



U.S. CHAMBER OF COMMERCE

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By electronic submission

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**U.S. CHAMBER OF COMMERCE'S GLOBAL
INTELLECTUAL PROPERTY CENTER**

2016 SPECIAL 301 SUBMISSION

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February 5, 2016

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Re: 2016 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), in cooperation with the Chamber's International Division, is pleased to submit written comments in response to the Office of the U.S. Trade Representative's (USTR) 2016 Special Review: *Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment and Announcement of Public Hearing*. The goal of our submission is to highlight key challenges faced overseas by U.S. creative and innovative industries seeking to create high quality U.S. jobs, grow our economy, and increase exports. 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. In 2007, the Chamber established the GIPC to lead 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. Intellectual property-intensive companies account for nearly 35 percent of U.S. gross domestic output, drive 60 percent of U.S. exports, and support 40 million American jobs directly and indirectly. However, the benefits enjoyed by intellectual property-intensive industries are not limited to U.S. borders. Economies of all shapes and sizes have a stake in implementing meaningful intellectual property regimes, which provide faster access to innovative products, provide a framework for fostering home-grown talent, and attract significant foreign investment.

The GIPC set out to create an intellectual property roadmap for countries seeking to foster robust intellectual property policies that facilitate the creation of jobs, continued

innovation, and access to new technologies. The result, the Chamber's 2016 International IP Index, *Infinite Possibilities*, is an empirical assessment of the strengths and weaknesses of 38 developmentally and geographically diverse countries.

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; particular challenges posed by theft of intellectual property on the Internet; the need to improve enforcement efforts and promote greater resources for the protection of intellectual property; and the importance of intellectual property to domestic economies. We included 17 countries in this report, which were chosen based on factors including the size of the market, the geo-political significance of the market, or 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 all other available trade mechanisms and dialogues, 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,



David Hirschmann
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President and CEO, U.S. Chamber's Global
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Myron Brilliant
Executive Vice President
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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 10, 2016, the U.S. Chamber will be releasing the Fourth Edition of the International IP Index, *Infinite Possibilities* (Index), which provides a roadmap for countries seeking to create jobs, promote economic growth and investment, and build innovative and creative economies. This cross-disciplinary, empirical assessment of intellectual property protection and enforcement in 38 economies provides a snapshot of what countries are doing well and what they can be doing better.

The Index identifies 30 factors that are indicative of an intellectual property environment that fosters growth and development and applies those factors to a geographically and developmentally diverse group of economies. These economies are (italics indicate new countries added for 2016 edition): *Algeria*, Argentina, Australia, Brazil, *Brunei*, Canada, Chile, China, Colombia, *Ecuador*, France, Germany, India, Indonesia, *Israel*, *Italy*, Japan, Malaysia, Mexico, New Zealand, Nigeria, Peru, *Poland*, Russia, Singapore, South Africa, South Korea, *Sweden*, Switzerland, Taiwan, Thailand, Turkey, Ukraine, United Arab Emirates, the United Kingdom, the United States, *Venezuela*, and Vietnam. Together these countries constitute over 85% of estimated world gross domestic product in 2014¹.

The Index also notably includes statistical correlations which provide further evidence of the direct link between the relative strength of IP environments and important socioeconomic indicators. The Third Edition of the Index focused on 15 such socioeconomic outcomes, finding direct positive correlations between IPR strength and R&D expenditures, high-value job growth, access to digital technologies, biotechnology innovation, and access to creative content just to

¹ World Bank, GDP Ranking 2014 (September 2015 update), World Development Indicators, The World Bank 2014

name a few. The 2016 Index will further this research by finding direct associations between IP protection and access to finance and number of researchers in R&D, for example.

The Index is not intended to be an industry Special 301 Report and, as such, not all countries included in the Chamber Index are included in the Chamber's Special 301 submission. The GIPC Index is also not meant to be a comprehensive guide to all factors that make up a robust intellectual property protection and enforcement system. Rather, the Index serves as a discretionary policy tool to those countries wishing to evaluate the strengths and deficiencies in their intellectual property environments.

We would be happy to provide a copy of the Chamber Index next week following the release of the report to provide further evidence to support the issues raised throughout.

Global Measure of Physical Counterfeiting

As part of the 2016 International IP Index, the U.S. Chamber also updated the global counterfeiting measure. The standard measure used to gauge global counterfeiting, The OECD's General Trade-Related Index of Counterfeiting of Economies (GTRIC-e), was last updated in 2009, relying on customs data from the mid-2000s. As a result there is a question of whether or not it is still a reliable indicator of overall levels of physical goods counterfeiting.

To address this challenge, the fourth edition of the Index now incorporates a new proprietary Global Measure of Physical Counterfeiting. The Measure has been developed by the U.S. Chamber of Commerce and Pugatch Consilium to provide a new global measure of physical trade-related counterfeiting. It provides a total and per economy estimate for each of the 38 economies included in the Index of rates of physical trade related counterfeiting. The full methodology, data used and explanation of the modeling is provided in the Annex of the 2016 Index.

Trading Up: The Evolution and Implementation of Intellectual Property Rights in U.S. Free Trade Agreements

Intellectual property (IP) is a critical driver of economic growth and the development of new ideas, technologies, and solutions globally. The increasing importance of IP in a global economy was recognized and advanced with the successful negotiation of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Concluded almost 20 years ago, TRIPS established an important global baseline of IP protection and enforcement.

For the United States, IP-intensive industries are the foundation of its global competitiveness. Recognizing the increasing growth of innovative and creative exports, a U.S. priority has been to negotiate robust IP protections through its bilateral and regional trade agreements. If U.S. trade agreements are to meaningfully expand market access for these industries, modern and predictable IP rights, and the enforcement of those rights, are critical.

Yet negotiating high standard agreements is not enough. The question is whether innovative and creative industries can rely on the commitments made on paper to be faithfully implemented and enforced.

The purpose of this report, *Trading Up: The Evolution and Implementation of Intellectual Property Rights in U.S. Free Trade Agreements*², is to provide an initial assessment of whether U.S. FTA partners are abiding by their IP commitments. To provide a snapshot of progress to date, this study covers four regionally and economically diverse countries – Australia, Canada, Chile, and Korea – which have negotiated trade agreements with the United States over the past 20 years. For each country, this study examines implementation of ten core IP obligations across IP disciplines.

² U.S. Chamber of Commerce's Global Intellectual Property Center, *Trading Up: The Evolution and Implementation of Intellectual Property Rights in U.S. Free Trade Agreements*, January 2015.

Overall, the study highlights that, while there are both positive implementation developments and challenges across all four countries, Australia has most successfully implemented its FTA obligations thus far. Korea is a close second; however, given that the agreement only recently entered into force, it is still too early to tell whether Korea is faithfully implementing and enforcing all of its obligations. Both Chile's and Canada's implementation track records lag significantly behind those of Australia and Korea.

Moreover, since the North American Free Trade Agreement (NAFTA), of which Canada is a party, was concluded a decade before the next agreement assessed (Chile), the IP chapter of NAFTA does not include many of the IP provisions assessed in this study. For a better understanding of how Canada's IP system would stack up against more recent U.S. FTA IP provisions, we also assessed Canada's laws and practices against those obligations found in many of the United States' post-NAFTA agreements. Benchmarked against more recent FTAs, Canada would fall short in a number of categories.

This assessment demonstrates that it will be critical to ensure implementation of those commitments before the agreement enters into force with each country. More broadly, this study highlights the need for continued vigilance and, where appropriate, action after the ink on the FTA is dry. Without a commitment to enforcement, the promise of a high-standard IP chapter risks going at least partially unfulfilled.

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.

Intellectual property laws have sought for several centuries to protect this right of creators and innovators as a tool to promote the creation and distribution of goods and the advancement of the arts and sciences. Scientists, artists, and other creative minds are asked to share their personal intellectual wealth for the benefit of society and, in return, are motivated by the market forces enabled by property rights to create new breakthroughs. Intellectual property provides an incentive for individual innovation and serves the public interest by facilitating the creation and dissemination of knowledge and culture.

In recent years, however, there has been a concerted effort to change the public perception and debate on intellectual property, often based on distorted or inaccurate claims and in contradiction to the careful balance already integrated into the system. Globally, there are increasing calls to limit how innovators are able to protect the property rights in their inventions and creations and even calls to limit the scope of what can be protected. Opponents of effective intellectual property laws claim that these laws are a barrier to the free development and distribution of new technologies or the protection of the environment and public health. These arguments are often erroneous on their own terms – real life experience demonstrates over and over that protection of intellectual property promotes the diffusion of creativity, innovation, and technology. Moreover, the arguments are flawed by their failure to acknowledge that the creativity and technology they take for granted may not exist at all or might be unavailable to the public were it not for the certainty and incentives provided by intellectual property law. Policies driven by an undue focus on exceptions and limitations to intellectual property rights represent a short-sighted policy outlook. Creating and instituting a meaningful intellectual property framework is, indeed, a long-term economic strategy and should not be traded away for “get rich quick” schemes, which are

likely unsustainable and most certainly unwelcome by the responsible global business community.

It is important for the U.S. Government to remain vigilant against efforts to permit unwarranted exceptions 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. Irrespective of the seemingly altruistic-sounding objectives voiced by critics of intellectual property, destroying or undermining the protection of intellectual property will not help achieve these goals. To the contrary, weakening protection of intellectual property is likely to have detrimental impacts on economic growth, jobs, innovation, and the economic rule of law – all of which are interrelated and self-reinforcing.

The sections below outline some particular areas of concern, many of which are referenced in our country assessments, including our recommended actions.

Importance of Bilateral and Regional Free Trade Agreements

As policymakers seek to strengthen intellectual property systems on a global basis, the scarcity of meaningful policy vehicles must be a chief consideration. On the broadest basis, 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 large swath of the WTO's membership. Meanwhile, intellectual property dialogues at multilateral institutions are increasingly mired in global development politics that effectively prevents substantive progress on a norm-setting agenda.

Accordingly, bilateral and plurilateral trade agreements are, and will likely continue to be, the most dependable vehicles to build consensus around policy commitments to strengthen intellectual property standards internationally. Among such agreements, U.S. trade agreements stand out for the strength of their intellectual property chapters, with the U.S.-Korea Free Trade Agreement (KORUS) representing a high-water mark. These agreements contain strong commitments related to statutes, administration, and enforcement that institutionalize respect for intellectual property in the participating countries.

Plurilateral agreements, such as the recently concluded Trans-Pacific Partnership (TPP) Agreement and the ongoing Trans-Atlantic Trade and Investment Partnership (TTIP) negotiations have special significance, both for their enlarged country scope and, consequently, their enhanced precedential value. Accordingly, it is of paramount importance to optimize the outcomes from these rare opportunities to win meaningful international commitments to strengthen IP. It is for that reason that, notwithstanding the generally strong overall provisions of the TPP's intellectual property chapter, the absence of a commitment for a stronger term of regulatory data protection for biologics, for instance, becomes a glaring omission. It will therefore be incumbent upon the U.S. administration and Congress in working toward ratification and implementation of the Agreement to identify a path forward that sends markets and policymakers an appropriate signal regarding the U.S. and TPP commitment to IP-led innovation by enhancing the effective outcome for biologics.

Similarly, as TTIP negotiations continue, it is essential that the potential agreement reflect the leadership legacy of both parties in the intellectual property space, re-affirming the strong intellectual property foundations of both that are found in existing law and practice, and extending bilateral cooperation to encourage the adoption of similarly strong standards of respect for IP multilaterally.

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. 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 2016 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 inventor's rights which the TRIPS Agreement provides. American leadership in multilateral organizations is essential to creating a global environment which rejects these negative policies and instead support innovation and access to new technologies through strong IP rights.

For example, the November 2015 TRIPS Council meeting was beset by negotiations related to extending a waiver to least developed countries for implementing pharmaceutical-related IP obligations as agreed upon when they acceded to the TRIPS Agreement. Interest groups had advocated for an indefinite extension to this waiver, which would have been counterproductive to the creation of an enabling environment for innovation in these economies. U.S. leadership in the WTO, was critical to secure a compromise including a time-limited extension. Although this period arrived at (17 years) represents a time markedly longer than previous extensions considered by the TRIPS Council, its indefinite alternative would have had set disastrous precedent for IP rights in global trade and the WTO.

Furthermore, a similar negative agenda to undermine innovation was also pursued in the UN Framework Convention on Climate Change (UNFCCC) negotiations in Paris in late 2015. Officials from the U.S. Department of State, in coordination with experts from the Office of the U.S. Trade Representative (USTR) and the U.S. Department of Commerce, were able to secure a final UNFCCC text which could facilitate the continued investment by U.S. companies to invest in the technologies necessary to achieve our mutual socioeconomic and environmental goals. Though significant challenges to IP still remain in the Paris Agreement's implementation and subsequent negotiations—especially related to the technology development and transfer chapter—this result was in the face of considerable demands to weaken the related IP infrastructure, a move that would have done more to impair, rather than improve access to critical solutions.

This coming year will be marked by numerous uphill battles in multilateral institutions. First and foremost, we ask the U.S. government to continue to push back on the “exceptions and limitations” agenda within the work programs of the World Intellectual Property Organization. Specifically, the Standing Committees on Patents and Copyrights, the Committee on

Development and IP, and the Intergovernmental Committee on IP and Genetic Resources, Traditional Knowledge, and Folklore have all will be considering packages of proposal which could expand exceptions and limitations, thereby undermining incentives for innovation and for disseminating new technologies to the people who need them.

The Chamber, further, is very concerned about the recently announced UN High Level Panel on Access to Medicines (UNHLP). Transparency and fairness questions aside, the UNHLP appears to be a direct attack on the very principle of intellectual property rights. The Panel's scope claims to be 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." While our member companies welcome a discussion on health technology and access to care, they believe the UNHLP should provide an opportunity for an informed, balanced and inclusive dialogue. 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.

