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**U.S. CHAMBER OF COMMERCE**

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**By electronic submission**

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Washington, DC

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

**2015 SPECIAL 301 SUBMISSION**

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February 6, 2015

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Re: 2015 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. Wilson:

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) 2015 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 GIPC's 2015 International IP Index,

*UP: Unlimited Potential* (GIPC Index), is an empirical assessment of the strengths and weaknesses of 30 developmentally and geographically diverse countries.

Our 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 18 countries in this report, double that of the Chamber's 2014 submission. These countries 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. That is to say that although these countries each present particular challenges to U.S. intellectual property rights holders, they should not necessarily be taken to represent the worst performers globally.

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  
Intellectual Property Center



Myron Brilliant  
Executive Vice President  
Head of International Affairs, U.S. Chamber of  
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## **Building a Global Community of First Markets**

Indisputably, the United States benefits greatly from the intellectual property rights system. The protection of copyrights, patents, trademarks, and trade secrets creates jobs, spurs innovation, enhances consumer safety, and facilitates access to new technologies. These benefits, however, are not limited to U.S. borders, American industry, or patients. Adequately and sufficiently protecting intellectual property is a boon for the global economy as a whole. Every nation has the opportunity to enter the community of first-markets, but the non-discriminant protection of intellectual property is a necessary precondition to succeed in fostering local entrepreneurship and attracting foreign investment.

Outside the circle of intellectual property-protecting countries, innovators struggle to bring groundbreaking ideas to market in successful fashion, denying all of us effective access to much of the world's creative capacity. Time and again, we've seen that some countries have a tendency to idealize their economies as "importers of intellectual property," thereby questioning the domestic benefit of a strong intellectual property regime and almost certainly ensuring a self-fulfilling prophecy.

The U.S. example is illustrative where, due to a strong intellectual property framework, fully three-fifths of exports are generated by intellectual property-intensive industries, supporting some 40 million jobs.<sup>1</sup> Furthermore, California's Silicon Valley—the birthplace of the information-age—leads all other major international locales in patent filings.<sup>2</sup> Interestingly, nearly one-half of all patents granted there are to immigrant inventors, underlying the notion that global entrepreneurs seek environments with strong intellectual property rights. Nations which skirt enforcement against counterfeiting and piracy or fail to establish predictable and meaningful intellectual property regimes ostensibly lose talent as well as lose the faith of the international business community.

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<sup>1</sup> "Intellectual Property and the U.S. Economy," Department of Commerce, April 2012.

<sup>2</sup> "3 Clues To How Geography Fuels Innovation," National Public Radio, September 05, 2012. <http://www.npr.org/2012/09/05/160394967/3-clues-to-how-geography-fuels-innovation>

With the guidance of the U.S. government and industry, we can together help build the next generation of net-exporters of intellectual property through bilateral cooperation, multilateral trade agreements, and helpful, informative exercises like the Special 301 Review, which identifies significant challenges intellectual property- intensive industries face in key markets.

## **The Global Intellectual Property Center 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 4, 2015, the Chamber's GIPC released the 3<sup>rd</sup> Edition of the International IP Index, *UP: Unlimited Potential (GIPC Index)*<sup>3</sup>, 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 30 economies provides a snapshot of what countries are doing well and what they can be doing better.

The GIPC 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: Argentina, Australia, Brazil, Canada, Chile, China, Colombia, France, Germany, Indonesia, India, Japan, Malaysia, Mexico, New Zealand, Nigeria, Peru, Russia, Singapore, South Africa, South Korea, Switzerland, Taiwan, Thailand, Turkey, Ukraine, United Arab Emirates, the United Kingdom, the United States, and Vietnam.

The GIPC Index is not intended to be an industry Special 301 Report and, as such, not all countries included in the GIPC 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 GIPC Index serves as a discretionary policy tool to those countries wishing to evaluate the strengths and deficiencies in their intellectual property environments.

We have attached a copy of the GIPC Index to our submission to provide further evidence to support the issues raised throughout.

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<sup>3</sup> U.S. Chamber of Commerce. (2015). GIPC International IP Index: *UP: Unlimited Potential*.

## **Challenges to Intellectual Property Protection and Enforcement**

### **Erosion of Intellectual Property Rights**

#### **Public Perception and Trends**

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 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 protectionist “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.

To underscore the value of protecting and promoting intellectual property, the GIPC has been operating the *IP Delivers* campaign, which provides fact-based research and information reflecting the realities of intellectual property in the marketplace. It is critical that policy makers and their constituencies have access to balanced and practical assessments of the current and future state of intellectual property protection and the economic growth and innovation it fuels.

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

## **Copyrights**

Increasing theft of digital media over the Internet presents the biggest threat to copyright protection. Estimates indicate that nearly 25 percent of all Internet traffic worldwide is in furtherance of copyright infringement.<sup>4</sup> Another study found that a handful of the top intellectual property-infringing Internet sites received 53 billion page views per year—a problem that continues to grow.<sup>5</sup>

In recent years, there has been an effort to attack copyright protection on the Internet by arguments that protecting copyrights amounts to “censorship” or somehow interferes with the human rights of infringers. These arguments demean the concepts they claim to vindicate.

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<sup>4</sup> Technical report: An Estimate of Infringing Use of the Internet, Envisional, January 2011.

<sup>5</sup> MarkMonitor. (2011, January). *Traffic Report: Online Piracy and Counterfeiting*.

Protecting the property of private entities – created through investment of time, capital, and talent – against wholesale, massive theft has no comparison or relation to government-sponsored, viewpoint-based censorship for political purposes.

The World Intellectual Property Organization (WIPO) has provided international norms for protecting copyright in the digital economy. The Berne Convention and the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, the WIPO Copyright Treaty (WCT), and the WIPO Performances and Phonograms Treaty (WPPT) (collectively known as the “WIPO Internet Treaties”) provide an essential baseline for copyright protection in the digital era. The global acceptance of those norms was reaffirmed in June 2012 with the adoption of the Beijing Treaty on Audiovisual Performances. The Chamber supports the administration’s efforts to continue to urge countries, which have not yet done so, to ratify and fully implement these treaties.

It is encouraging that the world has, once again, agreed on the need for vibrant copyright protection in the digital environment. Nonetheless, many of these principles are now nearly two decades old. With constant changes in the physical and online marketplaces, it is clearer than ever that these principles represent the most basic required protections. As USTR undertakes this Special 301 review process, it should also consider the extent to which additional protections are provided in a country, either through voluntary agreements, adoption of “best practices” by relevant organization and business sectors, or by laws or court rulings.

## **Patents**

Innovations protected by patents continue to face numerous policy challenges on the international stage. Several multilateral institutions have chosen to focus educational papers on encouraging the maximization of intellectual property flexibilities for some technologies protected by patents, such as medicine and clean energy technology.<sup>6</sup> These studies promulgate the notion that intellectual property is a barrier to access for innovative technologies while making little to no comment on endemic problems such as high import tariff rates and corruption rates as barriers to access. The misconception of intellectual property as a barrier has a

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<sup>6</sup> Fink, Carsten. (2004, November). *Intellectual Property and the WTO*. [siteresources.worldbank.org/.../Resources/.../IPR-WTO\\_Fink.doc](http://siteresources.worldbank.org/.../Resources/.../IPR-WTO_Fink.doc).

potentially negative impact on investment in these areas, which could subsequently lead to less innovation of products to address global challenges.

The patent system provides important incentives for innovation in a wide variety of sectors. Recognizing the importance of patent protection, the TRIPS Agreement requires World Trade Organization (WTO) members, as a general rule, make patents available for inventions in all fields of technology. These rules include important provisions which, when properly implemented, both ensure incentives for innovators and protect the public interest against any possible abuse. It is essential that the U.S. Government remain vigilant to ensure no weakening of patent rights in international fora, to avoid hindering innovation and the development and diffusion of technology.

Several country proposals in international fora have already sought to portray intellectual property rights as a barrier to technology transfer and dissemination. Their proposals, as in the case of parallel efforts in the climate change negotiations, would harm a wide range of U.S. industries and technologies and would be counterproductive from economic, sustainability, and development perspectives as well.

Additionally, laws which seek to link disclosure of the source/origin of a genetic resource to patentability requirements are viewed as barriers to the successful development of new products based on genetic resources. The U.S. should promote rules that provide adequate disclosure to competent national authorities and continue to resist rules that would link any such disclosure to the requirements of obtaining a patent. We are also concerned by actions of certain countries that undermine or threaten to eviscerate patent rights, thereby putting innovative industries at a disadvantage.

### **Trademarks**

Bolstering the protection of trademarks through advocacy and enforcement mechanisms, the GIPC established the Global Brand Council (GBC), which is comprised of companies who own the rights to some of the world's most well-known and established brands. The GBC is at the front lines of advocacy against the sale of counterfeit hard goods sold online or in the brick-and-mortar world.

Trademark owners have been subject to unwarranted efforts to weaken protections in the name of public health. The Chamber remains particularly concerned by government policies that reduce or eliminate the ability of manufacturers to distinguish and consumers to identify trusted, regulated, and well-known brands.

As outlined in previous Special 301 submissions, an unfortunate precedent was set in Australia in November 2011 when the government passed legislation that stripped trademark owners of their ability to use their brand on tobacco products. A handful of countries are considering similar legislation, however, Australia still remains the sole outlier in implementing ‘plain packaging’ laws and is presently the subject of a WTO dispute settlement case on those laws. While the Chamber supports advancing public health, we are deeply concerned about the approach taken by Australia and the unintended consequences created. First and foremost, we are concerned that the mandated elimination of the use of an entire industry’s trademarks is not only inconsistent with international intellectual property obligations. Furthermore, this action establishes a dangerous precedent with implications for a wide range of industries. Government mandated abrogation of legally sanctioned intellectual property, as in the case of Australia’s plain packaging law, is both unprecedented and unwarranted and will incentivize additional efforts to erode intellectual property protection.

We urge the U.S. Government to take a stand against efforts to undermine intellectual property in any sector and for governments to consider narrowly tailored and evidence-based alternatives that effectively protect public health, while also defending the international system for protecting trademarks.

### **Protection of Undisclosed Information**

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

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.

We commend 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 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.

