



U.S. CHAMBER OF COMMERCE

By electronic submission

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

2014 SPECIAL 301 SUBMISSION

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Re: 2014 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 Mr. McCoy:

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) 2014 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, and 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 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 the United States gross domestic output, drive 60 percent of U.S. exports, and support 40 million direct and indirect American jobs. It is also critical to promoting innovative and creative economies around the globe.

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 2014 International IP Index: *Charting the Course* (Index) is an empirical assessment of the strengths and weaknesses of 25 economically and regionally diverse countries. We highlight India as a country with particular challenges with respect to intellectual property protections. Because India has not shown a record

of engagement on these issues and the environment has deteriorated significantly since last year, we are now recommending that India be designated a Priority Foreign Country. Please find within this submission specific policy examples across a range of industry sectors which are affecting the IP community in India and causing concerns throughout the business community.

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. We included 8 countries in this report. These geographies were chosen due to the sheer size of the market, the scope of the market, or specific intellectual property issues within the country.

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

Sincerely,



David Hirschmann
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President and CEO, U.S. Chamber's Global
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Importance of Intellectual Property to Jobs, Economic Development, and Competitiveness

Today's global intellectual property system is designed to incentivize individuals and businesses small and large to invest in innovation and creativity that enrich our lives. The resources applied to research and development (R&D) and the creative process fuel innovative and creative industries, which, in turn, lead to novel creations – from lifesaving medicines and environmentally friendly technologies, to first-class entertainment and a range of attractive consumer goods. These stimulate the economy, create jobs, and enhance competitiveness.

Intellectual property-intensive companies account for nearly 35 percent of the United States' gross domestic output, drive 60 percent of U.S. exports, and support 40 million American jobs. The global intellectual property system is designed to spur creativity and innovation and to promote the spread of knowledge by protecting creators' and inventors' rights. This time-proven system also helps provide assurance to consumers that the products they use are authentic, safe, and effective. Further, sound intellectual property policies and the enforcement of intellectual property in the United States and abroad are essential to advancing the United States and the global economic recovery, driving America's competitiveness and export growth, and creating high-quality, high-paying American jobs.

America's intellectual property-intensive industries and the workers they employ are facing increasing challenges in bringing their ideas and innovations to the international marketplace, due to unpredictable and insufficient intellectual property regimes in a number of foreign markets. Our innovative economy faces growing threats from counterfeiting and piracy networks operating both online and in the traditional marketplace. Moreover, some foreign governments are actively seeking to weaken intellectual property in their own countries and in multilateral institutions, thereby undermining the ability of businesses to innovate, to continue to bring the newest and most effective technologies to market, and to differentiate brands.

The Global Intellectual Property Center International IP Index

The Chamber is committed to promoting environments that foster innovation and creativity in the U.S. and abroad. Earlier this year, the Chamber's GIPC released the 2014 International IP Index, *Charting the Course* (Index)^[1], 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 25 countries provides a snapshot of what countries are doing well and what they can be doing better.

The Index identifies 30 factors that are indicative of an intellectual property environment that fosters growth and development and applies those factors to a geographically and developmentally diverse group of countries. These countries are: Argentina, Australia, Brazil, Canada, Chile, China, Colombia, France, Indonesia, India, Japan, Malaysia, Mexico, New Zealand, Nigeria, Russia, Singapore, South Africa, Thailand, Turkey, Ukraine, United Arab Emirates, the United Kingdom, the United States, and Vietnam.

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

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

^[1] U.S. Chamber of Commerce. (2013). GIPC International IP Index: *Charting the Course*.

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. There are increasing calls globally 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 failing 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. This attack on the very foundations of intellectual property is dangerous because intellectual property serves not only as a primary engine for growth and jobs, but is also the main incentive and source of solutions to many of the world's most pressing challenges.

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 for 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.

This year, the GIPC has added an additional resource to *IP Delivers*, the IP Research Database, which facilitates access for policy makers to peer-reviewed and official studies on the impact of intellectual property for the global economy and the innovation environment.

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

Copyrights

Increasing theft of digital media over the Internet presents the biggest threat to copyright protection. Estimates indicate that nearly as much as 25 percent of all Internet traffic worldwide is in furtherance of copyright infringement.¹ Another study found that a handful of the top intellectual property-infringing Internet sites received 53 billion page views per year. And, it is a problem that continues to grow.²

¹ Technical report: An Estimate of Infringing Use of the Internet, Envisional, January 2011.

² MarkMonitor. (2011, January). *Traffic Report: Online Piracy and Counterfeiting*.

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. 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. Building upon 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 that 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.³ These studies promulgate

³ Fink, Carsten. (2004, November). *Intellectual Property and the WTO*. siteresources.worldbank.org/.../Resources/.../IPR-WTO_Fink.doc.

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 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 Agreement on TRIPS requires World Trade Organization (WTO) Members, as a general rule, to 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, in order 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 an economic, sustainability, and development perspective 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 disadvantaging innovative industries.

Trademarks

There have also been unwarranted efforts to weaken trademark protections in the name of public health. The Chamber is particularly concerned by government policies that reduce or eliminate

the ability of manufacturers to distinguish and consumers to identify trusted and well-known brands.

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. Although several countries have considered similar legislation, they have subsequently been abandoned or postponed. Australia 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, 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.

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 recently 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 Office of the U.S. Intellectual Property Enforcement Coordinator (IPEC) 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. We also commend the recent enactment of two bills which closed a loophole in the protection of trade secrets and enhanced penalties against economic espionage.

Data Submitted for Market Approval: The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires that Members protect confidential commercial information contained in regulatory submissions from unfair commercial use and disclosure⁴. 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 in several critical life-science sectors. We urge the U.S. government to continue working with

⁴ WTO TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights; Article 39.

our trading partners to ensure meaningful implementation and adherence to the spirit and letter of these international commitments.

Data Confidentiality: The current and proposed policies of the European Medicines Agency (EMA) provides unrestricted access to and publish the clinical trial data and other confidential business information (CBI) contained in regulatory submissions for marketing approval. Rather than providing the general public and patient populations with additional useful information on medications, these practices harm patient privacy, undermine the integrity of the regulatory system and undermine incentives for innovation by allowing competitors to gain unfair commercial advantage over innovators.

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, 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)⁵ intellectual property provisions as a benchmark when negotiating other bilateral or regional trade agreements. The Trans-Pacific Partnership Agreement (TPP) is the next immediate opportunity where such standards should be pursued and built upon with important trading partners.

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 Issues

The Internet has the potential to develop into the greatest marketplace of goods and ideas in history. However, just as legitimate businesses and consumers have embraced the Internet, unfortunately so have irresponsible business practices. 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.

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 on the Internet, 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, so it is critical that law enforcement has the tools, resources, and will to fight theft in both the online and physical environments.

⁵ 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.

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 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 in an incredible 16,000 cases worldwide in one fell swoop. That action underscores that international cooperation on intellectual property enforcement is possible, and when it occurs, it is highly effective. However, this 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. Information in databases such as WhoIs is often entirely fictitious and Internet governance bodies, such as Internet Corporation for Assigned Names and Numbers (ICANN), have done far too little to address this reality. Even in the cases where criminals can be identified, they may well be located in (or flee to) countries with inadequate enforcement systems. Some countries, even some developed countries, lack or have unclear or inadequate laws, while others may impose impractical standards such as numerical thresholds that artificially 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, and further, the continued operation of these criminals undermines domestic enforcement efforts by providing alternatives to the illicit operations that we target here. It is precisely this harm that has given rise to the widespread recognition of the need for tools to disrupt foreign rogue websites, and to implement strategies to take the money out of internet 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 important 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 other previous threat to intellectual property. These “rogue sites” are a plague on openness, safety, and freedom on the Internet, and unfortunately profit off the hard work of America’s innovative creative industries and the thousands they employ.

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 sometimes 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 and some websites even copy the advertisements of well-known companies

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 good 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, unsuitable, 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 disturbing and toxic substances. 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, 12 percent of all known sites that distribute unauthorized content are

actively distributing malware to user who download content. ⁶Finally, Internet-based piracy is particularly harmful because a single pirated file on the Internet-based piracy platforms can be the source of massive, ongoing theft of creativity.

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.

Moreover, we are concerned by recent developments in Antigua and Barbuda which would, if implemented, be inconsistent with international intellectual property obligations and promote intellectual property theft online. In addition, state sanctioned theft of intellectual property owned by private entities would only come at great expense to Antigua and Barbuda itself. We urge the U.S. Government to strongly condemn any such actions and to consider all available remedies should Antigua and Barbuda take action to permit the unauthorized distribution of materials protected by intellectual property.

Baseline of Protection

There are certain baselines concerning minimum protection for and enforcement of intellectual property, including certain elements specifically intended to address the digital and online environments, which all countries should meet.