Similar anti-business issues continue to plague the World Health Organization (WHO). Most notably are the current negotiations for the Framework for Engagement with Non-State Actors (FENSA). Adoption of this text which would exclude engagement with industry and other non-state actors ad hoc, most notably paragraph 44 and 44bis, 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. Even the WHO has raised alarm over these

issues, through its issuance of an October 14, 2015 “non-paper”³ on the effects of FENSA. This WHO non-paper cites that “there is a significant risk that FENSA could also have detrimental consequences on the work of the WHO” by creating a “systematic overload” for a potential clearance system; “collapse” of the system which would create major bottlenecks and delays in decision making; and jeopardizing the WHO’s ability to respond to emergencies. 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 patent rights, including several countries pushing for the development of a manual to guide countries in setting aside intellectual property rights. Statements that challenge the link between innovation and intellectual property are often made, and efforts to improve the patent backlog such as via worksharing are bizarrely rejected as an affront to sovereignty. While WIPO could engage in efforts to enhance the functioning of patent systems, those laudable endeavors are regularly thwarted by the countries who could benefit most from their implementation.

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, UNFCCC, WIPO and other issues or negotiations taken up by UN agencies will only be able to successfully address issues such as promoting both innovation 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

³ World Health Organization, “Implication of Implementing the Framework of engagement with non-state actors), October 14, 2015 (<http://www.who.int/about/collaborations/non-state-actors/Implication-implementing-Framework.pdf?ua=1>) .

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.

Although national laws often protect trade secrets from theft or misappropriation by a competitor, many do not 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, forced 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.⁴ Similarly, a competitor can make use of confidential information it receives, as long as the party providing it originally received it legitimately.⁵ 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.

Unfortunately, the lack of protection in the first instance is not the only shortcoming for businesses in need of protecting confidential information. 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 encouraged that various Members of the U.S. Congress have introduced legislation to address the increasing threat of trade secrets misappropriation and the Chamber will continue to support such efforts.

⁴ See Austria's Act Against Unfair Competition (UWG), Section 12

⁵ See UWG Section 11

Internet-Based Intellectual Property Theft

Intellectual property-based businesses, like all businesses, seek to maximize connections 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. The problem of online theft of intellectual property is massive and growing. This theft is direct harm to innovators, creators, and other IP owners, and is a public policy problem because of the considerable role intellectual property plays in a healthy economy.

Protecting intellectual property is as important on the Internet as it is in the brick-and-mortar world. 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. When intellectual property is undermined through counterfeiting or piracy, it is a direct threat to all of the benefits that come with intellectual property, including 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. It is critical that law enforcement authorities have the tools, resources, and will to fight theft in both the online and physical environments.

Both rights holders and the U.S. enforcement agencies recognize the need to protect these vital interests against theft. 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.

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—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 global patchwork of laws and enforcement efforts invites the criminal enterprises behind online counterfeiting and piracy to shop for a forum in which they can elude justice. 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.

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 are a relatively new threat to rights holders, but their potential for harm is 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 profit from the hard work of America's creative industries and the millions they employ.

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 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 recent 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.⁶ Finally, Internet-based piracy is particularly harmful because a single pirated file on Internet-based piracy platforms can be the source of literally millions of perfect copies—meaning massive, ongoing theft of creativity.

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 take action by foreign governments to address any Notorious Markets in their jurisdiction a top priority.

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 major examples include the provisions of 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

⁶ *Digital Bait*, Digital Citizens Alliance, December 2015

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.

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 has been an important step forward 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

It is important that the United States continue to work with foreign governments in order to promote the enforcement of existing international obligations, and the laws implementing them. 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.

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.”⁷ 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 to operate” therein.⁸ “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.”⁹

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. 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.

⁷ World Customs Organization Glossary of International Customs Terms. (2006, May). http://wcoomdpublishations.org/downloadable/download/sample/sample_id/123/

⁸ WCO Guidelines on Controlling Free Zones in Relation to IPR Infringements, Para. 2. (January 12, 2005).

⁹ *Ibid*

Transshipment

Overseas criminals and remote sellers ship counterfeit hard goods into the United States primarily 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.¹⁰ 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.¹¹

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 and 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

¹⁰ *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.

¹¹ The Association of Convenience & Petroleum Retailing. *Remote Sales of Tobacco* (Retrieved March 19, 2010). www.nacsonline.com/NACS/Government/Tobacco/Pages/RemoteSalesofTobacco.aspx.

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.¹²

Since our previous submission, the issue of counterfeit shipments in Express and Mail has continued to fester and has become an increasing concern, as noted by the U.S. Customs and Border Protection, the World Customs Organization¹³ and the U.S. Intellectual Property Enforcement Coordinator.¹⁴ 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 is 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.

We recommend an approach to combat the problem in the United States by:

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 any years now. The HMRC has strategically redeployed additional HMRC staff to postal depots in the form of tactical Anti-Illicit Trade

¹² 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").

¹³ 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

¹⁴ 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-ipeec-joint-strategic-plan.pdf>

Teams. This approach continues to show sustained enforcement success.¹⁵ 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.

USTR's 2011 Special 301 Report noted that, "important elements of a deterrent enforcement system include requirements that pirated and counterfeit goods, as well as materials and implements used for their production, are seized and destroyed."¹⁶ 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.

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.

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

¹⁵ HM Revenue & Customs. www.hmrc.gov.uk.

¹⁶ Office of the United States Trade Representative. (2011). 2011 Special 301 Report, p. 11.

comprehensive strategy to protect and promote intellectual property.¹⁷ We are encouraged by the proactive work of Mr. Daniel Marti in his role as IPEC and we further encourage the Administration and Congress to authorize IPEC with the requisite authority, staff, and budget to achieve effective intellectual property protection. 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. business 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. In addition to adding resources to the IP Attaché program, the Chamber is supportive of making sure our Attaches have the appropriate titles and ranks so they may more effectively reach and engage with the decision-makers on IP in their respective jurisdictions.

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

¹⁷ Office of the Intellectual Property Enforcement Coordinator. Executive Office of the President. (2010, June). *2010 JOINT STRATEGIC PLAN ON INTELLECTUAL PROPERTY ENFORCEMENT*, pg. 2.

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 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 exceptions 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. Many who have been advocating for expanded exceptions and limitations have been quite clear in opposing the basic foundation of all intellectual property protection.

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). Certain Committees in the OECD, in particular, seem to have developed a bias against intellectual property, which is very alarming. These forums provide important opportunities to engage like-minded partners and emerging powers to ensure the development of strong intellectual property frameworks that drive innovation.

Argentina

U.S. industry remains concerned about a number of IP areas in Argentina, particularly in the pharmaceutical IP space. It is important to note, however, that the Chamber is encouraged by election of a new president in Argentina in December 2015 whose administration has already demonstrated a willingness to address challenging bilateral issues such as those detailed below. The Chamber encourages the U.S. government to work with the new Argentinian government to seek remedies for the following areas of concern, as laid out by the GIPC Index.

Patents and Related Rights

Patentability Requirements: In 2012, Argentina released Guidelines for the Examination of Patent Applications on Pharmaceutical Inventions. The guidelines restricted the requirements for the patentability of pharmaceutical inventions, including making second-medical-use patents unavailable. The guidelines also added additional patentability criteria for pharmaceutical and agrochemical patents which go beyond the novelty, inventive step, and industrial application requirements under the TRIPS agreement. Furthermore, in 2015, Congress considered a proposal to link approval of pharmaceutical patents to wider public health objectives that would go beyond a decision from the Argentinian patent office, Instituto Nacional de la Propiedad Industrial (INPI), and include the opinion of the Ministry of Health. INPI also continues to suffer from major patent backlogs. Consequently, companies face significant challenges securing and enforcing their patents for biopharmaceutical and biotech inventions. The Chamber encourages the U.S. Government to work the Argentinian government to ensure that patentability requirements in Argentina do not discriminate against any specific sector of the IP industry and that the requirements meet Argentina's obligations under TRIPS.

Patent Enforcement/Injunctive Relief: Argentina does not have an effective patent enforcement and resolution mechanism. Under Article 83 and 87 of Law No. 24,481 preliminary injunctions are available to rights holders as a means of patent enforcement during the course of an infringement trial. In practice, however, rights holders report that despite these provisions they are typically unable to obtain injunctive relief in a timely manner during the course of

infringement proceedings. The Chamber recommends that the U.S. government work with their Argentinian government counterparts to create a more effective patent enforcement mechanism to ensure that all industry can protect and defend their innovations in the market.

Regulatory Data Protection: Argentina does not currently provide for regulatory data protection. Law No. 24,766 specifically provides no period of protection and does not define what characterizes “dishonest use” of data. Because the legislation does not explicitly protect against unfair commercial use, the law is inconsistent with Argentina’s obligations under Article 39.3 of TRIPS. The U.S. Chamber recommends the U.S. Government collaborate with their Argentinian government colleagues to ensure that Argentina fulfill its international obligations under the TRIPS agreement in order to maximize the protection for pharmaceutical IP in the market.

Patent Application Backlog: The Argentinian patent office (INPI) continues to suffer from a significant patent backlog. Industry reports that it takes, on average, eight to nine years to receive a patent. The U.S. Chamber recommends that the U.S. government work with the Argentinian government to examine best practices for patent examiners and discuss the implementation of a Patent Prosecution Highway to expedite patent approval times moving forward.

Copyrights and Related Rights

ISP Liability: Argentinian law does not have any specific provisions on ISP liability relating to online piracy, nor are any notice and takedown requirements in place. Courts tend to take the position that an ISP can only be found liable for online infringement if it has acted with “malice or negligence.” Currently, industry notifications receive very little response from ISPs. Rights holders must approach the court for a formal injunction in order to prevent online copyright infringement. However, recourse through the courts is often poor. While some ISPs have special procedures for processing rights holder claims, others still require a judicial order before taking any action. A draft bill addressing ISP liability was submitted to the Argentine Congress in March 2013, but provides only a partial solution. Under the proposed measure, ISPs would be held liable for infringing content if they have knowledge and do not remove access to it, however

such knowledge must be based on a court order and not merely on notice from rights holders. The Chamber encourages the U.S. government to urge their Argentinian counterparts to institute effective and timely mechanisms to combat online copyright infringement.

Online Piracy: Digital piracy remains a major threat to the copyright industries. Additionally, local industry reports that the Argentinian media frequently refers to pirates as entrepreneurs, further underscoring the need for educational initiatives on the detrimental effects of piracy to Argentinian innovators. Illegal operation of cyberlockers, P2P file sharing and direct downloads remain the major infringement methods used. Software piracy continues to be quite high, with no improvement or change in the overall situation. Argentina also suffers from a lack of adequate resources and support (for example, special police crime units dedicated to online piracy) for the enforcement of copyrights pertaining to the online sphere. The U.S. Chamber suggests that the U.S. government collaborate with the Argentinian government to strengthen the measures available to combat online copyright infringement.

Unlicensed Software Use: Software piracy throughout Argentina remains high. The BSA's Global Software Survey found that 69% of software in Argentina was unlicensed, the commercial value of which was estimated to be \$950 million USD. The Chamber recommends that the U.S. government work with the Argentinian government to introduce effective measures to combat both online piracy and unlicensed software use.

Enforcement

Ineffective Enforcement: Key gaps in Argentina's criminal enforcement regime present challenges for innovative industries seeking to defend their IP in the market. Argentina has in place a basic framework for civil remedies and criminal standards. The Civil Code provides for damages in general but with no specific reference to IP rights, and injunctive relief is available in certain areas (for example, trade secrets, patents, and utility models). Preliminary measures are executed quickly in specific areas such as software; however, in many cases, especially in relation to pharmaceuticals, the process is still drawn out. Criminal courts are directing some focus to physical and online counterfeiting and piracy. Argentina's criminal enforcement regime,

however, still suffers from non-deterrent or slow judgments, with courts often assigning the minimum penalties provided for in the law, not including penalties at all in the judgment, or postponing the judgment. These deficiencies in the court system are due to inadequate human resources and poor infrastructure as well as a culture of viewing criminal penalties as mere formalities in cases of IP infringement. The U.S. Chamber recommends that the U.S. Government collaborate with the Argentinian government to share best practices in enforcing against IP infringement in order to more effectively protect innovative companies' IP in Argentina.

Australia

Australia is the highest-income country included in the U.S. Chamber's 2016 Special 301 Submission. The sheer size and scale of the Australian economy amplifies intellectual property deficiencies and greatly affects ability for American companies to operate and innovate within the Australia.

In a few cases, Australia appears not to have implemented some aspects of its IP obligations under the Australia-U.S. Free Trade Agreement (AUSFTA). Details of which are delineated below and in full in the GIPC-Covington and Burling 2015 study "Trading Up," which assesses implementation of intellectual property rights included in FTAs with select U.S. trading partners. Furthermore, ten years since the entry-into-force of AUSFTA, Australia concluded another major trade pact which advances intellectual property rights with the United States, this time embodied in the regional Trans-Pacific Partnership (TPP) Agreement.

In conjunction with moving forward with making necessary changes to its IP system through to come into compliance and implementation of the TPP, 2016 also marks a year-long wholesale review of the Australian intellectual property environment, which was introduced by the Productivity Commission in September 2015. The U.S. Chamber welcomes this review and encourages Australia to fully embrace a high-standard, 21st century intellectual property framework which incentivizes innovation and creativity.

Patents and Related Rights

Patentability Requirements: In 2015, the Australian High Court reversed the 2014 ruling of the Federal Court that had upheld the patentability of isolated genetic material in *D'Arcy v. Myriad Genetics*. In the decision, the Court found that isolation of genetic material does not constitute an inventive step since it considered that the protected substance – the genetic material – is essentially the same information as in its natural form. This decision weakens the patentability of biotechnology and diagnostic-related inventions. In addition, the IP office reports a decrease of patent applications in 2014 compared to 2013 of around 13%, particularly among innovation patents (with a near 10% drop).

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 patent¹⁸. 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.”¹⁹ 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.

Market-Sized Damages: In addition, the Australian government currently has a practice of pursuing inordinately high damages in the event an injunction is granted but the patent is later invalidated, without apparent distinction between bad faith and good faith efforts to enforce the patent. For example, in one recent case the government intervened to seek AUD 450 million in damages after a patent was invalidated despite the fact that the trial court originally found the patent valid. In practice, patent holders may be deterred from making use of available

¹⁸ 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

¹⁹ Id. at 143.

procedures, even when there is a good faith basis for their belief that they have a valid patent. The U.S. Chamber urges Australia to strengthen its notification system for patent holders and provide guidelines for damages for patent adjudication.

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. This 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. Additionally, the Chamber notes Australia’s ambition to further develop its domestic pharmaceutical industry as a matter of priority attention, as well as the proposal to create a A\$20Billion Medical Research Fund to help Australia achieve even greater international prominence as a center for medical search and (presumably) pharmaceuticals development. 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.