***Data Submitted for Market Approval:*** The WTO TRIPS Agreement requires that Members protect confidential commercial information contained in regulatory submissions from unfair commercial use and disclosure.<sup>7</sup> There continue to be many challenges in the implementation of these requirements in Member state law. These challenges include: (1) the failure of several jurisdictions to provide an exclusivity period or other protection against "unfair use" and (2) the failure to adequately protect data submitted in marketing approval applications from disclosure. The continuation of policies underpinning these challenges undermines the incentive to innovate

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<sup>7</sup> WTO TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights; Article 39.

in several critical life-science sectors. We urge the U.S. Government to continue working with our trading partners to ensure meaningful implementation and adherence to the spirit and letter of these international commitments.

### **The Multilateral Environment**

Specialized multilateral institutions under the United Nations (UN) system continue to play an important role in developing intellectual property policy and encouraging and facilitating the undertaking of international research. However, the effectiveness of these agencies to promote the growth of creative and innovative economies is sometimes hindered by the propagation of a view that intellectual property hinders economic growth and access to solutions to global challenges. Such debates detract from the positive development missions of multilateral institutions, particularly in those whose mission and expertise is specifically focused on improving intellectual property protection. Furthermore, this negative view of intellectual property often accompanies a broader discounting of contributions made by the private sector.

The GIPC has had some successful engagement with UN organizations in the past year and we are eager to continue to develop and improve these interactions. However, several organizations in the UN continue to impose or consider limitations on consultation with the private sector and this worrisome trend threatens to undermine the credibility of UN institutions in policy making.

### **Importance of Bilateral and Regional Free Trade Agreements**

The Chamber is optimistic that regional and bilateral trade agreements can provide new solutions to emerging intellectual property challenges.

The Chamber is supportive of the negotiation of bilateral and regional free trade agreements (FTAs) that can speed up the process of global trade integration and further unify and update intellectual property protections.

The Chamber urges the U.S. Government to look to the United States – Korea Free Trade Agreement (KORUS)<sup>8</sup> intellectual property provisions as a benchmark when negotiating other bilateral or regional trade agreements. The Trans-Pacific Partnership (TPP) Agreement is the next immediate opportunity where such standards should be pursued and built upon with important trading partners. If these countries can reach consensus on a strong set of protections for copyrights, patents, trademarks, and trade secrets, the TPP promises to create a new global benchmark for IP. And in doing so, they may establish a community of “first markets,” an economic bloc of \$28 trillion in collective GDP that will provide a substantial safe haven for innovation. The precedential value for setting standards in this critical trading region as well as the sheer scope and size of the TPP necessitates that the U.S. pursue high-standard benchmarks for IP.

The Chamber supports the Transatlantic Trade and Investment Partnership (TTIP) as a vehicle for increasing trade between the United States and the European Union and meaningfully address measures that hinder IP protection and enforcement, such as those driven by industrial policy priorities or that otherwise impede market access and trade or undermine the rights of IP holders.

The TTIP negotiations should assess and address specific areas where both partners can achieve the goals of economic growth and job creation by strengthening IP provisions, recognizing the unique nature of the relationship and the frameworks that each country has already adopted.

### **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 is a public policy problem because of the considerable role intellectual property plays in a healthy economy.

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<sup>8</sup> Congressional Research Service. *U.S.-South Korea Free Trade Agreement (KORUS FTA): Provisions and Implications*. By William H. Cooper, Mark E. Manyin, Remy Jurenas, and Michaela D. Platzer. 2011 P42-43.

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 has 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 become more active than ever before, as demonstrated by 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 and 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 pirate sites.

### **Rogue Sites/Notorious Markets**

Physical markets continue to be significant contributors to piracy and counterfeiting, but fighting intellectual property theft on the Internet is imperative. 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. These “rogue sites” are a plague on openness, safety, and freedom on the Internet, and unfortunately profit from the hard work of America’s creative industries and the thousands they employ.

*A Threat to Consumers:* One of the problems is that it is difficult for consumers to determine which websites are legitimate. Rogue sites often 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 rogue 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.

Rogue sites undercut an intellectual property system that helps provide assurance to consumers that the products they use are authentic, safe, and effective. Consumers can rely on trusted brand

names to know instantly the level of safety and quality of the goods they are purchasing. When that system is in danger, consumer confidence is undermined.

Rogue sites put 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, rogue sites have been found to be selling 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 fiery explosions instead of 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. In a study done by McAfee, twelve percent of all known sites that distribute unauthorized content are actively distributing malware to users who download content.<sup>9</sup> Finally, Internet-based piracy is particularly harmful because a single pirated file on Internet-based piracy platforms can be the source of massive, ongoing theft of creativity.

***Inclusion in the Special 301:*** USTR has recognized the problem of rogue sites in the context of its prior Special 301 Out-of-Cycle Reviews of Notorious Markets. We urge USTR to factor the Notorious Market findings into the annual Special 301 review and make action by foreign governments to address and fix 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

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<sup>9</sup> Paula Greve, Digital Music and Movies Report: The True Cost of Free Entertainment, McAfee, 2010.

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), most notably the KORUS FTA. These modern standards have been accepted on five continents and have been a model for intellectual property protection and enforcement to FTA partners and non-FTA partners, alike.

Full and complete implementation of these baseline standards is essential to begin to address the forum shopping and flight from jurisdiction-to-jurisdiction that we have seen repeatedly in the fight against criminals engaged in online intellectual property theft. We urge the USTR to continue to make this a top priority and that where our trading partners consistently 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 rogue sites 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, voluntary steps to avoid the misuse of their services by criminals. "See no evil" is not a responsible business practice in today's more 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 FTAs and laws. 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.”<sup>10</sup> 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.<sup>11</sup> “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.”<sup>12</sup>

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

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<sup>10</sup> World Customs Organization Glossary of International Customs Terms. (2006, May). [http://wcoomdpublications.org/downloadable/download/sample/sample\\_id/123/](http://wcoomdpublications.org/downloadable/download/sample/sample_id/123/)

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

<sup>12</sup> *Ibid*

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.

### **Transshipment**

Overseas rogue sites 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.<sup>13</sup> Overseas remote sellers often mis-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.<sup>14</sup>

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 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.<sup>15</sup>

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 Organization<sup>16</sup> and the U.S. Intellectual Property

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<sup>13</sup> *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.

<sup>14</sup> The Association of Convenience & Petroleum Retailing. *Remote Sales of Tobacco* (Retrieved March 19, 2010). [www.nacsonline.com/NACS/Government/Tobacco/Pages/RemoteSalesofTobacco.aspx](http://www.nacsonline.com/NACS/Government/Tobacco/Pages/RemoteSalesofTobacco.aspx).

<sup>15</sup> USPS, “*Basic Eligibility Standards for Priority Mail*,” available at <http://pe.usps.com/text/dmm300/123.htm> (November 1, 2010); [www.discountcigarettesbox.com](http://www.discountcigarettesbox.com) (last visited November 17, 2011) (“The parcels are sealed and cannot be opened for postal inspection”).

<sup>16</sup> *Illicit Trade Report 2013*, World Customs Organization, Page 68, accessed at <http://www.wcoomd.org/en/topics/enforcement-and-compliance/activities-and->

Enforcement Coordinator.<sup>17</sup> Counterfeit goods seized in express and mail shipments now not only make up 81% of all counterfeit seizures cases, but also account for 25% of MSRP value seized, up from 17% the year ago.<sup>18</sup>

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 Teams. This approach continues to show sustained enforcement success.<sup>19</sup> 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. With increased enforcement at the United States depots, we anticipate similar results.

***Streamlining of Processes:*** We encourage the U.S. Government to review, streamline, and improve its guidelines and procedures for the seizure and destruction of counterfeit goods. We believe these updated procedures will facilitate an increased amount of seizures. Such an effort should focus on those goods designated as non-mailable and goods classified as “Consumer Safety and Critical Technology Products.”

Equally as important to stopping transshipment of counterfeit goods is the destruction process, both of seized counterfeit goods and the machinery used to produce these goods. Once these

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programmes/~media/WCO/Public/Global/PDF/Topics/Enforcement%20and%20Compliance/Activities%20and%20Programmes/Illicit%20Trade%20Report%202012/ILLCIT%202013%20-%20EN\_LR2.ashx

<sup>17</sup> 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>

<sup>18</sup> Intellectual Property Enforcement Fiscal Year 2013 Seizure Statistics, Prepared by U.S. Customs and Border Protection Office of International Trade, Pg. 13, accessed at [http://www.cbp.gov/sites/default/files/documents/ipr\\_annual\\_report\\_2013\\_072414%20Final.pdf](http://www.cbp.gov/sites/default/files/documents/ipr_annual_report_2013_072414%20Final.pdf)

<sup>19</sup> HM Revenue & Customs. [www.hmrc.gov.uk](http://www.hmrc.gov.uk).

goods are seized, it is vital they be destroyed in a proper manner. 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."<sup>20</sup> 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.

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<sup>20</sup> Office of the United States Trade Representative. (2011). 2011 Special 301 Report, p. 11.

## **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 comprehensive strategy to protect and promote intellectual property.<sup>21</sup> While the Chamber is pleased with the IPEC's work so far, successful implementation of the IPEC's strategy will require a sustained commitment from both the administration and Congress. We urge the Administration to confirm swiftly the new IPEC, and we urge the Administration and Congress to ensure that the IPEC has the requisite authority, staff, and budget to achieve effective intellectual property protection.

### **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

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<sup>21</sup> Office of the Intellectual Property Enforcement Coordinator. Executive Office of the President. (2010, June). *2010 JOINT STRATEGIC PLAN ON INTELLECTUAL PROPERTY ENFORCEMENT*, pg. 2.



the U.S. economy. As such, the Chamber urges dedicated funding and support for the program, allowing it to expand and improve.

### **Preserve 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 forums, 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. The Chamber encourages the U.S. government to work with the Argentinian government to seek remedies for the following areas of concern, as laid out by the GIPC Index.

### **Patents, Related Rights, and Limitations**

**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, the Argentinian patent office, Instituto Nacional de la Propiedad Industrial (INPI), suffers from major patent backlogs. Industry reports suggest that companies face significant challenges in securing and enforcing patent protection for biopharmaceutical and biotech inventions in Argentina. The Chamber urges 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.

