated to trading in infringing and/or counterfeit goods pose a potential for harm far greater than any previous threat to intellectual property. 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.

A Threat to Consumers: One of the problems is that it is difficult for consumers to determine 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 intellectual property 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.

IP theft puts customers at risk. Counterfeit goods are frequently produced in unregulated, unsafe, and even unsanitary conditions. Since they are, by definition, produced by criminals, they may contain unknown and untested substances. Indeed, criminals have been found using their websites to sell goods made from noxious materials. For example, perfumes, cosmetics, and even headphones have been manufactured with toxic substances. Counterfeit medicines sold online have been found to contain arsenic, tin, anti-freeze, chalk, and boric acid, among other dangerous chemicals.

Counterfeit airbags have caused explosions instead of properly inflating, and counterfeit extension cords pose a serious fire risk. Further, consumers unwittingly put themselves at risk of credit card fraud, identity theft, and malicious computer viruses by visiting websites that offer pirated or counterfeit goods. A study by the Digital Citizens Alliance found that one third of all piracy sites exposed their users to malware – 12 million U.S. users are exposed to malware each month due to those sites. Almost half of the malware was “drive-by-downloads” meaning that visitors did not even have to click to download to become infected.³

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 is 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.

³ *Digital Bait*, Digital Citizens Alliance, December 2015

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 in cooperation to educate consumers about respect for intellectual property 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 intellectual property. 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.

Enforcement

In order to promote the enforcement of existing international obligations, it is important that the United States 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 United States 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.⁴ 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.⁵

In the context of fraudulent websites designed to look authentic, this small package problem is all the more insidious. Consumers, thinking they are buying legitimate goods, actually pay *more* than they would for an obvious counterfeit sold on a blanket on a street corner, and the counterfeiters reduce their loses if a shipment is found, in contrast to the seizure of a large shipping container.

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.⁶

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 Organization⁷ and the U.S. Intellectual

⁴ *Mailing Standards of the United States Postal Service, International Mail Manual*, § 711 (Aug. 11, 2011), incorporated by reference in the *Code of Federal Regulations*, 39 C.F.R. § 20.1.

⁵ The Association of Convenience & Petroleum Retailing. *Remote Sales of Tobacco* (Retrieved March 19, 2010). www.nacsonline.com/NACS/Government/Tobacco/Pages/RemoteSalesofTobacco.aspx.

⁶ 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”).

⁷ *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

Property Enforcement Coordinator.⁸ 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.

Increased Enforcement: Customs organizations worldwide are battling this very issue. The United States has the opportunity to study the successes and best practices from other customs organizations globally to make progress against this pressing issue. For example, Her Majesty's Revenue and Customs (HMRC) 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.⁹ 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

⁸ 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>

⁹ HM Revenue & Customs. www.hmrc.gov.uk.

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 intellectual property, 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 intellectual property 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 intellectual property chapters of the United States' Free Trade Agreements (FTAs). These modern standards have been accepted on five continents and have been a model for intellectual property 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 intellectual property 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.

Free Trade Zones

Free Trade Zones (FTZs) are generally considered to be “a part of the customs territory of a Contracting Party where any goods introduced are generally regarded, in so far as import duties and taxes are concerned, as being outside the customs territory.”¹⁰ FTZs are typically established by governments to promote legitimate trade and offer the advantage of providing a free trading environment “whereby a minimum level of regulation is demanded of those companies approved

¹⁰ World Customs Organization Glossary of International Customs Terms. (2006, May). http://wcoomdpublishations.org/downloadable/download/sample/sample_id/123/

to operate” therein.¹¹ “As a result, companies derive a wide range of benefits, for example, exemptions from duty and taxes, simplified administrative procedures, and duty free imports of raw materials, machinery, parts, and equipment.”¹²

Even though FTZs typically operate within the legal parameters of sovereign law, the reduced enforcement environment of these areas are often exploited by criminals running contraband and counterfeit operations. Given the special status of these areas and the lack – or unwillingness – of authorities or customs police to enforce within them properly, FTZs are a growing concern for brand owners. Particular attention could be applied to Panama’s Colon Free Trade Zone, the second largest FTZ outside of Hong Kong. Industry reports transshipments of illicit products through Panama due to the lack of coordination between FTZ authorities and customs. The Chamber encourages the United States to work with countries to make sure that the FTZs have proper inventory controls and that 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. In addition, all customs services should have the authority to seize and suspend suspect goods that are in transit while they determine the legitimacy of those products and not merely those that are destined to an internal market. Furthermore, the Chamber also urges USTR to work with the private sector to develop a list of “notorious” FTZs which are abused by illegal networks and engage with relevant global, regional and local stakeholders to disrupt these illicit activities.

Resources Needed to Provide Effective Protection

In order to have truly effective intellectual property protection, the necessary tools and resources must be available. The Chamber believes that there are a number of steps that the U.S. Government, in conjunction with stakeholders, should enact to further the goals of strong and comprehensive intellectual property protections abroad.

¹¹ WCO Guidelines on Controlling Free Zones in Relation to IPR Infringements, Para. 2. (January 12, 2005).

¹² *Ibid*

Expand the Efforts of the Intellectual Property Enforcement Coordinator (IPEC)

In November 2009, the Senate confirmed the first-ever U.S. IPEC within the Executive Office of the President. Among the IPEC's statutory responsibilities is the development of a comprehensive strategy to protect and promote intellectual property.¹³ The IPEC's 2017-2019 Joint Strategic Plan is an important roadmap to a more responsive, transparent, and operationally efficient global enforcement plan. We are encouraged by the proactive work of the previous IPECs to date. We encourage the incoming Administration and the new Congress to authorize IPEC with the requisite authority, staff, and budget to achieve effective intellectual property protection and to promote IP as a foundation for global economic growth and consumer safety. This will require a sustained commitment from both the Administration and Congress.

Expand Intellectual Property Assistance Overseas

A critical component to America's economic growth and competitiveness is the ability of U.S. businesses to access and maximize growth in foreign markets. However, lack of adequate intellectual property protection and enforcement—particularly in developing countries—represents a significant barrier for U.S. companies. Intellectual Property Attachés stationed at American embassies and consulates are important assets in helping to address these issues. In addition to assisting U.S. firms, Attachés help coordinate the intellectual property-related activities of other federal agencies within a country, and help provide technical assistance to law enforcement agencies, judges, and others within the host country on intellectual property issues. The current Attaché program has been very successful in advancing protection of U.S. intellectual property overseas, helping U.S. businesses export and expand, and, in turn, furthering the U.S. economy. As such, the Chamber urges dedicated funding and support for the program, allowing it to continue to expand and improve. Of significant importance to the Chamber and its members is ensuring that U.S. Government technical IP expertise is present and engaged in multilateral institutions, like the United Nations. In addition to adding resources to the IP Attaché program, the Chamber is supportive of making sure our Attaches have the appropriate titles and

¹³ Office of the Intellectual Property Enforcement Coordinator. Executive Office of the President. (2010, June). *2010 JOINT STRATEGIC PLAN ON INTELLECTUAL PROPERTY ENFORCEMENT*, pg. 2.

ranks so they may more effectively reach and engage with the decision-makers on IP in their respective jurisdictions.

Another helpful U.S. Government resource is the Intellectual Property Law Enforcement Coordinator (IPLEC) program which places experienced DOJ attorneys at U.S. missions in key regions to enhance foreign law enforcement partner capacity to investigate and prosecute IP crimes, and to develop regional enforcement networks. Based on positive feedback, in 2016 the single initial IPLEC was expanded to four. The IPLECs have had a real impact on the transnational online organized criminal marketplace for copyrighted works. Given its track record of success, the IPLEC program should receive continued funding and support to reflect its role in leveling the playing field for U.S. innovators and creators.

Continue to Support International Collaboration

Because criminal networks involved in the trafficking of counterfeit goods are complex and pervasive, it is of increasing importance to continue to collaborate with international organizations. The International Criminal Police Organization (INTERPOL) offers police from around the world the opportunity to collaborate and share information and leads among offices. The Chamber supports the efforts of law enforcement within the United States and abroad to work within existing legal frameworks to enhance information sharing and collaboration to disrupt counterfeiting and illicit networks.

Promote and Defend a Strong International Intellectual Property Legal Framework

The Chamber urges the Trump Administration to continue to promote and defend a robust international system of intellectual property rights and norms, and oppose any efforts to weaken or expropriate intellectual property in international institutions, whether in WIPO, WTO, WHO, United Nations Framework Convention on Climate Change (UNFCCC), the Post-2015 Development Agenda, or other multilateral institutions, or in free trade agreement (FTA) negotiations. It is also important that the Administration remain vigilant against efforts to impose unwarranted or broadened exceptions and limitations to patent, trademark, and copyright protections that would stifle creativity, innovation, and the development of new technologies that contribute to global well-being and economic growth.

The U.S. Government should also be a vocal supporter of strong intellectual property protections in regional fora, such as the Asia Pacific Economic Forum (APEC) and the Organization for Economic Cooperation and Development (OECD). The Directorate for Science, Technology and Innovation in the OECD, in particular, seem to have developed a bias against intellectual property, which is very alarming. These fora provide important opportunities to engage like-minded partners and emerging powers to ensure the development of strong intellectual property frameworks that drive innovation.

Australia

Australia is the highest-income country included in the U.S. Chamber's 2017 Special 301 submission. Despite the size and scale of the Australian economy, the country's IP laws continue to lag behind its peers. The U.S. Chamber looks forward to working with the Australian government to address the below shortcomings in Australia's IP framework in order to create a legal and regulatory ecosystem which incentivizes innovation and creativity.