Copyrights and Related Rights

Safe Harbor: On December 23, 2015 Australia’s Department of Communications and the Arts released an Exposure Draft of the Copyright Amendment (Disability Access and Other Measures) Bill 2016 for public comments by February 12, 2016. Among the proposed changes are draft provisions that would allow for search engines, universities and libraries to obtain 'safe harbor' protection if they comply with conditions aimed at reducing online copyright infringement, concepts to which industry groups have previously opposed.

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.

Enforcement

Effective border measures: Under the Copyright and Trade Marks Acts, customs officials are not given *ex officio* authority to act against goods they suspect of infringement; a rights holder must first submit a notice objecting to the importation of infringing goods before an official may detain or suspend the goods. With a notice from the rights holder, officials are authorized to seize a certain type of good in transit, “transshipped goods;” other types of in-transit goods are not officially subject to seizure. This is because transshipped goods remain under customs control while being shipped through Australia to other destinations, and are therefore subject to seizure if a notice of objection is in place and the rights holder can demonstrate that the goods are infringing. Although the Raising the Bar Act of 2012 introduced amendments to strengthen custom action, no specific amendments relate to the *ex officio* actions of customs officials. Further, the TPP Agreement will require Australia to fully implement *ex officio* authority.

Given the reported increase in the number and quality of imported counterfeit goods in circulation in Australia, the U.S. Chamber urges Australia to grant customs official *ex officio* authority to better equip them with the tools necessary to effectively enforce IP laws against counterfeiting.

Brazil

In recent years, both the Brazilian private sector and government have increasingly recognized the role that strong IP protections and enforcement standards play in fostering innovation, stimulating economic growth, and attracting foreign investment in Brazil. The U.S. Chamber is particularly encouraged by the appointment of a new head of the National Industrial Property Institution (INPI), Luiz Otavio Pimental, who fully understands the critical link between IP and innovation in Brazil. Further, 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 Approval Delays: Industry continues to report extensive patent approval delays – as long as 13 years – with Brazil's patent office, INPI. Brazil faces challenges training and retaining patent examiners, and the INPI is unable to hire new examiners due to budget constraints. However, the National Confederation of Industry (CNI) reported that the growth rate of the patent backlog has slowed over the last four years. The backlog grew by six percent in 2014, down from an eleven percent growth in 2013²⁰. The Chamber believes the new President of INPI is cognizant of the need to reform the organization, expedite the patent approval process, and further address the patent backlog. The U.S. Chamber supports the recently signed Patent Prosecution Highway (PPH) pilot program to expedite patent applications in the oil and gas sector by utilizing search and examination results from PTO reviews of similar patent

²⁰ Federation of Industries of The State of São Paulo and National Confederation of Industry. 2015 Special 301 submission, pg. 7.

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.

Dual Patent 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. The interpretation of Article 229-C as creating a dual examination system for pharmaceutical patents is inconsistent with Brazil's obligations under Article 27.1 of TRIPS, and leads to further delays and uncertainty in patent applications. We believe 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).

Patentability: Industry is also concerned with the pending patent reform initiative, which emulates many of the troublesome requirements of India's section 3(d), which adds an additional requirement for patentability. Provisions in the reform initiative would narrow patentability criteria and disallow patents for new uses or new forms of known substances unless a significant improvement to the known efficacy is present. In addition, there have been suggestions to repeal the 10-year minimum patent period guarantee which is in place to safeguard innovators for the long delays and backlog at INPI and reduce an innovators' exclusivity period to a fraction of the 20-year period. If enacted, these reforms would significantly weaken Brazil's patent environment. In order to create an environment which fosters pharmaceutical innovation and attracts biomedical innovation, the Chamber urges the U.S. Government to collaborate with the Brazilian government to update the pending initiatives to adequately protect the patentability of all pharmaceutical innovations.

Regulatory Data Protection: Brazilian law does not currently provide regulatory data protection (RDP) for 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 use innovations in order to prevent ANVISA from utilizing the innovator's data for a period of time.

Technology Transfer Agreements: 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.

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. In particular, the growth in broadband use has accelerated the expansion of piracy of copyrighted works to the Internet, which is stunting the development of a legitimate marketplace. 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 the implementing regulations of Brazil's Internet Law (Marco Civil) do not prevent an intermediary from taking measures to address infringing activity conducted over its networks.

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. Industry reports suggest that, while initially successful,

the CNCP initiative has become largely inoperative over the last three years. Additionally, while the Rio de Janeiro and Recife IP police led several enforcement efforts, Customs and Border Protection officials have largely reduced their focus on anti-counterfeiting enforcement throughout the rest of the country. The U.S. Chamber strongly encourages the U.S. government to collaborate with the Brazilian government colleagues to ensure that previously success initiatives, like those of the CNCP, have the resources and local government support to more effectively combat hard goods 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. Additionally, in November 2015, Brazilian law enforcement undertook "Operation Blackbeard," which resulted in the shutdown of notorious infringing site megafilmeshd.net (which previously had an Alexa ranking in Brazil of 44). We hope the good result in this case will lead to increased federal law enforcement investigation of online piracy in Brazil. However, industry reports that these initiatives need sustained and increased resources, including dedicated personnel with a clear and defined mandate that includes particular actions to be taken against which the personnel will be reviewed, 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 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 which 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 51,656 advertisements, links, or websites which hosted copyright-infringing content²¹. However, unlicensed software use still accounts for 50% of all software use in Brazil, according to the BSA Global Software Survey. The U.S. Chamber recommends that the U.S. government collaborate with the Brazilian government to introduce more effective 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. 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: 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 successfully rely on this legislation and their special treatment from the INPI to protect their trademarks and IP rights before and

²¹ Federation of Industries of The State of São Paulo and National Confederation of Industry. 2015 Special 301 submission, pg. 15.

during the tournaments. Given the success of the legislation at helping to protect registered marks, the U.S. Chamber encourages the U.S. government to work closely with the Brazilian government to ensure that similar legislation is passed ahead of the 2016 Olympics.

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 20-year old agreement and Canada's implementation thereof has remained a concern for industry.²² Thus, as the U.S. Chamber Index demonstrates, Canada's IP climate remains behind other developed countries. The recent conclusion of the Trans-Pacific Partnership (TPP) agreement, once ratified and implemented, presents an opportunity to strengthen its IP framework, and the U.S. Chamber stands ready to work with both the U.S. and Canadian governments to ensure the legislations is passed into law.

The Chamber encourages the U.S. Government to work with their Canadian counterparts to address the following areas of concern which, in turn, will help further U.S. and Canadian global competitiveness.

Patents and Related Rights

While we acknowledge progress on some topics, patent protection in Canada lags significantly behind the protection provided in other developed countries, as evidenced by the U.S. Chamber Index. The Government of Canada recently amended the PM (NOC) Regulations to address recent jurisprudence which held that an innovator cannot list a patent claiming a single medicinal ingredient of a Fixed Dose Combination (FDC) product on the Patent Register. These judicial interpretations were contrary to Health Canada's long standing policy, as set out in the Health Canada Guidance Document, which explicitly allows for such a practice. These amendments restore certainty with respect to the listing criteria for patents on FDC products, which otherwise would not have been eligible to obtain the benefits of the PM (NOC) Regulations.

²² Global Intellectual Property Center. *Trading Up: The Evolution and Implementation of Intellectual Property Rights in U.S. Free Trade Agreements*, at 12-13 (2015). <http://www.theglobalipcenter.com/wp-content/uploads/2015/01/Trading-Up-Final3.pdf>

Notwithstanding these developments, the Chamber has the following key areas of concern in the patent space in Canada.

Patent Utility: Canadian courts have recently applied a heightened standard for patent utility by imposing a subjective patentability test on inventions, which represents a significant erosion of the patent right. This unique test is accompanied by a heightened evidentiary burden, requiring innovators to demonstrate the effectiveness of a pharmaceutical in light of the court’s subjectively construed “promise” and raises uncertainty as to how much information needs to be disclosed in patent applications. 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 27 decisions, leading to the revocation of 24 patents on the grounds of inutility²³, 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 use of this heightened standard will significantly affect the growth of Canada’s innovative environment, which in turn affects Canada’s economic growth and global competitiveness. Recent data included in the annex to the U.S. Chamber Index found that Canada ranks significantly behind other developed countries in terms of its level of high-tech outputs, as measured by the Global Innovation Index’s Innovation Output Sub-Index.²⁴ This gap in the growth of high-tech sectors, as compared to countries of similar levels of economic development, may be due to key gaps in patent protection in Canada’s system, including the application of the patent utility test. The U.S. Chamber urges the U.S. Government to work with their Canadian government counterparts to introduce a legislative fix so that Canadian courts can no longer administer this subjective standard during judicial proceedings.

²³ U.S. Chamber of Commerce. (2016). U.S. Chamber International IP Index: *Infinite Possibilities*.

²⁴ Global Innovation Index, 2014.

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 recently released text of the Comprehensive Economic and Trade Agreement (CETA), if ratified and implemented, would introduce an effective right of appeal for patent holders before generic entry into the marketplace. However, effective regulatory implementation of the legislation will be critical to ensuring that the IP standards included in CETA will be truly effective. Industry looks forward to the release of the implementing regulations to ensure that the regulations do not undermine the legislation's original commitments.

In a further positive step, in June 2015, we are 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. More broadly, the Chamber encourages the Canadian government to promptly ratify and implement CETA as the legislation would strengthen Canada's innovative environment framework.

Patent Term Restoration: Canada's IP environment would also improve significantly with the implementation of patent term restoration (PTR), which provides additional patent life to compensate for the time lost during the clinical trials and regulatory approval process. While CETA would provide sui generis protection through a separate and independent term of protection, the PTR would only be two years. However, many other developed nations, including the United States, European Union, and Japan, provide a five-year term 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 type of a 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 would provide a positive first step toward establishing a fulsome 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.

Regulatory Data Protection: Canadian law currently provides for eight years of regulatory data protection (RDP) for both small molecules and biologics, with an additional six months for pediatric indications. However, 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 to 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 (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 and further ratify the CETA agreement.

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 a positive step towards bringing the Canadian term of protection for copyright in line with the highest international standards. The Chamber encourages the Canadian government to further extend the term for all copyrighted works to at least 70 years, as required by the TPP.

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.

Finally, the Chamber also believes that the following changes to Canada's copyright system would significantly strengthen the IP environment: 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..

Trademarks

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. The introduction of such a measure 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, and setting a negative precedent for intellectual property policy.

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 CEO of the Canadian Intellectual Property Office (CIPO) recently announced that the amendments will not be implemented until 2018. The Chamber recommends that the Canadian government works to seek accession to these agreements.

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 in 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 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.

Chile

Chile is currently party to two free trade agreements (FTAs) with the United States: the 2004 United States-Chile FTA (Chile FTA) and the recently concluded (and yet-to-be enacted) Trans-Pacific Partnership (TPP) Agreement. In both pacts, Chile has agreed to enhance its intellectual property system. However, in the case of the Chile FTA, the country has yet to meet the majority of the IP standards it had committed to, creating challenges for U.S. knowledge-intensive industries doing business in-country. Chile's performance vis-à-vis its FTA obligations is also covered at length in the GIPC-Covington and Burling 2015 study "Trading Up."

Patents and Related Rights

Chile is currently undertaking reforms to its Industrial Property Law. A new draft was under discussion in 2015, although not yet released publicly. Similar to previous drafts of the amendments, the new draft law also reportedly contains provisions that would strengthen the enforcement of pharmaceutical patents, as well as the ability to obtain injunctions. Positively speaking, the amendments are also aimed at streamlining opposition procedures for patents and opportunities for appeals, and negatively, would place limits on additions to patent applications.

Patentability Requirements: The Chile FTA requires Chile to make patents available for inventions that are new, involve an inventive step (are non-obvious), and are capable of industrial application (useful).

Chilean law sets out these three requirements for patentability. In practice, however, there are concerns that Chile has modified the standard required by the FTA by applying a heightened standard for non-obviousness. Specifically, in the area of pharmaceutical patents, Chile requires major structural differences between a claimed compound and previously existing compounds, even where the technical solution in the new compound is not part of the prior art. While other countries may treat structural similarities as presumptively indicating obviousness that requires some showing to overcome, Chilean law goes further in appearing to erect an absolute bar to patentability in the case of structural similarity.

Another practical obstacle to full implementation of Chile's FTA commitments is the difficulty in obtaining a patent within a reasonable timeframe. Applicants for pharmaceutical patents have observed that wait times have averaged eight years; this delay has been improved, but is still approximately five years. Such significant delays indicate that patent protection may sometimes not be available in a meaningful sense.

Chile has implemented the non-obviousness standard in a way that may restrict patentability in cases in which the three-part test, as ordinarily understood, is met. Moreover, the practical obstacles facing patent applicants conflict with Chile's obligation to make patents available as long as the prescribed standard is met. The U.S. Chamber urges Chile to fully implement its FTA IP commitments.

Patent Linkage: The Chile FTA requires Chile to implement a system of patent linkage. Specifically, Chile is obligated "to make available to the patent owner the identity of any third-party requesting marketing approval" during the term of a patent, and to "not grant marketing approval to any third party prior to expiration of the patent term" without consent of the patent owner.

In 2004, the Health Ministry adopted Resolution 5572 stating that it would publish a list twice a month of registrations being sought and indicating whether it is similar to another product. The resolution also provides for email notification to patent holders. However, this Resolution as implemented has been widely regarded, including by USTR, as failing to establish an effective patent linkage system.²⁵ In addition to delays in notification in practice, the Resolution does not include any mechanism for ensuring that marketing approval is not granted when there is a valid patent in place. While Chile has claimed that the availability of ordinary infringement remedies

²⁵ Michael B.G. Froman, USTR, 2014 Special 301 Report, at 44, <http://www.ustr.gov/sites/default/files/USTR%202014%20Special%20301%20Report%20to%20Congress%20FINAL.pdf>.

satisfies this obligation²⁶, burdensome post-approval remedies are insufficient to satisfy Chile's commitment not to grant marketing approval in the first place.

In recognition of the shortcomings of current regulations, the Chilean government has introduced a bill to create a new patent linkage system. The goal of the bill is to improve the transparency of the approval process and to provide better information on the patents affected by new applications for approval. Moreover, the bill would provide for a 12-month automatic stay of regulatory approval. The bill has survived a pre-enactment challenge in the Constitutional Court, but is not expected to pass in the near term.