**Regulatory Data Protection:** Argentinian law does not provide adequate regulatory data protection. Specifically, the law allows Argentinian officials to rely on the data submitted by originators to approve requests by competitors to sell similar products. However, Argentina's TRIPS obligations under Article 39.3 require that the law prevent authorized reliance for a period after the approval of the innovative medicine in Argentina. The Chamber recommends that the U.S. government encourage the Argentinian government to institute a term of regulatory data protection that is compliant with Argentina's obligations under TRIPS.

### **Copyright**

**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. The Chamber encourages the U.S. government to urge their Argentinian counterparts to institute effective and timely mechanisms to combat online copyright infringement.

## Australia

The Australia-U.S. Free Trade Agreement (AUSFTA) remains one of our most significant trade pacts in the last 20 years. While the U.S.-Australian trade relationship has grown steadily as a result, it is set to reach new high levels pending the conclusion of a high-standard Trans-Pacific Partnership Agreement, of which both countries are party. However, there remain some issues in Australia's implementation of its prior FTA commitments as well as troubling developments in the trademark space.

### **Patents, Related Rights, and Limitations**

**Patent Linkage:** Australia has a patent linkage system, but the inadequate mechanism for notifying patent holders of applications to market unauthorized copies of drugs, as well as the deterrent effect of unduly high damages on those seeking to enforce patent rights, are in tension with Australia's FTA commitments.<sup>22</sup>

According to a government study, non-innovative producers in practice do not notify the patent holder—as required under AUSFTA commitments—but instead certify their belief that their product does not infringe a valid patent. As a result, the government recognizes that the notification system “does not appear to work well.”<sup>23</sup> 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. However, the Australian government currently has a practice of pursuing 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,

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<sup>22</sup> Global Intellectual Property Center. *Trading Up: The Evolution and Implementation of Intellectual Property Rights in U.S. Free Trade Agreements*, at 26-27 (2015). <http://www.theglobalipcenter.com/wp-content/uploads/2015/01/Trading-Up-Final3.pdf>

<sup>23</sup> Tony Harris et. al., *Pharmaceutical Patents Review Report*, at 143-44 (2013) [http://www.ipaustralia.gov.au/pdfs/2013-05-27\\_PPR\\_Final\\_Report.pdf](http://www.ipaustralia.gov.au/pdfs/2013-05-27_PPR_Final_Report.pdf).

patent holders may be deterred from making use of available procedures, even when there is a good faith basis for their belief that they have a valid patent. The government, furthermore, has not taken a similar position in relation to losses experienced by innovator companies as a result of premature generic entry.

### **Trademarks**

As noted previously, Australia set a troubling precedent by restricting the use of trademarks in trade through its 2011 Tobacco Plain Packaging Act—the only statute of its kind globally. The law is presently the subject of a WTO dispute settlement case. While the Chamber supports advancing public health, we are deeply concerned about the approach taken by Australia and the unintended consequences created. First and foremost, we are concerned that the mandated elimination of the use of an entire legal industry’s trademarks is not only inconsistent with international intellectual property obligations, but that this action also establishes a dangerous precedent with implications for a wide range of industries. Government mandated abrogation of legally sanctioned intellectual property, as in the case of Australia’s plain packaging law, is both unprecedented and unwarranted and will incentivize additional efforts to erode intellectual property protection.

Two recent studies by KPMG highlight the unintended consequences such policies can create. In October 2013 KPMG found that in the wake of Australia’s plain packaging law, sales of branded black market cigarettes rose 154%. In a second study in April 2014, KPMG reported that since the enactment of plain packaging the decrease in the consumption of legal cigarettes has been largely offset by the increase in consumption of illegal cigarettes, with total consumption of tobacco in Australia remaining broadly stable.<sup>24</sup>

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<sup>24</sup> KPMG (2014), *Illicit Tobacco in Australia*, pg. 29

## **Brazil**

In recent years, both the Brazilian private sector and the Brazilian government have increasingly recognized the role that strong IP protections and enforcement standards play in fostering innovation and spurring economic growth. However, a number of specific challenges remain, particularly in the patent space. The GIPC Index outlines the following areas where Brazil would benefit from strengthening specific IP protections. In order to support efforts in Brazil to improve the intellectual property regime, we encourage the U.S. Government to pursue the following specific goals with its counterparts in Brazilian government.

### **Patents, Related Rights, and Limitations**

**Prior Consent:** The Brazilian National Health Surveillance Agency (ANVISA) continues to have the right to provide prior consent to pharmaceutical patents that are being examined by the Brazilian Patent Office (INPI). Consequently, decisions on whether to grant a pharmaceutical patent are based on examination not solely by patent specialists and officials at INPI but also by ANVISA. This standard of dual examination is inconsistent with Brazil's obligations under Article 27.1 of TRIPS. We encourage the U.S. Government to work with the Brazilian government through bilateral dialogues to update legislation to address the dual examination standard in order to ensure that Brazilian law is both TRIPS compliant and improve the intellectual property environment.

**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.

**Technology Transfer Agreements:** All 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.

**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.

**Patent Prosecution Highway Agreement:** The Chamber supports the negotiation and implementation of a United States-Brazil Patent Prosecution Highway (PPH). The PPH is a key tool to help expedite the patent examination process in order to rapidly bring new technologies to market. In 2014, the U.S. Chamber and U.S. Section of the Brazil-U.S. Business Council sent a letter to U.S. Commerce Secretary Penny Pritzker requesting a PPH with Brazil. The Chamber's letter followed a letter to Minister Mercadante from the Brazil Section of the Brazil-U.S. Business Council (CEBEU) of Confederation of National Industries (CNI) and the Brazil Section of the U.S.-Brazil CEO Forum supporting the creation of a PPH between the U.S. and Brazil. Due to the interest by both U.S. and Brazilian industry, the Chamber recommends that the U.S. Government begin a dialogue with the Brazilian government to create an agreement introducing

a PPH. Such efforts could have a significant impact on reducing the growing patent application backlog faced by INPI.

## **Copyright**

**Piracy:** Internet Piracy in Brazil is a serious concern. The explosive growth of broadband has accelerated the migration of piracy of all kinds of copyrighted works to the Internet. Sites targeting the Brazilian market that link to infringing cyberlocker services are a priority. The prevalence of online piracy 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.

In recent years, the National Council Against Piracy and Intellectual Property Crimes (CNCP) has developed several successful initiatives to combat hard good piracy, such as the “City Free of Piracy” initiative, which both provide enforcement mechanisms to counter piracy and educate consumers about the dangers of counterfeit goods. However, industry reports that these initiatives need increased resources in order to operate effectively and increase initiatives to include the online space. The Chamber recommends that the U.S. Government work with the Brazilian government to help bolster the resources needed to ensure these successful initiatives can continue to thrive.

**Pay-TV Piracy:** Brazil continues to take steps to address pay-TV piracy by trying to pass legislation that would criminalize the unauthorized reception and decryption of encrypted satellite signals. Brazilian law enforcement has also made efforts to address the problem, however, there are currently not enough resources to address the magnitude of the issue.

**Pay-TV Local Content/Forced Localization:** Brazil has implemented local content quotas and other local requirements for production and distribution for international programmers and continues to propose more forced localization requirements in several IP intensive sectors. Forced localization requirements and the resulting quotas restrict market access, which has the opportunity to fuel piracy and proliferate IP theft. The U.S. Chamber recommends that the U.S. Government work with their Brazilian government counterparts to remedy industry’s concerns



regarding the forced localization requirements in order to ensure that copyright intensive industries in Brazil can continue to grow and thrive.

## **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.<sup>25</sup> This condition makes setting high standards in the Trans-Pacific Partnership Agreement—of which Canada is a negotiating party—all the more important for gaining meaningful cooperation on IP.

Unfortunately, as the GIPC Index demonstrates, Canada's IP climate remains far behind other developed countries. 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.

### **Copyright**

In recent years, the Canadian government has taken a number of steps to improve IP protection in the copyright space. In particular, the Chamber applauds the Canadian government's recent ratification of the World Intellectual Property Organization's (WIPO) Internet Treaties. Additionally, the 2012 amendments to Canada's Copyright Modernization Act included a system of notification between rights holders and Internet service providers (ISPs). However, the amendments did not include a requirement for intermediaries to take down infringing materials upon becoming aware of such materials. The amendments furthermore create a safe harbor for ISPs and other online intermediaries with no concurrent obligation to take reasonable steps to address online infringement within their knowledge and control. The notice-and-notice provisions of the Act came into effect January 2, 2015. While the Chamber applauds the Canadian government for introducing a system of notification, we believe that this system should operate alongside a notice and takedown system to enhance the effectiveness of efforts to combat online copyright infringement. We recommend that the U.S. government work with their

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<sup>25</sup> 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>

Canadian counterparts to ensure that Canadian intermediaries have an obligation to expeditiously remove infringing materials upon becoming aware of such materials, and to otherwise promote reasonable practices to enhance cooperation in addressing internet piracy and thereby expand commercial opportunities for Canadian and American creators alike.

We express our grave 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 urges 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 extending the term of protection.

### **Patents, Related Rights, and Limitations**

Patent protection in Canada lags significantly behind the protection provided in other developed countries, as evidenced by the GIPC Index. 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 an arbitrary patentability test on invention, 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 is inconsistent with international norms and Canada's treaty obligations under NAFTA and TRIPS. The patent utility requirements have caused nearly 20 patents to be invalidated for inutility, notwithstanding the fact that these

important medicines were found to be safe and effective—in other words, useful—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 GIPC Index found that Canada ranks significantly beyond other developed countries in terms of its level of high-tech outputs, as measured by the Global Innovation Index's Innovation Output Sub-Index.<sup>26</sup> 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 heightened standard during judicial proceedings.

**Right of Appeal:** Under Canada's existing Patented Medicines Notices of Compliance (PMNOC) regulations, patent holders do not have an effective right of appeal. However, the PMNOC 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- negotiated with the European Union), if ratified and implemented, would introduce an effective right of appeal for patent holders. The Chamber urges the U.S. government to work with their Canadian government colleagues to ensure the swift ratification and implementation of CETA as the legislation would markedly improve Canada's IP system.

**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 the recently released text of 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 provides for advanced

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<sup>26</sup> Global Innovation Index, 2014.