Australian Productivity Commission

In September 2015, the Australian Productivity Commission announced it would undertake a year-long review of Australia's intellectual property environment. The draft report, released in April 2016, included a number of troubling recommendations that would jeopardize the strength of Australia's IP system. While industry was grateful for the opportunity to comment on the draft report, the final version released in December 2016 included many of those negative recommendations, including: introducing a fair use exception; undermining the current copyright term; reforming extensions of patent term for pharmaceutical products; and examining opportunities to raise the inventive step threshold for patentability. The report also fundamentally concludes that as a "net-importer" of IP, Australia can devalue intellectual property rights in order to cheapen access to creative and innovative products. The U.S. Chamber believes the conclusions included in the final report would significantly weaken Australia's IP framework, undermine innovative and economic growth, and endanger Australia's global competitiveness. In fact, in response to the Productivity Commission, the WTO's Chief Economist Robert Koopman asserted that "it's important for Australia not to view itself as an island of IP - a net importer - rather than thinking about it in a more global context and how its position might evolve." The U.S. Chamber recommends that the U.S. government discourage the Australian government at large from embracing the report's recommendations.

Patents and Related Rights

Market-Size Damages: The Australian Department of Health is seeking damages from biopharmaceutical innovators who pursue unsuccessful patent claims. The damages are used to refund Australia's pharmaceutical reimbursement scheme (PBS) when the government had to

pay the higher price for the patented medicine during the enforcement period. 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 continued application of market-size damages will create uncertainty for investors and discourage the investment in new, life-saving cures. The U.S. Chamber urges USTR to prioritize work to address Australia's market-size damages policy and 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.

Patent Linkage: The AUSFTA requires Australia to implement a system of patent linkage. Specifically, 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.

Australia maintains a patent linkage system under which a manufacturer seeking approval must submit a certificate that: (1) it believes on reasonable grounds that it is not infringing a valid

patent; or (2) that it proposes to market the product before the end of a patent term, and it has notified the patentee. According to a government study, non-innovative producers in practice do not notify the patent holder, but instead certify their belief that their product does not infringe a valid patent¹⁴. However, relevant patent holders are not afforded enough time to assess the reality of such certification, making the notification system ineffective.

As a result, the government recognizes that the notification system “does not appear to work well.”¹⁵ Patent holders only learn of the application when the unauthorized copy of a drug appears on the Australian Register of Therapeutic Goods, often leaving insufficient time to take action. The Australian linkage system also lacks an automatic stay provision to prevent the marketing of products covered by a patent, but it appears to pursue this result in a different way through the use of preliminary injunctions. The U.S. Chamber recommends that the U.S. government encourage the Australian government to implement an effective patent linkage mechanism that promotes legal and business certainty for both the patent holder and the generic manufacturer by allowing patent disputes to be resolved in an efficient and timely manner before a generic product is launched.

Regulatory Data Protection: Current Australian law allows only for five years of regulatory data protection for biologic medicines—drugs made up of living matter that are incredibly expensive and risky to produce. The Australian Productivity Commission’s final report, discussed above, found that there were no grounds to extend the period of data protection for any pharmaceutical product, including biologics. . 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.

¹⁴ Tony Harris et. al., Pharmaceutical Patents Review Report, at 143-144 (2013)
http://www.ipaustralia.gov.au/pdfs/2013-05-27_PPR_Final_Report.pdf

¹⁵ Id. at 143.

Copyrights and Related Rights

Australia's Department of Communications and the Arts released an "Exposure Draft" in December 2015. Among the proposed piecemeal changes included the expansion of the safe harbor protections which would have put Australia out of compliance with its bilateral FTA with the U.S. The proposals would effectively provide immunity to an uncertain class of unregulated providers without concomitant obligations to prevent online infringement. It is expected that this bill will be taken up again in 2017.

Trademarks

Plain Packaging: In 2011, Australia set a troubling precedent by restricting the use of trademarks in trade through its 2011 Tobacco Plain Packaging Act. A policy of plain or standardized packaging severely restricts or even eliminates the use of trademarks and the corresponding trade dress on affected products and limits the ability of trademark owners to utilize their brands, trademarks, and trade dress. As a general matter, such policies, however well intended, have the direct impact of eroding the multi-faceted benefits of trademark laws, including corporate accountability and consumer confidence. If broadly applied, plain packaging would be highly detrimental both to intellectual property systems and to well-functioning markets.

Brazil

In recent years, both the Brazilian government and private sector have increasingly recognized the fundamental link between IP and innovation in Brazil. In August 2015, Luiz Otavio Pimentel was appointed as head of the National Industrial Property Institution (INPI), and the U.S. Chamber is encouraged by the work undertaken to date to improve Brazil's IP system. 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. In order to support efforts in Brazil to improve the intellectual property 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 and Trademark Approval Delays: Industry continues to report extensive patent and trademark approval delays, with a 10-15 year backlog for patents and a 3-year backlog for trademarks. However, in 2015, the INPI introduced a number of initiatives and structural reforms in an effort to begin to reduce the backlog. In 2016, INPI hired an additional 70 patent examiners. In November, the Official Gazette published Ordinance No. 357, which gave INPI the authority to hire an additional 30 new examiners and 40 new IP “technologists.” Additionally, Resolution 76/2013 created an accelerated patent examination mechanism for priority patent fields.¹⁶ However, the fast track mechanism can only be used for green technology patents and patents related to cancer, HIV, or neglected diseases. Finally, 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. The National Confederation of Industry (CNI) reported that INPI's new initiatives have led to a “downward trend” in the patent backlog and a 5.4% reduction in backlog of trademarks over the last year.¹⁷

¹⁶ Federation of the Industries of the State of São Paulo, National Confederation of Industry—Brazil, and Brazil Industries Coalition. 2016 Special 301. Pg. 8.

¹⁷ Federation of the Industries of the State of São Paulo, National Confederation of Industry—Brazil, and Brazil Industries Coalition. 2016 Special 301. Pg. iv.

However, backlogs persist and continue to present a significant problem for innovative and creative industries seeking to adequately protect their products in Brazil. 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.

Additionally, the U.S. Chamber supports the Patent Prosecution Highway (PPH) pilot program, signed in November 2015, which helps expedite patent applications in the oil and gas sector by utilizing search and examination results from USPTO reviews of similar patent applications. We encourage the U.S. government to ensure that the PPH is expanded beyond the oil and gas sector as it will provide a critical mechanism to expedite the patent approval process for all IP-intensive industries.

Patentability and Dual Examination: Article 229-C of Brazil's Patent Law empowers the National Health Surveillance Agency (ANVISA) to grant prior consent to pharmaceutical patents that are being examined by INPI. Article 229-C can be interpreted as the creation of a dual examination system for pharmaceutical patents, which is inconsistent with Brazil's obligations under Article 27.1 of TRIPS, and leads to further delays and uncertainty in patent applications. In June 2015, a Federal District Court in Rio de Janeiro reiterated ANVISA's role in the patent examination process. The Court ruled that ANVISA was permitted to review pharmaceutical patents, noting that the insertion of ANVISA into the review process was an essential element in safeguarding public health. The ruling also held that a denial by ANVISA of a patent application should result in a refusal by the INPI. The U.S. Chamber believes that the function of ANVISA in reviewing the health and safety of pharmaceutical products must be distinct from that of INPI which reviews patent applications and prior art to ensure that legal requirements for patents grant are met. We urge that a proper interpretation of 229-C which recognizes the unique role of ANVISA and INPI be implemented, for example as have been put forward by the Office of the Federal General Attorney (for e.g., see Opinion No. 210/PGF/AE/2009).

Regulatory Data Protection: Brazilian law currently provides regulatory data protection (RDP) 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 RDP 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 to introduce RDP for human-applied innovations in order to prevent ANVISA from utilizing the innovator's data for a period of time.

Technology Transfer Agreements: 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 backlog at the INPI. Despite these positive incentives, regulatory and formal requirements can limit the attractiveness of licensing intellectual property assets in Brazil. Technology transfer agreements must be registered with INPI, which frequently exercises its right 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 U.S. Chamber encourages the U.S. government to work with its Brazilian counterparts to introduce licensing policies which encourage technology transfer in order for new, innovative and creative technologies to be commercialized in Brazil.

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. Specifically, industry reports that over 50% of the products on the main Brazilian e-commerce platform, Mercadolivre.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 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 Minas Gerais State, industry reports that counterfeit factories outnumber legitimate factories. The Brazilian government created the National Council Against Piracy and Intellectual Property 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. 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 rightsholders from utilizing the judicial system to protect their IP. Additionally, the U.S. Chamber recommends that the U.S. government collaborate with the 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.

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

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 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 Association of Brazilian 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

¹⁸ Federation of Industries of The State of São Paulo and National Confederation of Industry. 2015 Special 301 submission, February 2016, pg. 15.

The BSA Global Software Survey reports that the use of unlicensed software use has decreased slightly from 50% of all software use in Brazil in 2013 to 47% in 2015.¹⁹ 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 theatres continues to present a problem for copyright-intensive industries and further fuels online piracy in Brazil. The International Intellectual Property Alliance (IIPA) reported that 90% of all pirated films in Brazil originated from camcording in theatres.²⁰ In 2016, the U.S. motion picture industry detected at least 30 illicit audio or video recordings linked to Brazilian movie theaters, second only to Mexico for camcord piracy in Latin America. As a result, the Motion Picture Association 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 proof that the infringer intends 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” (Law No. 12,663). The Law provided special protections (including recognition as famous marks) for FIFA–and World Cup–related trademarks, as well as the fast-track procedures put in place for INPI to process and register FIFA-related applications. The legislation also addressed the issue of “ambush marketing” outlining civil as well as criminal penalties. Post–World Cup legal analysis suggests that both FIFA and its partners were able to

¹⁹ Business Software Alliance (BSA) (2014). *Seizing Opportunity Through License Compliance* BSA GLOBAL SOFTWARE SURVEY, May 2016.

²⁰ International Intellectual Property Alliance (IIPA). 2016 Special 301 Report on Copyright Protection and Enforcement. February 2016, pg. 4.

successfully rely on this legislation and their special treatment from the INPI to protect their trademarks and IP rights before and during the tournaments.

Similarly, ahead of the 2016 Olympic Games, the Brazilian Patent and Trademark Office (BRPTO) passed Rule #167/2016 which allowed for fast-track examination of industrial design applications for sporting goods. The government also passed the Brazilian Olympics Act, which allowed for temporary special protection for the organizers' trademarks, and creates civil and criminal penalties for violators. The U.S. Chamber applauds both the expedited industrial design application process and Olympics Act, which provided critical protection for innovative companies operating in Brazil, and looks forward to working with the U.S. and Brazilian government to collaborate on further initiatives to protect trademarks and industrial design on a broader scale throughout Brazil.