Regulatory Data Protection: The Chile FTA obligates Chile to ensure that, for a period of five years, a third-party applicant may not rely on an innovator's undisclosed safety and efficacy data submitted in support of the innovator's application for marketing approval of a pharmaceutical product. This protection applies to a product which utilizes a new chemical entity, which product has not been previously approved.

Chilean law provides that "undisclosed test data or other information regarding the safety and efficacy of a pharmaceutical which utilizes a new chemical entity" may not be "disclose[d] or utilize[d]" to grant sanitary registration to a product without consent for a period of five years.

However, there is a potentially significant exception under which data protection can be denied based on "reasons of public health, national security, non-commercial public use, national emergency or other circumstances of extreme urgency," or if the product is subject to a compulsory license.²⁷ The expansive set of exceptions are not contemplated by the FTA and, depending on how they are implemented, provide the potential for circumventing its requirements.

²⁶ Inside U.S. Trade, At FTA Comm'n, U.S. Presses Chile on Brand Name Drug Protections(Aug. 25, 2011), <http://insidetrade.com/Inside-US-Trade/Inside-U.S.-Trade-08/26/2011/at-fta-commission-us-presses-chile-on-brand-name-drug-protections/menu-id-172.html>.

²⁷ Law 19,039 (Chile) art. 91; Supreme Decree No. 107/08, Diciembre 1, 2010 (Chile).

Furthermore, five years of data protection 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. The U.S. Chamber recommends that Chile close the overly-broad exceptions to regulatory data protection.

Discrimination Based on Field of Technology: The Chile FTA requires patents to be available for any invention under the patentability requirements “in all fields of technology,” creating a non-discrimination rule. Chile’s patent law specifically excludes from patent protection all “systems, methods, economic, financial, or commercial plans and principles.”

While not explicitly addressed to software inventions, this exclusion has been interpreted as a categorical restriction on the patentability of computer-implemented inventions.²⁸

The heightened requirements for establishing non-obviousness for a pharmaceutical patent, discussed above, also appear to discriminate against the pharmaceutical industry. The U.S. Chamber recommends that Chile employ a system which does not discriminate against certain fields of technology.

Copyrights and Related Rights

Piracy: Piracy remains a major challenge in Chile. According to estimates from the European Trade Commission, the content industry annually loses around 35% in revenues to piracy in Chile. Particularly problematic areas include illegal streaming and satellite signal piracy and retransmission, with open signals and new technologies for accessing them increasingly available in the region and little redress possible through the existing legal framework. The local journalism organization, AIPEF Chile, estimates that pirated content and services represent 7%

²⁸ Marino Porzio, *Chile*, Latin Lawyer (Apr. 7, 2014), <http://latinlawyer.com/reference/topics/52/jurisdictions/3/chile/>; World Intellectual Prop. Org., Intellectual Prop.&Socio-Econ.Dev. Country Study Chile, at 10 (2013) http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_11/cdip_11_inf_4.pdf

of the paid-TV market, which though seemingly low, leads to losses of around \$66 million annually and a drop in market growth of around 2-4% year-on-year. Circumvention devices are also widely available online and in brick and mortar marketplaces. The U.S. Chamber urges Chile to direct enforcement attention and resources towards combatting online piracy and eliminates the availability of circumvention devices.

ISP Liability: Chile’s notice and takedown procedure does not meet the requirements of its FTA with the U.S. In particular, ISPs are only required to remove infringing content upon having “effective knowledge” (defined as notice by a court, not simply from a rights holder). In light of the fact that the rate of prosecution is low, the operation of the takedown system is significantly undermined. Law No.20,435 introduced a voluntary system under which ISPs are to forward notices from rights holders to suspected infringers. The recording industry has recently reported improved cooperation with major ISPs in Chile in relation to the voluntary system, however, the fact remains that there are no consequences for ISPs or users that fail to act after acquiring the requisite knowledge of an infringement outside of a court order. The U.S. Chamber recommends that Chile fully implement its FTA IP commitments and introduce a meaningful notice-and-takedown system for copyright infringement.

Technological Protection Measures: The Chile FTA requires Chile to provide for liability for any person who knowingly circumvents TPMs, or who manufactures, imports, distributes, sells, or rents devices or provides services for the purpose of circumvention.

Chilean law lacks specific protections against circumvention of TPMs, including with respect to the acts of circumventing access controls and trafficking in devices. Companies report, moreover, that circumvention devices are sold freely in online and physical marketplaces in Chile.²⁹ The U.S. Chamber urges Chile to enact all of its IP obligations under the Chile FTA and specifically make the use and sale of circumvention devices illegal.

²⁹ Int’l Intellectual Prop. Alliance, Special 301 Submission Cover Letter, at 20 (2014) <http://www.iipa.com/pdf/2014SPEC301COVERLETTER.pdf>.

Government Legalization of Software: The Chile FTA requires Chile to issue appropriate laws, orders, regulations, or decrees to “actively regulate” the acquisition and management of software for government use, in order to confirm that agencies only use properly licensed software.

A Presidential Directive from 2001 requires government agencies to maintain licenses for all software products that they use. However, neither this order nor any additional order post-dating the FTA provides additional guidance or measures in order to “actively regulate” agencies’ use of software. Moreover, industry reports suggest that while some agencies regularly license their software and government expenditure on software licenses has increased, piracy continues to be a problem in government agencies. The U.S. Chamber recommends that Chile provide additional guidelines and resources to fulfill its FTA commitment to “actively regulate” the acquisition and management of software for government use.

Camcording: The Chamber urges Chile to strengthen its criminal laws against the unauthorized camcording of films in theatres. The U.S. and Canada, key trading partners in the TPP, recognize that unauthorized camcording is itself a crime. The Chamber encourages the U.S. Government to work with the Chilean government to strengthen the camcording law to allow for the criminalization of such acts.

Trademarks

Plain Packaging: A bill that would introduce plain packaging for tobacco products was approved by the Chilean Senate and the lower house of Congress may take up the measure in 2016. 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.

Trade Secrets and Market Access

While under Chilean law it is mandatory for biopharmaceutical and agrochemical companies to submit undisclosed, proprietary test data in order to obtain market authorization for new chemical entities, the existing Industrial Property Law does not provide sufficient guarantee that this data will not be shared with third parties or relied upon to approve other products. The U.S. Chamber urges Chile to adopt important safeguards to ensure that trade secrets like proprietary, undisclosed test data are not shared with third parties.

Enforcement

Civil and Procedural Remedies: Existing Chilean law provides criminal penalties for IP rights infringement. However, criminal penalties are quite low, and are typically what is sanctioned by courts. Prosecution of IP infringement is hindered by gaps in the legal framework and lack of resources.

The Chile FTA requires the availability of damages (including the infringer's profits) and the destruction of infringing goods as a remedy for infringement of intellectual property rights. Chilean laws governing trademarks, copyrights, and patents make available a range of civil remedies required by the FTA, including damages, injunctions, and the destruction of infringing goods. However, industry groups have reported that enforcing intellectual property rights in Chile is hindered by procedural obstacles, delays, and a lack of judicial capacity regarding complex intellectual property matters. Patent holders report difficulties in patent enforcement related to a lack of technical expertise. Software companies have expressed concern that *ex parte* search requests, intended to discover and destroy infringing goods, are made publicly available, providing advance notice of a search and thwarting the ability to secure a remedy. The U.S. Chamber recommends that Chile close these legal gaps that hinder the prosecution of IP infringement cases and increase educational programs to fill the gap of technical expertise on intellectual property matters.

Effective Border Measures: Law No.19,912 gives customs officials *ex officio* authority to detain goods entering Chile, but only for five days, after which a formal seizure order is required

to retain the goods. Such a short period limits the ability of customs officials to effectively assess whether goods are infringing and for rights holders to respond to customs notices of seized products. Rights holders report a need for greater resources devoted to customs operations and a better defined procedure for dealing with small packages containing infringing goods. Chile still requires a clear legal basis for detaining and seizing suspected transshipments. The U.S. Chamber recommends that Chile increase the time-frame that customs officials can detain goods as well as provide more resources to customs enforcement.

China

The Chamber continues to work closely with the Government of the People's Republic of China ("PRC" or "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 China's recent institutional reforms focused on intellectual property including the establishment of three specialized intellectual property courts and the publication of all intellectual property-related administrative penalty decisions. Pending amendments to the Copyright Law and the Patent Law also demonstrates China's continued efforts to protect the interests of the intellectual property rights owners. Throughout the legislative process, the relevant ministries and judicial authorities have demonstrated commitment to meaningful public participation and transparency.

At the same time, counterfeiting and piracy in China remain at epidemic levels, particularly in the online environment, and China remains the largest source of counterfeit and pirated goods in the world. According to a recent study of 38 countries, China is responsible for 72% of the global supply of counterfeit goods with the next largest supplier at less than one percent. This situation continues to undercut the job growth that results from innovation, stands contravene to market order in China and endangers consumers in China, the United States, and around the world. Critical inventions made still lack sufficient protections in spite of an active reform agenda in China.

We were encouraged by the commitments from the 2015 Strategic and Economic Dialogue (S&ED) and some moderate gains at the Joint Commission on Commerce and Trade (JCCT) to address intellectual property-related issues. China's commitment that trade secrets submitted to the government in administrative or regulatory proceedings are to be protected from improper disclosure to the public and only disclosed to government officials in connection with their

official duties in accordance with law. We also welcomed China agreeing to study how to strengthen confidentiality protection measures, limiting the scope of government personnel having access to trade secrets, limiting the information required from companies to include only information reasonably necessary for satisfying regulatory purposes, and stipulating that any requirements on government agencies to publicly disclose information appropriately allow for the withholding of trade secrets. We are hopeful that these outcomes will improve the protection of companies' confidential business information. The Chamber recommends continued monitoring of 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 and drive innovation that favor domestic champions and create barriers for foreign companies to compete with domestic Chinese counterparts in the marketplace. The Made in China 2025 plan—a 10-year blue print to improve China's manufacturing competitiveness—is 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. Other examples of this include indigenous innovation accreditation; continued government-led standard setting that often excludes foreign parties from participation and sets standards that are inconsistent with international standards to the detriment of consumers; and forced or coerced technology transfer and licensing policies by local administrative authorities. Separate from the discriminatory application of innovation policies, critical concerns surround the arbitrary patentability standards in rejecting or invalidating pharmaceutical patents; the large presence of low- or no-quality utility model patents; China's draft service invention regulations; and China's continued lack of effective trade secret protection.

MOFCOM Import-Export Rules: China's Ministry of Commerce (MOFCOM) Technology Import-Export Administrative Regulations 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 liable for infringing 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. Moreover, with respect to foreign licensors, it is unclear whether the regulations are applicable only to the assignment of patents and the right to apply for patents or are broad enough to cover all technical information communicated across the Chinese border. 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

Impact of Fourth and Fifth Plenum: The Chamber welcomed details from China's Fourth Plenum of the 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, Reporting and Responsibility of Leaders Intervention of Judicial Activities and Interference with the Handling of Specific Cases*, 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.

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 is developing new mechanisms to publish guiding cases. We note that hiring technical assessors can help in adjudicating complex patent cases although more time will be needed to evaluate the efficacy of the technical investigators. Moreover, the Chamber 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 and hope court disclosure will become a normal procedure.

The Chamber also notes that the court has a fast growing caseload, especially those of non-patented cases. The very purpose of the intellectual property court may be somehow compromised as these courts at intermediate court level have no power to render final judgments in high-stake cases, including those judiciary reviews of PRB and TRAB decisions. We have heard that there are discussions about elevating the IP courts to appellate level courts. 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 Revision: The new Trademark Law as amended in 2013 entered into effect officially in May 2014. The real benefits of the new Trademark Law remain to be seen. The long-awaited Supreme Court's Trademark Judicial Interpretation is still pending. The Chamber has 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.³⁰

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.³¹ 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. However, foreign brands also became unfortunate victims. For example, New Balance was sued by a party which allegedly registered the Chinese transliteration of New Balance and the local court in Guangzhou punished New Balance with an award up to 98 million in Renminbi. This was the highest award in the court's history. The Chamber will closely monitor the situation.

Bad Faith Trademark Registrations: China's recent amendments to its Trademark Law increase the risk that brand owners will be held hostage to pirates registering marks in bad faith. For example, under the amended law, if a brand owner opposes a preliminary approved mark and loses, the mark will be immediately registered; only a cancellation proceeding before the Trademark Review and Adjudication Board (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

³⁰ 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>

³¹ 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>.

faith registrant may also be able to take enforcement action against the brand owner's own use of the trademark.

Enforcement: China appears to maintain a similar level of active enforcement efforts against counterfeiters in 2015, but the 2015 official statistics have not yet been released.³²

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 national police have shifted focus on cross-border enforcement actions against major counterfeit drug makers, which have made marked achievements in 2014.³³ We welcome an update on similar statistics for 2015. The Chamber wishes that the national and local police keep investing more dedicated police officers in the intellectual property crime unit and, 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.

³² Complete data for 2015 is not available as of this writing. The available data is noticeably more limited than previous years. In 2014, China reported that a total of 13,905 individuals were convicted in 10,803 cases. Such data is similar to what happened in 2013, where 10,566 suspects were convicted. <http://www.court.gov.cn/zixun-xiangqing-14207.html>.

³³ The official report states that the MPS has been successfully coordinating with Interpol in cross border actions. In August 2014, the MPS coordinated the police teams in 6 provinces in large scale raid actions against counterfeiters, netting 2,224 suspects in 1,544 cases. The national police also reportedly cracked down drug counterfeiters in 7,078 cases in Jan-October 2014. <http://www.ipraction.cn/article/xxgk/gzdt/bmdt/201412/20141200039449.shtml>

The number of criminal transfers seems to remain low.³⁴ 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.

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: Despite the gradual increase of enforcement, 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 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.

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 welcome by the Chamber.

³⁴ It was reported by the SAIC that in the first half of 2015, 126 cases were transferred to criminal investigation out of nearly 23,900 cases that the AICs opened up for investigation in China. <http://finance.people.com.cn/n/2015/0827/c1004-27524116.html>

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.

Patents and Related Rights

Patent Linkage: China is now in the process of amending its Drug Administration Law. This provides a very unique opportunity to examine some of the fundamental flaws in protecting pharmaceutical intellectual property rights.