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. Despite these challenges, the ratification of CETA would provide a positive first step toward establishing a fulsome PTR regime. The U.S. Chamber urges the U.S. government to work with their Canadian counterparts to ensure that the PTR system implemented through the provisions of CETA is consistent with other developed economies.

**Regulatory Data Protection:** Canadian law currently provides for eight years of regulatory data protection (RDP) and the recently concluded CETA text further confirms and enconces eight years of data protection in Canada. 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. This is viewed as a negative development by the life sciences sector. The Chamber recommends that the U.S. Government work with the Canadian government to ensure that Health Canada puts in place strict safeguards to limit and control the release of clinical trial data and further ratify the CETA agreement.

### **Trademarks**

As part of CETA and a wider reform process, the Canadian Parliament is considering amendments to the Trade-Marks Act, as well as accession to the Madrid Protocol, the Nice Agreement, and the Singapore Treaty on the Law of Trademarks. Major changes to the Trade-Marks Act would include the elimination of any need to use a trademark in Canada or abroad prior to registration; elimination of required filing grounds at the time of filing for a trademark application; and the elimination of a statement of use or intention to use a trademark in Canada. 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. The Chamber recommends that U.S. government collaborate with their Canadian colleagues, when possible, to ensure these agreements are ratified into law.

## **Enforcement**

Canadian border officials have not traditionally had *ex officio* authority powers 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 *Combatting 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. However, while Customs officers are given a right of detention, it is not clear whether this right, in practice, will extend to goods for which rights holders have not made a “request for assistance.”

Further, the final text of Bill C-8 failed to include provisions prohibiting the shipment of in-transit goods. The omission of such provisions jeopardizes our 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 urges the U.S. Government to 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 a critical U.S. trading partner, and IP is an essential component of that relationship. As the U.S. is currently in the process of negotiating the TPP agreement with Chile, U.S. industry would be particularly encouraged by the full implementation of the IP chapter of the 2004 Chile Free Trade Agreement (FTA) prior to the conclusion of the TPP as it would markedly strengthen Chile's IP system. In the interim, the following concerns remain.

### **Patents, Related Rights, and Limitations**

**Patentability:** The U.S. Chile-FTA requires that an invention can receive patent protection if it is new, non-obvious, and capable of industrial application. However, industry reports that Chile has applied a heightened standard for the non-obvious requirement whereby an invention must demonstrate a major structural difference between a claimed compound and previously existing compounds. This heightened standard is also inconsistent with Chile's obligations under TRIPS. Further, long delays at the Chilean patent office – an average of five years for pharmaceutical patents – make it difficult to obtain patent protection in a reasonable and timely fashion. The Chamber encourages the U.S. Government to work with the Chilean government to bring their patentability requirements in line with Chile's obligations under the FTA and TRIPS agreement.

**Patent Linkage:** Chile has yet to implement a patent linkage mechanism despite its obligation to do so under the FTA with the United States. Since 2012, the Chilean Congress has considered an amendment to the Industrial Property Law No.19,039 which would introduce a fairly promising patent linkage system, including a public registry of known patents relevant to new market approvals and proof in new applications that such patents are not infringed. This law, if ratified and implemented, would represent a promising step for pharmaceutical IP protection in Chile. The Chamber recommends the U.S. Government to work with the Chilean government to encourage the passage of these amendments to the Industrial Property Law in order to meet Chile's obligations under the U.S.-Chile FTA.

### **Copyright**

**Frameworks that Promote Action Against Online Piracy:** The U.S.-Chile FTA requires that Chile implement legal incentives for cooperation between ISPs and copyright holders in order to

combat online copyright infringement. Law No.20,435 introduced a voluntary system under which ISPs are asked 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, ISPs that fail to act after acquiring the notice of an infringement face no consequences, outside of the copyright-holder seeking court order. The Chamber urges the U.S. Government to work with the Chilean government to introduce a system which promotes the expeditious takedown of material, including consequences for the ISPs if they fail to act, in order for Chile to meet its obligations as part of the FTA.

Additionally, in the FTA, Chile agreed to make the sale of pirate decoders and distribution of pirated pay-TV signals a legal offense. Draft legislation to address the problem of piracy in the pay-TV space had previously been introduced in Congress, but was not brought to a final vote. The Chamber encourages the Chilean government to engage stakeholders and work toward reintroducing, voting, and enacting this legislation.

**Technological Protection Measures (TPMs):** The U.S.-Chile FTA requires Chile to provide liability for those who knowingly circumvent TPMs or who import, manufacture, or sell circumvention devices. However, Chile has yet to implement specific protections against circumvention of TPMs. Industry also reports that circumvention devices are widely sold throughout the online and physical marketplaces. The Chilean Executive and Legislative branches had previously introduced legislation that would create criminal penalties for circumventing TPMs and circumvention devices; however, there has been little movement to actually pass such legislation. The Chamber encourages the U.S. Government to collaborate with the Chilean government to introduce legislation which fulfills Chile's FTA obligations regarding TPMs.

### **Trademarks**

**Plain Packaging Legislation:** The Senate of Chile is currently considering legislation which could signify the destruction of trademarks and branding rights. The legislation—which would expand the plain packaging of tobacco products—would further restrict the legitimate use of trademarks in trade and set a negative precedent for companies from both the U.S. and Chile. The U.S. Chamber clearly recognizes the public health objectives of reducing smoking and also



respects the right of countries to regulate in the national interest. At the same time, trademark destruction through plain packaging is an inappropriate policy response, as it undermines protection of legitimate uses of intellectual property.

## **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 all intellectual property-related administrative penalty decisions. Pending amendments to the Copyright Law and drafting of the judiciary interpretations for patent infringement cases also demonstrates work 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 U.S. market. This situation continues to undercut the job growth that results from innovation and endangers consumers in China, the United States, and around the world. Critical inventions made by our members still lack sufficient protections in spite of an active reforms agenda in China.

The Chamber recommends continued monitoring of China's intellectual property regime due to a full range of practical 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 with the purpose of driving innovation that instead favor domestic champions and create barriers for foreign companies to compete with domestic Chinese counterparts. 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.

We were encouraged by the commitments from the 2014 Strategic and Economic Dialogue (S&ED) and the Joint Commission on Commerce and Trade (JCCT) to address many intellectual property-related issues. For example, the recognition of trade secret protection (discussed in greater detail below) as essential to maintaining fair competition and developing an innovative economy was welcome. We are delighted that China intends to vigorously investigate and prosecute trade secret theft cases and to protect trade secrets contained in materials submitted by companies as part of regulatory, administrative, and other proceedings according to Chinese law.

**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 Plenum:** China continued issuing its ambitious roadmap for institutional and economic reforms at its Fourth Plenum.<sup>27</sup> Apparently, the new round of reforms intends to adopt ideas from a rule of law system. China vows to support the value of the laws, making it harder for officials to make arbitrary decisions. China also promises to be transparent and to engage in a deeper level with outside experts in the legislative process. The Fourth Plenum calls for lifelong accountability imposed on the administrative agencies for making major decisions. To deter local protectionism, the Fourth Plenum also addresses some detailed aspects of the system, such as setting up circuit courts and cross-regional courts to deal with major local cases, recruitment of more qualified judges and prosecutors and implementing a registration-based filing system for new court cases.

The Chamber hopes that all these measures, in conjunction with the ongoing reforms such as specialized courts, 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 on intellectual property matters.

Apparently, China is experimenting with various institutional reforms through specialized intellectual property courts and the circuit courts with respect to funding and judicial appointments. The Chamber will closely monitor the progress and find out if the reforms have real benefits to intellectual property protection.

## **New Intellectual Property Courts**

China fulfilled its promise about specialized courts made at Third Plenum at an unprecedented pace. By the end of 2014 China launched three specialized intellectual property courts at intermediate court levels in Beijing, Shanghai and Guangzhou. These specialized courts were created to better deal with "technology centric" matters such as patent and trade secret cases. We are particularly encouraged that China has made efforts to put experienced intellectual property judges to sit in the new courts.

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<sup>27</sup> The full text of the Communiqué in English translation [http://www.china.org.cn/china/fourth\\_plenary\\_session/2014-12/02/content\\_34208801.htm](http://www.china.org.cn/china/fourth_plenary_session/2014-12/02/content_34208801.htm)

It is well noted 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. The new courts may also be overwhelmed by a huge caseload of non-patent cases. In spite of all these concerns, the Chamber remains hopeful that these new courts will deliver consistent decisions through a group of specialized judges, especially on intellectual property cases involving complicated technologies. The Chamber will continue monitoring the real impact of the new intellectual property courts. Feedback from members may eventually contribute to the future reform of the courts.

### **Trademark**

**Trademark Law Revision:** The new Trademark Law as amended in 2013 entered into effect officially in May 2014, together with the new implementing regulations. The real benefits of the new Trademark Law have not been visible to Chamber members, as the Trademark Office has been battling the software issues that partly paralyzed the trademark examination work.

The Chamber has submitted its report to the draft new Judicial Interpretation 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.<sup>28</sup>

**Damages:** The increased cap of statutory damages in the amended Trademark Law has raised significant hopes for the courts to impose meaningful damages against infringers. China has seen fast growing trademark disputes in 2014, including those happening between reputable firms. The final outcomes may develop a solid judiciary practice for awarding damages, including punitive damages against willful infringement. The Supreme People's Court issued a special report in October 2013 announcing a number of representative cases as examples of

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<sup>28</sup> 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>

improvement of remedies in intellectual property rights cases.<sup>29</sup> 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. While China is not a case law country, the specific examples give some hope for brand owners to pursue civil damages. The Chamber will closely monitor whether or not local courts will follow the “trend” nationwide.

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

**Enforcement in 2014:** China maintains a high level of active enforcement efforts against counterfeiters in 2014, as evidenced by its official release of statistics.<sup>30</sup> The statistics show that the number of convicted counterfeiters increased by about 40% compared to 2013.

Notably, the level of administrative enforcement seems to be declining. The actual number of cases and the criminal transfers had a significant reduction.<sup>31</sup> The Chamber is concerned that

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<sup>29</sup> 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>.