Many of these standards have been accepted globally as part of major trade and intellectual property agreements and treaties. Some of the major examples include the provisions of the TRIPS Agreement of the WTO and the WIPO Copyright Treaty, and Performances and Phonograms Treaty, commonly known as the WIPO Internet treaties. Other examples reflect widespread and/or regional standards that are quickly becoming globally accepted, such as the provisions of the intellectual property chapters of the United States' 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.

⁶ Paula Greve, Digital Music and Movies Report: The True Cost of Free Entertainment, McAfee, 2010.

Full and complete implementation of these 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 United States in the last two years, 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 in each case implementation has been uneven at best. We are also on the cusp of full implementation of the copyright alert system, a major 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 in the effort 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.

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

Free Trade Zones

Free Trade Zones (FTZs) are generally considered to be “a part of the customs territory of a Contracting Party where any goods introduced are generally regarded, in so far as import duties and taxes are concerned, as being outside the customs territory.”⁷ FTZs are typically established by governments to promote legitimate trade and offer the advantage of providing a free trading environment “whereby a minimum level of regulation is demanded of those companies approved to operate” therein.⁸ “As a result, companies derive a wide range of benefits, for example, exemptions from duty and taxes, simplified administrative procedures, and duty free imports of raw materials, machinery, parts and equipment.”⁹

Even though FTZs typically operate within the legal parameters of sovereign law, the reduced enforcement environment of these areas are often exploited by criminals running contraband and counterfeit operations. Given the special status of these areas and the lack – or unwillingness – of authorities or customs police to enforce within them properly, FTZs are a growing concern for brand owners. The Chamber encourages the United States to work with countries to make sure that the FTZs have proper inventory controls, and that customs agents have the authority to confiscate, seize, and destroy goods that are determined to be illicit – without undue requirements placed on right holders to prove the seized goods are counterfeit. In addition, all

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

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

⁹ *Ibid*

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 mail services and airmail, such as the China-based express mail service (EMS) of the China Post. These shipments arrive at any of ten international mail facilities with U.S. Customs Service locations and are inspected for entry by U.S. Customs Border and Protection Service (CBP), before being transferred to the U.S. Postal Service (USPS) for delivery to U.S. consumers.¹⁰ Overseas remote sellers often 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.¹¹

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.¹²

In the United Kingdom, Her Majesty's Revenue and Customs ("HMRC") demonstrates that effective enforcement is attainable. HMRC has implemented several procedures to detect counterfeit and contraband. It is our understanding that HMRC has dedicated one international mail facility to receive, screen and x-ray all incoming consumer parcels. All suspect parcels are

¹⁰ *Mailing Standards of the United States Postal Service, International Mail Manual*, § 711 (Aug. 11, 2011), incorporated by reference in the *Code of Federal Regulations*, 39 C.F.R. § 20.1.

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

¹² USPS, "Basic Eligibility Standards for Priority Mail," available at <http://pe.usps.com/text/dmm300/123.htm> (November 1, 2010); www.discountcigarettesbox.com (last visited November 17, 2011) ("The parcels are sealed and cannot be opened for postal inspection").

then “quarantined” into a separate area of the mail facility for further inspection, screening and potential seizure.

To allow for proper inspection of incoming mail, HMRC also deploys a tactical Anti-Illicit Trade Team. The team has daily briefings, which are informed by local and international intelligence. At these briefings, HMRC officials review seizures from the previous days and weeks. This review enables the team to set the inspection focus for the day. The focus might be based on origins of shipment, characteristics of parcel or types of counterfeit sought. This team assists the screeners in identifying suspect shipments and inspecting the “quarantined” parcels.

To facilitate easier seizure, HMRC has also streamlined the seizure process for various counterfeit and contraband goods. For example, shipments of goods that are designated as non-mailable in the UK, such as cigarettes, are seized in aggregate. Instead of having individual seizure events for each shipment, all of the shipments for a given period are treated as a single seizure event. The seized products are subsequently destroyed.

We recommend a similar approach to combating the problem in the United States by:

Increased Enforcement – In the case of the HMRC, the tactical redeployment of additional HMRC staff to postal depots in the form of tactical Anti-Illicit Trade Teams resulted in a substantial year-over-year increase in seizures.¹³ 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.

Engagement with Foreign Law Officials – One of the biggest postal smuggling threats emanates from China. We have noticed some improvement through U.S. officials working with Chinese partners from Customs and the Ministry of Public Security to gain a thorough understanding of the scale and scope of the problem. We encourage the U.S. Government to work with the Chinese Government’s Fiscal Crime Liaison Officers to devise strategies for tackling the illicit supply at its source.

¹³ HM Revenue & Customs. www.hmrc.gov.uk.

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 goods are seized, it is vital they must 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.”¹⁴ The Chamber urges the U.S. Government to work with its trading partners to ensure 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.

¹⁴ 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.¹⁵ 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 nominate swiftly a 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. businesses to access and maximize growth in foreign markets. However, lack of adequate intellectual property protection and enforcement, particularly in developing countries, represents a significant barrier for U.S. companies. Intellectual Property Attachés stationed at American embassies and consulates are important assets in helping to address these issues. In addition to assisting U.S. firms, Attachés help coordinate intellectual property related activities of other federal agencies within a country, and help provide technical assistance to law enforcement agencies, judges, and others within the host country on intellectual property issues. The current Attaché program has been very successful in advancing protection of U.S. intellectual property overseas, helping U.S. businesses export and expand, and, in turn, furthering the U.S. economy.

¹⁵ Office of the Intellectual Property Enforcement Coordinator. Executive Office of the President. (2010, June). *2010 JOINT STRATEGIC PLAN ON INTELLECTUAL PROPERTY ENFORCEMENT*, pg. 2.

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), or other multilateral institutions, or in 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.

Brazil

In recent years, there was a recognition that both in the Brazilian private sector and among the economic policy-related agencies of the Government of Brazil (GOB) that higher intellectual property (IP) rights protection and enforcement standards play a key role in fostering innovation, growth, and social and economic development. However, there continues to be a number of specific challenges faced by United States businesses in protecting and enforcing their rights in Brazil, most notably in the proposed changes to Brazilian Patent Law. The Index also outlines many areas of concern where industry hoped to see progress from Brazil in 2013. 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 the GOB.

Patent

Prior Consent

The proposed changes to Brazil's Patent Law (H.R. 5402/2013) would make the granting of patents for pharmaceutical products dependent upon prior consent from the Brazilian National Health Surveillance Agency (ANVISA). Therefore, the decision to grant a patent is not based solely upon the examination officials at the Brazilian National Industrial Property Institute (INPI). The Article would create a dual examination requirement which could be a violation of Article 27 of TRIPS. We encourage the U.S. Government to work with the GOB through bilateral dialogues and engage with the Brazilian National Congress to ensure that the proposed changes to the Patent Law, including the prior consent provision, are both TRIPS compliant and improve the intellectual property environment.

Patentability

The proposed changes to the Patent Law (H.R. 5402/2013) would also narrow patentability criteria even further disallowing patents on new uses or new forms of known substances unless a significant improvement to the known efficacy is present. The Chamber believes that such

changes to the Patent Law, represents a significant erosion of the IP environment. In order create a economy which fosters innovation, we recommend that the U.S. Government work with the GOB to reconsider the patentability requirements in the proposed law.

Data Protection

The Chamber is concerned that data protection for pharmaceuticals made for human use are not covered by existing regulation. As a result, innovative pharmaceutical and biotechnology companies have found it difficult to operate in Brazil. To improve its innovative environment, we encourage Brazil to implement five years of data protection for pharmaceutical innovators and twelve years for biologic medicines.

Patent Prosecution Highway Agreement (PPH)

The Chamber supports the negotiation and implementation of a United States-Brazil Patent Prosecution Highway (PPH). The PPH is a key policy tool to improve the bilateral intellectual property environment and to foster trade in knowledge between both countries. The Brazilian private sector and INPI have already shown great interest in pursuing such agreement with the United States, creating momentum for its achievement.

Compulsory Licensing

The Chamber encourages the U.S. Government to continue to engage the GOB on the benefits of a strong intellectual property rights protection and enforcement regime in order to avoid the use of unwarranted compulsory licensing by Brazil, in particular by helping facilitate dialogue between stakeholders.

Copyright

Piracy

The Chamber encourages the GOB to strengthen the Brazilian National Anti-Piracy Council (CNCP) human resources infrastructure and focus on increasing its resources to adequately enforce its broad mandate, particularly in connection with emerging issues in the digital world. Furthermore, we stress the importance of ensuring that rules that may be adopted with respect to internet governance and responsibility, such as in Marco Civil, maintain a clear distinction between legitimate and infringing content, and do not interfere with the ability to effectively and quickly address the distribution of infringing materials over the internet.