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, thus eviscerating 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 has no reason not to explore the patent linkage mechanism.

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. However, there is various anecdotal evidence that the Chinese examiners have shifted their approach to increasingly rely on inventiveness grounds to reject targeted pharmaceutical patent applications. This has raised

very serious concerns to the Chamber. We are closely monitoring the developments and ask U.S. government to continue discussions on this issue with its Chinese counterparts.

Regulatory Data Protection: 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 DAL and DRR 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 draft 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 2016 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.

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 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.

Patent Protection and Enforcement: The latest proposed amendment to the Patent Law was issued by the State Council at the end of 2015.

The Chamber just submitted joint comments on SIPO’s draft Amendments to the Patent Law with the American Chamber of Commerce in China on SCLAO’s Amendments to the Patent Law in December 2015. The primary concerns in both drafts pertain 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 the 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 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 also to harass and burden competitors so as to impede their competitiveness and innovation capabilities in China.

Given all of the issues raised by the proposal to enlarge the power of administrative agencies, the Chamber urges USTR to work with SIPO and SCLAO to carefully consider all of the positive and negative implications of such authority before SIPO moves forward.

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 on 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.

We were pleased to see that SIPO amended its Patent Examination Guidelines in March 2013 to officially permit patent examiners to conduct patent searches to examine novelty of utility model application and design patent applications.³⁵ 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 working plan to implement the national IP strategy in 2015-2020. One of the new quantitative measures is the invention patent 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

³⁵ The official decision is at http://www.sipo.gov.cn/zwgg/jl/201311/t20131106_876947.html

in 2013 to 75,000 in 2020.³⁶ All these measures tie to filings without accounting for the quality or the issued or maintained patents. This raises a strong concern that the national or local governments may continue using subsidies to incentivize filings.

Again, the Chamber urges the Chinese government to reduce or eliminate government subsidies for design patent filings and mandate substantive examination of utility model and design patents prior to initiating litigation.³⁷ The Chamber also recommends that the inventiveness criteria for utility model patents be raised to the same level as invention patents. We also suggest conducting substantial examinations for utility model patents, in an effort to improve the quality of utility model 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.

Patentability of Graphical User Interface and Partial Designs: Last year, SIPO officially adopted new amendment to the Patent Examination Guidelines, which allowed the patentability of graphical user interface (GUIs) patents bringing China into alignment with international best

³⁶ See http://www.gov.cn/zhengce/content/2015-01/04/content_9375.htm.

³⁷ 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

practices. While the Chamber strongly supports the changes, we remain concerned about the lack of a substantive examination for GUI design patents. This omission has the potential to lead to a similar situation as the utility model patent system, whereby many low or no quality patents are granted and frivolous lawsuits initiated by owners of junk patents over-inundate the courts. We are keen to learn how SIPO is planning to deal with such issues, especially given the fact that there may be very few prior art in the GUI field from China. The Chamber hopes that SIPO will actively carry out cooperation projects with other patent office's such as USPTO and the European Patent Office (EPO) with a focus on conducting effective prior art searches through international patent database. A cooperative relationship whereby SIPO may utilize the USPTO and EPO's databases to conduct prior art search would be extremely beneficial to upholding the quality and novelty of GUI design patents. Assisted by these patent searches, Chinese patent examiners will have more exposure on how to determine whether a GUI design patent application has patentability as required under the Patent Law. This increased level of scrutiny will hopefully decrease the number of issued patents that have quality issues and thus, increase the trust and confidence on the level of design patent quality.

Last year the Chamber noted that the amendments to the Guidelines for Patent Examination 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.

Inventor Remuneration

SIPO's draft service invention regulations are of great concern to industry in China. The draft regulations provide regulations on the ownership of inventions, the employment relationship, and the companies' commercialization of inventions. In partnership with AmCham China, the

Chamber provided detailed comments to SIPO on the measures in December of 2012 and in August 2014 and May 2015.³⁸

If implemented as drafted, the provisions in the draft regulations will negatively affect the ability of U.S. companies to make choices about how to commercialize intellectual property assets derived from their employees in China and will increase legal and financial risks. For example, under Article 19.2, the draft regulations could take away an employer's ability to contract around SIPO's default rules and replace the current autonomy that an employer has with extremely onerous regulations. Employers are also required to make a decision about how best to protect an asset very quickly, even if an invention has not been fully conceptualized by the inventor.

Although the Chamber is pleased to see that technical secrets included in previous iterations of Article 4 of the draft SIRs has been deleted. We note, however, that "know-how" is still referenced in article 24. 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.

³⁸ The U.S. Chamber of Commerce and the American Chamber of Commerce in China comments on SIPO proposed Service Invention Regulations:

<http://image.uschamber.com/lib/feed13797d6c06/m/1/Joint+USCC+AmCham+Comments+on+SIPO.pdf>

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.³⁹

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 provided detailed comments to the State Administration for Industry and Commerce (SAIC) in December 2012 on an unofficial draft of its intellectual property rights enforcement guidelines under the Anti-Monopoly Law (draft guidelines) and 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).⁴⁰ The Chamber also provided detailed comments to the National Development Reform Commission on its Questionnaire on the Proposed Antitrust Guidelines against Abuse of Intellectual Property in September 2015. In all of these documents, the Chamber stressed the importance of China's recognition that competition law authorities should view intellectual property rights as complementary to the end goal of promoting consumer welfare, not a threat to it, requiring special treatment under the Anti-Monopoly Law. The Chamber hopes that the antimonopoly enforcement agencies will agree with this universally held view among leading competition enforcement agencies and abandon plans to incorporate an "essential facilities doctrine" for intellectual property rights, and we urge USTR to track this process closely.

³⁹ 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

⁴⁰ 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

In our April 2014 submission on SAIC’s draft Rules, the Chamber acknowledged that while draft rules contain various improvements over the previous version of the draft guidelines, we have significant concerns, namely about Article 8 and Article 14. Article 8(2) would force dominant undertakings to license their intellectual property to those who could show access to such intellectual property was “essential” for them to compete in the relevant market because it cannot be practically avoided, and the refusal to license would cause an adverse impact on competition and innovation in such market. Such a broad expansion of the meaning of intellectual property abuse would undermine Chinese innovation that produces dominant domestic companies. Article 14 implies that SAIC would deem it an abuse of intellectual property for an undertaking with a dominant market position to send an infringement assertion letter to someone whose conduct “obviously” does not constitute infringement of intellectual property rights. This standard is too difficult to apply.

In addition to the apparent questions about their legitimacy, the chilling effects of the draft rules and circulation of draft guidelines must be fully taken into account. The antitrust-related intellectual property issues are complex and require sophisticated analysis. More importantly, from a regulatory perspective, the industries need clear guidelines that apply to all three AML agencies in China, not just SAIC. The Chamber urges close consideration of all possible impacts these proposal could have on competitiveness and innovation. The Chamber also looks forward to engaging the Chinese government on upcoming revisions to China’s Anti-Monopoly Law, which was listed as a preparatory project in the State Council’s 2015 Legislative Plan.

As one of the three AML agencies in China, China NDRC appears to take a leading role in the making and enforcement of IP related antitrust rules. Currently there seems to be a lack of transparency and clear standards with regard to many related issues. While NDRC issued the draft IP Abuse Antitrust Guidelines (the “draft Guidelines”) on Dec 31 2015, NDRC only allowed a very short period of time (20 calendar days) for public comments. Since the draft Guidelines will likely be considered departmental measures, they may be approved without being required to seek public comments for a second time. It is noted that the underlying financial implication of an IP abuse antitrust violation by a large global company could often be

astronomical. We urge NDRC to allow additional opportunities and longer period of time for global industries to provide inputs and comments before finalizing the draft Guidelines.

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).⁴¹ The Chamber submitted comments to SAC on the previous draft version of the Standards Measures in January 2013.⁴²

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

⁴¹ See official release at http://www.sipo.gov.cn/zcfg/flfg/zl/bmgfxwj/201401/t20140103_894910.html

⁴² The U.S. Chamber of Commerce submitted comments to SAC in January 2013 on SAC Draft Administrative Rules on National Standards Involving Patents (Interim)

<http://image.uschamber.com/lib/feed13797d6c06/m/1/Chamber+Comments+on+SAC+Rules+engch.pdf>

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 technology 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”). 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 after Chinese New Year. 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 Draft 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.

Trade Secret Protection

The protection of trade secrets in China remains quite challenging. Some news reports indicate draft amendments to the Anti-Unfair Competition Law support improved trade secret protection and enforcement at the administrative level and at the November 2015 U.S.-China Joint Commission on Commerce and Trade, China declared its intention to clarify rules on preliminary injunctions, evidence preservation orders and damages. However, this draft amendment has not yet been made public. Additionally, damages for trade secret violations remain relatively low.

Currently, Civil and administrative protection for trade secrets in China still relies on the Anti-Unfair Competition Law (AUCL), which was promulgated in 1993. The method of misappropriation, 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.⁴³ 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).⁴⁴ 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 three years, a punishment which provides limited deterrence.⁴⁵

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. As a result, it sometimes forces plaintiffs to withdraw their civil case where

⁴³ 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.

⁴⁴ Or bankruptcy by the trade secret owner.

⁴⁵ Losses great than ¥2.5M (~\$375k USD) qualify for longer prison terms.

possible.⁴⁶ 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.⁴⁷ In part, the limited availability is due to the tremendously high burdens of proof discussed above.

It is imperative that both China and the U.S. follow through on ensuring these commitments are implemented as they were intended.

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 most recent 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

⁴⁶ 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.

⁴⁷ 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).⁴⁸ Not surprisingly, the legitimate market has responded positively to this crack down on illegal activity by growing significantly.

oHowever, 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 privacy. 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-Media Box/Set Top Box (STB)/Over-The-Top (OTT) Box Piracy. The manufacture, distribution, and use of devices facilitate massive infringement. These devices are generally manufactured in China and exported to overseas markets, particularly throughout Asia. These devices are often manufactured or promoted and advertised to enable infringement of copyright or other illegal activities. Chief among these are: 1) enabling users to decrypt without authorization encrypted pay television programming; 2) facilitating easy access to remote online sources of unauthorized entertainment content including music, music videos, karaoke, movies, games, published materials and TV dramas; and 3) permitting storage of unauthorized content, including the ability of manufacturers to pre-load devices with hundreds of high definition (HD) motion pictures prior to shipment, allowing vendors to load content upon import and prior to sale or as an “after sale” service, or allowing users to employ direct download sites or torrents to download materials onto the devices. The Chamber notes that Beijing Intellectual Property Court has held a STB manufacturer liable for streaming unauthorized content under secondary liability theory in 2015.

⁴⁸ 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. SAPPRFT acknowledged the problem through notices in 2015 recognizing the threat camcording poses to the film industry, calling for Chinese movie theaters to be aware of and take steps to address the problem, and requiring availability of digital watermarking. While these are positive developments, experience has shown that a critical step is enacting an effective criminal law against the act of camcording. An effective law does not require a showing of intent to

distribute, which significantly complicates enforcement and is unnecessary since there is no legitimate reason to camcord a film.

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. 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. GIPC urges China to address concerns that have been raised about these new OTT regulations.

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. Some scholars argued that live sport programming should be protected as "cinematographic works and works created by means similar to cinematography." The Chamber is very pleased to see that Chaoyang District Court in Beijing recognized the copyrightability of live sports broadcasts in a relating to the Chinese soccer league. The legal jurisprudence is clear and should be maintained on appeal. 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 amendment to the Criminal Code led by the National People's Congress Standing Committee in last couple of 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

The U.S. Chamber 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.

U.S.-Colombia Trade Promotion Agreement Commitments

The U.S. and Colombia Trade Promotion Agreement (TPA), which entered into force in May 2012 included a substantial IP chapter. Yet, Colombia has yet to fulfill many of the IP commitments included in the agreement. In particular, Colombia has not implemented provisions relating to its copyright obligations, including ISP liability and protection against circumvention of DRM. The Chamber encourages the U.S. government to work with the Colombian government to implementation the outstanding provisions of the TPA in order to strengthen Colombia's overall IP system.

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" as described in the Decree 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 introduction of legislation which would update the provisions of Colombian law regarding the abbreviated pathway to ensure that Colombia's law is consistent with WHO and FDA standards.

Patents and Related Rights

NDP Provisions: 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 71.1 of the NDP would allow the Ministry of Health and Social Service (MHSS) to review preliminary patent applications on health products, similar to the prior consent mechanism currently in place in Brazil. The additional patent review mechanism is inconsistent with Colombia's obligations under TRIPS. Additionally, Article 71.2 of the NDP allows 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 licenses 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.

Second Use Patents: Further, 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.

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. 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.

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.

Copyrights and Related Rights

Digital Rights Management Legislation: Under current Colombian law, digital rights management (DRM) measures are only included in the Criminal code and are punishable by a fine. However, widespread music and book piracy suggests that enforcement of the DRM provisions is lacking. Further, the proposed Law 306 contains measures aimed at implementing

Colombia's FTA obligation that would introduce protection against the circumvention of technological protection measures (TPMs). The law would also prohibit the manufacture, import, distribution, and sale of circumvention devices. However, there has been no movement on this law in 2015. The Chamber encourages the U.S. government to work with the Colombian government to ensure that this law – and other measures which would satisfy Colombia's TPA obligations – are passed and enacted swiftly in order to improve Colombia's IP environment.

Ecuador

In order for Ecuador to harness the benefits which robust IP systems provide, a number of policy changes could be made to strengthen the overall IP environment. Ecuador, one of the new economies added to the U.S. Chamber Index in 2016, lags behind many of its Latin American counterparts in a number of key IP sectors. The U.S. Chamber believes Ecuador should pursue the following policy changes in order to strengthen the IP ecosystem.

Patents and Related Rights

Compulsory Licensing: In October 2009, Ecuador issued Executive Decree No. 118, a compulsory license decree with the stated intent of improving access to medicines and strengthening domestic pharmaceutical manufacturing and R&D. Under this Decree, nine compulsory license petitions have been granted by the Ecuadorian Intellectual Property Institute (IEPI) since 2010, six of which were issued in 2014, and twelve more are currently under consideration. Industry is particularly concerned about the compulsory license process in Ecuador, in addition to the volume and rate at which such licenses are being granted. The compulsory licenses that have been granted to date have not been 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 World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The U.S. Chamber recommends that the U.S. government work with their counterparts in the Ecuadorian government to ensure that the compulsory licensing standards are in line with Ecuador's obligations under TRIPS.