<sup>30</sup> Complete data for 2014 is not available as of this writing. The official sources at the National Leadership Office against Counterfeits and IP Infringement states that for the first 9 months of 2014 the national administrative authorities handled a total of 112,700 cases and cracked down 1,938 underground factories. The same report indicated that the police successfully handled 16,100 cases and a total of 15,700 individuals were convicted in 11,600 criminal cases. <http://www.ipraction.cn/article/xxgk/gzdt/bmdt/201412/20141200038816.shtml> In contrast, the same statistics last year indicated that 35,385 individuals were arrested in 234,000 cases in the first three quarters of 2013. <http://www.ipraction.cn/2013/12/10/ARTI1386662596694798.shtml>. The same sources revealed that 10,566 suspects were convicted in a total of 6,773 criminal cases concluded by the criminal courts nationwide.

<sup>31</sup> As of the end of November 2014, the Administration for Industry and Commerce (“AIC”) nationwide handled 63,300 IP infringement cases with a total case value up to 954 million RMB. The AIC transferred 328 cases to judiciary authorities for criminal enforcement. <http://www.ipraction.cn/article/xxgk/gzdt/bmdt/201501/20150100042258.shtml>. Comparatively, in 2012,

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 the effect it prevents AIC authorities from seizing counterfeits from or penalizing resellers who allege having 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 number of criminal transfers also significantly dropped from 2012. 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.

The national police have shifted focus on cross-border enforcement actions against major counterfeit drug makers, which has made marked achievements.<sup>32</sup> 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.

**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.

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AIC nationwide docketed 120,400 cases and transferred 1576 cases to criminal authorities, among which Guangdong AIC alone transferred 1,232 cases. [http://www.gov.cn/gzdt/2013-03/15/content\\_2355009.htm](http://www.gov.cn/gzdt/2013-03/15/content_2355009.htm)

<sup>32</sup> 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>

In January 2014, the State Administration for Industry and Commerce (SAIC) issued Measures for Online Trading and Related Services (“Online Trading Measures”) to replace the SAIC Order 49 that was issued in 2010. The Online Trading Measures seem 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, although the final version of the Online Trading Measures include some additional liability against online trading platforms and vendors who fail to obtain governmental license to sell certain types of products (e.g., medicine) in response to the comments made by the Chamber. We urge USTR to increase attention and focus on improving the online environment and press for effective policy changes.

We have taken note of the helpful effort of the Beijing Higher People’s Court in addressing liability of online trading platforms in its December 2012 “Answers to Various Questions Regarding Hearing of Intellectual Property Rights Disputes Involving E-commerce.” However, even such efforts have not made up for the lack of effective remedies in Chinese civil procedures, e.g., unwillingness of the courts to use preliminary injunctions or civil sanctions (fines or short term detention) to deter trademark violations.

Taobao.com reportedly expresses a willingness to cooperate with more brand owners, before and after its IPO listing in New York Stock Exchange. However, massive amounts of counterfeit goods continue to be distributed via Taobao.com, indicating the need to do significantly more. Taobao 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. Taobao must also diligently cooperate with brand owners in civil actions by complying with court orders to seal funds in counterfeiters’ accounts at Alipay, which is the payment service provider affiliated with Taobao and also the largest in China of its kind.



## **Patent**

**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.

**Interpretation of Article 26.3 of China’s Patent Law:** 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 are 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:** According to WTO commitments, China must protect data submitted in the context of a drug registration application from unfair commercial use. However, the Chamber is concerned about inadequacies in China’s current regulatory regime that allow for unfair commercial use of safety and efficacy data generated for marketing authorization. China’s regulatory procedures permit the CFDA to grant marketing approval to products that have previously been approved outside of China. Non-originator applicants can submit published material and reference regulatory decisions by foreign regulatory agencies as justification for approval. In addition, limited local clinical trials are required to gain approval.

During the 2012 JCCT, the Chinese government agreed, in order to promote scientific advancement and to establish effective regulatory data protection, to define a new chemical entity in a manner consistent with international research and development practices in order to ensure regulatory data of pharmaceutical products are protected against unfair commercial use and unauthorized disclosure. The Chamber is concerned that little progress has been made by China to meet this commitment. The Chamber urges the U.S. Government to work closely with the Ministry of Health and other stakeholders in 2015 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.<sup>33</sup> 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 are pleased that Chinese officials reported that the campaign will continue in future years.

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<sup>33</sup> See [http://www.ipr.gov.cn/gndtarticle/updates/govupdates/201305/1755519\\_1.html](http://www.ipr.gov.cn/gndtarticle/updates/govupdates/201305/1755519_1.html). In one example, the MPS conducted nationwide raids in over 18 provinces on April 19, 2013, netting arrest of 104 suspects in 45 cases.

The Chamber is highly 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). Possible reforms of Criminal Code and Drug Administration Law will be critical in dealing with the illegal bulk chemical factories—which are not under jurisdiction of CFDA—have been supplying illegal APIs over the Internet to domestic and overseas counterfeiters, causing a serious threat to patients.<sup>34</sup> 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, producing breakthrough results in 2015.

**Patent Protection and Enforcement:** The proposed amendment to the Patent Law has remained silent in 2014. Some have suggested that the delay is related to the controversy as to whether State Intellectual Property Office (SIPO) and its local offices should be given pervasive powers to enforce patents through administrative channels or whether that authority should remain with the judiciary.

The Chamber, together with the American Chamber of Commerce in China, submitted comments on SIPO's draft Amendments to the Patent Law in November 2012 and on the State Council Legislative Affairs Office's (SCLAO) Amendments to the Patent Law in April 2013<sup>35</sup>. The primary concerns in both drafts pertain to the expansion of the remedial powers of local administrative agencies. The local intellectual property offices will be empowered to impose injunctive relief, damages, fines and penalties for patent infringement, powers previously limited to the more experienced judicial authorities. 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

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<sup>34</sup> China reported that World Anti-Doping Agency director general David Howman cited China as the source of "99 percent of the raw materials" used to make illegal drugs. . [http://www.chinadaily.com.cn/sports/2013-02/19/content\\_16236168.htm](http://www.chinadaily.com.cn/sports/2013-02/19/content_16236168.htm)

<sup>35</sup> The U.S. Chamber of Commerce and the American Chamber of Commerce in China jointly submitted comments on SIPO's Draft 4<sup>th</sup> Amendments to the Patent Law and SCLAO's draft 4<sup>th</sup> Amendment to the Patent Law.

<http://image.uschamber.com/lib/feed13797d6c06/m/1/2012+Chamber+AmCham+Patent+Law+Comments.pdf>

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 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.<sup>36</sup> 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 in 2013 to 75,000 in 2020.<sup>37</sup> 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.

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<sup>36</sup> The official decision is at [http://www.sipo.gov.cn/zwgg/jl/201311/t20131106\\_876947.html](http://www.sipo.gov.cn/zwgg/jl/201311/t20131106_876947.html)

<sup>37</sup> See [http://www.gov.cn/zhengce/content/2015-01/04/content\\_9375.htm](http://www.gov.cn/zhengce/content/2015-01/04/content_9375.htm).

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.<sup>38</sup>

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 Patent Reexamination Board's examination and judicial review.

**Patentability of Graphical User Interface:** SIPO issued a new draft amendment to the Patent Examination Guidelines for public comment in October 2013, which grants the protection of graphical user interface (GUIs) patents, reversing its current policy that does not recognize GUI patents.<sup>39</sup> We are pleased that SIPO appears prepared to recognize the patentability of GUIs under China's Patent Law. The rapid technological development in the IT industry and other information technology areas has made GUI designs a critical factor in determining the success of a product. Availability of patent protection for GUI designs will incentivize designers and local design companies to innovate. This will also bring China into alignment with international best practices. We applaud SIPO for being attentive to the feedback from stakeholders on this issue.

While the Chamber strongly supports the proposed amendments, 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.

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<sup>38</sup> 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](http://www.uschamber.com/sites/default/files/reports/1211_china_patent_paper.pdf)

<sup>39</sup> See SIPO official notice at [http://www.sipo.gov.cn/yw/2013/201310/t20131031\\_873560.html](http://www.sipo.gov.cn/yw/2013/201310/t20131031_873560.html)

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 offices 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.

The Chamber also notes 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. Certain industries have a fundamental product base that is ubiquitous but nonetheless generate products that are significantly distinct from one another in the design of certain areas. The design changes on the part of a product that differ from company to company or year to year should be available for patent protection. The Chamber hopes that USTR will continue carrying out dialogues with SIPO in this area and with anticipation that it will lead to similar revisions to the relevant sections in the patent examination guidelines.

### **Inventor Remuneration**

SIPO's draft service invention regulations from 2012 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.<sup>40</sup> In October 2013 SIPO informed the Chamber with specificity that the latest version of the draft regulations was endorsed by an internal committee within the government.

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<sup>40</sup> 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>

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. Moreover, the draft regulation also applies to trade secrets, which 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 included in the final regulations. We urge USTR to closely follow this process.

### **Anti-Monopoly Law**

The Chamber has a long history of robust engagement with Chinese authorities on all aspects of the implementation of China's Anti-Monopoly Law (AML). In September 2014, the Chamber commissioned a report providing detailed analysis on China's application of its AML.<sup>41</sup>

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-

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<sup>41</sup> 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](https://www.uschamber.com/sites/default/files/aml_final_090814_final_locked.pdf)

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).<sup>42</sup> In all of these documents, the Chamber iterated 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 SAIC 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.

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 must be fully taken into account. SAIC should abandon the plan of enacting the draft rules and return to the issuance of intellectual property guidelines. 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

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<sup>42</sup> 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](http://image.uschamber.com/lib/feed13797d6c06/m/1/Chamber+Comments+on+SAIC+AML+IP+Abuse+Nov++2012_CH+EN.pdf)



in China, not just SAIC. The Chamber urges close consideration of all possible impacts these proposal could have on competitiveness and innovation.

### **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).<sup>43</sup> The Chamber submitted comments to SAC on the previous draft version of the Standards Measures in January 2013.<sup>44</sup>

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.

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 engage in discussions with the U.S. on standards-setting and licensing processes at the conclusion of the 2014 Joint Commission on Commerce and Trade,

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<sup>43</sup> See official release at [http://www.sipo.gov.cn/zcfg/flfg/zt/bmgfxwj/201401/t20140103\\_894910.html](http://www.sipo.gov.cn/zcfg/flfg/zt/bmgfxwj/201401/t20140103_894910.html)

<sup>44</sup> 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>

foreign invested companies can still only participate in the standard-setting process by invitation, meaning that most American companies and their Chinese subsidiaries are unable to participate in the standard-setting process. 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.