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 November.²¹ We urge the U.S. government to work with Brazil towards a speedy adoption of the protocol.

²¹ See Year in Review: A Look Back at the Madrid System's 125th Year. 14 Dec 2016. Available at: http://www.wipo.int/madrid/en/news/2016/news_0027.html

Canada

As our closest neighbor, ally, and top export market, an effective economic partnership with Canada is critical to U.S. global competitiveness. While acceding to the North American Free Trade Agreement (NAFTA) was an important step in advancing Canadian intellectual property rights, many core IP obligations are absent from the 23-year old agreement. The U.S. Chamber looks forward to a discussion with the new Administration on how the agreement can be strengthened and modernized. Additionally, the IP standards embodied in the Comprehensive Economic and Trade Agreement (CETA) between Canada and the EU may introduce changes for IP policy, particularly in the life sciences sector, and the U.S. Chamber looks forward to the swift ratification and implementation of that legislation in accordance with letter and spirit of the treaty in 2017. Finally, Canada's commitment to the IP standards included in the final Trans-Pacific Partnership (TPP) agreement present an opportunity to further strengthen Canada's IP framework. Yet, in the interim, Canada's IP climate remains behind other developed countries, as the U.S. Chamber Index demonstrates. The U.S. Chamber recommends addressing the following IP concerns in order to create a more robust IP framework in Canada.

Patents and Related Rights

Patent Utility: Since 2005, Canadian courts have 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 is 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". The heightened standard appears to be inconsistent with international norms and Canada's treaty obligations under NAFTA and TRIPS. The Canadian Federal Court has ruled on 28 decisions, leading to the invalidity of 25 patents on the grounds of inutility, notwithstanding the fact that these important medicines were found to be safe and effective by Health Canada, and were indeed used by hundreds of thousands of Canadian patients. The continued application of the onerous patent utility standard creates tremendous uncertainty for biopharmaceutical innovators operating in the Canadian market and has significant implications for pharmaceutical investors. An October 2016 study by Charles

River Associates reiterated that IP uncertainty has become an important factor that may deter some companies from making R&D investments in Canada.²²

In November 2016, the Supreme Court of Canada heard oral arguments in the long running case *AstraZeneca Canada Inc. v. Apotex Inc.* AstraZeneca is appealing a 2015 judgment by the Federal Court of Appeal which, in turn, upheld a lower court finding of lack of utility. 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.” A final verdict is expected in early 2017. 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 Canada’s existing Patented Medicines Notices of Compliance (PM (NOC)) regulations, patent holders do not have an effective right of appeal. However, the PM (NOC) regulations allow for a generic company to appeal a decision in a Notice and Compliance proceeding. The final text of CETA may introduce an effective right of appeal for patent holders. However, effective regulatory implementation of the legislation will be critical to ensuring that the IP standards included in CETA will be truly effective. The Chamber encourages the Canadian government to promptly ratify and implement CETA accordance with letter and spirit of the treaty. If implemented correctly, the legislation would strengthen Canada’s innovative environment. We look forward to collaborating with the government on the implementing regulations to ensure that the regulations do not undermine the legislation’s original commitments.

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.

²² Charles River Associates (2016). *The impact of IP and the promise doctrine on pharmaceutical R&D activity in Canada*. <http://www.crai.com/sites/default/files/publications/The-impact-of-IP-and-the-promise-doctrine-on-pharmaceutical-RD-activity.pdf>

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. While CETA would provide *sui generis* protection through a separate and independent term of protection, the PTR would be a maximum of two years. Many other developed nations, including the United States, European Union, and Japan, provide up to five years of protection. Further, the PTR term included in CETA permits (although it importantly does not require) an exception for advanced manufacturing, whereby the Canadian government could limit the scope of protection during the two-year period in order to make exceptions for generic manufacturers to produce and export patented medicines. This loophole in Canada’s proposed PTR mechanism is not found in the United States’ or other developed countries’ patent systems. Any implementation of PTR that does not confer full patent rights, e.g., that would provide such an exception for “manufacturing for export” or other infringing activities, would not be consistent with the fundamental purpose of restoring patent term lost due to marketing approval delays and should be avoided. Despite these challenges, the ratification of CETA should provide a positive first step toward establishing a PTR regime. The U.S. Chamber encourages 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.

Copyrights and Related Rights

In recent years, the Canadian government has taken a number of steps to improve IP protection in the copyright space. In particular, the Canadian Government extended the copyright term for sound recordings to 70 years in the Economic Action Plan Act of 2015. The extension of this copyright term is the first step towards bringing the Canadian term of protection for copyright in line with the highest international standards. The Chamber encourages the Canadian government to extend the term for all copyrighted works to 70 years, in line with global norms

Additionally, in 2017, the Government will conduct its five year review of the amendments to the Copyright Modernization Act. We believe this provides a critical opportunity to further modernize copyright protection in Canada. Specifically, the Chamber would support the following changes: 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; and creating a more balanced and effective intermediary safe harbor regime including notice and takedown. Industry stands ready to work with the Canadian government to review the legislation.

Finally, we express our concern over a 2014 decision of the Canadian Copyright Board which set the royalty rate for Internet music streaming services at less than one-tenth of U.S. rates and at one-tenth of negotiated rates. The Chamber encourages the Canadian government to require Canadian tribunals to defer to marketplace agreements and rates.

Trademarks

Plain Packaging Legislation: In its pre-election party platform published in autumn of 2015, the Liberal Party of Canada stated that if elected it would seek to “introduce plain packaging requirements for tobacco products, similar to those in Australia and the United Kingdom.” Following the party’s electoral victory, the Prime Minister included a reference to plain

packaging in his mandate letter to the Minister of Health. In May 2016, the Canadian Department of Health issued the consultation document “Consultation on ‘Plain and Standardized Packaging’ for Tobacco Products.” In addition to proposals of standardizing tobacco packaging and restricting the use of trademarks, brands, and related IP, the consultation also included proposals for standardizing the appearance, color and physical size of tobacco products. The introduction of standardized packaging applied to any industry would significantly restrict the use of brands, trademarks, and trade dress on retail packaging, undermining the benefits of trademarks to businesses and consumers alike; setting a negative precedent for intellectual property policy.

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 Intellectual Property Office, (CIPO) indicated that Canada is still preparing to comply with the treaties.²³ 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

Canadian border officials have not traditionally had *ex officio* authority to search and seize goods suspected of infringing IP rights, and Customs officials needed to obtain a court order to seize and detain goods suspected by customs officials of IP infringement. However, Parliament passed Bill C-8, the *Combating Counterfeit Products Act*, which received Royal Assent in December 2014. The bill introduced more robust border measures, including new civil and criminal options as well as expanded powers for Customs officials by enabling the detention of goods suspected of copyright or trademark infringement. During the June 2015 review of the trade policies and practices of Canada through the World Trade Organization (WTO), the Canadian Government

²³ Canadian Intellectual Property 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](https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/IP_Canada_Report_2016_en.pdf/$file/IP_Canada_Report_2016_en.pdf)

clarified the scope of *ex officio* authority included in the bill. The Canadian Government stated that: “The border provisions of the *Combating Counterfeit Products Act* came into force on January 1, 2015. Under its provisions, border service officers have the authority to seek and detain shipments suspected of containing trademark counterfeit or copyright pirated goods (*ex officio* authority). The Request for Assistance filed by a rights holder will allow the border service officer to exchange certain information in order for the rights holder to begin a court action to deal with the offending goods.” 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 United States. The Chamber recommends that the U.S. Government collaborate with the Canadian government in order to ensure that American consumers are protected from the threat of in-transit counterfeit goods.

China

The Chamber continues to work closely with the Government of the People's Republic of China to improve the protection and enforcement of intellectual property rights across a broad range of intellectual property policy concerns on behalf of our diverse membership.

The Chamber appreciates the Chinese government's continued efforts to emphasize the protection of intellectual property rights as a basic critical tool to foster innovation. In particular, we recognize the Chinese IP judges' efforts to increase damage awards and implement various judiciary reforms, including setting up more specialized intellectual property courts at local and appellate court levels. Increasing transparency, such as accepting amicus type submissions, developing a case database system, and curating its guiding case system are positive signs for the judicial protection of IP rights in China.

At the same time, China still has not made other significant changes to its IP system, despite internal demand from its local economy. The stalled amendments to the *Copyright Law* and the controversial expansion of the administrative enforcement of patents under the proposed amendments to the *Patent Law*, for example, represent steps backwards.

Further action is needed for China to establish an innovative society that provides a level playing field and equal opportunity to all companies regardless of the origin of their IP. A suite of industrial policies act to obtain intellectual property from foreigners or exclude foreign technology from the marketplace and need to be addressed.

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. 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.

We were encouraged by the commitments from the 2016 Strategic and Economic Dialogue (S&ED) and the Joint Commission on Commerce and Trade (JCCT) to address intellectual

property-related issues. Both countries reaffirmed their commitment to refrain from conducting or knowingly supporting cyber-enabled theft of intellectual property, including trade secrets or other confidential business information, with the intent of providing competitive advantages to companies or commercial sectors. The Chamber also welcomed China's new commitments secured in 2016 on bad faith trademarks, technology transfer, online infringement of intellectual property rights, sports broadcast copyright protection, trade secrets etc. We are hopeful that these outcomes will improve the protection of companies' confidential business information. The Chamber encourages the government to continue to monitor developments in China's intellectual property regime due to a full range of intellectual property concerns outlined below.

Innovation Policies

Further action is needed for China to establish an innovative society that provides a level playing field and equal opportunity to all companies regardless of the origin of their IP. China still maintains many policies to localize IP that favor domestic champions by creating barriers for foreign companies. Addressing the continued use of industrial policy tools by the Chinese government to either obtain intellectual property from foreigners or exclude foreign technology from the marketplace—needs to be a top priority.

