



U.S. CHAMBER OF COMMERCE

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By electronic submission

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Washington, D.C.

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

2013 SPECIAL 301 SUBMISSION

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February 8, 2013

Stanford K. McCoy
Assistant U.S. Trade Representative for Intellectual Property and Innovation
Office of the U.S. Trade Representative
Washington, DC

Re: 2013 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) 2013 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 more than \$5.8 trillion of the United States gross domestic output, drive 74 percent of U.S. exports, and support 55.7 million direct and indirect American jobs.¹ It is also critical to promoting innovative and creative economies around the globe.

Late last year, 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 2012 International IP Index: *Measuring Momentum* (Index), is a first-of-its kind empirical assessment of the strengths and weaknesses of 11 economically and regionally diverse countries. While the Index, which we have appended to our submission and to which we refer throughout our submission, demonstrates progress by a number of countries in advancing intellectual property protections, it also highlights significant challenges by countries across the board to combat effectively intellectual property theft and the resulting harms caused to industries and consumers.

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; and the need to improve enforcement efforts and promote greater resources for the protection of intellectual property. In addition, we also highlight seven countries that present particular challenges with respect to intellectual property protections. These countries are Brazil, Canada, China, India, Mexico, Russia, and Ukraine.

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

¹ U.S. Chamber of Commerce. (2012). *IP Creates Jobs for America*. Washington, DC.

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,

A handwritten signature in black ink, appearing to read "David Hirschmann". The signature is fluid and cursive, with the first name "David" being more prominent.

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

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

Myron Brilliant
Senior Vice President, U.S. Chamber of Commerce
International Division

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 – that stimulate the economy, create jobs, and enhance competitiveness.

Intellectual property-intensive companies account for more than \$5.8 trillion of the United States gross domestic output, drive 74 percent of U.S. exports, and support 55.7 million direct and indirect American jobs.² 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.

² U.S. Chamber of Commerce. (2012). *IP Creates Jobs for America*. Washington, DC.

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. Late last year, the Chamber's GIPC released a first-of-its-kind International IP Index, *Measuring Momentum* (Index)³, 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 11 countries provides a snapshot of what countries are doing well and what they can be doing better.

The Index identifies 25 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: Australia, Brazil, Canada, Chile, China, India, Malaysia, Mexico, Russia, the United Kingdom, and the United States.

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.

³ U.S. Chamber of Commerce. (2012). GIPC International IP Index: *Measuring Momentum*.

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 innovative thinkers to protect the economic and cultural benefits resulting from any scientific, literary, or artistic work, and other innovations and creativity which they produce.

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 also as 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.

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

1. Copyrights

Increasing theft of digital media over the Internet presents one of the biggest threats to copyright protection. Estimates indicate that nearly as much as 25 percent of all Internet traffic worldwide is in furtherance of copyright infringement.⁴ 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.⁵

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. The Chamber unequivocally condemns censorship and human rights abuses. 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 digital economy. Building upon the Berne Convention and the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, the WIPO Copyright Treaty

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

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

(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. And the global acceptance of those norms was reaffirmed less than a year ago with the adoption of a new 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.

2. 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.⁶ These studies promulgate the notion that intellectual property is a barrier to access for innovative technologies while making little to no comment on endemic problems such as high import tariff rates and corruption rates as barriers to access. The misconception of intellectual property as a barrier has a 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, 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

⁶ Fink, Carsten. (2004, November). *Intellectual Property and the WTO*. siteresources.worldbank.org/.../Resources/.../IPR-WTO_Fink.doc.

ensure incentives for innovators and protect the public interest against any possible abuse. It is essential that the U.S. Government remain vigilant in ensuring no weakening of patent rights in international forums, 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.

3. 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. This trend continued into New Zealand, where the Cabinet approved the principle, and in the United Kingdom, where the government is holding hearings on the issue. While the Chamber supports advancing public health, we are deeply concerned about this approach and the unintended consequences it may create. 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 in the fashion underway in these countries is both unprecedented and unwarranted and will incentivize additional efforts to erode intellectual property protection. This bill could lead to a series of unintended consequences, including downward competitive price pressures in the market brought on by the lack of brand differentiation and an influx of far lower priced illicit and counterfeit tobacco products facilitated by the regulatory structure in the bill, which will only benefit the returns to organized crime and create additional challenges for law enforcement and government revenue collection.

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.

4. 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. 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 look forward to the release of that strategy, which we believe must include all available trade, legislative and other tools to address trade secret and economic espionage-related concerns. We also commend the enactment late last year of two bills which closed a loophole in the protection of trade secrets and enhanced penalties against economic espionage.

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. Several multilateral organizations have proposed or implemented limitations on consultation with the private sector in policy deliberations. This worrisome trend threatens to undermine the credibility of these institutions in policy making.