### **Trade Secret Protection**

The U.S. International Trade Commission has estimated the value of U.S. IP stolen by Chinese entities to total \$48 billion, including lost sales (76 percent of the total) and lost royalties and license fees (24 percent).<sup>45</sup> 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

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<sup>45</sup> USITC, *China: Effects of Intellectual Property Infringement and Indigenous Innovation Policies on the U.S. Economy*, USITC Publication 4226, May 2011.

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).<sup>46</sup> Providing the required proof to initiate a criminal investigation can be difficult, if not impossible. Even if an investigation is successful, the misappropriator is generally not imprisoned for more than three years, a punishment which provides limited deterrence.<sup>47</sup>

Civil and administrative protection for trade secrets in China 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.<sup>48</sup> 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.

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

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<sup>46</sup> Or bankruptcy by the trade secret owner.

<sup>47</sup> Losses great than ¥2.5M (~\$375k USD) qualify for longer prison terms.

<sup>48</sup> 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.

possible.<sup>49</sup> 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.<sup>50</sup> In part, the limited availability is due to the tremendously high burdens of proof discussed above.

Notably, in 2014, China took several meaningful steps to signal that it is placing greater priority on protecting trade secrets, such as naming trade secrets protection as one of MOFCOM's top three priorities in 2014. Furthermore, there were several commitments in the Strategic & Economic Dialogue and the JCCT that established in concrete detail specific measures to protect trade secrets, including:

- Limiting disclosure of trade secrets during the administrative licensing process to government officials that are absolutely essential for review, and holding them accountable for protecting the information in their possession
- Limiting the information required from companies to include only information reasonably necessary for satisfying regulatory purposes
- Stipulating that any requirements for government agencies to publicly disclose information appropriately allow for the withholding of trade secrets.
- Optimizing administrative and regulatory procedures within the legal system and strengthening confidentiality protection measures

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

China has also signaled over the past year that it is exploring options for either improving existing laws for protecting trade secrets or creating a new law. Whether the new specialized IP courts will really make a difference in this area remains to be seen.

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<sup>49</sup> 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.

<sup>50</sup> 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.

**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**

**Online Piracy:** With respect to online piracy, there has been some progress in government enforcement against infringements. We also notice that companies are forming coalitions to sue major video sites such as Baidu and in some cases being supported by the Chinese courts and National Copyright Administration of China (NCAC).<sup>51</sup> Other companies are entering into agreements with online providers for enhanced protection such as the Microsoft and Alibaba MOU in January 2015. However, China still lacks effective tools to encourage cooperation of Internet intermediaries, to ensure rapid takedown of infringing content, to take action against repeat infringers, and to provide proactive measures to address privacy. The NCAC national campaign and the Network Rules judicial interpretation 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

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<sup>51</sup> 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](http://usa.chinadaily.com.cn/2013-11/20/content_17119636.htm)

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 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.

**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, most recently with the Judicial Interpretation on Online Copyright Liability issued by the Supreme People's Court.

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 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.

**Criminal Code Revision:** The 9<sup>th</sup> amendment to the Criminal Code led by the National People's Congress Standing Committee skipped intellectual property issues completely. 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

While the U.S. and Colombia ratified a free trade agreement in 2011 which included an IP chapter, certain provisions of the FTA have yet to be enforced. The GIPC Index highlights several key ways, including the implementation of the FTA provisions, which would significantly strengthen Colombia's IP system. The Chamber encourages the U.S. Government to work with their Colombian government counterparts to seek the following changes to Colombia's IP system.

### **Patents, Related Rights, and Limitations**

**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 introduce 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.

**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 introduce clarifying legislation which extends RDP to biologics.

### **Copyright**

**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. While the law is currently under consultation, 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 FTA obligations – are passed and enacted swiftly in order to improve Colombia's IP environment.

### **Ratification of International Treaties**

While Colombia has signed and ratified several of the key international treaties measured in the GIPC Index, including the WIPO Internet Treaties, the government has not yet ratified the Patent Law Treaty and the Singapore treaty on the Law of Trademarks. The Chamber recommends that the U.S. Government work with the Colombian government to encourage the ratification and implementation of both treaties in order to strengthen Colombia's overall IP system.

Colombia has also acceded to the Brussels Convention relating to the distribution of Programme-Carrying Signals Transmitted by Satellite, and continues to take steps to address problems with pay-TV piracy; however, the problem persists – particularly in the area of local community cable television operators, or *comunitarias*. The Chamber encourages the U.S. Government to continue its support of the Colombian government's work with the *comunitarias* to bring them into compliance with respect to intellectual property.

## **Ecuador**

The intellectual property environment in Ecuador is incredibly challenging for the pharmaceutical sector. Among other things, Ecuador has issued six compulsory licenses for patented medicines; amended its criminal laws decriminalizing all intellectual property rights violations; charges patentees approximately \$140,000 in total annuities for a patent's maintenance (as compared to \$12,600 in the U.S.); and recently issued Decree 522, which appears to deny the use of trademarks for any medicine once patents have expired.

### **Patents, Related Rights, and Limitations**

**Compulsory Licensing:** In October 2009, Ecuador issued Executive Decree No. 118, a compulsory license decree with the stated intent of improving access to medicines. 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. To date, 32 applications for compulsory licenses have been presented; 12 of which are still pending, two were denied, eight were desisted and one expired. Furthermore, ten of the 32 petitions received by IEPI were filed by Ecuador's public pharmaceutical firm, Enfarma.

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).

**Regulatory Data Protection:** Although Ecuador has ostensibly taken the necessary steps to revise the Ecuadorian Intellectual Property Act to provide protection for undisclosed test data or other information submitted to obtain marketing approval of pharmaceutical products, the actual protection provided remains, in practice, inadequate.

This is because the implementation of RDP in Ecuadorian law prohibits the release of undisclosed test or other data except to protect the public interest, but, in practice, reliance on such data by a generic manufacturer seeking marketing approval is not considered an act of

unfair competition. This renders RDP in Ecuador not only ineffective but also inconsistent with Ecuador's obligations under TRIPS Article 39.3.

**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.

### **Trademarks**

In 2014, Ecuador issued Decree 522, which appears to limit the use of trademarks for any medicine once patents have expired. This measure appears to deny another important form of IP protection that is critical to ensure that innovator companies can distinguish their products from others. A trademark for a medicine helps doctors and patients identify the quality, safety, and

intrinsic effectiveness of a given product – reputational capital that manufacturers strive to build over time.

### **Enforcement**

**Decriminalization of IP Violations:** Also in 2014, Ecuador’s criminal laws were amended effectively decriminalizing all IP violations through the elimination of relevant enforcement and sanction provisions. This removes important enforcement tools to protect against counterfeit goods, including medicines, and worsens Ecuador’s already low levels of IP enforcement.

## **European Union**

Despite the generally high levels of intellectual property protection and enforcement established among the Member States of the European Union, a variety of government restrictions and regulations make the effective protection of intellectual property rights more difficult. It is our hope that many of these issues can be addressed through the bilateral exchange of best practices and through an effective IP chapter in the Transatlantic Trade and Investment Partnership (TTIP).

### **Patents, Related Rights, and Limitations**

**Patent Enforcement:** Innovative companies facing patent disputes from follow-on products have no opportunity to resolve patent disputes before the launch of these infringing products. This makes it difficult for innovators to adequately resolve disputes without significant legal costs and non-compensable market losses.

**Data Disclosure and Confidentiality:** Until October 2014, the European Medicines Agency (EMA) was considering proposed policies which would provide the unrestricted access to publish the clinical trial data and other confidential business information (CBI) contained in regulatory submission for marketing approval. Following a GIPC report which expressed concern with these proposals<sup>52</sup>, the EMA released its final policy guidelines, which include significant potential safeguards to stakeholders, including: limitation of access, redacting, consultation periods, and potential judicial intervention in the case of disagreement. However, concerns remain over the definitions of commercially confidential information (CCI), member-state implementation and functioning of these guidelines, as well as potential recourse mechanisms in instances of misuse and accessed data. Going forward, the EMA must ensure the full implementation and application of key new features of this policy.

### **Copyright**

**European Single Market:** The European Commission's proposal to create a single EU market for intellectual property potentially creates problems for a number of creative industries.

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<sup>52</sup> "Heading in a Different Direction? The European Medicine Agency's Policy on the Public Release of Clinical Trials Data," Global Intellectual Property Center, May 2014.

Although the proposal's objectives for easing rights management and the functioning of collecting societies are commendable, the audiovisual sector does not easily function as a solitary market given different social and economic norms across the EU, as reflected in the EU's own varying state-specific cultural regimes. A top-down approach to collective rights management and the exclusive rights of copyright owners should be maintained.

## **Trademarks**

**Intention to Introduce Legislation Which Restricts the Use of Trademarks:** Several countries have considered proposals similar to Australia's plain packaging legislation, though many have abandoned or postponed action. However, two years ago, the European Union established a tobacco products directive which would restrict the use of trademarks in legal trade. Select member states—Ireland, France, and the United Kingdom—appear to be pushing ahead with plain packaging legislation. In the UK, draft regulations have been published by the Department of Health. The U.S. Chamber clearly recognizes the public health objectives of reducing smoking and also respects the right of countries to regulate in the national interest. At the same time, trademark destruction through plain packaging is an inappropriate policy response, as it undermines protection of legitimate uses of intellectual property.

## **India**

The election of Indian Prime Minister Sri Narendra Modi in 2014 provided an important opportunity to re-establish a collaborative and productive working relationship on intellectual property issues between India and the United States. There are reasons to be optimistic that the new government will take steps to strengthen India's intellectual property environment. Notably, the U.S. and Indian governments have re-opened a formal dialogue through the bilateral Trade Policy Forum, with the creation of an Intellectual Property Working Group as a core element. Moreover, the Indian government has appointed an IPR Think Tank, which has drafted a proposal for a national IPR policy stating among other things, "[T]he objective of the IPR strategy is to transform India into an innovative economy as would reflect in high rankings in appropriate development and innovation indices." We are encouraged by these developments, and urge the U.S. government to again provide an opportunity for a mid-year status check of India's intellectual property regime, which will ensure that subsequent steps are appropriately recognized. In the meantime, although the administration's rhetoric has been positive and the deteriorating intellectual property environment seems to have stabilized, there is currently no substantive basis for a change in India's previous designation from the 2014 Special 301 Review.