Cable TV Local Content/Forced Localization

Brazil's recently implemented local content restrictions for Cable TV have a negative effect on the access of foreign intellectual property owners to Brazil's market. These new restrictions limit foreign-owned and created productions in Brazil and are an attempt to force the transfer of intellectual property to Brazilian nationals.

Pending Federal Legislation

The Chamber encourages both governments to discuss current intellectual property rights regime reform in Brazil, particularly in the fields of copyrights and the Internet. There are a number of intellectual property-related bills being considered in Brazil. It is imperative that new laws in Brazil strengthen protection for intellectual property and do not erode or limit the ability or liability of rights holders to protect their intellectual property, particularly online. Additionally, as Brazil revises its law on criminal penalties, it has an opportunity to provide a more clear law against the scourge of camcording.

Other

WTO Cotton Dispute

The Brazilian Foreign Trade Board (CAMEX) recently announced that they will formally reopen public consultations on potential cross-retaliation on U.S. IP rights as a result of the WTO cotton

dispute. The Chamber supports a definitive solution to the WTO cotton dispute in order to avoid hundreds of millions of dollars in Brazilian trade retaliation and ‘cross-retaliation,’ respectively, against U.S. goods and intellectual property rights. In the meantime, the Chamber supports full compliance with the U.S.-Brazil Cotton Framework Agreement, which includes resumption of payments to the Brazilian Cotton Institute by the USG.

Canada

The Chamber is concerned about the inadequate level of intellectual property protection and enforcement in Canada. Canada's intellectual property regime lags behind that of many developed nations. Indeed, Canada scored markedly below other high income countries in the Index. In order to sufficiently modernize Canada's intellectual property laws and enforcement practices and to position Canada as a strong partner in promoting high intellectual property standards in regional and multilateral forums, we recommend the following reforms.

Copyright

The Chamber continues to be concerned with the lack of copyright protections in Canada, despite the passage in 2012 of the legislation C-11. The Chamber commended the Canadian government for its enactment of this legislation after so many years, which demonstrated a resolve and appreciation for the importance of protecting creative works. However, as noted above, Canada continues to lag significantly behind other developed countries. We continue to urge Canada to do more to combat intellectual property theft, particularly online. The Chamber firmly believes in the need for continuing reform in Canada, including *inter alia*: clarifying the terms of the right of making available, on behalf of record companies and performers; providing greater incentives for timely cooperation on the part of Internet service providers and other Internet intermediaries in addressing the use of their services for infringing purposes; ensuring and enhancing the application of statutory damages for online infringement; applying national treatment to U.S. rights holders without exception; and extending term of protection. The Chamber also urges USTR to work with the Canadian government to ratify the WIPO Copyright Treaty (WCT) and WIPO Performances and Phonograms Treaty (WPPT).

Patent

Right of Appeal

Canada's intellectual property system provides inadequate stability and certainty for innovative pharmaceuticals. One of the most significant challenges facing pharmaceutical and biopharmaceutical innovators in Canada is the lack of an equitable right of appeal under The Patented Medicines (Notice of Compliance) (PMNOC) regulations. Under the PMNOC regulations, while a generic company can appeal a decision in a Notice of Compliance proceeding, a patent holder effectively does not have this same right. Canada should work to correct this significant regulatory inequity by providing a meaningful and effective right of appeal to patent holders, thereby avoiding significant harm to innovative pharmaceutical and biotechnology companies operating in Canada.

Patent Term

Canada could also secure greater stability and certainty by providing Patent Term Restoration (PTR) and clarifying certain restrictions in its data protection regulations. We are concerned about the requirement that innovative products must be 'marketed in Canada' in order to receive and maintain data protection. This marketing requirement does not appear to be supported by either Article 39.3 of the TRIPS Agreement or Article 1711 of the North American Free Trade Agreement (NAFTA). We would welcome greater clarity with respect to this additional requirement in order to avoid harm to innovators if the drug is not marketed in Canada.

Test for Utility

The Chamber is also concerned about recent decisions by the Canadian Federal Courts which have imposed an onerous test for patent utility that is inconsistent with Canada's past practice and international obligations. Canada's heightened utility test impermissibly narrows the scope of inventions that receive patent protection and discriminates against innovative pharmaceutical inventions. As a result, patents that have been upheld in other jurisdictions around the world as useful are being invalidated on the basis of utility in Canada. Addressing the utility issue is critical given that it undermines the ability of innovative pharmaceutical companies to defend their existing patents in the court system, and also limits their ability to file new patents with the Canadian Intellectual Property Office (CIPO).

Enforcement

The Chamber has concerns across multiple industry sectors that Canada does not have sufficient tools to combat the transshipment of counterfeit and pirated goods through its borders. In particular, Canada should provide *ex officio* authority to its Customs officials to allow for the seizure of counterfeit and pirated products at the border under Customs' independent authority to seize infringing goods and greater resources and tools to combat intellectual property rights infringements, including illicit trade of counterfeit goods, to both its customs and law enforcement authorities. The Chamber understands that pending legislation in the Canadian Parliament addresses this, and we urge its swift passage.

Other

The Chamber does note that Canada recently signed the Comprehensive and Economic Trade Agreement (CETA) with the European Union. Adequate implementation of the CETA provides Canada with the opportunity to greatly improve its IP environment, particularly with respect to some of the challenges faced by the innovative pharmaceutical sector.

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 the broad range of intellectual property policy concerns on behalf of our diverse membership.

The Chamber appreciates the Chinese government's continued work and efforts to emphasize the protection of IPR as a basic critical tool to foster innovation. In particular, we recognize China's efforts to amend critical legislation including the Copyright Law, the Patent Law and the recently passed amendments to the Trademark law. Throughout the legislative process, the relevant ministries 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 innovations and endangers consumers in China, the United States, and around the world.

The Chamber recommends continued monitoring of China's IP 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 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 2013 Strategic and Economic Dialogue (S&ED) to foster an open and fair trade and investment relationship and to recognize the importance of trade secret protection (discussed in greater detail below) in developing an innovative Chinese economy. We also welcome recent efforts by China to limit the use of indigenous innovation policies in government procurement and to liberalize foreign company access to government-run or semi-governmental projects including, for example, in the wind power sector. We were encouraged by China's past commitments to delink its innovation policies from government procurement preferences. However, despite guidance from the central government, enforcement and legislation at the local level continues to stray from the top-level messaging.

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 could 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 Third Plenum

In November 2013, China issued its roadmap for institutional and economic reforms at its Third Plenum.¹⁶ Notably, a few significant reforms were announced in China's judicial system. China will explore the establishment of specialized intellectual property courts. The Chamber hopes that the specialized courts will greatly enhance the Chinese courts' ability to enforce IP rights, especially in hotbed areas, and develop a deep level of IP expertise and sophistication on IP matters.¹⁷

The resolution also states that China will streamline all funding and judicial appointments for the local courts under provincial levels. If implemented, local governments may no longer control the budget of local courts or the salaries of local judges. This may significantly reduce the impact of local protectionism by providing more judicial independence from the local government. The Chamber will follow the progress that China will make in implementing all of these reforms.

Transparency

China's Supreme People's Court (SPC) announced in November 2013 that all court judgments or rulings must be published on the Internet within seven days of the effective date.¹⁸ The new rules are expected to make almost all the court decisions from higher and intermediate courts available to the public. The SPC reportedly has also been allocated resources to build the IT infrastructure to ensure timely publication. This decision, if fully implemented, has the potential to benefit the quality of adjudicating IP cases. The public will be able to analyze firsthand decisions that are rendered by the Chinese courts. However, there is a risk that Chinese judges may not provide sufficient details in their analysis and reasoning in the judgments. We will closely follow how this impacts the actual adjudication process, and we would ask our government counterpart to monitor this process as well.

¹⁶ The full text of the resolution <http://cpc.people.com.cn/n/2013/1115/c64094-23559163.html>

¹⁷ Beijing, Guangzhou and Jiangsu province will be among the first group of localities where such specialized courts will be established. <http://news.sina.com.cn/c/2013-12-09/032528919567.shtml>

¹⁸ See http://news.ifeng.com/shendu/dycjrb/detail_2014_01/02/32662467_0.shtml. The website "Judicial Opinions of China" (<http://www.court.gov.cn/zgcpsw>) is the designated online portal for publishing the decisions.

In November 2013, the State Council issued its rules mandating that all penalty decisions in counterfeiting and infringement cases be made public.¹⁹ We hope that the implementation of this rule will provide more clarity and transparency on the enforcement of IP rights in China.

Trademark

Trademark Law Revision

The passage of the Trademark Law Amendment in 2013 was a significant legislative accomplishment. The Chamber applauds China's amendments of the Trademark Law for its strengthening the deterrent impact of administrative enforcement and boosting the ability of trademark owners to obtain more meaningful compensation from civil courts. The amendments are also expected to shorten the time required to obtain enforceable rights in trademarks. The Chamber had the opportunity to submit comments on prior drafts of the law, and our members were pleased with the level of transparency and thoughtfulness in the legislative process. China is currently drafting new Implementing Regulations (IR) and we also understand that the Supreme People's Court (SPC) is drafting a judicial interpretation (JI) to assist local courts in dealing with the revised law.