Regulatory Data Protection: Ecuador does not provide for an effective term of regulatory data protection. Article 191 of the Intellectual Property Law provides a basis for the protection of submitted biopharmaceutical test data. However, no term of protection is specified in this legislation and rights-holders report that *de facto* protection of their data is limited as regulators have relied on this data for the approval of follow-on products. In 2014, Ecuador acceded to the EU's FTA with the Andean Community and is due to sign and ratify this agreement. This treaty includes a minimum term of 5 years of regulatory data protection due to be implemented by the

early-2020s. In the interim, the U.S. Chamber encourages the U.S. government to highlight with their Ecuadorian government counterparts the need to introduce an effective term of regulatory data protection in order to ensure that pharmaceutical test data is adequately protected.

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.

Excessive Patent Fees: Since October 2012, fees for patents have drastically increased in Ecuador, particularly with regard to maintenance and examination fees. Maintenance fees have increased between 800% and 3529% (i.e., up to \$4,514 and \$20,760 for the 10th and 20th year, respectively). The cumulated annuities amount to \$24,964 for 10 years and \$139,767 for 20 years. These amounts are 12 and 24 times higher than Colombia, 7 and 12 times higher than Brazil, and 7 and 11 times higher than the United States, respectively.

Similarly, examination fees were raised from \$196 to between \$964 and \$1,510.40 depending on the number of pages or claims. Further, Ecuador now charges \$151.04 per page for claims exceeding 19 pages, significantly higher than the \$16 per page charged for international patent applications over 30 pages.

Copyrights and Related Rights

Software Piracy: Ecuador has a high rate of software piracy estimated by the BSA in their latest survey at 68% of total software. Since the late 2000s and presidential decree 1014, the Government of Ecuador has had a policy of mandating government use of open-source software.

Neither the presidential decree nor the subsequent Government strategy document (*Estrategia Para La Implantación de Software Libre*) specified the need for the use of only licensed software (regardless if it is proprietary or not) and no evidence is available of guidelines containing such language or their active implementation and application. Only an indirect requirement for the use of licensed software is made in the 2014 National E-Government Plan (*Plan Nacional de Gobierno Electrónico*). The U.S. Chamber encourages the U.S. government to work with the Ecuadorian government to introduce further measures to combat the use of unlicensed software.

Enforcement

Decriminalization of IP Violations: The enforcement environment against IP rights infringement in Ecuador is difficult. In 2013, amendments to the Intellectual Property Law removed criminal penalties and sanctions for IP rights infringement with the result being that Ecuador's IP rights enforcement environment stands firmly outside international standards. While mechanisms for civil and administrative enforcement remain available, rights-holders face significant challenges accessing them. The judicial process is drawn out with legal redress being difficult to obtain and, by international standards, unpredictable. Both the World Bank's *Doing Business* report and the World Justice Project's *Rule of Law Index* note the long delays in accessing civil and commercial justice as being particularly pronounced. Ecuador does not have in place a system of pre-established or statutory damages for IP rights infringement. Administrative remedies are available through the IEPI. However, since the 2012 Executive Decree 1322 and subsequent reorganization of the IEPI, rights-holders report that such administrative recourse mechanisms remain *de facto* unavailable with IEPI's enforcement activity significantly reduced. The U.S. Chamber recommends that the U.S. government collaborate with the Ecuadorian to implement appropriate civil and criminal penalties for IP rights infringement in order to strengthen Ecuador's enforcement environment.

India

President Obama has characterized the U.S. – India relationship as one of the “defining strategic partnerships of the 21st Century,” and set a goal of expanding bilateral trade in goods and services from \$100 billion/year to \$500 billion/year over the next five years. A clear commitment by the Government of India to establish, adequately resource and effectively implement an IP-led innovation model will surely help to achieve this goal.

Over the past 12 months, there has been important evidence of a re-calibration of the political attitude towards IP in India. This past year was marked by several sustained dialogues 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. The level and frequency of engagement between the U.S. and Indian governments was encouraging and with many seasoned observers noting that they had not seen this level of engagement with the Government ever before. Prime Minister Modi, himself, has been one of the most vocal proponents for robust IP standards and we have seen some positive developments on the ground, particularly in the area of IP judgments. Positive decisions by the Delhi High Court in 2015 in MSD (Merck) v. Glenmark and Roche v. Cipla reflect the increased capacity and competency of Indian judges to resolve patent infringement cases, assess damages, and order injunctive relief.

Nevertheless, no substantive changes have been made to improve India’s statutory or regulatory framework for IP, which has consistently been found to fall short of international best practices. This is also reflected in the U.S. International Trade Commission’s (“ITC”) Report, “Trade and Investment Policies in India 2014-2015.” which notes that the Modi government has not enacted any new laws, policies or regulations to ameliorate the IPR barriers identified in the ITC’s 2014 India Report. While the Indian government has not made any substantive changes to the existing IP laws, the passage of the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Bill in December 2015, represents a positive first step to protect the interests of intellectual property rights holders by creating specialized commercial benches

within the High Courts to more efficiently adjudicate commercial disputes, including IP disputes, having a threshold value greater than 1 crore rupees (approximately USD \$150,000).

We recognize the willingness of the Modi government to engage with industry and the U.S. government on these issues. The government has already undertaken a review of the Indian IPR environment to prepare a National IPR Policy intended to “transform India into an innovative economy.” We hope that the Government of India releases a forward-leaning IP policy that unambiguously protects and enforces IP. We would again encourage the Indian Government to provide all relevant stakeholders with a meaningful opportunity to comment on the final National IPR Policy before it is adopted and implemented.

As we await the final National IPR Policy, we note the limited progress that has been made in 2015 under the Modi government to strengthen the Indian IP environment. Specifically, the Indian IP office has continued its extensive modernization efforts and has engaged with stakeholders in a transparent manner to discuss changes to the Patent Rules. Industry was also encouraged that the Government of India finalized the Guidelines for Examination of Patent Applications for Computer Related Inventions. While the Patent Rules remain under discussion, the Indian Government took a meaningful step to clarify the patentability of computer related inventions (e.g. software patents) in India with the release of the Final Guidelines for the Examination of Patent Applications for Computer Related Inventions in September 2015. Unfortunately, the December 15, 2015 suspension of implementation of the Final Guidelines, without explanation, was a major setback. Reports that the suspension of the Final Guidelines was triggered by a complaint filed with the Prime Minister’s office, if accurate, are a blot on the transparency and predictability of the Indian administrative system.

Industry’s initial expectations that the Modi government would move quickly to address serious IP issues of concern have now been tempered. The launch of the Make in India, Digital India, and Start-Up India initiatives underscore the importance of IP protections to India’s continued economic growth and the development of its technology and manufacturing base. The lack of progress to improve the IPR environment in India thus far has been disappointing, and we note that the most significant IP issues remain unaddressed. However, we are encouraged by the

positive tone of the bilateral dialogue and the decrease in adverse intellectual property events. Accordingly, there is currently no substantive basis for a change in India's previous designation from the 2015 Special 301 Review. We note that the release of the long-awaited National IPR Policy in 2016 could alter the IP landscape. Therefore, an important role for the ongoing dialogues will be to make a mid-year progress assessment. In 2014, an Out-of-Cycle review allowed the U.S. government to assess the level of engagement with the Indian Government and resulted in a renewed commitment to discuss and resolve IP issues of concern under a newly formed High Level Working Group on IP. Today, our two governments are already engaged in a sustained dialogue that has the potential to "bring about substantive and measurable improvements in India's IPR regime for the benefit of a broad range of innovative and creative industries." These established bilateral mechanisms can provide an important opportunity for both government and industry to address recommendations made in the final National IP Policy, discuss remaining gaps in the IP landscape, and monitor the implementation of recommended reforms. It is our sincere hope that the process underway in India will strengthen the statutory, regulatory and administrative IP environment in India to enhance legal certainty for innovators.

India's overall business environment has improved and likewise India is taking a hard look at its IP-related competitiveness. Much work remains and we look forward to addressing, among other things, patentability requirements that remain outside established international best practices; improving specific IP rights for the life sciences sector; improving the enforcement environment by working with Indian authorities to combat high levels of physical and online piracy; and, finally, working with the Government of India to encourage their participation and accession to core international treaties that collectively establish high international standards for intellectual property protection and enforcement.

Patents and Related Rights

Patentability Requirements: 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 new Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals have not done anything fundamentally to address these challenges of interpreting section 3(d). We would encourage the Government of India to further clarify the Guidelines to improve consistency of examination and to provide more predictability for applicants in this important industry sector.

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.

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 to the Indian Patent Office in terms 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, 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 Ayyangar 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. While the Government of India of India has privately reassured Industry that it would not use Compulsory Licenses for commercial purposes, a public commitment to forego using compulsory licensing for commercial purposes would enhance legal certainty for innovative industries.

While no additional compulsory licenses for biopharmaceuticals were issued by Indian authorities in 2015, the Indian Government continued to examine applications for compulsory

licenses under Section 84 and Section 92. In a positive development, the Controller General of the Indian Patent Office denied Lee Pharmaceuticals' Section 84 compulsory license application for AstraZeneca's diabetes drug, Saxagliptin. The Controller General found that Lee Pharma had failed to establish a prima facie case that the drug was not reasonably available in India at an affordable price or not worked within the territory of India. The Ministry of Health and Family Welfare continues to make recommendations to utilize the Section 92 compulsory license mechanism to address the problem of access and affordability of drugs. A final decision in the two compulsory applications under Section 92 for Bristol Myers-Squibb's Dasatinib and Novartis' Onbrezis is still awaited. The Modi Government should restore the confidence of innovative pharmaceutical industry by formally closing these matters and send a clear and unmistakable signal that intellectual property rights will not be disturbed unless there is just cause. We would also urge the Modi government to formally dissolve the inter-ministerial panel appointed under the UPA government to select medicines for compulsory licenses and commit to the repudiation of the use of compulsory license as a commercial tool.

The threat of compulsory licensing is not confined to the pharmaceutical industry alone. It also has implications in other key sectors and the uncertainty remains. India's national Manufacturing Policy created the Technology Acquisition and Development Fund (TADF) tasked with improving access to "the latest patented green technology" including through the use of compulsory licensing. India's draft National IP Policy also promotes the use of the fund. Similarly, India's draft National Competition Policy includes a blanket requirement for intellectual property rights owners to grant third party access to "essential facilities," which appear to cover a wide range of technologies including communications and IT equipment. The endorsement of forced technology transfer mechanisms in policy documents does little to allay the concerns of IP-intensive industries.

Copyrights and Related Rights

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. 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 sub-contracting that place within the countries. In many cases, if confidential business information is stolen, the innovator will have no avenue for relief.

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.

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.

India also drives an agenda of weakening intellectual property in a variety of international norm-setting arenas, such as the UNFCCC, UNDP, WTO, WHO and WIPO. In 2015, the Indian

delegation at the UNFCCC sought to undermine the incentives to develop green technologies by compromising intellectual property protections through the use of forced technology transfer mechanisms and enhanced patentability standards. India's positions are especially troubling considering the influence India wields within the group of developing countries, and particularly, Africa.

Indonesia

As the world fourth most populous country—ranking behind only China, India, and the United States—and as a member of the G-20, Indonesia has immense homegrown talent. However, a strong, predictable, and meaningful intellectual property framework is a necessary precondition to unleashing the innovative potential of the Indonesian people. Indonesia has made moves to improve its intellectual property regime, particularly in regards to copyright, but has much to do before becoming a world-class innovation hub.

Furthermore, Indonesian president Joko Widodo has made indications of his intention to accede to the Trans-Pacific Partnership (TPP) Agreement, which would require putting Indonesia on par with its neighbors in signing up to robust IP standards. We applaud this ambitious aspiration, and note that joining TPP would require significant, sustained change in Indonesia’s legal and regulatory environment.

Patents and Related Rights

Draft Patent Law: The 2001 Indonesian Patent Law does not allow for second or medical use patents and published, official guidelines are not in place. Despite this, practice notes and experience by local legal practitioners suggest that ‘Swiss-style’ claims are allowed. Similarly, with regards to computer-implemented inventions (CIIs), the environment is not clear. Article 7 of the Indonesian Patent Act stipulates that “any theory and method in the field of science and mathematics” is not patentable and not to be considered an invention. As with second use claims although there is no specific reference to software or CIIs, legal practice in Indonesia and existing case law suggest that the environment for patent protection for CIIs is challenging, with no clear guidance in place. Data from WIPO on the top fields of technology in Indonesian patent applications between 1999-2013 does not list computer, software, or related technologies in the top ten technologies filed for.

In 2015, the Indonesian Government introduced a new draft patent law. This draft includes a number of important changes to the existing law, many of which are very concerning. First and foremost the new draft article 19 seems to put forward a localization requirement not only

through paragraph 1 with regards to the mandating of manufacturing of all patented products in Indonesia but also, paragraph 2 states that making use of the relevant patented product or process shall support domestic employment, investment, and technology transfer. Indonesia already has in place a set of policies that force rights-holders to share their intellectual property to gain access to the Indonesian market. Currently, these policies target the life sciences sector in particular. It would be a very negative development should this localization continue and effort now be expanded further to include all sectors and potential patent holders. The draft patent law further introduces provisions similar to the troublesome requirements of India's section 3(d), which restrict the patentability of certain valuable inventions. It includes a requirement to disclose the origin of genetic resources and traditional knowledge which could result in a cancellation of a patent along with setting up possible grounds to cancel a patent when a compulsory license does not prevent the patent from being used in a manner to cause public loss (Article 128). The U.S. Chamber recommends that the Government of Indonesia undertake significant revisions to its draft patent law to address rights-holders concerns.

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 2015, but the legal framework for these licenses under the Patent Law was retained in the draft legislation described above submitted to the Indonesian House of Representatives. The U.S. Chamber urges Indonesia to comply with TRIPS obligations when it considers the issuance of

compulsory licenses as well as eliminate the legal framework for “government use” compulsory licenses from the draft patent law.

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.

Annuity 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 the major patent offices and it should require the attention of the U.S. Government in its negotiations and dealings with the Indonesia government.

Copyrights and Related Rights

Frameworks for Cooperation to Prevent Piracy: Copyright has been one area where Indonesia has made significant 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. 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 deep hole from which creative community begins in Indonesia. Piracy is endemic; enforcement is anemic. 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 government must 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.