Reflecting the legacy of previous governments, India's overall environment for intellectual property remains poor, notwithstanding important signals that India may take steps to enhance its IP-related competitiveness. At the present time, patentability requirements remain outside established international best practices; there is a lack of specific IP rights for the life sciences sector; the enforcement environment remains challenging, with persistent high levels of physical and online piracy; and, finally, India is not a contracting party to many of the core international treaties that collectively establish an international standard for intellectual property laws and enforcement.

### **Patents, Related Rights, and Limitations**

**Patentability Requirements:** Indian patent law has in place an additional requirement to patentability that goes beyond the required novelty, inventive step, and industrial applicability requirements. 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 provision has the particular effect of deterring investment in 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.

This point was relevant in another case involving Roche’s Tarceva, where the generic company, Cipla, was found not to have infringed on Roche’s patented product even though the active ingredient is the same. This approach to patentability requirements is inconsistent with the TRIPS Agreement, which specifies three basic patentability requirements.

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). 2014 did see some positive steps taken by the Indian authorities to protect rights holders. For instance, the decision by the Indian Intellectual Property Appellate Board to stay the Indian Patent Office’s 2013 order revoking Pfizer’s patent on Detrol was a positive development.

**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. A proactive commitment by India to refute the use of

compulsory licensing for commercial purposes would greatly enhance legal certainty for innovative industries.

While no additional compulsory licenses for biopharmaceuticals were issued by Indian authorities in 2014, in two negative developments, the Bombay High Court in July of 2014 upheld the compulsory license granted to Natco for the sale of Bayer's cancer drug Nexavar and the Supreme Court of India rejected Bayer's appeal in December 2014. Furthermore under the previous administration in early 2014, a panel was appointed by the Indian Government to examine the issuing of compulsory licenses for over 20 different medicines from a broad range of therapeutic areas. However, industry understands that the compulsory license panel, has been dissolved under the Modi Administration. Yet, the current Ministry of Health continues to make recommendations to compulsory license medicines under Section 92 of the Indian Patent Act. In order to provide pharmaceutical investors with the certainty that their innovations will be protected in India, we urge the government of India to commit to the repudiation of the use of compulsory license as a commercial tool.

The threat of compulsory licensing also looms within other sectors. 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.<sup>53</sup> India's draft National IP Policy promotes the use of the fund.<sup>54</sup> Similarly, India's 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.<sup>55</sup>

### **Copyright**

**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.

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<sup>53</sup> National Manufacturing Policy. October 25, 2011. Section 4.4

<sup>54</sup> National IPR Policy (Draft). December 24, 2014. Section 5.4.1

<sup>55</sup> National Competition Policy, 2011. Section 5.1(vi)

**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.

### **Trade Secrets and Market Access**

India 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. In a positive step, working in dialogue with a variety of stakeholders including the international business community, the Indian Government earlier in 2014 announced a revision to its Preferential Market Access (PMA) policy. Originally, the PMA policy had included procurement by private sector entities as well the public sector. However, with the new policy in place, the private sector has been exempt from the policy.

### **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 toward weakening intellectual property in a variety of international norm-setting arenas, such as the UNFCCC, WTO, WHO and WIPO. In 2014, an Indian delegate went as far to suggest that “there is not direct linkage between IP and innovation.”<sup>56</sup> India’s positions are especially troubling considering that its patent office has been tasked with coordinating the exchange of views amongst the BRICS countries on the international intellectual property agenda.<sup>57</sup>

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<sup>56</sup> TRIPS Council. IP/C/M/73/Add.1, Paragraph 423

<sup>57</sup> “BRICS Intellectual Property Offices Cooperation Roadmap”, Magaliesburg May 2013.

## **Japan**

Japan remains one of our most important trading partners and is a clear leader in the ongoing negotiations for the Trans-Pacific Partnership (TPP) Agreement. Though Japan scores towards the top of the GIPC Index, a primary concern remains.

### **Patents, Related Rights, and Limitations**

**Inventor Remuneration:** Article 35 of the Japanese patent laws ensures “reasonable remuneration” for employers; however, in practice, Japanese courts have ordered higher remuneration for employees than what had been previously agreed upon in employment contracts. This bias against employers could create an uncertain investment environment in Japan by disrupting business budget planning processes and souring employer-employee relations, especially in cases where employee action is unpredictable.

## Mexico

As a member of the North American Free Trade Agreement (NAFTA) and a negotiating partner to the TPP, Mexico is a key U.S. trading partner. Mexico has made improvements to its IP system and enforcement efforts in recent years, including granting *ex officio* authority to law enforcement officials. However, the Chamber believes that the Mexican government should implement the following changes in order to strengthen Mexico's IP environment.

### **Patents, Related Rights, and Limitations**

**Patent Linkage:** The Chamber believes that Mexico should continue to seek regulatory certainty related to patent linkage, consistent with its 2003 linkage decree, in order to help encourage the development and promotion of innovative pharmaceuticals and patient access to cutting edge, cost effective treatments. The 2003 linkage decree mandates coordination between the regulator, Federal Commission for Protection Against Health Risk (COFEPRIS), and the Patent Office (IMPI). Unfortunately, this decree is not currently implemented in a comprehensive and consistent manner. IMPI and COFEPRIS need to be aligned with numerous court precedents to establish a broader scope of patent linkage for the full range of pharmaceutical patents. Full linkage will avoid resorting to costly and long litigation proceedings for the publication of formulation and use-type patents. The Chamber recommends that the U.S. Government work with the Mexican government to introduce and implement full patent linkage provisions.

**Regulatory Data Protection:** Mexico's commitments under NAFTA require that the government provide adequate and effective protection against unfair commercial use and unauthorized disclosure of data submitted to obtain marketing approval for pharmaceutical products. In June 2012, COFEPRIS published guidelines that provide protection against use of undisclosed test data by any person for the purpose marketing approval for a maximum of five years. However, it is unclear if RDP will be granted to both large and small molecules. The Chamber encourages the Mexican government to clarify the guidelines in order to fulfill Mexico's NAFTA obligations.

## **Copyright**

**Frameworks that Promote Action Against Online Piracy:** The lower house of the Mexican Congress, the Chamber of Deputies, is currently discussing amendments to Federal Copyright Law and Criminal Code. The draft law includes measures that introduce ISP liability; ISP takedown of infringing sites following notice from the Mexican Institute of Industrial Property (IMPI); a graduated user warning system involving IMPI and ISP cooperation; and heightened penalties for online copyright infringement for individuals and ISPs. If passed and implemented, these measures would substantially improve Mexico's copyright protections.

**Camcording:** The Chamber urges 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.

**Other Recommendations:** To further strengthen Mexico's IP environment, the Chamber encourages the Mexican government to implement the WIPO Internet Treaties, to which Mexico acceded in 2002, and ensure that performers and record companies have the ability in law and practice to prevent the uncompensated use of their recordings by broadcasters and establishments.

## **Enforcement**

As noted above, the Chamber commends the Mexican government's decision to provide *ex officio* authority to law enforcement officials. Industry has reported a large number of successful inspections and *ex officio* raids against hard goods copyright infringement, software piracy, and counterfeit medicines. However, criminal enforcement is hampered by a lack of coordination and resources among the different authorities targeting intellectual property crimes. In order to strengthen enforcement efforts, the Chamber recommends that the Mexican government increase coordination between government authorities and provide those authorities with additional

resources to combat hard goods and online copyright infringement, as well as the production and sale of counterfeit medicines. The Chamber also encourages the U.S. government to continue to urge the Mexican government to provide ex officio authority for its customs officials to allow for the seizure of counterfeit and pirated goods.

## **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, the court's troubling practice 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 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 for damages. 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

Because Peru is a TPP negotiating partner, the Chamber would be encouraged by a number of changes to Peru's IP system, as outlined by the GIPC Index. While the U.S.-Peru Trade Promotion Agreement (USPTPA) included a number of IP provisions, Peru has yet to meet the USPTPA obligations. In particular, the Chamber recommends that the U.S. Government work with the Peruvian government to seek the following updates to the existing laws.

### **Patents, Related Rights, and Limitations**

**Patentability Requirements:** Peru's Industrial Property Rights Law provides for 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 countries/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, placing a notice on the website does not constitute an adequate and effective enforcement system as it does not provide patent holders the time or opportunity to seek injunctive relief. 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:** The Peruvian government has yet to implement patent term restoration, an obligation under 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.

**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. A proposed law currently under consideration, Bill 995/2011, would require new drug applications to publicly disclose sensitive information as a precondition of obtaining a sanitary registration. Approval of the bill would essentially render null and void a crucial component of RDP, non-disclosure, and would significantly hinder pharmaceutical patent protection in Peru. As such, the Chamber recommends that that the U.S. Government encourage the Peruvian government to introduce regulatory data protection for all innovative pharmaceutical products for a minimum term of five years.

### **Copyright**

**ISP Liability:** The Peruvian government has yet to introduce a notice and takedown system of copyright-infringing content online, an obligation under 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 reduce online piracy in Peru.

**Piracy:** The Peruvian government has introduced several successful initiatives to combat piracy. For example, Law No. 28289 included criminal sanctions and customs procedures to deter copyright infringement. Pay-TV piracy remains a problem; however, efforts to address the problem are ongoing and could be addressed via FTA IP obligations. However, both physical and online piracy continues to grow. Industry calculations estimate an 80 percent rate of music piracy and a 65 percent rate of software piracy in 2013. Moreover, Peru has been cited as having the highest levels of unauthorized camcording of U.S. motion pictures in Latin America. The Chamber encourages the U.S. Government to encourage the Peruvian government to introduce further legislative measures to combat physical and online piracy.

## **Trade Secrets**

Current Peruvian law provides for a limited level of trade secret protection, which is derived from unfair competition law. However, industry reports that no noted criminal enforcement of trade secret violations has taken place. Moreover, evidence suggests that it is arduous to prove in administrative and judicial proceedings 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.

## Russia

Given the recent 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. The GIPC Index further enumerates areas where the Russian IP system could improve.