Patenting in Strategic Technologies: Critical concerns surround patent applications by foreign companies in certain sectors. A Swiss researcher analyzed over a half a million patent applications in China and proved that China's patent office discriminates against foreign applications in fields of strategic technologies with biopharmaceutical industry as a particular focus.²⁴

Preventing Deglobalization: An Economic and Security Argument for Free Trade and Investment in ICT: The Chamber recently issued this report which documents the scope of China's national security policies that are affecting the ability of foreign companies to operate. Decreased openness to foreign firms and their technology results in not only in a reduction in domestic innovation but also economic growth. The report found that China's efforts to nativize

²⁴ http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2803379.

its information communication technology sector would equate to a reduction in China's GDP of nearly \$3 trillion annually by 2025.

13th Five Year Plan (FYP): Although the 13th FYP makes notable efforts to rebalance China's economy away from investment and toward consumption, services, and innovation, it does less to rebalance the role of the state and the market. The use of the term indigenous innovation in the FYP, signals the importance of achieving technology self-sufficiency. In addition to the national 13th FYP, the Chamber is concerned about recently-released and forthcoming provincial, municipal, and sector-specific FYPs which also reflect the enduring role of the state in the market.

Cybersecurity Law: In November 2016, the Standing Committee of the National People's Congress (NPC) approved the Cybersecurity Law, and will take effect in June 2017. The Cybersecurity Law includes provision that will impose security and testing requirements and security reviews on software and IT products and other restrictive measures—including data residency and cross-border data flow—that may hinder the ability of foreign companies to bring advanced technology or further invest in China. The Cybersecurity Law is viewed as a framework law for China's use and proliferation of the “secure and controllable” standard.

High and New Technology Enterprises (HNTE): Despite efforts made in the S&ED innovation dialogue and other fora, the latest revisions to the HNTE program in February 2016 do not address or eliminate the foreign business community's concerns. Rather, more restrictive provisions on IP usage mean foreign multi-national companies will find it more difficult to meet the program's requirements.

Made in China 2025: The Made in China 2025 plan is a 10-year blueprint to improve China's manufacturing competitiveness and a primary example of China's efforts to support indigenous innovation, domestic production, and Chinese IP. The plan gives specific domestic and international targets for IP in a variety of industries, from integrated circuits to agricultural equipment.

Market Access Restrictions: China maintains a host of market access restrictions to U.S. copyright-protected content – from a cap of 34 (20 +14) revenue sharing films, to extensive

measures that largely exclude foreign content from China's broadcast and payTV sectors, to an opaque and uncertain censorship regime, to limits (legal and practical) on import and distribution. 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 recent years. In 2014, 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. This year will be the first year the new regulations go into full effect. The new regulations added substantial uncertainty to the market 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.

Inventor Remuneration: SIPO's draft service invention regulations are of great 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 American Chamber of Commerce (China), the Chamber provided detailed comments to SIPO on the measures in December of 2012 and in August 2014 and May 2015.²⁵

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.

²⁵ The U.S. Chamber of Commerce and the American Chamber of Commerce in China comments on SIPO proposed Service Invention Regulations:

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 and the willingness of our members to transfer technology and conduct research and development. 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.

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.²⁶

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:

²⁶ 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

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).²⁷

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*.

The Anti-Monopoly Commission of the State Council is taking the lead to consolidate the various versions of the guidelines prepared by NDRC, SAIC, MOFCOM and SIPO²⁸. 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 SAIC and NDRC draft guidelines raised 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

²⁷ 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

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, which was listed as a research project in the State Council’s 2016 Legislative Plan.

National Standards and Patents: Following years of deliberation and consultation with industries and professionals, the Standardization Administration Commission (SAC) and SIPO jointly issued the Administrative Measures on National Standards Involving Patents (Interim) on December 19, 2013 (Standards Measures).²⁹ The Chamber submitted comments to SAC on the previous draft version of the Standards Measures in January 2013.³⁰

The Chamber appreciates that SAC and SIPO removed several controversial provisions, including compulsory licensing and low royalty fee licensing from the earlier draft back in 2009. This constitutes a notable step forward in China’s recognition of markets to appropriately price intellectual property rights incorporated into standards as well as the international best practice in standard-setting activities.

At the same time, the Chamber noted several areas still require further clarification. In particular, the Standards Measures seem to suggest that the Chinese government retains the powers to negotiate with any patent owners who refuse to give a licensing commitment to compulsory standards. The Chamber also would like clarity on whether the patent applications that are required to be disclosed include non-published applications and legal liabilities for failure to disclose. The Chamber will continue to actively monitor how SAC applies the concepts

²⁹ See official release at http://www.sipo.gov.cn/zcfg/flfg/zl/bmgfxwj/201401/t20140103_894910.html

³⁰ The U.S. Chamber of Commerce submitted comments to SAC in January 2013 on SAC Draft Administrative Rules on National Standards Involving Patents (Interim)

of compulsory and low-royalty fee licensing in the future. We look forward to working with USTR to ensure these provisions are appropriate.

More broadly, as part of its National IP Strategy, China has focused on improving its standards-related policies, including regulating “the process of turning a patent into a standard.” While we appreciate China’s commitment to welcome U.S.-invested firms in China to participate in the development of national recommendatory and social organization standards in China at the 2015 Joint Commission on Commerce and Trade, foreign invested companies can still only participate in the standard-setting process for mandatory standards by invitation, meaning that most American companies and their Chinese subsidiaries are unable to participate in the standard-setting process for mandatory standards. This obviously impacts their ability to be heard as part of the standard-setting process and their competitive opportunities in the Chinese market due to possible non-compliance with (future) product standards or the setting of standards that are specifically geared towards a Chinese competitor’s technological advantage.

In September of 2014, the Chamber submitted comments on the *Supreme People’s Court Judicial Interpretation on Certain Issues Concerning the Application of Law in the Trial of Patent Infringement Cases*. Our members expressed strong concerns that Article 27 does not make clear that it applies to “non-compulsory” standards only. Further, it does not distinguish that a FRAND commitment must be voluntary or that it applies only to patents that are required to comply with the standard. Moreover, Article 27 does not limit the term “patent” to patents that are essential to implement the technical requirements of a standard (often called “standard-essential patents”). We appreciate the concerns above are partly addressed in the final text of the Judicial Interpretation published in April of 2016.

The U.S. Chamber would welcome the opportunity to coordinate with USTR on its engagement with the SPC regarding the Chamber’s key issues with this judicial interpretation.

In December 2014, the MIIT-affiliated think tank Electronic Intellectual Property Center released a draft template of IPR Policies of Industry Standardization Organizations. This policy includes controversial provisions where even U.S. industry does not have consensus. We understand that the template is under revision and will be released again in the future. While this template was issued by MIIT’s IPR Center, not MIIT, and they are voluntary, the Chamber is

concerned that standard-setting organizations would be inclined to adopt the template simply as a matter of complying with the only existing guidelines on these processes.

In February 2015 the State Council approved the Deepening of Standardization Work Reform Plan. According to the State Council's decision on reforming the standardization system, the Chinese government will gradually reduce the number of (national and industrial) recommended standards and promote the transition of recommended standards toward public interest standards covering safety, health, and environmental issues. It appears that the general trend for China's standardization system is for the market to play a stronger role and replace government recommended standards with voluntary, consensus-based "social organizations" or consortia standards. The plan also noted that international standards should be used wherever possible. In contradiction to the stated goals of the State Council reform plan, the National People's Congress Amendment to the Law on Promoting the Transformation of Scientific and Technological Achievements may provide incentives to develop indigenous standards. In the Chamber's comments to the NPC we stated that Article 13 appears to provide greater authority to the State in the formation of standards, which is contrary to China's broader goals of allowing the market to play a stronger role in standards development.

The standardization mechanism in China is under substantial reform. The Legislative Affairs Office of China's State Council published draft amendments to the '*Standardization Law of the People's Republic of China (For Deliberation)*' for public comment in April of 2016. The amendment allows the "social organization" to set standards, which is consistent with international practice. The Chamber will continue to monitor its development.

Also, in the proposed amendment of *Patent Law*, SIPO specifically adds that the exercise of patents shall not hurt public interest or be used to eliminate or restrict competition in an unreasonable manner. We acknowledge and understand SIPO's worries, but we are concerned with the ambiguity and breadth of the proposed amendment, which could be used to undermine legitimate patent rights. It is important to ensure there is no conflict between the *Patent Law* and the *Anti-Monopoly Law*, and that legitimate patent rights are not unintentionally undermined. When it comes to SEPs, SIPO proposes that if a standardization participant fails to disclose its SEPs, a default licensing commitment is presumed for such SEPs. The royalty rates are subject

to negotiation or otherwise brought over by the parties to SIPO or courts to determine. We urge USTR to advise Chinese legislators to reconsider and delete both amendments. .

Import-Export Rules: The *Technology Import-Export Administrative Regulations* administered by China's Ministry of Commerce (MOFCOM) impose greater risks and liabilities on foreign technology licensors than what China's *Contract Law* imposes on domestic licensors. For example, a foreign licensor is required to indemnify licensees for any infringement of a third party's rights due to the licensee's use of the licensed technology and also can not own the improved technology made by the licensee. This uncertainty carries significant potential risk for American and other non-Chinese technology and advanced manufacturing companies and is another example of a policy apparently aimed at encouraging companies to develop technology locally.

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. In addition to these recent policy developments, the Chamber is optimistic that new bilateral mechanisms, including the high-level U.S.-China judicial dialogue, will support judicial reforms and result in fuller implementation of rule of law in China.

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 been 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 will open the 19th CCP Central Committee in 2017. The Chamber encourages China to further strengthen and implement the relevant rules above.

Intellectual Property Courts: The establishment of three specialized intellectual property courts in Beijing, Shanghai and Guangzhou 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 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 Chinese version of “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. We commend these efforts.

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.³¹

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.³² 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. Chamber will keep monitoring the 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

³¹ 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>

³² 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>.

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. The highlight of this year is the victory granted by the Supreme People's Court in a trademark case of pirating Michael Jordan's name. The recognition of bad faith of the Chinese sport brand Qiao Dan is highly commended by the Chamber. It is hoped that the Chinese courts will continue such practice and take a firm position against bad faith registrants.