The Chamber has prepared a special report on proposed changes to the IR and JI 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.²⁰

Damages

The Chamber is pleased that the amended Trademark Law includes provisions that permit civil courts to impose 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

¹⁹ See <http://www.chinanews.com/gn/2013/11-20/5527290.shtml>

²⁰ 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>

of improvement of remedies in IPR cases.²¹ The cases involved reduction of the burden of proof on IP 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 and who the judges will discretion in actual cases.

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 2013

China continued to expand its enforcement efforts in 2013 against counterfeits, as evidenced by its official release of statistics.²² Local police were reportedly pursuing cross-regional counterfeiting cases to demonstrate their achievements.²³ Comparing the figures of enforcement China has released in the past few years, criminal prosecutions and convictions for intellectual property violations are increasing steadily.²⁴ At the same time, transfers from administrative

²¹ See the transcript of the press conference of the Supreme People’s Court and and video broadcast at <http://www.chinacourt.org/article/subjectdetail/id/MzAwNEhKN4ABAA%3D%3D.shtml>.

²² Complete data for 2013 is not available as of this writing. The official sources at the National Leadership Office against Counterfeits and IP Infringement states 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.

²³ In an official release by a provincial PSB (Hunan) in August 2013, the provincial police reported that it had initiated 20 nationwide campaign, netting arrests of 293 individuals. <http://www.ipraction.cn/2013/08/19/ARTI1376881962938207.shtml>

authorities to police for criminal investigation remains low even if the net figure reportedly doubled in 2012 compared to those in 2010.²⁵ 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 Ministry of Public Security has been taking the lead nationwide to keep the momentum against counterfeiting and passing-off of well-known brands in high-tech, food, drug, 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 counterfeited goods as well as the upstream manufacturing and distribution of these goods.

In October 2013, the State Administration for Industry and Commerce (SAIC) asked for public comments on the Draft Measures for Online Trading and Related Services (“Draft Measures”) to replace the SAIC Order 49 that was issued in 2010. We were very hopeful that the old Order 49 would be a useful tool in reducing the sale of counterfeits online. Regrettably, Order 49 did not live up to its promise. The issuance of these Draft Measures arguably may apply to intellectual property protection and yield some benefits to brand owners. However, the Draft Measures, which seem to intend to address unfair competition and consumer protection issues, lack deterrence against both individual vendors involving counterfeit transactions and online trading platforms. The Draft Measures do not provide any administrative liability against online trading platforms and do not even provide penalty against vendors who fail to obtain governmental license to sell certain types of products (e.g., medicine). We urge USTR to increase attention and focus on improving the online environment and press for effective policy changes.

²⁵ In 2012, the Administrations for Industry (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

We have taken note of the helpful effort of Beijing Higher People’s Court in addressing liability of online trading platform 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, 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

In November of 2013, China released a draft amendment of the Drug Registration Rules (DRR) for public comment. The proposed amendments to the DRR related to the drug approval process have significant implications on research and development in the pharmaceutical sector, including how market approval for drugs should be handled before patent expiration (patent linkage).

The Chamber is deeply concerned with the proposed deletion of Article 19 of the DRR. The official explanatory note states the motivation of such changes is that the amendment will bring the draft Rules into compliance with the 2008 Patent Law. The Chamber believes this is misdirected and the CFDA will unknowingly disrupt the very delicate balance of interests between originators and generics and result in unintended consequences. Article 19 effectively

prohibits CFDA from granting marketing approval for a follow-on product prior to the expiration of the patent on the original pharmaceutical.

First, China does not have any official patent linkage system in its drug approval system similar to that found in the United States. The current DRR Article 18 and 19 require generic manufacturers to disclose possible risks of patent infringement and provide that a generic manufacturer may not submit an application for registration until two years prior to the expiry of the patent on the original product. Further, the current Article 19 states that CFDA should not grant market approval for a follow-on product until after the patent expires on the original product. The combination of these rules, while not constituting a patent linkage system, is at least recognizant of the necessity to balance the interests of originators and generics. The proposed deletion of Article 19 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.

Interpretation of Article 26.3 of China’s Patent Law

In December 2013, SIPO announced that it will cease the current practice of applying the examination guidelines related to Art. 26.3. Both during Vice President Biden’s trip to China and at the U.S.-China Joint Commission on Commerce and Trade, China also confirmed this positive policy change. The Chamber would like to recognize the efforts and the success of the U.S. government in encouraging China to reverse its policy. SIPO will now allow patent applicants to submit lab data during the patent prosecution stage as proof of inventiveness. SIPO also explicitly agrees that any of its newer versions of the patent examination guidelines will not have retroactive effects. These changes are encouraging and indicative of dramatic shift in response to our members’ concerns, and we urge USTR to closely engage with SIPO to ensure its actual practice does not deviate from the promises.

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 Joint Commission on Commerce and Trade, the Chinese government agreed, in order to promote scientific advancement and to establish effective regulatory data protection, to define 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 Ministry of Health and other stakeholders in 2013 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; (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 Ministry of Public Security (MPS) and local PSBs have enlisted significant amount of resources in targeting pharmaceutical counterfeiting in the past few 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.²⁶ Chinese police reported progress in going after online sales of counterfeit medicines. The Chamber is encouraged by the special campaign initiated by China Food and Drug Administration (CFDA) targeting at online sales counterfeit medicines and are pleased that Chinese officials reported that the campaign will continue in 2014.

While the Chamber is encouraged by China's approach to counterfeit pharmaceuticals, the Chamber hopes that the Chinese government will start to effectively deal with the enduring problems related to manufacturing and sales of counterfeit active pharmaceutical ingredients (API). 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 serious threat to patients.²⁷ 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. The Chamber hopes that the U.S. government will actively engage with the Chinese government about possible reforms of Criminal Code and Drug Administration Law as well as taking other regulatory measures to combat illegal API problems.

Patent Protection and Enforcement

The Chamber, together with the American Chamber of Commerce in China, submitted comments on State Intellectual Property Office (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 2013²⁸. The primary concerns in both drafts pertain to the expansion of the remedial powers of local administrative agencies. The local IP 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

²⁶ See 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.

²⁷ China reported that World Anti-Doping Agency director general David Howman sited 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

²⁸ The U.S. Chamber of Commerce and the American Chamber of Commerce in China jointly submitted comments on SIPO's Draft 4th Amendments to the Patent Law and SCLAO's draft 4th Amendment to the Patent Law.

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

litigation, costs, and produce conflicts with judicial actions. In addition, there is potential for increased assertion of low or no-quality patents by domestic entities to disrupt foreign-owned patent holders and options to forum shop for the most attractive venue. This will greatly increase the potential for abuse by patent holders that seek not just appropriate compensation, but also to harass and burden competitors so as to impede their competitiveness and innovation capabilities in China.

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

Patent Quality and Utility Model Patents

We are 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.²⁹ The Chamber submitted comments to SIPO expressing our appreciation at the broader responsibility granted to the patent examiners, but also conveying our concern that the guidelines do not require patent examiners to conduct the patent searches.³⁰ The patent searches are intended to reduce or otherwise deter the filings of low quality patent applications. Without a substantive review, the low or no-quality patents represent a significant business risk to innovative companies, domestic and foreign alike. SIPO has confirmed in a recent public meeting that the growth rate of utility model and design patent application has dropped significantly and patent examiners have increasingly rejected applications that obviously lack patentability after patent searches. Such changes directly address the long standing concerns regarding the threat that the proliferation of low quality, utility model patents present to foreign companies. The Chamber has placed a high priority on this issue and its negative impact on China's patent system.

We encourage China to continue improving the utility model patent system in various ways. In the Chamber's November 2012 report on China's utility model patent system, we also

²⁹ The official decision is at http://www.sipo.gov.cn/zwgg/jl/201311/t20131106_876947.html

³⁰ The Chamber submitted comments to SIPO in March 2013 on its draft Patent Examination Guidelines.

encouraged the Chinese government to reduce or eliminate government subsidies for utility model patents and design patent filings and mandate substantive examination of these patents prior to initiating litigation.³¹

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.³² 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.

³¹ 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

³² See SIPO official notice at 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 2012.³³ SIPO has not released any updates on the legislation this year. However, in October 2013

³³ 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>

SIPO informed the Chamber with specificity that the latest version of the Draft Regulations was endorsed by an internal committee within the government.

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 IP 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.

Intellectual Property Misuse

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).