### Patents, Related Rights, and Limitations

President Putin in March 2014 signed into law a new set of amendments to the Russian Civil Code, including Part IV which covers all major forms of intellectual property rights offered in Russia. However, a number of challenges remain in the area of patent protected inventions.

**Patent Term Restoration:** The Civil Code Part IV article 1363 provides a mechanism for patent term restoration for biopharmaceuticals, agrochemicals, and pesticides. The 2014 amendments introduce several new layers and requirements for rights-holders when applying for this restoration. The new amendments require the issuing of an additional patent incorporating the claims of the original patent, which could lead to confusion and potential uncertainty particularly with regards to questions of validation of the patent (either in a potential infringement or revocation proceeding). Additional procedural requirements have also been added in the form of ROSPATENT (Russian Patent Office) now being able to request additional materials from an applicant with response time being three months. This has the potential to add additional administrative burdens to rights holders and applicants.

**Regulatory Data Protection:** On August 22, 2012, Russia officially acceded to the World Trade Organization (WTO). Russia's commitments on regulatory data protection embedded in the Law on the Circulation of Medicines are an integral part of Russia's WTO obligations and came into force on the date of Russia's WTO accession, FL61, Article 18, Part 2. However, industry is concerned that provisions in FL 61 and other regulations do not effectively implement, or are contrary to, fulfilling these commitments and significantly lower regulatory data protection. Notably, the amendments to the law allow for the submission of a registration for generic drugs four years following marketing authorization for original small molecule drugs and three years for an original biologic medicine (4+2 and 3+3). This implies that a drug could be placed on the market before the expiration of the six-year period since there are no transparent mechanisms or

procedures in place to ensure data exclusivity. As the FL 61 contains no specific provisions on the protection of pre-clinical or clinical trials data to be used for generic registration prior to the expiration of the RDP period, industry is concerned that the amendments to FL 61 will further weaken RDP in Russia. Industry will continue to advocate for the introduction of concrete intellectual property protection mechanisms in Russia.

### **Trade Secrets**

As part of the Amendments to the Civil Code Part IV, Russia also amended its laws relating to trade secrets and know-how. Specifically, these amendments clarify that trade secret protection is now available to entities even if no “trade secret regime” has been introduced. Nevertheless, the environment for the protection of trade secrets remains very challenging in Russia. Industrial espionage is rife and protecting confidential information and trade secrets difficult. The OECD’s Trade Secrets Protection Index ranked Russia second to last, behind China and India, with particular weaknesses in its enforcement environment.

### **Copyright**

**Civil Code Part IV:** 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. Additionally, these amendments included interim judicial measures which give the Moscow City Court the power of issuing temporary injunctions in these cases. Since the beginning of 2014, new legislation has been discussed—but yet to be introduced—by the Russian Duma and relevant stakeholders to extend these provisions to other forms of content which are not initially protected.

**Enforcement Against Piracy:** 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 2014 “Online Notorious Markets.”

**Ratification and Implementation of International Treaties:** Russia has still yet to fully implement the WIPO Internet Treaties. The United States should work with Russia to ensure implementation of these treaties. Russia's intellectual property regime would also be improved by providing thorough and clear criminal provisions against illegal camcording of motion pictures in theaters.

## **South Africa**

Overall, South Africa's national IP environment is challenging, with both laws and enforcement mechanisms lacking. Moreover, South Africa is in the process of considering a patent reform bill, as well as plain packaging legislation for tobacco products. Both bills in their current format, if passed, would fail to improve the national IP environment.

### **Patents, Related Rights, and Limitations**

A wide-ranging patent reform package is being discussed by the South African government and developed by the Department of Trade and Industry. This package contains a number of measures that are not encouraging for rights holders, particularly in the life sciences area. For example, it proposes a more expansive use of compulsory licensing and the introduction of pharmaceutical patentability requirements in the style of Section 3(d) of the Indian Patent Act (adding a fourth step of "enhanced efficacy," above and beyond the TRIPS-mandated three-step test). Moreover, the reform package as drafted would not provide provisions for patent term restoration or introduction of a regulatory data protection framework currently lacking in South African law.

### **Copyright**

The South African Copyright Act provides rights holders with general exclusive rights; however, there are no specific references to the online space. Nevertheless, industry noted improved enforcement against pirated goods and online piracy in 2014. For example, in March 2014, Microsoft's Digital Crimes Unit (DCU) and Anti-Piracy teams worked together with the South African Police Service's Directorate Priority Crimes Investigations tracking, successfully raiding, and arresting suspected software pirates. A number of raids resulted in the confiscation of fake software and the arrests of several suspects. Furthermore, a South African court heard the first online piracy case in the country, which centered on the uploading of a film to a torrent site. The judge found the defendant guilty and handed down a three year prison sentence suspended for five years. While these results are encouraging, online piracy is a growing challenge. Industry figures from 2014 suggest that South Africans downloaded approximately one million pirated movies per month and had the highest rate of illegal downloading in Africa.

### **Trademarks**

The South African government has announced its intention to introduce plain packaging legislation for tobacco products in 2015. The South African Minister of Health Aaron Motsoaledi stated in July 2014 that the legislation would be introduced irrespective of the current WTO investigations against Australia. The introduction of plain packaging in South Africa would significantly restrict the use of trademarks on retail packaging of tobacco products and severely limit the effective rights of affected trademark owners.

### **Membership and Ratification of International Treaties**

South Africa is not a contracting party to the Singapore Treaty on the Law of Trademarks or the Patent Law Treaty. South Africa is a signatory to, but has not yet ratified, the WIPO Internet treaties.



## South Korea

The Korea-U.S. (KORUS) free trade agreement remains the gold-standard for intellectual property protections. However, two years after enactment of KORUS, South Korea still has far to go in implementing the agreed upon provisions. In 2014, the U.S. Chamber called on South Korea to “rededicate” itself to open trade and reducing barriers to entry for business. This issue of implementation has become even more significant since the Korean government expressed interest in joining the Trans-Pacific Partnership (TPP) Agreement negotiations.

### **Patents, Related Rights, and Limitations**

**Patent Linkage:** Amendments to the Korean Pharmaceutical Affairs Act (KPAA) in 2012 introduced a patent linkage system which partially satisfies South Korea’s commitments under the KORUS. However, the current system entails several hurdles for innovator companies. The patent listing requirements appear to call for innovators to share patent information beyond what is typically provided in similar patent lists (e.g. in the United States’ Orange Book) and listing applications can be rejected by the Korean Ministry of Food and Drug Safety (MFDS) if they do not meet specific criteria. In addition, it is possible for patent information submitted by rights holders to be modified somewhat in the final list published by MFDS.

**Patent Enforcement:** Concerns have been raised that the new system, as such, does not strengthen patent enforcement. As part of further implementation of KORUS and under proposed amendments to the KPAA, innovator companies would be able to secure, based on an MFDS decision, a 12-month stay on the sale of a generic drug in case of an infringement dispute. Furthermore, the U.S. Chamber recommends that MFDS base patent enforcement decisions and implementation on a system which considers the actual patents granted by the Korean IP Office—not the redrafted claims. The amendments are expected to be approved by the National Assembly shortly and enter into force in 2015. Nevertheless, draft amendments to the National Health Insurance Act, currently under consideration, may weaken the new system by requiring innovators to provide the Korean 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.

## **Thailand**

Thailand remains a part of the critical Asia Pacific regional economy. However, the country found itself at the very bottom of this year's GIPC Index, descending to a spot previously held by India. Thailand's score in the GIPC Index fell from the previous year, primarily due to the private use and academic exceptions to copyright, in addition to its inattention to combatting wide scale piracy. The Thai National Legislative Assembly is considering many bills throughout the intellectual property fora which could fill outstanding gaps in Thailand's IP framework, although existing proposals do not fully resolve these gaps. Nonetheless, upon enactment, the amendments would likely raise Thailand's score on the GIPC Index. Industry, however, remains concerned about Thailand's intellectual property system as a whole, but the country's current political situation makes engagement even more tenuous and difficult.

### **Patents, Related Rights, and Limitations**

**Patentability:** Thailand lacks the level of high technology needed to apply the standard of worldwide novelty for patents 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.

### **Copyright**

**Notice and Takedown:** Although the current available draft of amendments to the Copyright Act would introduce liability of ISPs for online copyright infringement and the requirement to takedown infringing content upon knowledge of such content, this requirement would not be based on direct rights holder notice, but rather on a court order. The amendment as such falls

short of international notice and takedown standards. There is also ambiguity on the scope of liability of ISPs, including the possible expansion of ISPs' liability beyond failure to cooperate with takedown of infringing sites. In addition, the draft copyright amendments introduce language that would clarify exceptions to copyright, particularly in regards to private use, education, and software. Nevertheless, in an environment where book piracy occurs on an extensive scale, the amendments do not appear to place adequate limits on the extent of material that may be duplicated or on third party use of material made available by educational institutions.

**Digital Rights Management:** The copyright amendments would introduce the concept of technological protection measures as well as penalties for circumventing TPMs. However, the amendments do not address key concerns related to the sale and distribution of circumvention devices. In addition, the amendments do not appear to protect against inadvertent acts of circumvention.

### **Trademarks**

**Plain Packaging:** Thailand's Ministry of Public Health is currently considering a plain packaging law, the Tobacco Consumption Control Act, which includes language prohibiting the display of product names, marks, and importer or manufacturer names on tobacco products. While there has been little movement on the law as such, new regulation on the size of health warnings may have the effect of restricting the existing size of trademarks on tobacco product labels. The U.S. Chamber clearly recognizes the public health objectives of reducing smoking and also respects the right of countries to regulate in the national interest. At the same time, trademark destruction through plain packaging is an inappropriate policy response, as it undermines protection of legitimate uses of intellectual property.

**Well-Known Marks:** The Trademark Act does not formally recognize well-known marks; however, it is possible to achieve protection through various means. Proposed amendments to the Trademark Act would aim to implement the Madrid protocol and strengthen the legal framework for the protection of well-known marks, including introducing penalties for refilling, selling, and distributing products that bear well-known marks listed in the Department of Intellectual Property's (DIP) records. If passed, this would represent a positive step forward in addressing the

prevalence of online sales of counterfeit medicines. Currently, however, there are reports that the DIP's Board of Well-Known Marks is not actively reviewing applications, severely weakening the ability to acknowledge and protect well-known marks in Thailand.