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 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, 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 new 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, 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.³³ For the study, OECD collected data from custom offices in the EU and United States and the research team are 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 percent of the global supply of counterfeit goods with the next largest supplier at less than 1 percent. 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 Index³⁴, 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.

³³ 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.

³⁴ <http://www.theglobalipcenter.com/gipcindex/>

China appears to have maintained a similar level of active enforcement efforts against counterfeiters in 2016, but the 2016 official statistics have not yet been released.³⁵ 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 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 the 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 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 fields.

The number of criminal transfers seems to remain low.³⁶ 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 lack of 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

³⁵ Complete data for 2016 is not available as of this writing. The available data is noticeably more limited than previous years. In 2015, China reported that a total of 12,741 individuals were convicted in 10,809 cases. Such data is similar to what happened in 2014, where 13,905 suspects were convicted. http://legal.china.com.cn/2016-04/21/content_38294352.htm.

³⁶The official report of SIPO states that in 2015, around 15,000 cases were transferred to criminal procedure out of nearly 178,000 cases that the enforcement authorities opened up for investigation in China. <http://www.sipo.gov.cn/gk/zscqbps/201605/P020160512408444011272.pdf>

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 a concern on 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.

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 Measures lack sufficient deterrence against both individual vendors involving counterfeit transactions and online trading platforms. The Chamber urges Chinese legislators to take serious concern on the matter in the upcoming draft of *Electronic Commerce Law*.

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, 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 just released a draft new e-Commerce Law for comments and the U.S. Chamber provided comments. To note, the draft law includes a counter-notice process which allows counterfeit sellers to easily defend themselves from notice and takedown actions and places IPR holders in a very unfavorable position. The law must also be able to address the ability of counterfeiters to escape prosecution by maintaining anonymity. These are significant problem which we hope will be addressed in the next revision.

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 which 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) taken some initiatives to stop counterfeits in transit at airports and other international express deliveries. 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) – has been trying to regulate the entire sector for years through industry standards and new ministerial rules, some of which touch on legal duty of inspection for counterfeits. However, as 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 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 special police force dedicated to food and drug safety in local areas have resulted in sharp increase of successful criminal prosecution. 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 Criminal Code and Drug Administration Law to deal with the 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: China does not have any official patent linkage system in its drug approval system similar to that found in the United States. The current system in China has the potential of allowing market approval of generic drug anytime during the life of new chemical entity (“NCE”) patents, adding to legal and business uncertainty and weakening the economic incentive to encourage the discovery of new drugs for treating human diseases. It is important for China to look closely at its current drug examination system and ensure innovators have the capability to challenge pending generic applications. The newly established intellectual property court in Beijing actually makes it possible, for the first time in China’s judicial history, for a dedicated court to hear patent disputes occurring in the course of the drug examination system. China should be encouraged to explore the patent linkage mechanism. The Chamber looks forward to China exploring the opportunity to take the mechanism in to account in further legislation and judicial interpretations.

Data Supplementation for Patent Applications in China: 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. The Chamber supports the proposed amendments to the *Guideline for Patent Examination* SIPO released in November of 2016 which conditionally accepts supplemental data. According to the amendment, experimental data submitted after the application date shall be taken into consideration by the examiner.

However, in the amendments it seems that the applicant can only supplement data to further strengthen the technical effects which already have some data in the original document. It is still unclear whether the applicant can supplement data to support the assertive technical effect, for example supplementing data to prove the technical effect of some chemicals which was mentioned but not produced and tested in the original application document. We encourage the U.S. government to monitor the implementation of this new provision concerning data supplementation.

Regulatory Data Protection (RDP): Though formally China provides a six-year term of RDP for 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. At the same time, the *Opinions Concerning the Reform of the Review and Approval System for Drugs and Medical Devices* issued by the State Council from 2015 confirm the definition of a new drug as being one with a first global launch in China, suggesting that RDP only applies to such products. *China Food and Drug Administration's Chemical Drug Registration Category Reform Plan* (Category Plan) appears to re-categorize innovative medicines into a generic drug category. The Category Plan creates a definition of "new drug" as "one that has never been approved in any country," rather than one that has never been approved in China. Under this proposed definition of "new drug," a Chinese or foreign company with a drug that is approved abroad would appear to no longer be eligible for regulatory data protection. Moreover, Technical Guidelines for the Research, Development and Evaluation of Biosimilars issued by CFDA in 2015 do not explicitly extend RDP to biologics and only provide for a "monitoring period" or regulatory marketing exclusivity (up to a maximum of 5 years) to locally manufactured biologics. The Chamber urges the U.S. Government to work closely with the Ministry of Health and other stakeholders in 2017 to ensure this commitment is implemented as soon as possible and that it contains the necessary four key principles: (1) RDP should be granted to any product that is "new" to China; (2) New Chemical Entities (NCE) must be defined in a manner that makes it clear that it applies to both small molecules and biologics; (3) the scope of the definition of NCE should be clearly understood by all parties utilizing that definition, regardless of whether the new medicine is chemically synthesized or biologically produced, China's commitment to provide six years of regulatory data protection applies; and (4) the criteria for determining whether new preparations, indications or combinations (complexes) will be afforded RDP, as well as the degree of evidence required to meet those criteria, must be clear. For example, in the United States, the clinical data submitted by an applicant to the U.S. Food and Drug Administration to obtain approval for a new preparation, indication or combination via the new drug application (or NDA) process meets the standard for obtaining RDP, and should also be considered sufficient to meet the "substantial clinical data" threshold contained in the final sentence of China's proposed definition of NCE.

Patent Protection and Enforcement: SIPO's proposed amendments on the Patent Examination Guidelines are interesting and worth closer monitoring. Apparently, the SIPO is intended to give a lot more flexibility in allowing the patentability of software patents. If this is indeed becoming the patent examination standard, it is expected that companies may find it easier to obtain patents for software. The Chamber will highly encourage the U.S. Government to study the impacts of such changes and its benefits to American companies.

The latest proposed amendment to the Patent Law was 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. SIPO also published its amendments to *Guidelines on the Enforcement of Patent Administration* in February of 2016. Although the Chamber appreciates SIPO's efforts to improve the procedure its enforcement activities, it also shows SIPO's determination to reinforce its power in administrative enforcement. Given all of the issues raised by the proposal to enlarge the power of administrative agencies, the Chamber urges U.S. Government to work with SIPO and SCLAO to carefully consider all of the positive and negative implications of such authority before SIPO moves forward.

Notably, the Supreme People's Court published the long-awaited *Judicial Interpretations of the Supreme People's Court Concerning Certain Issues on the Application of Law for the Trial of Cases on Disputes over Infringement on Patent Rights (II)* (“the Second Interpretation”) in April

2016, which addresses issues such as claim construction, indirect infringement, injunction, damages and standard essential patents (SEPs). The Second Interpretation and other moves by the Chinese courts will likely attract more patent litigation in China. The U.S. government needs to monitor the litigation to determine if U.S. companies end up subject to attacks of frivolous patent claims.

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 the 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.³⁷ 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 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 2020.³⁸ All these measures tie to filings without accounting for the quality of the patents; number of patents actually issued or the percentage of maintained patents. This raises a strong concern that the national or local governments may continue using subsidies to incentivize large numbers but not necessary 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

³⁷ The official decision is at http://www.sipo.gov.cn/zwgg/jl/201311/t20131106_876947.html

³⁸ See http://www.gov.cn/zhengce/content/2015-01/04/content_9375.htm.

prior to initiating litigation.³⁹ 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 it is 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 right 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 *Patent Examination Guidelines* of 2016 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 draft Anti-Unfair Competition Law (AUCL) amendment was published for public comments in February of 2016. The relevant amendments are positive, but far from enough. For example, on a positive note, the Chamber supports the

³⁹ 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

shift the burden of proof to the defendants in trade secret cases, provided that the right holders can prove “substantial similarity” and “access to confidential information”. However, damages for trade secret violations remain relatively low. Also, 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.⁴⁰ Courts also differ in their application of the AUCL’s “business operator” requirements, which creates the problem of initiating enforcement actions against current or former employees, who misappropriate the company trade secrets without actually conducting a business.

Even if a trade secret misappropriation is actionable, proving it is extremely difficult. There is no discovery available and oral testimony carries little to no 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 to no 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 RMB500,000 (~\$75,000 USD).⁴¹ 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 not imprisoned for more than three years, a punishment which provides limited deterrence.⁴²

⁴⁰ 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.

⁴¹ or bankruptcy by the trade secret owner.

⁴² Losses great than ¥2.5M (~\$375k USD) qualify for longer prison terms.

Unfortunately, China's courts also lack effective measures to prevent the leakage of evidence presented during civil enforcement. Therefore, the act of seeking relief can actually exacerbate the damage and plaintiffs are forced to withdraw their civil case.⁴³ Even if it makes sense to pursue civil enforcement, the damage may continue until the case is finally adjudicated. Preliminary injunctions to bar a trade secrets use, while available, are extremely rare.⁴⁴ In part, the limited availability is due to the tremendously high burdens 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.

Forced Regulatory Disclosure of Trade Secrets: Chinese regulations sometimes require companies to submit technical and functional features of their product as well as the testing method adopted in the companies' "enterprise standards" for recordal with local quality and technical supervision authority in order to ensure compliance. Failure to provide the information may prevent access to the Chinese market. The information furnished, however, is unprotected from further disclosure. In fact in many circumstances, local agencies will provide the information to third parties outside of the government agency. This requirement and practice puts companies' technical secrets at risk of leaking to the public domain. China's commitment at the JCCT is a positive step towards addressing these issues.

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

⁴³ 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.

⁴⁴ 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. However, in August 2013, the Shanghai First Intermediate People's Court issued China's first preliminary injunction in a commercial secrets case in favor of Eli Lilly & Co.

National Copyright Administration of China (NCAC).⁴⁵ Not surprisingly, the legitimate market has responded positively to this crackdown on illegal activity by growing significantly.