Trademarks

The protection of trademarks in Indonesia is a challenge. Physical counterfeiting of goods is rife – particularly for medicines – and the legal framework is rudimentary with enforcement action limited. Raid statistics suggest that Indonesian authorities perform only a handful of raids against alleged IP infringers in a given year.

Well-known marks are offered only limited statutory and practical protection. Although unregistered trademarks are protected through Indonesia's treaty obligations, under the current legal framework rights holders must register their trademarks before initiating actions. Moreover, local legal analysis suggests that Indonesia's first-to-file system has been widely abused by local operators, who have registered internationally well-known marks. For example, a long-running dispute between the Indonesian National Sports Committee (KONI) and the International Olympics Committee (IOC) on the use of the Olympic five-rings logo was only resolved this

year through court action by the local Olympics Committee despite KONI having registered the logo with the Indonesian trademark authorities and actively used it since the late 2000s.

The draft Trademark Law proposed by the Indonesian Government and currently being considered by the Indonesian House of Representatives does not improve the existing framework, providing only minimal reference to well-known marks. Article 21 of the draft legislation states that a trademark application can be rejected on the basis of it showing similarity to well-known marks but well-known marks are not defined in the law and no list of remedies available is provided. While specifying overall usage, activity and investment size as markers of a well-known mark, the accompanying explanatory note to the proposed legislation is not clear as to within which geographical jurisdiction its suggested parameters of evaluation would apply i.e. including or excluding Indonesia in any potential analysis. More broadly, the proposed draft legislation is silent on what legal measures are available for rights-holders with no in-depth definition of types of infringement and remedies available.

Mexico

Mexico is now party to two free trade agreements with the U.S. that include significant intellectual property rights obligations: The 20-year old North American Free Trade Agreement (NAFTA) and the recently-concluded Trans-Pacific Partnership (TPP) Agreement. Mexico has been a great beneficiary of trade liberalization, with exports increasing 600% since the implementation of NAFTA. Mexico has moved to embrace public-private partnerships for intellectual property-intensive industries, has a burgeoning tech industry growing at 3 times the rate of the world average, and is starting to dabble in setting up a competitive life sciences industry.

While the deck is stacked in favor of Mexico becoming a success story, more effort should be undertaken to improve its intellectual property regime and its enforcement to bring it to world-class standards. But recent setbacks- especially related to protection of pharmaceutical IP rights and indirect requirements for technology transfer in new energy policies- could put Mexico's upward trajectory in jeopardy. The Chamber welcomes further engagement between the Government of Mexico and the U.S. Patent and Trademark Office IP Attaché stationed in Mexico City.

Patents and Related Rights

Patent Enforcement and Patent Linkage: The biopharmaceutical industry reports that it continues to experience major challenges surrounding the approval and enforcement of patents in Mexico. It is not clear that formulation patents are recognized consistently by the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) when approving follow-on products. Where cases of infringement are brought, substantial delays at both the administrative and judicial levels hinder rights holders' ability to secure damages effectively (that can reach on average of around 10 years). Nevertheless, in a positive step for rights holders in 2015 a Mexican court ruled that notification of patent holders and their ability to be heard during the market authorization process (and not only after) is a constitutional right and should have a legal basis

within the Linkage Regulation. However, this ruling has not been applied yet by Mexican authorities.

The U.S. Chamber urges Mexico to further clarify the constitutional rights of patent holders to be heard during the market authorization process as well as seek to eliminate administrative and judicial delays in patent enforcement cases.

Regulatory Data Protection: COFEPRIS published guidelines in June 2012 that provide protection against use of undisclosed test data by any person for the purpose of marketing approval for a maximum of five years. However, the effective application of the guidelines remains an ongoing concern. One specific issue is the extent to which RDP will be granted to both large and small molecules. On top of ongoing uncertainty in the legal framework, in 2015 Mexican authorities reportedly indicated that RDP would not be considered as applicable to biologics.

Furthermore, this 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. The U.S. Chamber encourages Mexico to formally extend regulatory data protection to cover biologic medicines in addition to extending the data protections term to 12 years.

“Bolar Exemption” Abuse: Under the “Bolar exemption,” Mexico is allowing generic manufacturers unfettered access to import active and raw materials contained in patented pharmaceuticals up to three years before the patent expiry. While *Roche v. Bolar* allows for this importation, it is clear that given reported import volumes, Mexico is failing to monitor and limit these materials, calling into question that some importers may be stockpiling or selling patent-infringing medicines. The U.S. Chamber recommends that the Mexican government provide enhanced guidelines for importation procedures under the “Bolar exemption” and properly enforce such guidelines.

Copyrights and Related Rights

Frameworks that promote action against online piracy: No major movement occurred on amendments to the Copyright Law that would introduce a graduated user warning system and ISP liability for online copyright infringement, notwithstanding the support of a very large coalition of Mexican cultural industries. Digital piracy continues to represent a major challenge for rights holders. The Attorney General (Procuraduría General) estimates that in 2015 the copyright (and consumer brand) industries will lose around 13 billion pesos (over USD750 million) due to pirated and counterfeit products. Moreover, according to the Mexican Intellectual Property Association (AMPPI), around 60% of the population purchases pirated goods, representing a value of at least 7% of GDP.

Camcording: The Chamber encourages Mexico to strengthen its criminal laws against the unauthorized camcording of films in theatres. Currently, in order to enforce against camcord piracy, the authorities must prove that the infringer intends to distribute and profit from the camcorded film. However, both the U.S. and Canada, key trading partners through NAFTA and the TPP, recognize that unauthorized camcording is itself a crime. The Chamber encourages the U.S. Government to work with the Mexican government to strengthen the camcording law to allow for enforcement without proof of intent to distribute and profit.

Trademarks

Unregistered Marks: The Industrial Property Law establishes the exclusive right to use a mark upon registration. However, unregistered trademarks are offered a certain degree of protection, regardless of whether use occurs within the jurisdiction of Mexico or abroad. An unregistered trademark proprietor will be able to file a cancellation action against a registration based on prior use, however the proprietor of the unregistered trademark must make application for registration and be awarded registration prior to such action. Furthermore, legislation does not provide the owner of the unregistered trademark with exclusive rights. Thus, unregistered trademark owners remain exposed to potential damage by use of an identical or confusingly similar mark, without the possibility of initiating legal action.

Trade Secrets and Market Access

Localization Requirements: Though generally speaking Mexico has scaled back its use of mandatory localization policies, including limits of FDI and local content requirements, mandatory requirements for localization have increased for certain sectors. For instance, the energy and gas sector is subject to new local content requirements, including transfer of technology, which entered into force in 2015. Under these requirements the minimum level of local content across the supply chain must be 25% as of 2015 and is set to rise to 35% by 2025. Such requirements include the potential for forced sharing of IP assets as part of acquiring the local content.

Panama

Panama enjoys unparalleled access to the U.S. market due to the U.S.-Panama Trade Promotion Agreement (TPA), which entered into force in 2012. As part of the TPA, Panama agreed to a set of principles on the protection and promotion of intellectual property rights. However, concerning practices of the country's judiciary could be putting the country at odds with its TPA, TRIPS, and BIT commitments.

Trademarks

The Chamber recommends USTR address concerns regarding the judicial protection of intellectual property in Panama. In 2014, the Panamanian Supreme Court set a troubling precedent for U.S. investors seeking to enforce their IP rights abroad. Specifically, Panama's Supreme Court penalized Bridgestone Americas, Inc. for merely opposing a trademark application by a Panamanian company, Muresa Intertrade S.A., for the mark "Riverstone" to be used for tires. After Bridgestone lost the opposition proceeding, Muresa sued Bridgestone claiming damages resulting from the opposition filing. Despite the fact that two lower courts found Bridgestone acted in good faith in initiating a typical opposition proceeding, the Panamanian Supreme Court reversed the two lower courts' decisions, and instead awarded damages to Muresa in the amount of \$5 million dollars plus \$431,000 in legal fees. This outcome discourages U.S. companies from using legitimate efforts to protect their IP investments overseas.

Peru

Peru is now party to two free trade agreements with the United States: The 2009 United States-Peru Trade Promotion Agreement (USPTPA) and the Trans-Pacific Partnership (TPP) Agreement, both of which enshrine obligations in the protection and promotion of intellectual property rights. Despite its intention to ratify the TPP, Peru is trending towards an intellectual property regime with significant exceptions and limitations, including: limiting the ability to patent and protect existing patents, particularly for pharmaceutical products as well as extending exceptions to copyright through several iterations of amendments that do not contain necessary limitations on abuse of these exceptions.

Furthermore, the Chamber welcomes the announcement of establishing a U.S. Patent and Trademark Office IP Attaché for the Andean Region in Peru in early 2016.

Patents and Related Rights

Patentability Requirements: Peru's Industrial Property Rights Law establishes the protection of patents provided they meet the requirements of novelty, inventiveness, and susceptibility to industrial application. However, the patentability requirements lack clarity as to the protection of biotechnologically-derived pharmaceutical products. In addition, Peru does not consider treatment methods as patentable subject matter, and the Andean Court of Justice has barred the recognition of second medical use patents within Andean Community member economies. The patent examination process involves major delays and patent authorities tend to lack technical expertise. Indeed, the patent office, INDECOPI, reports in 2015 that between 2010 and 2014 it rejected 50% of pharmaceutical patent applications, including second use, method and biotechnology patents relating to several AIDS and cancer treatments. In doing so, patent officials reiterated that while based on a technical evaluation as well as existing laws governing the Andean Community, its approach is also intended to ensure access to medicines by limiting the scope of patentability of pharmaceuticals and may not necessarily match the approach taken in other economies. The U.S. Chamber encourages the U.S. Government to urge the Peruvian government to clarify and update the scope of the patentability requirements.

Patent Enforcement and Resolution Mechanism: Under Article 16.10.3 of the USPTPA, Peru is obligated to ensure patent holders are made aware of potentially infringing biopharmaceutical applications prior to market authorization. The Peruvian Health Authority (PHA) maintains a publicly available list of drug registration applications on its website, however, it alone is not sufficient to provide an effective patent enforcement system. It does not address existing challenges in relation to the ability to secure timely relief through the court system, which can take, on average, more than four years. The U.S. Chamber recommends that the U.S. Government work with their Peruvian government counterparts to introduce an effective patent enforcement mechanism.

Patent Term Restoration: Peru has not implemented patent term restoration provisions in its law as is required by Article 16.9.6(c) of the USPTPA. The Chamber encourages the Peruvian government to introduce patent restoration in order to both fulfill their USPTPA commitments and, in turn, improve Peru's pharmaceutical IP environment.

Compulsory licensing: In 2014-15, the Ministry of Health along with several NGOs requested a compulsory license on the antiretroviral atazanavir. In 2015, the Ministry of Health issued a Supreme Decree for the compulsory license; however, approval was not obtained from certain government departments, including the Ministry of Economy and Ministry of Justice. Rather, the patent holder and the Peruvian government ultimately came to an alternative agreement. Nevertheless, the case is suggestive of a fragmented approach within the Peruvian government and the potential need for enhanced interagency coordination towards the use of compulsory licensing.

Regulatory Data Protection: Peruvian law provides for a 5 year term of RDP for pharmaceutical products under Legislative Decree 1072. However, the Peruvian Health Authority (PHA) has rejected regulatory data protection for several biologics. The refusal to grant RDP for biologics is inconsistent with Peru's obligations both under Article 16.10.2 of the USPTPA and the TRIPS agreement. In addition, the biopharmaceutical industry reports that products which have benefitted from RDP in Peru are granted on average a three-year term of protection.

Furthermore, this 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 recommends that the U.S. Government encourage the Peruvian government to introduce regulatory data protection for all innovative pharmaceutical products.

Copyrights and Related Rights

ISP Liability: Peru has to date not made provision for notice and takedown of infringing content online, despite its obligation to do so in Article 29(b)(ix) of the USPTPA. The Chamber encourages the Peruvian government to introduce such a system in order to meet their USPTPA obligations and to take other actions to reduce online piracy in Peru.

Exceptions and Limitations: Peruvian law provides a list of limitations and exceptions to copyright. In late 2014, the Peruvian Congress passed Law 2314/2012, which increases exceptions for use of copies for educational purposes and for libraries. Specifically, the measure provides for academic exceptions to copyright for public distribution to staff and students, including copying of the entire work as long as it is not intended for commercial purposes. In 2015, additional amendments to the copyright law were discussed that would further expand exceptions to copyright for public use and for so-called “social” or personal events. The U.S. Chamber urges the Peruvian government to heed the calls for increasing exceptions and limitations and protect local creators and generators of copyright.

Camcording: The Chamber urges Peru to strengthen its criminal laws against the unauthorized camcording of films in theatres. The U.S. and Canada, key trading partners in the TPP, recognize that unauthorized camcording is itself a crime. The Chamber encourages the U.S. Government to work with the Peruvian government to strengthen the camcording law to allow for the criminalization of such acts.

Trade Secrets and Market Access

Peruvian law provides for a limited level of trade secret protection, which is derived from unfair competition law. A 2014 report from the OECD notes that the Peruvian approach only allows protection for the legal right of “fair competition” irrespective of other rights affected by violations of trade secrets. In addition, to date no noted criminal enforcement of trade secret violations has taken place. Moreover, evidence suggests that the burden of proof is high in administrative and judicial proceedings to demonstrate unauthorized disclosure of trade secrets by former employees. The U.S. Chamber recommends that the U.S. Government work with their Peruvian government counterparts to enforce the existing trade secrets laws in order to discourage future violations.

Enforcement

Peru has a limited legal framework for civil and criminal remedies, however it has made efforts to strengthen enforcement for IP-related infringement. For example, recent amendments increased the minimum sentencing for copyright infringement to four or more years and established the creation of four specialized IP courts and one special appeals court with national jurisdiction on IPR crimes. Nevertheless, the overall enforcement environment remains insufficient. Prosecutors do not pursue piracy cases through to the final stages of judgment and the judiciary often lacks independence in relation to sensitive IP decisions. For criminal prosecutions, delays can last between three and five years and the judiciary typically views IP crimes as benign. As a result, Peru maintains high levels of piracy and has struggled to deter or change the culture of piracy in the economy. The U.S. Chamber recommends that the Peruvian government continue to enhance its enforcement efforts and dedicate resources to pursuing legal and judicial integrity in adjudicating IP cases.