As part of our ongoing work to track China's implementation of the AML and provide input to the Chinese government regarding U.S. practices in the field, the Chamber provided detailed comments to the State Administration for Industry and Commerce (SAIC) in December 2012 on an unofficial draft of its intellectual property rights enforcement guidelines under the Anti-

Monopoly Law (draft Guidelines) and in May 2013 on SAIC's draft Rules on the Prohibition of Abuses of IP Rights for the Purposes of Eliminating or Restricting Competition (draft Rules).³⁴ In both submissions, 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 May 2013 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 IP 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 IP abuse would undermine Chinese innovation that produces dominant domestic companies. Article 14 implies that SAIC would deem it an abuse of IP for an undertaking with a dominant market position to send an infringement assertion letter to someone whose conduct "obviously" does not constitute infringement of IPR. 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 IP Guidelines. The antitrust-related IP issues are complex and require sophisticated analysis. More importantly, from a regulatory perspective, the industries need clear guidelines that apply to all three AML agencies in China, not just SAIC. The Chamber

³⁴ 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

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).³⁵ The Chamber submitted comments to SAC on the previous draft version of the Standards Measures in January 2013.³⁶

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 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." Also, since foreign invested companies can only participate in the standard setting process by

³⁵ See official release at http://www.sipo.gov.cn/zcfg/flfg/zl/bmgfxwj/201401/t20140103_894910.html

³⁶ 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>

invitation, 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.

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).³⁷ In criminal cases theft is determined not by the conduct itself but by the consequences of the loss. Article 219 of the Criminal Law and relevant judicial opinions as well as economic crime prosecution guidelines require a loss by the trade secret owner or illegal profit by the misappropriator valuing at least RMB500,000 (~\$75,000 USD).³⁸ 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.³⁹

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.⁴⁰ Courts also differ in their application of the AUCL's "business operator" requirements, which creates the problem of initiating enforcement actions against current or former employees, who misappropriate the company trade secrets without actually conducting a business.

³⁷ USITC, *China: Effects of Intellectual Property Infringement and Indigenous Innovation Policies on the U.S. Economy*, USITC Publication 4226, May 2011.

³⁸ Or bankruptcy by the trade secret owner.

³⁹ Losses great than ¥2.5M (~\$375k USD) qualify for longer prison terms.

⁴⁰ The crime of theft and civil as well as administrative violation of trade secret through the conduct of "theft" referred to under Article 219 of the criminal law and Article 10 of the AUCL respectively are defined by Article 264 of the Criminal Law and only applies to tangible assets.

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 possible.⁴¹ 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.⁴² In part, the limited availability is due to the tremendously high burdens of proof discussed above.

We remain hopeful that recent Civil Procedure Law reforms will address some or all of the problems that companies face in enforcing trade secrets protection in China. We also urge the U.S. Government to continue pressing China to implement commitments on trade secrets enforcement agreed to at the 2013 Strategic & Economic Dialogue and Joint Commission on Commerce and Trade, including strengthening procedures and remedies.

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

⁴¹ 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.

⁴² 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.

furnished, however, is unprotected from further disclosure. In fact in many circumstances, local agencies will provide the information to anyone who asks. This requirement and practice puts companies' technical secrets at risk of leaking to the public domain.

Copyrights

Online Piracy

With respect to online piracy, there has been some progress in government enforcement against infringements. We also notice that domestic companies are forming coalitions to sue major video sites such as Baidu and are being supported by the Chinese courts and National Copyright Administration of China ("NCAC").⁴³ 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 II 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.

Copyright Law Amendments

China is considering a significant set of amendments to its Copyright Act. The GIPC 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. The Chamber heard that the amendments have been placed on tier two of the legislative agenda for China. Given the importance of the legislation, the Chamber encourages China to place the Copyright Act 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

⁴³ NCAC imposed a fine of RMB 250,000 against Baidu in December 2013 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

has made significant strides, most recently with the Judicial Interpretation on Online Copyright Liability issued by the Supreme People's Court. We urge China to continue its forward progress, particularly on the issues we have previously identified in our comments, and to resist any appeals to move backwards on copyright protection and enforcement in China.

Criminal Code Revision

The National People's Congress Standing Committee announced in the beginning of 2014 that it has listed amendment of the Criminal Code into its official agenda. The Chamber looks forward to the exact schedule of the public comment process on the amendment for intellectual property provisions in the PRC Criminal Code and hopes that industry will have the opportunity to comment on proposed changes in the law.

In the meantime, we hope the Government of China will provide clarification on 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.

Enforcement

Following the concerns from local and foreign rights holders, and coupled with problems from fake food and medicine, the Government of China initiated and intensified enforcement campaign throughout 2013. Our members have reported that intellectual property enforcement bodies across China are noticeably more active in conducting raids, seizures, and arrests. Consistent with that report, the Chinese government has indicated that the campaign resulted in increases in the number of criminal and administrative enforcement actions. These efforts generated goodwill and some degree of optimism about the possibility of a future for intellectual property protection in China.

The ultimate judgment of this campaign's success will be determined by whether it reduces levels of intellectual property violations and correspondingly, increases legitimate sales. We believe that these outcomes will occur only when the intellectual property environment in China has changed. And a necessary element for that environmental change is the increased prosecution of offenders and the consistent application of deterrent-level penalties. Such actions can give the 2012-2013 special campaign lasting significance and can be enhanced after the amendments to the Criminal Code permit prosecution of a greater range of criminal copyright infringement.

India

The Chamber strongly recommends that India be designated a Priority Foreign Country.

Over the past two years, the IP environment in India has deteriorated rapidly, making India an outlier in the international community. While the then-President of India declared this decade to be India's "Decade of Innovation" in 2010, India's policies are inconsistent with the former President's rhetoric.

India has the weakest IP environment of all countries, according to both the 2014 and 2012 editions of the Chamber's International IP Index, which maps the IP environment in 25 countries around the world based on existing international standards and best practices. The studies found that the continued use of compulsory licenses, patent revocations, and weak legislative and enforcement mechanisms raise serious concerns about India's commitment to promote innovation and protect creators.

India's failure to develop and adhere to international best practices in the field of IP rights has hindered its economic development, especially over the last year when its IP environment deteriorated considerably. The resulting lack of confidence has directly impacted India's foreign direct investment⁴⁴. In 2011 and 2012, \$35.1 billion of foreign direct investment flowed into India; by 2013, that number dropped dramatically to \$22.4 billion, according to India's Department of Industrial Policy and Promotion⁴⁵. Further, World Bank data indicates that charges and receipts from IP-based assets increase economic growth and while payments to Indian residents for the use of IP assets was \$300 million in 2011, the payments to the other BRIC economies ranged from between \$600 million to more than \$1 billion, placing India at a significant competitive disadvantage⁴⁶.

⁴⁴ A recent study by the Organization for Economic Co-operation and Development (OECD) concludes that a 1 percent change in the strength of a national IP environment, based on a statistical index, is associated with a 2.8 percent increase in foreign direct investment inflow.

⁴⁵ Wolfgang, Ben, "U.S. drug industry upset with Indian policies on patents," *Washington Times* September (2013) <http://www.washingtontimes.com/news/2013/sep/26/us-drug-industry-upset-with-indian-policies-on-pat/>

⁴⁶ World Bank, Databank, Science and Technology Indicators, Charges for the use of intellectual property, receipts (BoP, current US\$), indicator source note.

As demonstrated below, industries across all sectors face significant challenges in securing adequate and effective IP protections and enforcement in India- including with respect to patents, copyrights and trade secrets - and are being denied fair and equitable market access in India for their IP. And in spite of recent calls for greater investment by foreign industry, the Indian government continues to put forward discriminatory measures to advance local production at the expense of foreign companies. While the Chamber commends the Government of India (GOI) for recognizing the importance of intellectual property in their National IPR strategy and taskforce, to date there has been no demonstrable progress in confronting or overcoming the issues around intellectual property protection, particularly as they affect the pharmaceutical and copyright industries.

Many of these problems have been identified year after year by USTR in its Special 301 report. Indeed India has been designated as either Priority Watch List or Priority Foreign Country every year since the report's inception in 1989. Not only is India making no effort to correct the challenges identified repeatedly in USTR's Special 301 report, consistent with the statutory definition of a Priority Foreign Country, they are also continuing to impose measures and take actions that rise to the level of the most onerous or egregious IP acts, policies or practices that have the greatest adverse impact on U.S. businesses. Moreover, India has demonstrated no effort to engage in bilateral dialogue to address these concerns, while they continue to be a leader in efforts to weaken IP internationally.

Patents

Developments related to patents in India last year created more concerns and challenges for companies who wish to invest in India's innovative potential.

As described more fully below, this negative trend is affecting U.S. industries across sectors in a number of ways. First, India uses the additional criteria of "enhanced efficacy over existing therapies" when considering the patentability of new pharmaceuticals. This impermissibly adds a fourth criterion to the internationally accepted test under TRIPS. As a result, products that receive patents around the world are being denied these same protections in India.