However, China still lacks effective tools to encourage cooperation of Internet intermediaries, to ensure rapid takedown of infringing content, to take action against repeat infringers, and to provide proactive measures to address piracy. The NCAC national campaign, the Network Rules judicial interpretation, 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 which are 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) 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, published materials and TV dramas; and/or 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 has held a set top box manufacturer liable for streaming unauthorized content under secondary liability theory in 2015.

⁴⁵ In January 2015, MPAA filed suit for copyright infringement against Xunlei a video and music file-sharing firm. Last June, MPAA entered into a Content Protection Agreement with Xunlei to protect MPAA member’s works; but the agreement failed to produce results. In December 2013, NCAC imposed a fine of RMB 250,000 against Baidu for its illegal distribution of pirated content over its video service. See <http://www.gapp.gov.cn/news/1656/184440.shtml>. A coalition of Chinese firms also filed a number of lawsuits against Baidu in October 2013 and at least two cases were decided by a Beijing court against Baidu. See http://usa.chinadaily.com.cn/2013-11/20/content_17119636.htm

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.

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 or compensation to—publishers. These unauthorized services undermine the investment that international (and Chinese) publishers make in journal publishing which, in turn, 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. SAPPRT 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 right 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, legal professionals. Some judges and scholars disapprove or doubt the copyrightability of live sport programming, or believe it shall be protected under some general legal principals under Anti-unfair competition Law, while some scholars argue that live sport programming should be protected as "cinematographic works and works created by means similar to cinematography." The Chamber is now concerned that whether the highly regarded decision made by the Chaoyang District Court in Beijing—which recognized the copyrightability of live sports broadcasts in a relating to the Chinese soccer league— will be overturned by the Beijing IP Court.

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 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" requirements to pursue criminal liability against distributors of pirated works; 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 this law to reduce liability thresholds for counterfeiting and piracy.

Colombia

In years past, Colombia has been a leader in IP protections in Latin America, ranking among the top regional economies in the Index. Yet, in 2016, the Colombian Government implemented a number of troubling policies, most notably the declaration of public interest (DPI) for an innovative pharmaceutical medicine, which weakens Colombia's overall IP framework and deprives Colombia of the benefits provided by robust IP protection. The Index highlights several key ways to strengthen Colombia's IP system, which in turn will attract greater investment and improve their economic competitiveness both in the region and around the world. 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

Compulsory Licensing: Over the last year, the Ministry of Health and Colombian Government actively considered issuing a compulsory license on the innovative oncology drug, Glivec. In June 2016, the Colombian Government issued a 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. In the present case, following two price reductions in the last three years, Glivec is already priced 39% below what the Colombian government requires under its own pricing rules. Additionally, non-infringing generic forms of the same medicine are already available in the Colombian market. Issuing the DPI on these grounds further undermines the legal certainty critical to an effectively functioning IP regime in Colombia—not limited to just pharmaceuticals—and sets a harmful global precedent that intellectual property rights will become discretionary when a government no longer wishes to pay the cost previously agreed to with the innovative company. The DPI also appears inconsistent with Colombia's commitments under the U.S.-Colombia Trade Promotion Agreement (TPA), which incorporates relevant provisions of the General Agreement on Tariffs and Trade (GATT)/TRIPS. The U.S. Chamber strongly encourages the U.S. government to work with their Colombian government counterparts to revoke the Ministry of Health's resolution on the DPI.

Regulatory Data Protection: Decree 2085, which passed in 2002, provided for a five-year period of regulatory data protection (RDP) for both pharmaceuticals and agrochemicals. However, it is unclear if the application of RDP extends to biologics. In several cases in Colombia, the Sanitary Agency has not enforced data protection rights for the innovator. While the innovator has legal recourse, the process is lengthy and expensive, which deters innovators from utilizing legal measures to regain data protection. Decree 1782, which passed in September 2014, modified the registration process for biological medicines but did not provide further clarity regarding RDP for biologics. In order to strengthen patent protection in Colombia and encourage greater pharmaceutical innovation and investment, the Chamber encourages the U.S. Government to work with the Colombian government to encourage the introduction clarifying legislation which extends RDP to biologics and commit to enforce the 5 year period assigned for Regulatory Data Protection

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 and Social Service (MHSS) 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.

Additionally, Articles 69 and 70 allow for the broad review by MHSS 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. The U.S. Chamber urges the U.S. government to recommend to the Colombian government that the provisions of the NDP also fulfill Colombia's obligations under the TRIPS Agreement.

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 establishes 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 its U.S. and Colombia Trade Promotion Agreement (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, and 2016 has seen a large increase in the number of illegal camcorder movies traced to Colombian cinemas. 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 which encourage technology transfer to enable new, innovative and creative technologies to be commercialized in Colombia.

Ecuador

The tenure of President Rafael Correa in Ecuador was marked by the institutionalization of government intervention in the marketplace, including by the overt manipulation, and frequent expropriation, of intellectual property rights to serve political ends. In October 2016, Ecuador's National Assembly passed the Código Orgánico de Economía Social del Conocimiento, la Creatividad y la Innovación (the "Codigos Ingenios") touching on all facets of IP rights, research and development, and innovation. The new law represents progress in certain areas, such as its ratification of the WIPO Internet Treaties, and further regression in many other respects, including new requirements for local production, procurement, and manufacturing; new limits on patentability and patent-eligible subject-matter; and, limits on the number of renewable periods for trademark registrations.

Ecuador, included in the U.S. Chamber Index for the first time in 2016, scores 10.59 points out of a possible 35 and ranks 36th of 45 countries measured in the 2017 edition of the Index. At the time of research, the Codigos Ingenios had not yet officially become law and it remains unclear the extent to which this new legislation will interact with or override the existing Intellectual Property Law. On this basis, the legislation has not been reflected in Ecuador's score for this edition of the Index.

Patents and Related Rights

Patent Opposition: Under the 2006 Intellectual Property Law and in line with its commitments under Andean Decision 486, Ecuador provides a legal mechanism for challenging the validity of a pending patent application. The relevant articles 142-145 of the Law outline what is essentially a pre-grant opposition mechanism. Article 142 states that "within a period of 30 working days following the date of publication, anyone with a legitimate interest may, on one occasion only, file reasoned objections that may nullify the patentability or ownership of the invention." Unlike Decision 486, Ecuador's IP Law does not provide an overall maximum time limit on oppositions whereas article 44 of the Andean Decision provides a 6-month maximum time limit. There is limited evidence on the practical use of the opposition mechanism in Ecuador and the effect it has on the swift and effective prosecution of patent applications. However, given the long

general timelines for patent prosecution in Ecuador – local legal analysis suggests a typical patent takes 6-8 years from filing to grant – the current pre-grant opposition format is unlikely to help reduce these timelines.

Compulsory Licensing: More than any other country in the world, Ecuador under Correa practiced a policy of routine and discretionary use of compulsory licensing. During that time, compulsory licenses were not based on a clear demonstration of an urgent public health emergency or due process provided to the patent owners consistent with Ecuador's international obligations under the WTO's TRIPS Agreement. Fortunately, at the current time, the risk of compulsory licensing as a political or commercial tool in Ecuador appears to be greatly reduced.

Regulatory Data Protection: Article 509 of the Codigos Ingenios contains a defined five-year term of regulatory data protection for biopharmaceutical test data, the first time a defined term of protection will be included in Ecuador's Intellectual Property law. This will bring Ecuador into compliance with the EU's FTA with the Andean Community, which includes a minimum term of 5 years of regulatory data protection due to be implemented by the early-2020s. Prior to now, Article 191 of the Intellectual Property Law has provided a basis for the protection of submitted biopharmaceutical test data. However, no term of protection has been specified in law and rights-holders reported that *de facto* protection of data was compromised as regulators have relied on this data for the approval of follow-on products.

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 member countries, including Ecuador, 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. Settling the matter, Article 274 of the Codigos Ingenios, eliminates any patentability of second use inventions. While part of

Andean Decision 486, this had nevertheless not been codified previously in Ecuador's existing Intellectual Property Law.

Excessive Patent Fees: In 2012, Ecuador drastically increased its patent maintenance and examination fees to exponentially higher than those charged by its peers. While the application of those fees appears to have now been scaled back, we remain concerned that at least on a case-by-case basis, U.S. companies continue to be charged exorbitant fees for these routine, administrative processes.

Copyrights and Related Rights

Software Piracy: Since the late 2000s and presidential decree 1014, the Government of Ecuador has had a policy of mandating government use of open-source software. Now, Article 148 of the Codigos Ingenios introduces a requirement and order of prioritization for public sector procurement of software. This article stipulates that software should be open source and/or contain a significant amount of local Ecuadorean value added in either its production or the provision of services. Foreign suppliers are discriminated over domestic producers and suppliers.

Trademarks

The term of protection for trademarks has been amended by Article 365 of the Codigos Ingenios to limit renewals to two terms. This markedly stands in contrast to TRIPS article 18 which states that "the registration of a trademark shall be renewable indefinitely."

Enforcement

Decriminalization of IP Violations: The enforcement environment for IP rights in Ecuador is difficult. In 2013, amendments to the Intellectual Property Law removed criminal penalties and sanctions for IP rights infringement putting Ecuador firmly outside international standards. In late 2015, amendments to the Penal Code (Código Orgánico Integral Penal) were introduced with new limited sanctions put in place for the commercial infringement of trademarks and copyrights. Specifically, a new article 208A was inserted to the Code providing minimum and maximum fines for commercial infringement of these IP rights. The new law provides statutory fines which, depending on the scale of commercial infringement, range from a minimum of roughly USD 20,000 to a maximum fine of over USD 100,000. The fines are calculated based on

the “salarios básicos unificados del trabajador en general,” a standard salary measurement set by the Ecuadorean Government annually. In 2016 this unit was set at USD 366 per month. While it is a positive step for Ecuador to re-impose criminal sanctions and fines for trademark and copyright infringement these new sanctions do not include imprisonment and the fines are inversely proportioned to the scale of the infringement with small scale infringement receiving a larger fine in proportion to the value of the infringement.