Russia

Though Russia leads the BRICS economies in relative strength of intellectual property rights, its lead over China, specifically (as denoted in the Chamber International IP Index), is very narrow. Given the continued degradation of U.S.- Russian relations, the Chamber remains 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. However, this decision was reversed later in the year by an Arbitration Court which held that the local manufacturer company did in fact infringe Novartis' exclusivity and its submitted clinical research data as part of its original market authorization application. Local legal analysis suggests that the judgment provides important clarification on the scope of protection provided to clinical data submitted, strengthening the rights of innovators. Industry will continue to advocate for the introduction of concrete intellectual property protection mechanisms 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 has considered developing legislation to allow for the compulsory licensing of innovative medicines.

Copyrights and Related Rights

Online Piracy: In July 2013, 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. With regards to the application and enforcement of the 2013 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 was included as the first website on the Motion Picture Association's 2015 "Online Notorious Markets."

Unlicensed Software Use: According to BSA- The Software Alliance, Russia ranks among the top in the world of unlicensed software use. As of 2014, Russia's unlicensed rate amounted to 62%.

Camcording: The Chamber urges Russia to strengthen its criminal laws against the unauthorized camcording of films in theatres. Key trading partners of Russia's recognize that unauthorized camcording is itself a crime. The Chamber encourages the U.S. Government to work with the Russian government to strengthen the camcording law to allow for the criminalization of such acts.

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.

Trade Secrets and Market Access

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. A significant focus of Russia's biopharmaceutical policies has been on attempting to localize biopharmaceutical research and innovation. 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. In 2011, the Ministry of Economic Development issued Order No.211 creating a price preference of 15% afforded to locally produced drugs for state and municipal procurement and the opportunity for local manufacturers (foreign firms excluded) of products on the EDL to adjust product prices annually accounting for inflation rates. Subsequently, a stricter definition of "local production" has been adopted. This requires that a biopharmaceutical company locally produce the active pharmaceutical ingredient (API) or final deliverable form of a product in Russia to qualify for these benefits and also puts in place a requirement that imported pharmaceutical products could not be considered for state tenders if two or more generic equivalents were produced domestically.

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.

New measures introduced and/or coming into effect in 2015 have exacerbated this already difficult situation. For instance, new regulations with regards to the compilation of drug

registration dossiers has made market registration conditional on good manufacturing practices (GMP) inspection by Russian officials, consequently favoring local manufacturing. Import restrictions on foreign produced biopharmaceutical products have also been proposed by the Russian Government as has a redefinition of local manufacturing. Together these measures (scheduled to be applied in 2016) would even more strongly condition access to the Russian biopharmaceutical on complete local manufacturing and development.

South Korea

The Republic of Korea (South Korea) has faced significant issues with the full unfettered implementation of the U.S.-Korea Free Trade Agreement (KORUS), now approaching its fourth year in force. By all intents and purposes, Korea is a world-class technological innovator, however is facing difficulties attracting more diverse knowledge-intensive industries partially due to significant barriers to protecting intellectual property rights. Steps backward involved revisions to South Korea's rules on "fair use of IPRs" which, though including some positive measures safeguarding against patent trolls and aimed at easing standard setting processes, nevertheless introduced worrisome provisions limiting the ability of patent holders to exercise their rights effectively. In addition, at least two missed opportunities for addressing ongoing challenges occurred in 2015. Amendments to rules governing pharmaceuticals, though fulfilling some of Korea's obligations under the KORUS FTA, do so in a somewhat diluted manner and do not address existing challenges and loopholes in the system. Moreover, increasing evidence of unlicensed software across different government agencies was visible in 2015, with little action taken to address it.

A more detailed assessment on Korea's performance in implementing its IP obligations under KORUS is included in the GIPC-Covington and Burling 2015 study "Trading Up."

Patents and Related Rights

Patentability Requirements: The Patent Act provides for standard patentability requirements, including novelty, inventive step, and industrial applicability, and these principles are typically applied in practice. In addition, patent amendments that entered into force in 2015 streamline the patenting process and lift aspects of economy-specific red tape, including the ability to file Patent Cooperation Treaty (PCT) applications in English, rather than Korean, and set the filing date based on the date of PCT application. Nevertheless, challenges exist with regard to requirements for submitting additional materials with the patent application for certain types of inventions. Specifically, with regards to biopharmaceutical patents, Korean patent law and examiners require vast amounts of pharmacological data to be submitted in the original patent

application, not, as is the more common international practice, of submitting such data during either patent prosecution or post-grant validity proceedings.

Patent Enforcement and Resolution Mechanism: Amendments to the patent linkage system provided for in the Korean Pharmaceutical Affairs Act (KPAA) aimed at satisfying South Korea's commitments under KORUS were approved in 2015. The amendments clarify that the patent linkage regime – which involves a publicly available patent listing applicable to registered biopharmaceutical products, based on which generic companies are to notify rights holders of any patent directly associated with a generic application – applies to both chemical-based products and biologics. They also introduce a stay on generic sales of 9 months in case of an infringement dispute, although potential loopholes around a stay, such as initiation of an invalidation action, do exist and may undermine the effectiveness of the mechanism.

On a positive note, we understand that the Korean National Assembly recently rejected draft amendments to the National Health Insurance Act that could weaken the new system by requiring innovators to provide the government with an offset of profits accrued during the course of the stay should they lose the patent action (without a similar requirement for generic applicants) were not approved at the time of research. The U.S. Chamber urges Korea to close the loopholes in its patent linkage system and further asks the U.S. Government to continue to monitor this issue, including any draft amendments to the National Health Insurance Act that may undermine the patent linkage mechanism

Copyrights and Related Rights

Unlicensed Software Use: Since 2011, South Korea has instituted government-wide policies that require government agencies and public institutions to use properly licensed software as well as introduce dedicated monitoring of implementation on an agency-specific basis. Nevertheless, evidence from 2015 suggests that there is wide lack of implementation of the requirements, with local government agencies and state-run bodies engaging in unlicensed use of software and servers. For instance, the state-run Korea Power Engineering Company has reportedly only licensed less than 5% of the software it uses for its control units. There were similar reports in

2015 for the National Policy Agency. This comes on top of evidence from previous years indicating that use of unlicensed software has also existed in other agencies and public services, such as the Ministry of Defense and the education system. The U.S. Chamber of Commerce urges South Korea to complete implementation of its government policies in its administration and monitoring of government acquisition and use of software.

Trade Secrets and Market Access

South Korea has a robust IT marketplace and what is generally considered a strong and reliable legal system and judiciary. In recent years, however, concerns have arisen with regard to the enforcement activity of the Korea Fair Trade Commission (KFTC), particularly when it is inappropriately applied to U.S. technology companies which effectively deny fair and equitable market access and devalue IP rights. These concerns reflect the lack of sufficient transparency and due process in KFTC investigations and in its decision making process.

One notable feature of the landmark KORUS agreement is Chapter 16 dealing with Competition-Related Matters. This chapter sets forth significant antitrust-related obligations for both parties, including specific due process provisions and procedural safeguards. Despite these KORUS commitments concerns remain. More broadly, recent public statements by the KFTC appear to endorse a concerted effort by the KFTC to prioritize antitrust investigations with questionable motivations. These public statements have included pledges by the KFTC to protect domestic companies by regulating global companies and their intellectual property rights.

Trade Secrets: The Unfair Competition and Trade Secrets Prevention Act provides fairly standard protection against unauthorized disclosure and use of trade secrets. Relief is afforded in the form of injunctions, damages, and restoration of business reputation. Although the legal framework for trade secret protection is relatively strong, and a number of recent court cases suggest that relief is available for trade secret violations, significant challenges exist surrounding leaks of sensitive commercial information submitted to regulatory authorities, and in some cases, subsequent industrial espionage. These challenges reportedly affect a range of sectors, including

chemicals, cosmetics, and food products. Industry continues to advocate that the Korean government combat and enforce against the unauthorized disclosure of trade secrets.

Thailand

Last year, Thailand ranked at the very bottom of the GIPC International IP Index. This year, Thailand's score rose slightly, largely due to improvements to the copyright regime particularly in relation to protection against circumvention of TPMs, placing it just ahead of India and Venezuela on the 2016 U.S. Chamber International IP Index.

Nevertheless, despite a great deal of legislative activity in the area of copyrights and customs, among other areas, overall 2015 represented a year of missed opportunities and in some instances, concerning developments. Thailand's overall ranking on the Chamber IP Index could have risen much more had the measures, particularly copyright amendments, been more complete and in line with international standards. Instead, in several instances the system is arguably weaker or diluted in certain areas compared to before. For instance, in the area of customs enforcement, *ex officio* authority is not entirely clear based on the new Customs Act and ISP liability is restricted to notices based on court or ministerial order in at least two new laws. In addition, police and judicial efforts against IP infringement continued to be limited in several areas; major backlogs persist in the Department of IP (DIP) and in the courts; and several patent issues were left unresolved in 2015.

Patents and Related Rights

Patentability Requirements: An invention will be granted patent protection if it is new, involves an inventive step, and has industrial application. The patent law provides specifically that novelty will only be destroyed by an invention widely known or used in the domestic area prior to filing of the patent application. The law further provides for a standard of worldwide novelty; however, Thailand lacks the level of high technology needed to apply this standard, and as such it is unclear how effective the consideration of international prior art is in Thailand.

Thailand is not bound to the national treatment principle, which allows it to waive the inventive step requirement for Thai citizens (small or local competitors), but enforce it against foreign competitors. Patent examination guidelines released in late 2013 appear to limit patentability of medical use claims and of new uses for known substances. In addition, although the guidelines

were reportedly intended to streamline the patent examination process and help reduce severe patent backlogs, thus far the guidelines have resulted in further delays and requests for additional information from patent applicants, particularly for applications related to second medical use. As of December 2014, the backlog had reached over 20,000.

Compulsory Licensing: Thailand has a history of compulsory licensing of pharmaceutical products.

Copyrights and Related Rights,

Frameworks to Promote Action Against Online Piracy: Two bills amending the Copyright Act BE 2537 (1994) were published in the Official Gazette in 2015 (after being passed by the National Legislative Assembly and signed by the King), and came into force April 2015. The laws introduce several important measures that seek to close loopholes in Thai copyright law, however in several instances these are missing key language or provisions that would allow them to effectively limit infringing activities, particularly in the online sphere.

Sections 28/1 and 69/1 make camcording in public venues an infringement, although the language is not as strong as that in other economies – only actual reproduction is criminalized without specifically including intent to copy and distribute, essentially precluding preventative enforcement. The U.S. Chamber recommends that the Thai government pursue the preventative criminalization of camcording.

No landlord liability was introduced, which means that physical shops selling pirated goods are not held liable as intermediaries. The amendments introduce liability for ISPs and a kind of notice and takedown system but with several limitations that render the new law significantly less effective than anticipated and not a true notice and takedown mechanism. ISPs are not liable for non-hosted material, regardless of if they have knowledge it is infringing. In addition, rights holder notice must be accompanied by a court order for ISPs to be responsible to respond. The U.S. Chamber urges the Government of Thailand to adopt a notice-and-takedown system more in line with international practices.

In addition, the amendments involve a high burden of proof to demonstrate infringing sites. 2015 amendments to the Computer Crimes Act reinforce these same requirements and as such do not contribute to closing these loopholes. In 2014-15, rights holders reported a good rate of response (90%) from mainstream ISPs (though not for non-hosted content), however the new rules may jeopardize this trend. In terms of exceptions to copyright, among other exceptions Section 32/9 of the copyright amendments introduce a wide exception for use by disabled persons that goes beyond the Marrakesh Treaty. This comes hand in hand with continued negligence on the Thai government's part to book piracy in educational institutions, including in relation to broad interpretations of the disabled persons exception. In addition, unauthorized access to and retransmission of Pay TV and satellite programming as well as unlicensed public performance of copyrighted works (e.g. at entertainment venues) remain major challenges on the ground.

Digital Rights Management Legislation: The copyright amendments introduce the concept of TPMs as well as penalties for circumventing TPMs. However, though they address the act of circumvention, they fall short of Thailand's obligations in the WIPO copyright treaties since acts of circumvention only include those in which users are aware they are infringing TPMs. In addition, penalties only apply to actual circumvention and do not explicitly cover sales or distribution of circumvention devices. Also, the exceptions appear to be overly broad, without adequate definition around certain educational or public use exceptions. In parallel, the film and television industry reports a rise in set top box piracy, often involving circumvention of TPMs.

Camcording: The Chamber urges Thailand to strengthen its criminal laws against the unauthorized camcording of films in theatres. Key trading partners of Thailand's recognize that unauthorized camcording is itself a crime. The Chamber encourages the U.S. Government to work with the Thai government to strengthen the camcording law to allow for the criminalization of such acts.

Trademarks

Plain Packaging: Thailand is currently considering a draft tobacco control law that would allow the introduction of plain packaging for tobacco products. Specifically, the proposed enabling

law would allow the Minister of Health to prohibit the use of colors or branding on tobacco products and also includes a provision stating that regulations issued under the law would not violate intellectual property rights. In 2013, Thailand had previously considered a similar plain packaging directive to be applied to alcohol products. 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.

Enforcement

Transshipped Goods: Customs Act No.21 BE 2557 (2014), amending the Customs Act BE 2469 (1926), came into force in March 2015. It explicitly includes imported IP infringing goods as those that should be checked and detained if necessary. It also introduces greater clarity on how customs authorities should treat transshipped goods (including goods that transit through Thailand and those that change transport vehicles within Thailand). However, a major loophole appears to exist vis-à-vis transshipped goods since only suspected “illicit” goods in transit are to be seized, and under Thai IP law illicit (or infringing) goods are only those which are imported, not transshipped. 2015 also saw the introduction of a new recording program intended to streamline and improve recording of marks with DIP and Customs, and improve subsequent inspections. Nevertheless, it is not clear under the new rules if this means that marks that are not recorded under the new system will be monitored *ex officio* by Customs, and as such the new system may dilute the *ex officio* provision in Thai law. The U.S. Chamber calls on the Thai government to address the enforcement loophole regarding transshipped goods as well as clarify the application of *ex officio* authority under its new recording program.

Venezuela

Industry faces a number of significant challenges when seeking to protect their IP in Venezuela. Venezuela, one of the new economies added to the Index, falls behind all of its Latin American counterparts and the other economies benchmarked in the Index, ranking in last place overall. 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.