There's no adequate response to this. When challenged, Indian officials say that they are TRIPS compliant and a country of laws. They also add that if there are concerns better legal arguments should be presented to the Indian courts. However, India's policies are clearly discriminatory, in contravention to their obligations under TRIPS. In addition, other countries such as South Africa, Brazil, Argentina and even China are closely monitoring this new "Indian IP Model."

Technology Transfer and Compulsory Licensing

The Government of India is taking measures across sectors, including pharmaceuticals, medical, and green technologies, to advance a program to compulsory license foreign proprietary technology, in direct contravention of the more limited scope of compulsory license provisions in the WTO TRIPS Agreement. One primary purpose appears to be to enable domestic industries to avoid paying commercial rates for technologies and to shield domestic companies from foreign competition. For example, India has announced its intention to engage in policies that would violate the intellectual property rights of foreign green technologies in order to favor domestic companies.

According to India's new National Manufacturing Policy, for example, a domestic clean technology company has the option to ask the government to issue a compulsory license for a patented technology under one of the following two conditions: (1) if the patent holder is not providing the technology at a reasonable rate, or (2) if the technology is not being "worked on" in India. This policy is fraught with many challenges, such as vague definitions as to what is and is not a "green technology" and even more vague conditions under which a compulsory license would be appropriate. This raises a general concern that India's policy on compulsory licenses is not limited to pharmaceutical patents and can easily spread to other IP-intensive sectors of the economy.

The National Manufacturing Policy lists healthcare-related technology as another strategic industry, alongside clean technology, and related to this, India is reportedly in the process of expanding its "essential medicines" list to other product categories as well.

In March 2012, the Indian Patent Board issued a compulsory license on Nexavar, a Bayer drug used for cancer treatment. While the Patent Board claimed to be acting in accordance with the

Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, the fact that Nexavar is not manufactured locally is not a condition for issuing a compulsory license under TRIPS.

India, in contrast to 2012, has not issued any new compulsory licenses under Section 84 of the Indian Patent Act (Amended). The Chamber applauds the Indian Patent Office for rejecting a petition for a compulsory license from an Indian generic pharmaceutical company on an anti-cancer medicine on grounds that the Indian firm did not make a "prima facie" case for a compulsory license. However, in 2013, the Indian Government made clear that it is actively considering a number of innovative biopharmaceutical medicines in the areas of cancer and diabetes for a compulsory license under a separate provision of the Indian Patents Act (Section 92). While the Indian Government has yet to make a formal announcement about these and potentially other medicines, the Chamber is continuing to monitor the situation carefully to ensure that any actions taken by India with respect to CLs are consistent with India's international obligations. In the meantime, India's failure to address concerns regarding its local working requirement at a minimum has created significant economic harm and uncertainty for U.S. innovators.

Patent Denials

Another area of increasing concern is the recent pattern of patent denials on inventions that have been widely deemed as patentable in most other jurisdictions. The most prominent of these cases is the April 1, 2013 Supreme Court decision to deny a patent to an anti-cancer medicine that has been granted a patent in 40 other jurisdictions. In this case, the Supreme Court confirmed the rejection of the patent application, ending several years of efforts by the innovator company to gain patent protection in India. In the Supreme Court's reasoning, the invention did not fulfill the unique additional patentability criterion under Section 3(d) of the Indian Patent Law because it was an attempt of "evergreening" in view of an older patent application, an application that was never filed in India, not granted in India, and the product it referenced was never introduced in India.

Furthermore, the Supreme Court defined Section 3(d)'s requirement of increased efficacy to mean specifically "therapeutic efficacy," meaning that there should be demonstrated additional benefits evidenced in clinical trials. This requirement would exclude non-clinical advantages that

a new form of a known compound may have and which would be sufficient to pass the classical patentability criterion of inventive step. Non-clinical improvements can include important technical advances particularly useful for India, e.g. improving shelf life or increasing the efficiency of manufacturing processes thereby contributing to make pharmaceutical products more affordable.

Lastly in regards to the Supreme Court's decision, contrary to an internationally well-established principle of patent law that the wording of a patent claim can protect more than what is specifically disclosed in the patent application, the Court stated it is not in the interest of India to provide patentees with protection that goes substantially beyond what was specifically disclosed in the patent application; compounds which fall within a chemical formula of a claimed group of compounds in a patent application, but which are not specifically disclosed in the patent could be regarded as not protected. Already we have seen instances of patents having been found to be valid but not infringed based on the doctrine that a patent claiming a group of chemical compounds is not infringed by a specific compound that falls within the claimed group of compounds, but is not specifically disclosed in the patent.

India's actions are not about access to medicine. In many of these cases, the drug maker gave the drug to Indian consumers either free of charge or at a greatly reduced cost. In the case of Glivec, Novartis provided the leukemia drug to 95 percent of the 16,000 patient population for free, while the remaining 5 percent was heavily subsidized. The annual cost for Glivec generic treatment is approximately \$2,100 or three to four times the average annual income in India. Thus, it is actually more expensive for Indian patients to obtain access to these medicines after the patent revocation than it was before.

Patent revocations also go beyond the pharmaceutical sector. In July 2013, IPAB denied Monsanto's patent application for a genetically-engineered method of increasing climate resilience in plants, the first such denial under Section 3(d) for a patent not related to pharmaceuticals. The continued deterioration of the Indian IP environment will have far-reaching implications on foreign direct investment, technology transfer, and economic growth.

Patent Revocations

Following on the pattern which began in 2012, the Indian Patent Office and Intellectual Property Appellate Board (IPAB) rejected a number of patents of U.S. companies, biopharmaceutical patents that had been granted in many other jurisdictions and are globally recognized as being breakthrough and innovative. In general, these patents have been revoked as a result of post-grant oppositions or petitions by alleged patent infringers, with the rationale that the invention lacked inventiveness or was obvious.

In a continuation of a case that was begun in 2012, the patent covering a kidney cancer drug was re-examined on appeal and reinstated in 2013 for the time being. Separately, patents on two ophthalmic drugs and a well-known anti-cancer drug were revoked. While not involving a U.S.-based company, we note that a German entrepreneur and inventor had 19 patents related to wind energy revoked in 2013. A further 28 more patents are in dispute, with a total market value of about \$1 billion. While Indian courts decided in 2012 not to revoke a product patent held by a small U.S.-based biotechnology company, the same court revoked a related process patent granted to the same company.

Multi-Industry Concerns

India's National Manufacturing Policy and its draft IPR Policy are not the only evidence of the government's failure to provide for effective IPR protection and enforcement. Other examples include a 2010 discussion paper published by a department in the Ministry of Commerce (DIPP) and which argued that "compulsory licensing has a strong and persistent positive effect on domestic invention" and encouraged India's Controller General of Patents to grant a compulsory license if, among other things, he was satisfied that the patented invention is not being worked (*i.e.*, manufactured) in India.⁴⁷

Additionally, India's patent statute requires every patentee and licensee to furnish periodic statements that include significant details of how they are working each patented invention on a commercial basis in India or, if not worked, the reasons why and the steps being taken to work the invention.⁴⁸ Not only is this "Form 27" process highly burdensome from an administrative

⁴⁷ See http://dipp.nic.in/.../Discuss_paper/CL_DraftDiscussion_02September2011.doc.

⁴⁸ Known as Form 27, Statement Regarding the Working of the Patented Invention on Commercial Scale in India, available at: http://ipindia.nic.in/ipr/patent/patent_formsfees/Form-27.pdf.

point of view, but we are concerned that the information that is provided could be used at some point to justify compulsory licenses in a variety of industries, as specifically contemplated in the Form. Recently, Form 27 submissions have become publicly available – which is likely to result in even greater pressure on Indian authorities to compulsory license the covered products.⁴⁹ An additional problem is that most questions in Form 27 are only directly answerable in a one-patent-one-product context and cannot clearly be answered, for example, where multiple patents relate to a single product – which is the case for many of today’s most cutting-edge industrial, manufacturing, and information technologies, for example. Notwithstanding the impracticality of attributing a specific commercial value to one patented feature of a complex technology, the form calls for criminal and civil penalties for submission of false information.

Since 2012, India has also infringed, overridden, or revoked nearly a dozen pharmaceutical patents held by foreign firms, in part because the patented product was manufactured outside of India. These and other instances of broad compulsory licensing are based on Section 84 of India’s Patent Act⁵⁰ and pose a clear risk not only to U.S. pharmaceutical industries, but to advanced manufacturing, industrial, and other innovative U.S. businesses as well. The risk of a further broadening of India’s compulsory licensing practices to other categories of technology is very real, as evidence, for example, by the reports of additional “essential technologies” lists for on-pharmaceutical products that we already mentioned above.