Through the GIPC's *IP Delivers* campaign the Chamber is proactively engaged with UN member state policy makers and multilateral institution secretariat staff to provide fact-based

research and information reflecting the realities of intellectual property in the marketplace. It is critical that this audience has access to a balanced and practical assessment of the current and future state of intellectual property protection and the economic growth and innovation it fuels.

Importance of Bilateral and Regional Free Trade Agreements

The Chamber is optimistic that regional and bilateral trade agreements negotiated in 2013 will explore 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)⁷, 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.

Internet Issues

The Internet has developed into the greatest marketplace of goods and ideas. However, just as legitimate businesses and consumers have embraced the Internet, unfortunately so have criminals. 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

⁷ 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.

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.

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 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 and creative industries and the thousands they employ.

One of the problems in connection with sites that traffic in counterfeit goods is that it can be difficult for consumers to determine what 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 or even copying 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 users who download content.⁸ Finally, 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 TRIPS Agreement, 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

⁸ Paula Greve, Digital Music and Movies Report: The True Cost of Free Entertainment, McAfee, 2010.

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.

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.

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.”⁹ 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.¹⁰ “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.”¹¹

Even though FTZs are typically legitimate and reflected in sovereign law, they are often abused by counterfeiters and contraband criminals, given the lack of, or unwillingness of authorities of customs to police the trade within them properly. The Chamber encourages the United States to work with countries to make sure that FTZs have proper inventory controls, and that customs agents should 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 goods to be fake. In addition, all customs services should have the authority to seize suspect goods that are in transit while it determines their legitimacy, and not merely those that are destined to an internal market.

⁹ World Customs Organization Glossary of International Customs Terms. (2006, May). http://wcoomdpublishings.org/downloadable/download/sample/sample_id/123/

¹⁰ WCO Guidelines on Controlling Free Zones in Relation to IPR Infringements, Para. 2. (January 12, 2005).

¹¹ *Ibid*

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.¹² 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.¹³ 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.¹⁴ 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.¹⁵

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.¹⁶

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

¹² See e.g. www.salecheapcigarettes.com ("All packages delivered through International Post with Express Mail Service (EMS)"); www.cigoutlet.biz ("[w]e send cigarettes from Europe via air mail. Parcels are delivered to their addressees by Postal Services") (last visited November 28, 2011).

¹³ *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.

¹⁴ See www.discountcigarettesbox.com (last visited November 30, 2011); www.cigarette1.com www.cheapricecigarettes.com ("100% refunded if seized") (all last visited November 28, 2011).

¹⁵ The Association of Convenience & Petroleum Retailing. *Remote Sales of Tobacco* (Retrieved March 19, 2010). www.nacsonline.com/NACS/Government/Tobacco/Pages/RemoteSalesofTobacco.aspx.

¹⁶ 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 U.S. 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.¹⁷ 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.

¹⁷ 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.”¹⁸ 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.

¹⁸ 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.¹⁹ 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 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. As such, the Chamber urges dedicated funding and support for the program, allowing it to expand and improve.

¹⁹ Office of the Intellectual Property Enforcement Coordinator. Executive Office of the President. (2010, June). *2010 JOINT STRATEGIC PLAN ON INTELLECTUAL PROPERTY ENFORCEMENT*, pg. 2.

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). 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 2012, Brazil continued to make steady improvements in its intellectual property rights protection and enforcement regime. There is also 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 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. The Index²⁰ outlines many areas of concern where industry hopes 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 GOB.

Patent

Prior Consent

The Chamber continues to believe that the Brazilian National Health Surveillance Agency (ANVISA) acting beyond its congressional mandate when reviewing patent requirements in pharmaceutical patent applications filed with the Brazilian National Industrial Property Institute (INPI) linked to the Brazilian Ministry of Development, Industry, and Foreign Trade (MDIC). In its Opinion no. 2010 (2009), the Office of the Brazilian Attorney General (AGU) made it clear that ANVISA's sole responsibility with regard to patents is to proceed with the analysis of the sanitary risk to health of the patented pharmaceutical. As a result, INPI is the sole agency in Brazil with authority over the approval of patent applications. The Opinion, however, was not fully implemented, and ANVISA continues to exercise its authority beyond its congressional mandate. In this context, the Chamber encourages the U.S. Government to continue to work with MDIC and GOB agencies through bilateral dialogues, including the newly-established bilateral Intellectual Property Working Group, but also to discuss potential remedies directly with the Brazilian National Congress. Article 49(V) of the Brazilian Federal Constitution of 1988 allows the Brazilian National Congress to approve decrees halting Executive branch regulatory

²⁰ U.S. Chamber of Commerce. (2012) GIPC International IP Index: *Measuring Momentum*, p. 36-38

processes when such processes are carried out in a way that goes beyond congressional mandates.