India

The level and frequency of engagement between the U.S. and Indian governments in 2016 continued to be a source of hope for the future, marked by ongoing dialogue on a broad range of intellectual property rights issues between India and the U.S. under the Trade Policy Forum, the Strategic and Commercial Dialogue, and the High-Level Working Group on Intellectual Property.

Yet, at this time, substantive improvement in the IP environment in India remains merely aspirational. India released the long-awaited National IPR Policy in 2016, providing evidence of an evolving yet equivocal political attitude toward IP. The Policy expressed a positive inclination toward steps to improve IP administration, and 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 more resources in existing enforcement agencies; strengthening administrative capacities at India's intellectual property 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

However, the Policy's dismissal of the need for substantive changes to improve India's statutory and regulatory IP framework, which has consistently been found to fall short of international best practices, demonstrates the continued political challenges to realizing an IP environment favorable to an innovative and creative economy. Specifically, the Policy does not provide details with respect to inter-ministerial coordination on implementation, budget allocation, and did not address the challenges and uncertainties rights-holders face when it comes to protecting their patent rights (particularly in the biopharmaceutical sector including early notification of patent infringement and clarifying interpretation of Section 3(d) of the Patent Act), modernizing existing copyright laws or introducing international best practices, and new sector-specific IP rights such as regulatory data protection for submitted biopharmaceutical test data.

Ultimately, the year was characterized by several disappointing developments: balanced and reasonable Guidelines for Examination of Patent Applications for Computer Related Inventions (CRIs) issued in 2015 were withdrawn and re-issued in 2016 in a non-transparent fashion, with the result that the 2016 Guidelines will make most if not all software inventions ineligible for patent protection. Then, in response to public outcry, a government committee was formed to re-review the guidelines, with no deadline for decision, leaving software innovators in regulatory limbo. Subsequent high-level dialogues between the U.S. and Indian governments failed to result in any resolution of this matter. In fact, the strongest statement to emerge from bilateral dialogues in 2016 was an endorsement by the Indian Commerce Secretary of calls by an independent UN panel for broad use of “TRIPS flexibilities” to justify routine use of compulsory licenses against patented products. It is worth noting that India has been a strong champion of weakening of IP rights in multilateral organizations, including WIPO and the WHO. Meanwhile, the Seeds Directive issued in 2016 seemed to suggest a possible return in this sector to innovation-threatening compulsory licensing practices. The recent High Court of Delhi decision regarding photocopying copyrighted content was likewise highly discouraging.

Under these circumstances, we see no substantive basis for a change in India’s previous designation from the 2016 Special 301 Review and continue to see value in a meaningful mid-year progress assessment.

India’s score on the U.S. Chamber Index increased marginally from 24% (7.05 out of 30) in the fourth edition to 25% (8.75 out of 35) in the fifth edition. This principally reflects a relatively mixed performance in the five new indicators added to the fifth edition.

Patents and Related Rights

Patent Opposition: Section 25 of the Patents Act outlines the procedures and requirements for initiating 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 in India 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 2016 statistics suggests that 98% of patents granted in India in 2015 were for applications over 5 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. Moreover, this year there were several additional examples of products denied patent production under Section 3(d).

The Indian Patent 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 intellectual property 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 Government of India 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: Section 3 of the Indian Patents Act defines what is not considered to be an invention. Section 3(k) specifically excludes a “computer programme per se” from patent protection. Under Indian law, and as a matter of international practice, patents are not awarded for lines of code. Computer related inventions remain patent eligible subject matter, and claims directed to computer software operating in conjunction with corresponding hardware may be granted if the tests of novelty, inventive step and industrial applicability are satisfied.

However, the 2016 CRI Guidelines would make most if not all software inventions ineligible for patent protection, contrary to international practice and Indian law. Discriminating against categories of invention is inconsistent with Article 27(1) of the Agreement on Trade Related Aspects of Intellectual Property and is poor industrial policy. Patents are critical to innovation - they drive investment in R&D, attract angel and venture capital funding, and support economic growth and development through job creation and exports. It is crucial for patent examination guidelines to accurately convey the state of the law as interpreted by the courts and not impose additional restrictions or requirements. Moreover, in a world increasingly driven by software-implemented innovations, patent offices must be equipped to properly examine and grant quality patents to drive the growth of IT industries.

Indian courts have spoken clearly on the patentability of computer related inventions and have adopted the technical effect test, most recently in *Telefonaktiebolaget Im Ericsson v. Intex Technologies (India) Limited* finding that “it appears to me prima facie that any invention which

has a technical contribution or has a technical effect is not merely a computer program per se . . . it is patentable.” See also, *Enercon India v. Aloys Wobben* (IPAB held that a computer set up to operate in accordance with a specified program (whether by means of hardware or software for carrying out a technical process (and control thereof) cannot be regarded as a computer program per se. Claims comprising of a process implemented by a program (whether by means of hardware or software) to achieve a technical effect are patentable subject matter).(Emphasis added). The courts have also recognized that developments in software are equally as important as the hardware it interacts with. The idea that patents should only issue for novel software coupled with novel hardware, as laid out in the February 2016 Guidelines, is not consistent with the law, international practice or Indian jurisprudence. Many Indian courts have considered improvements to the software necessary to achieve the technical effect alone as patentable subject matter under the law. See, *Symbian Ltd v. Controller General of Patents and IBM/Computer Program Product* (Emphasis added).

Onerous Updates of Counterpart Prosecution: 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. Even more problematic, Section 8 provides independent grounds for invalidation of a patent—should the applicant fail to keep the patent office informed in writing of detailed particulars of all foreign patent applications that claim the same or substantially the same invention—which leads to uncertainty of the value of the underlying asset. We recommend India reconsider this requirement, in light of significant technology advancements and enhanced ability to access the necessary information since the Avyngar report’s recommendations.

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.

Legislative Criteria and Compulsory Licensing: Industry continues to be concerned by the potential threat of compulsory licensing. Statements by Indian officials at international organizations and the Minister of Commerce 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 World Intellectual Property Organization, the World Trade Organization, and in other fora.

While no additional compulsory licenses for biopharmaceuticals were issued by Indian authorities in 2016, the Indian Government continued 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 license as a commercial tool.

Copyrights and Related Rights

The decision by the Government of India 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.

Scope of limitations and exceptions to copyrights and related rights: On September 16, 2016, the High Court of Delhi issued a final judgment in the long-running court case between some of the world’s leading academic publishers (including both Oxford and Cambridge University presses and Taylor & Francis) and the University of Delhi and a local photocopy shop. The case was first launched in 2012 with the publishers suing both the University and the copy shop for infringement and enabling copyright infringement. The rights-holders argued that the University had not only allowed the operation of the copy shop on its premises but outsourced the production of University course materials to it. And in so doing it had gone beyond any reasonable interpretation of educational exceptions to copyright. The September 2016 judgment

dismissed the lawsuit with the judge stating that: “Copyright, specially in literary works, is thus not an inevitable, divine, or natural right that confers on authors the absolute ownership of their creations. It is designed rather to stimulate activity and progress in the arts for the intellectual enrichment of the public.” The judgment did not only not find anything wrong with the University providing a photocopied master-copy of course texts for students to photocopy themselves in the University library, but it also did not object to the obvious commercial gain derived from the copy-shop of providing this service to University students and staff. The judgment underlines the challenging environment rights-holders and creators face in protecting their intellectual property not only in court but more broadly and across all major forms of content in India. Only a few days prior to the judgment and in an unrelated matter, Bollywood actor Rajeev Khandelwal commented on the impact piracy is having in India and specifically on pre-release leaks and the pirating of a number of Indian feature films. He said: “Piracy means you are killing an industry...If this continues, filmmakers will fear investing money in a film, people will start losing jobs and the industry will fade away.”

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.

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.

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 amount of subcontracting that 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. The U.S. should encourage India to upgrade their legislative framework to offer meaningful trade secret protection.

India also has in place a number of policies making market access contingent on the sharing or divulging of intellectual property. 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 intellectual property and trade secrets. Industry remains committed to working with the Indian Government to resolve this issue.

Telecommunications Network Security: GIPC remains concerned about security testing requirements for ICT equipment that will enter into force on April 1, 2017. 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. Moreover, it appears that India lacks a sufficient testing ecosystem to implement this requirement by the 2017 deadline.

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 in a way that is detrimental to global ICT trade.

USTR should urge the Government of India 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 anticipated implementation of the National IPR Policy we encourage the creation of a “National Copyright Enforcement Task Force” within DIPP’s IPR cell, including 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 of 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).

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 urge the Government of India 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 Licenses: The Government of India should 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

In 2016, the Indonesian Parliament (People's Representative Council) passed a new wide-ranging patent law (Law 13 2016), which will further discourage investment in Indonesia's innovative and creative content sectors. While aiming to strengthen Indonesia's innovation infrastructure and encourage more high-tech economic development through the creation and use of new technologies, the law does not improve what was already a challenging patenting environment.

The Chamber commends the Government of Indonesia for improving market access for the film sector in 2016 and urges Indonesia not to squander this accomplishment by imposing an antiquated screen quota and other market access limitations. The Chamber also lauds Indonesia for following through on its commitment to combat online piracy.

Indonesia's overall score on the U.S. Chamber Index has decreased from 28.6% (8.59 out of 30) in the fourth edition to 27.5% (9.64 out of 35) in the fifth edition, giving it a ranking of 39 out of 45 economies measured. This reflects a relatively weak performance in the five new indicators added in the fifth edition and a deterioration of the environment as it relates to patents and related rights as an outcome of the new patent law.

Patents and Related Rights

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. 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.”

Parallel Importation: Article 167 of 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.”

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. 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. Indonesia's position contravenes its obligations under the TRIPS Agreement, which prohibits WTO members from discriminating based on whether products are imported or locally produced.

Software: 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.

Compulsory Licensing: The Indonesian government has since the mid-2000s 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 2016, 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.

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 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.

Annuitiy Payments: The Indonesian Patent Office is currently issuing invoices for past annuity payments on previously abandoned patents which 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

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. In October 2014, a new Copyright Law was adopted providing 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.

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 Indonesian Government must 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 (circa 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."