Finally, the Indian Government has so far failed to pass the National Innovation Act,⁵¹ which could have been a positive step towards providing a more robust IPR environment. The Innovation Act would include a range of measures to promote innovation (including an annual “Science and Technology Plan” and provisions to aid public/private partnerships, promote

⁴⁹ See <http://ipindiaservices.gov.in/workingofpatents/>

⁵⁰ Some of these actions have been based on Section 84 of India’s Patent Act that states: “(1) At any time after the expiration of three years from the date of the [grant] of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely:— (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India.” Section 84 of India

’s Patent Act violates the WTO TRIPS Agreement’s national treatment provision in Article 3, which mandates that WTO members protect IP regardless of its origin, as well as TRIPS Article 27.1, which explicitly prohibits discrimination in national patent laws based on “whether products are imported or locally produced.” Section 84 also exceeds several TRIPS compulsory licensing restrictions, for instance Article 31(h) requiring pricing to be based on the “economic value of the authorization.”

⁵¹ <http://www.dst.gov.in/draftinnovationlaw.pdf>.

innovation financing and establish special innovation zones). It would also codify rules on the protection of confidential information, which to date relies on common law principles, meaning that the scope of protection is unpredictable.

Regulatory Data Protection/Data Exclusivity

The Chamber also underscores the critical importance of regulatory data protection to the biopharmaceutical and agrochemical industries. Pursuant to Article 39.3 of the TRIPS Agreement, protection must be extended against unfair commercial use of scientific data by makers of generic copies of innovator products (i.e., products that must be shown for the first time to be safe and effective or to not cause significant risk). The GOI should provide a period of data protection that includes both non-disclosure and non-reliance, thereby recognizing the considerable effort and expense required to create these products. Despite acceding to TRIPS, India has yet to implement any meaningful protection for the data that must be generated and shared with regulatory authorities to prove that pharmaceutical and agricultural chemical products are safe and effective.

The Chamber encourages the United States to work with India to prevent the unauthorized disclosure of data submitted for marketing approval.

Copyright Law Reform

India has an extensive copyright industry, producing more feature films, than any other country in the world. However, the government's copyright legislation fails to adequately protect Indian creators and innovators. Although we commend the GOI for taking steps in 2012 in passing a Copyright Reform Bill, this legislation contains many deficiencies that cause it to fall short of its intended purpose to implement the WIPO Copyright Treaty. Moreover, there are numerous provisions that inappropriately and unproductively interfere with the free market for copyrighted works, including provisions that create legal uncertainty regarding transfer and ownership of rights, and rights of remuneration. This uncertainty has significant negative ramifications for distribution of India's creative works, since those involved in distribution chains, particularly new distribution models through the Internet, need legal clarity on ownership and cost issues. Finally, the amendments have broadened India's copyright exceptions in a manner that seems to

be incompatible with the Berne three-step test, including the expansion of the private use exception to the potentially broad and ill-defined ‘private and personal’ use, and thus could significantly undercut the rights of creative industries.

The motion picture industry continues to face further challenges relating to piracy in India. The revised copyright legislation fails to provide adequate and effective protections to prevent the unauthorized copying of movies in theaters and optical disc piracy. India is among the top ten countries in the world for Internet piracy. According to a study released by the Motion Picture Distributor’s Association (MPDA), pirated films out of India appear on the Internet in an average of 3.15 days, making India one of the top ten worst countries in the world. In addition, in 2012, the Entertainment Software Association (ESA) reported that India is sixth in the world in terms of number of connections by peers participating in the unauthorized file sharing of certain ESA member titles on public peer-to-peer networks. Lastly, camcording incidents in India continue to be a serious problem, with India accounting for 53 percent of all forensic matches in the Asia Pacific in 2012. We urge the United States to work with India to make sure that criminal anti-camcording provisions are adopted either separately or as part of a revision to the Copyright Bill and that an effective optical disc law is adopted.

The film industry is not the only victim of piracy in India. The recording and music groups estimate a total of \$431 million in lost revenue in 2011 to piracy, and the reported rate of PC software piracy in 2011 was 63 percent in India, with the commercial value of unlicensed U.S. software in India estimated to be more than \$2.9 billion.

Enforcement

In addition to strong intellectual property laws, better enforcement mechanisms are essential to combating intellectual property theft in India. Significantly more needs to be done to enhance the tools for rights holders and enforcement authorities to address the problem. A critical area of focus should be developing ways to incentivize intermediaries to cooperate with rights holders and enforcement officials to combat online intellectual property theft, including by imposing liability in appropriate circumstances on intermediaries that fail to take necessary measures to respond to acts of infringement.

In addition, judicial reform measures, such as the imposition of deterrent fines and imprisonment, and the establishment of specialized intellectual property courts, judges, and prosecutors are encouraged. The United States should also encourage India to empower customs officials to seize counterfeit and pirated goods *ex officio* and to destroy these goods, once judged illegal, so that they do not reenter the marketplace.

Trade Secrets

As highlighted in the GIPC Index, Indian law does not provide strong or specific protection for trade secrets or confidential information. The current applicable statute is the 1872 Contract Act. Common law does provide a measure of protection, and there is some judicial precedent. However, because legal redress through the Indian justice system is a long and arduous process, it is difficult to secure even this measure of protection. In addition, Indian law does not provide for closed proceedings in relation to the trade secret or confidential information, which can thus be made public during the course of litigation.

Other IP Challenges

India's tax policies provide further concern to industry, specifically, the policies related to compensation for captive development centers. U.S. multinationals generally assign routine development work to their India development centers. The development centers bear no financial risk for their development work and do not own any of the resulting IP rights. Accordingly, they are compensated on the internationally accepted cost-plus method. India's tax authorities are increasing their application of the profit-split method to determine development center compensation, effectively allocating a portion of the U.S. parent's IP profit to India. India's development centers operate similarly to other international development centers and should be similarly compensated on the internationally-recognized cost-plus basis to reduce controversy and minimize double taxation.

Multilateral Engagement

In addition to domestic policy actions such as those outlined above, we continue to be very concerned about India's policy position on intellectual property in a range of international fora. India has played a leading role in driving an IP weakening agenda at the UNFCCC, WTO, and

WIPO, where government officials consistently represent intellectual property rights as a barrier to economic advancement and access to technology for developing countries even though the evidence does not support this view. These claims threaten to undermine not only U.S. innovation and industries, but also economic development and innovation in India, where domestic companies are in the process of maturing their capabilities in the IP generation and policy advocacy space. They also continue to distract negotiators in these and other fora from the real technology, trade, environmental and healthcare-related issues that they are or should be seeking to address.

Unfortunately, India's influence with respect to intellectual property policy may be expanding. In May 2013, the BRICS IP Offices agreed on a roadmap for collaboration.⁵² The roadmap identifies India as the lead IP office to improve the influence of BRICS offices within WIPO and other forums.

⁵² Available at: <http://www.rupto.ru/rupto/nfile/786b6c92-696b-11e3-731c-9c8e9921fb2c/SIGNED-BRICS-IP-OFFICES-COOPERATION-ROADMAP.pdf>

Mexico

The Chamber commends Mexico for making advancements in improving its intellectual property protection and enforcement efforts in recent years, including by granting *ex officio* authority to its law enforcement officials and their ongoing participation in the TPP negotiations. However, a number of key areas remain to be addressed regarding intellectual property protection and enforcement. In addition the Index⁵³ identifies significant areas of concern where intellectual property industries seek progress from Mexico in 2013.

Patent

Patent Linkage

The Chamber believes strongly 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.

Regulatory Data Protection

In addition, we are concerned about Mexico's failure to uphold its North American Free Trade Agreement (NAFTA) commitment to provide adequate and effective protection against unfair commercial use and unauthorized disclosure of data submitted to obtain marketing approval for pharmaceutical products. While COFEPRIS published guidelines in June 2012 that provide

⁵³ U.S. Chamber of Commerce. (2014). GIPC International IP Index: *Charting the Course*

protection for five years against the use of undisclosed test data by any person for the purpose of marketing, it only provides this protection for new chemical entities and is unclear whether this protection will extend to include biologics. The Chamber urges clarity on this protection to ensure that biologics will be included under these new guidelines.

Copyright

The Mexican Congress recently passed a series of amendments to the Copyright Law. The amendments make very specific changes to certain enforcement provisions, including changing the process for infringement investigations, streamlining the infringement damages procedure, and increasing the fines for parties that fail to appear during mediation hearings. While these changes illustrate that the government acknowledges the importance of proper enforcement procedures, Mexico must continue to enhance its copyright protections. This includes fully implementing the WIPO Internet Treaties to which Mexico acceded in 2002, ensuring that performers and record companies have the ability in law and practice to prevent the uncompensated use of their recordings by broadcasters and establishments, and providing legal incentives for intermediaries to cooperate with rights holders in addressing the use of their services for infringing purposes.

Enforcement

Mexico's border enforcement is also inadequate. While we commend Mexico, as noted above, for providing *ex officio* authority to its law enforcement officials, its ability to combat the transshipment of pirated and counterfeit goods through its borders would be significantly enhanced by providing similar authority to its customs officials. We therefore ask the United States Government to continue to urge the Government of Mexico to provide *ex officio* authority for its customs officials to allow for the seizure of counterfeit and pirated goods.