Russia

Though Russia leads the BRICS economies in relative strength of intellectual property rights in the 2017 Chamber International IP Index, its IP environment scores below half the available amount desired to provide confidence in its market. The Chamber continues to remain concerned about the implementation of several of the key provisions outlined as part of the Intellectual Property Action Plan with the United States.

Patents and Related Rights

Regulatory Data Protection: Under its WTO commitments and the 2010 Law of Medicines, Russia has committed to implementing a RDP 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 RDP. 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 Intellectual Property 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. The U.S. Chamber urges the Russian government to put in place meaningful patent resolution and enforcement mechanisms.

Compulsory Licensing: Russia is considering drafting legislation to expand the use of compulsory licensing of innovative medicines.

Copyrights and Related Rights

Online Piracy: 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.

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 rightholders 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.

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), however 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 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 intellectual property 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- The Russian Government has targeted innovation as a main impetus behind diversifying and modernizing its economy primarily through the Strategy for Innovative Development of the Russian Federation 2020 (2020 Strategy), introduced in 2011. The 2020 Strategy covers a number of sectors for development such as aerospace and nuclear energy, nanotechnology, medical technologies, ICT and alternative fuels.

A major part of these efforts has been policies that aim to localize the R&D and manufacture of these technologies, with the biopharmaceutical and medical devices sectors particularly in the crosshairs. In 2010, the Government passed Federal Law 61-FZ on the Circulation of Medicines stipulating that clinical trials for innovative and generic medicines (bioequivalence studies) must be conducted in Russia if the product is to be submitted for registration.

2016 saw the intensification of these policies. For example, in November 2015, the Russian Government adopted Resolution No. 1289 “On Restrictions and Conditions of Access of Foreign Essential Medicines to State and Municipal Tenders,” which introduces a direct import ban within the procurement system. Access to state purchases of imported medicines will not be allowed when (at the time supplies are requested) at least two generics produced within the EEU are available for a given INN. Foreign manufacturers will only be able to participate in a public tender in cases where fewer than two bids from EEU manufacturers have been submitted. In addition, Decree 1125/2015 made the “National Immunobiological Holding Company” owned by state-run corporation Rostech the sole provider of immunobiological products for state needs for the period 2015-2017.

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

In July 2016, the Department of Trade and Industry (DTI) released its draft “Intellectual Property Consultative Framework.” The stated purpose of the Framework is “not to prescribe South Africa’s IP policy position, but to put forward the perspective of the DTI in a consultative instrument to facilitate what will be continuous engagement with governmental partners and society at large.” The Framework comes on the back of a long-standing debate in South Africa over IP rights and a number of legislative reform efforts over the past few years including a now withdrawn draft patent bill. 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. Like the Ministry of Science and Technology’s 2014 flagship policy document for the biotechnology sectors, The Bio-Economy Strategy, the Framework focuses on ways in which South Africa could better access existing and developed forms of IP including through the expanded use of exceptions and limitations, namely compulsory licenses and parallel importation. There is no equivalent discussion on the manner in which intellectual property can be created, commercialized and become an industrial asset. As such, a more holistic approach to instituting IP rights could help raise South Africa’s rank on the U.S. Chamber International IP Index, which currently sits below its BRICS counterparts—barring India—in the 2017 edition.

Patents and Related Rights

Substantive Search and Examination: The U.S. Chamber welcomes the Framework’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 Intellectual Property 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 restraints 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 sets out a high-level desire to allow for third-party opposition procedures as a cheaper alternative to revocation hearings. 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. The U.S. Chamber looks forward to working with the South African government as it considers alternative patent opposition measures.

Patentability Criteria: Under the TRIPS agreement, in order for an invention to be patentable it must meet the novelty, inventive step, and industrial applicability requirements - and no more. The CIPC currently does not have a full examination process in place. As the South African government looks to international best practice to strengthen its patentability criteria — as section 4.1.4 of the Framework suggests — 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 a ripe area for developing country activity.

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 addresses 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 United States, 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 notes 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 which 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 intellectual property 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 which 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 contain numerous positive provisions relating to DRMs and TPMs corresponding with those already contained in Chapter 12 of the Electronic Communications and Transactions Act.

In addition, the proposed amendments also introduce a system of “fair use” exceptions to copyright. At this time, no final bill had been presented to the South African Parliament.

However, in a separate development the High Court of South Africa finally made its judgment in the long-running court case between Moneyweb and Fin24 (two news websites) in May 2016. Of

particular significance was the Court's detailed outline and definition of criteria to help define the meaning of fair dealing and relevant exceptions and limitations contained in the current Copyright Act. While this judgment does not represent a sea change in South Africa's copyright environment—there are still numerous gaps in copyright law and significant challenges persist with regards to both digital and physical piracy—it nevertheless provides an important clarification to what had up till now been an area of copyright in which the case law was very sparse.

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 are 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.

More generally, the National Industrial Participation Programme (NIP) has been in place since the late 2000s. The NIP requires that foreign suppliers awarded government contracts within a month of signing a contract with the procuring entity also sign an obligation agreement where they commit to local economic activities. The ultimate purpose of the NIP is to build local capacity and partnering between local South African companies and international industry leaders.

2016 saw the intensification of both these public procurement policies and the NIP framework and in particular its localization requirements. For instance, the DTI in the 2016 Industrial Policy Action Plan 2016-17-2018-19 (IPAP) outlined new policies that strengthen these requirements. To begin with the IPAP confirms the Government's objective (first outlined in the 2014 five-year plan Medium Term Strategic Framework) of achieving a level of 75% local procurement. Specifically, the DTI is strengthening cross-governmental enforcement activities and ensuring

greater compliance and application of these localization requirements. Furthermore, the IPAP places 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.

Venezuela

Industry faces a number of significant challenges when seeking to protect their IP in Venezuela. Venezuela, for the second year in a row, ranks in last place overall in the Chamber's 2017 International IP Index. Strengthening Venezuela's IP environment will be critical to providing investors with the legal certainty needed to invest in the market. The U.S. Chamber believes the Venezuelan government should implement the following policy changes to improve the IP ecosystem.

Patents and Related Rights

As a general note, Venezuela currently has in effect the Intellectual Property Law of 1955. This law is outdated and contains several provisions that directly contravene Venezuela's obligations under the WTO TRIPS Agreement.

Patent Term: The standard term of protection for patents is 10 years in Venezuela. The U.S. Chamber recommends the U.S. government ask the Colombian government to increase the patent term to 20 years, the minimum provided under TRIPS.

Patentability Requirements: The Industrial Property Law (1955) provides for the standard patentability requirements of novelty, inventiveness, and industrial applicability. As stated, however, there is a great deal of ambiguity as to whether all three should be fulfilled for an invention to be patentable, or whether meeting just one requirement is sufficient, as well as a clear definition of each. In violation of Article 27 of the TRIPS Agreement, chemical preparations, use of natural substances, second use, and new forms of pharmaceutical inventions are specifically excluded from patentability in Venezuela. Inventions created using public funds or means are also not patentable. The Venezuelan Autonomous Intellectual Property Service (SAPI) has not issued a patent since at least 2007, and by some counts, since 2000. Pharmaceutical patents have not been granted since 2002. The U.S. Chamber encourages the U.S. government to work with the Venezuelan government to clarify the scope of patentable subject matter in order to bring Venezuela into compliance with its international obligations.

Regulatory Data Protection: Under the Treaty of Group of Three Article 18-22, Venezuela agreed to provide five years of data protection for pharmaceuticals and agrochemicals. However, industry reports suggest that regulatory data protection has not been granted in Venezuela since 2002. In order to prevent companies seeking market approval for a generic from utilizing an innovative company's data, the U.S. Chamber recommends that the U.S. government collaborate with the Venezuelan government in order to prevent the unfair commercial use of data.

Copyrights and Related Rights

ISP Liability: The Law on Copyright (1993) includes measures that provide for the moral rights of authors, however no specific provisions address rights relevant to digital exploitation of works. Moreover, Venezuelan laws do not establish the liability of intermediaries or ISPs specifically in the context of IP infringement. Rather, legislative penalties are applied to infringing entities directly. In practice, online and physical piracy of software, music and films are widespread in Venezuela. In addition, there is a general lack of knowledge concerning copyright protection in the online sphere, and copying of protected works, including for commercial purposes, is considered acceptable by the public at large. Still, local legal analysis suggests that ISPs demonstrate increasing awareness of online infringement and will in some cases take down infringing content if a cease and desist letter is sent. The U.S. Chamber recommends that the U.S. Government encourage the Venezuelan government to introduce mechanism to more effectively combat online copyright infringement.

Camcording: The unauthorized camcording of films in theatres continues to present a problem for copyright-intensive industries and further fuels online piracy in Venezuela. The U.S. Chamber would support legislative measures to provide criminal penalties for unauthorized camcording without proof that the infringer intends to distribute and profit from the camcorded film. We encourage the U.S. government to work with the Venezuelan government to implement measures criminalizing camcording in order to provide greater protection for copyrighted content in Venezuela.

Trademarks

Trademark Registration: Rights of trademark holders are not well defined in the Industrial Property Law. It does not explicitly prohibit the registration of marks that are similar or identical to marks determined to be well known. It does provide some protection against marks that have likelihood of confusion with existing, registered marks. Article 33 prohibits the registration of a trademark that is similar or identical to a registered mark or which may cause confusion as to origin or quality. Though directed towards registered marks, this provision has also served as a basis in some cases for protection of well-known marks, though generally recognition of well-known marks is uncommon. In addition, it is possible to secure remedies for trademark infringement under Venezuelan competition law, within which an infringing act may be deemed illegal if it is explicitly intended to compete with a product associated with the mark; causes damages to the trademark owner; and leads to customer confusion. Industry reports suggest that SAPI regularly approves and publishes applications for trademarks that are similar, if not nearly identical, to registered marks. In addition, counterfeiting is widespread, particularly of medicines and consumer goods such as apparel and footwear. The U.S. Chamber recommends the U.S. government encourage the Venezuelan government to introduce further legislative mechanisms which give greater certainty to trademark owners.