Camcording

We also urge Mexico to strengthen its criminal laws against the unauthorized camcording of films in theaters – there is no legitimate reason to camcord a film -- and to take steps to strengthen the enforcement of its copyright laws.

Trade Secrets

The Chamber commends the Mexican Government for providing protection of trade secrets in their law and criminal code, but there is still much work to be done in the enforcement of the law. Security experts report that 97% of industrial espionage cases go unpunished and of the cases that are brought to court only 56% result in damages or fines.

Russia

The Chamber remains cautiously optimistic that Russian accession to the WTO in 2012 will continue to serve as an impetus for implementing critical commitments to protect and enforce intellectual property rights as outlined in the intellectual property Action Plan developed with the United States. The Index⁵⁴ identifies significant areas of concern where intellectual property-intensive industries seek progress from Russia in 2014.

Patents, Related Rights, and Limitations

Significantly, Russia provides pharmaceutical patent owners a patent term extension for products delayed due to regulatory approval processes. However, a number of challenges remain in the area of patent protected inventions.

The Russian Civil Code Part IV does not provide for the patentability of computer-implemented inventions, and thus software patents are *de jure* unavailable in Russia. However, there are examples of patents being issued for some software-based technologies. This inconsistency should be remedied through clarity in the legal framework and an extension of patentability standards.

In 2010, the Government of Russia made initial positive efforts to provide six years of regulatory data protection for pharmaceutical products; however, despite three years passing, no progress has been observed. We encourage the United States to work with Russia to ensure the effective implementation of these data protection provisions.

Additionally, Russia has no law providing twelve years of regulatory data protection for biologic drugs. Adopting the U.S. standard for biologics would help resolve innovator and generic launch issues in Russia.

⁵⁴ U.S. Chamber of Commerce. (2014). GIPC International IP Index: *Charting the Course*

Trade Secrets

Trade secret theft, although punishable under the Civil Code Part IV, continues to be a significant problem in Russia, according to reports by the U.S. Government and intelligence agencies around the world.

Copyright

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 include interim judicial measures which give the Moscow City Court the power of issuing temporary injunctions in these cases. As these laws are still relatively new we are still cautiously optimistic that they may provide effective in improving the enforcement environment online in Russia. The Chamber encourages vigorous enforcement of these new powers against infringements.

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.

United States – Russian Intellectual Property Rights Action Plan

Intellectual property dependent industries will be watching very closely the implementation of the United States-Russian Federation Intellectual Property Rights Action Plan issued on December 14, 2012. We believe that there are significant actions which can be immediately taken by the Russian government as a part of this commitment to resolving long-standing intellectual property issues, including actions against sites identified as notorious markets, such as vKontakte.

Enforcement and the Rule of Law

Despite the ongoing and numerous challenges, the Chamber has observed a number of improvements in Russian intellectual property enforcement in 2013. These include the launch of

a new court specializing in intellectual property disputes, which will act as a court of first instance with regards to challenges to regulatory acts, establishing the validity of IP rights, and as an appellate court with regards to IP cases. The future effects of this positive effort are hard to determine presently, however, we urge the United States government to work with these new entities to improve effective IP enforcement and the rule of law in Russia.

Mislabeled Herbal Supplements

Medicinal products marketed as herbal supplements containing only natural ingredients have been found in previous testing to contain an active pharmaceutical ingredient under patent in Russia. These falsely labeled and marketed products can be purchased without a physician's prescription, endangering public health but also violating the patent holder's intellectual property rights.

Ukraine

Patent

Under the current compulsory license law in Ukraine it is uncertain whether a patent holder will receive a notification of a generic application for market authorization. It is also unclear whether the Ministry of Health conducts checks on patent and data validity for generics when granting marketing approval. These fundamental aspects of a legitimate compulsory licensing regime should be improved upon to assure innovators that their investment is being adequately protected by Ukrainian authorities.

Data Exclusivity

Despite improvements in the rules governing intellectual property enforcement, additional steps must be taken to ensure adequate protection for data submitted for marketing approval. Even though Ukraine has data protection laws, the Regulatory Agency has taken actions inconsistent with these laws. We ask the United States Government to work with the Government of Ukraine to ensure that the Regulatory Agency abides by its data protection obligations.

Copyright

Ukraine continues to lack effective enforcement against online copyright piracy. A draft law introduced in June 2013 provides a notice and takedown mechanism, but lacks critical components for effectiveness, including third party liability. The lack of liability would mean that failure to respond to a takedown notice would not result in consequences for the offending site.

Enforcement efforts to curb online piracy need increased focus, including efforts focused on the online notorious markets located in Ukraine identified in the 2012 Notorious Markets report and additional sites such as Futubox that are emerging as significant sources of unauthorized content.

In addition to the broader piracy problems experienced by rights owners in Ukraine, rogue collecting societies present an additional challenge to the successful commercialization of creative arts. These entities claim to have the rights to license artistic works for which they have

no authority. Ensuring that proper accreditation is required and adequately enforced for collection societies to operate in Ukraine would be an important step toward reducing the infringing actions of these bad actors.

Legislation

Ukraine's intellectual property laws continue to be in need of modernization. Agreements decided upon between the United States and Ukraine, in both 2006 and in 2010, designed to strengthen intellectual property reform have not been enacted. In fact, peer-to-peer hosting and illegal websites based in Ukraine have grown in the period since the original discussions. Ukraine should enact legislation to implement the WIPO Internet Treaties.

Enforcement

The Chamber commends Ukraine for granting full *ex officio* authority, but is concerned by the lack of use of this power. Customs officials need to be trained on the importance of and the technical aspects of how to carry out their new authorities to seize counterfeit and pirated goods without a court order.

Ukraine remains a poor environment for enforcement of intellectual property rights, including: high availability of counterfeit apparel, rampant copyright piracy, and the failure to curb illegal software use within government agencies.

South Africa

The Chamber appreciates the South African Government's increased focus on intellectual property protections. While the Chamber welcomes some aspects of the Draft National Policy ("Draft Policy") on Intellectual Property released in September 2013, there are also elements, outlined below, which cause a serious concern for industry. The Index also enumerates further concerns with the current IP environment in South Africa. In order to support efforts in South Africa to improve the intellectual property regime, we encourage the U.S. Government to pursue the following goals with the South African Government.

Patents

Patentability

Proposals are currently being considered in South Africa that state that developing countries can adopt IP policies that limit the extent of patenting and facilitate the introduction of generic competition. Further, the pharmaceutical patentability requirements included in the draft policy closely resemble that of Section 3(d) of India's Patent Act, which continues to be concerning to industry. The Chamber finds troublesome any IP policies which mirror India's due to the rapid deterioration in India's IP environment over the last two years. The Chamber believes that policies that deter incremental innovation will damage both the IP environment and the South African economy as incremental innovation provides incentives for companies to invest in a given country and bring new products to market. We urge the U.S. Government to work with the South African Government to reconsider the existing clauses in the Draft Policy, which would restrict, if not eliminate, forms of incremental innovation.

Compulsory Licensing

South Africa is also considering introducing a "public health perspective into national IP laws" that would include the South African Government implementing a broad compulsory licensing policy. The Chamber believes the introduction of a compulsory licensing policy would not only represent a significant deterioration in the South Africa's IP system but also deter investment in the South African market. We strongly encourage the South African government to remove the references to compulsory licensing from current proposals in order to both make South Africa an

attractive destination for foreign investment and ensure the government's national IP policy will create a robust system of IP protections.

Data Protection

Current recommendations call for the South African Government to comply with Article 39 of TRIPS in terms of data protection. It is the Chamber's understanding that the Government does not intend to withhold the disclosure of information from clinical trials in order to benefit generic companies. However, governments usually allow for the protection of data by providing an exclusivity period, which allows for follow-on products to rely on the data after the exclusivity period lapses. The Chamber encourages the U.S. Government to work with their South African counterparts to ensure that data exclusivity is included in the national IP policy moving forward.

Patent Extension

The Draft Policy acknowledges that the South African government is "under pressure to amend the Patents Act to allow for patent extension or restoration to compensate for time lost due to regulatory delays" at the Medical Controls Council (MCC), but does not make direct recommendation to introduce such a policy. We encourage the South African Government to introduce patent term extension in order to make up for time lost during regulatory approval process and allow for the innovator to recover their research and development investment in the creation of a product.

Copyright

Term of Protection

The Draft Policy does not make any changes to existing South African law, which only provides for a copyright term of the life of the author plus 50 years. As both developed and developing countries alike are recognizing the importance of extending the copyright term to 70 years, the Chamber recommends that the U.S. Government work with the South African Government to ensure that the final national IP policy includes the modern term of protection for copyright.