Data Protection

The Chamber is concerned that the GOB has not made sufficient efforts to provide certainty that test and other data submitted for marketing approval will be protected fully against unauthorized use. 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 12 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.

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.

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. While most of them are piecemeal reforms of the current legal framework a few are omnibus Brazilian Executive Branch-sponsored legislation such as the Internet Civil Framework Act and the Copyrights Amendment Act, sponsored by the Brazilian Ministry of Justice (MJ) and the Brazilian Ministry of Culture (MinC) respectively. It is imperative that these initiatives strengthen protection for intellectual property and certainly do not erode or limit the ability or liability of rights holders to protect their intellectual property.

WTO Cotton Dispute

Finally, 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.

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 developed nations in the Index²¹. 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 commends Canada for passage of Bill C-11, which went a long way toward implementing the WIPO Internet Treaties. The Chamber applauds enactment of this legislation after so many years, which demonstrated a resolve and appreciation for the importance of protecting creative works. As noted above, though, 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.

Patent

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

²¹ U.S. Chamber of Commerce. (2012). GIPC International IP Index: *Measuring Momentum*, p. 40-43

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.

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.

The Chamber is also concerned about recent decisions by the Canadian Federal Courts which have imposed an onerous test for utility that is inconsistent with both its past practice and its international obligations. The requirements impose burdensome patent criteria which narrows the scope of inventions that receive patent protection particularly for pharmaceutical inventions. These utility requirements do not appear supported by either Article 27.1 of the TRIPS Agreement or by NAFTA Article 1709.1. 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 within the Canadian Intellectual Property Office (CIPO).

Enforcement

In addition, we have concerns across 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.

We urge the U.S. Government to continue to actively engage Canada on improving its intellectual property protection and enforcement laws and practices in order to meet the high standards of a 21st century TPP agreement.

China

The Chamber continues to work closely with the Government of the People’s Republic of China (“PRC” or “China”) to protect and enforce intellectual property rights. The Chamber’s commitment to work on this issue is extensive. The Chamber is uniquely positioned to engage across the gamut of intellectual property policy concerns in China on behalf of our diverse membership.

The Chamber appreciates the Chinese government’s work and efforts to emphasize the protection of intellectual property as a basic critical tool to foster innovation. In particular, we recognize the efforts being taken by various Chinese ministries to amend critical legislative documents including the Copyright Law, the Trademark law, as well as the recently announced Judicial Interpretation on Internet Liability and others. Through these processes, the Intellectual Property Tribunal of the Supreme People’s Court (SPC) and the relevant ministries have demonstrated commitment to meaningful public participation and transparency. We thank the Court and the Chinese ministries for these processes and commend this approach.

With the historic Leadership transition taking place in China, the Chamber looks forward to working with the U.S. Government and the new Chinese leadership team, and urges that the protection and enforcement of intellectual property rights remain a top priority for the new Chinese government leaders. It is in this spirit that the Chamber launched a cooperative dialogue in 2013 with government and non-government stakeholders in China to enhance cooperation on intellectual property issues of key concern to the U.S. and Chinese business communities.

The Chamber recommends continued monitoring of implementation of China’s policy plans, as well as close engagement with relevant ministries, the National People’s Congress (“NPC”), appropriate Judicial organs, and other stakeholders. This will help to promote exchanges in best practices and encourage greater awareness of the obvious benefits that will be realized from more aggressive legislation and enforcement of intellectual property rights, including the protection for consumer interests as well as greater investments in R&D by domestic enterprises—large and small.

Even with the improvements seen in many of the amendments to intellectual property law, China remains a country of concern to the Chamber, due to a full range of intellectual property concerns—counterfeiting (both domestic and exports), copyright piracy, including online infringement, patents, and trade secrets – which are outlined below.

Trademark

Enforcement in 2011

Figures from 2010 trademark counterfeiting cases indicate modest increases in criminal prosecutions and convictions for intellectual property violations—the vast majority of which involved trademark counterfeiting.²² However, these statistics suggest that there are still continuing flaws in existing transfer procedures. The Chamber underscores the need for more innovative measures to allocate responsibility for individual counterfeiting cases and to promote cooperation between administrative authorities and the public security bureaus (PSBs) in the course of investigations.

The Ministry of Public Security recently announced that new rounds of actions in 2013 will target counterfeiting and passing-off of well-known brands in high-tech, food, drug, auto parts, and machinery fields. We are hoping such continuous efforts will benefit both domestic and international companies as trademark owners.

Pharmaceutical Counterfeiting

The PRC Criminal Code was amended in February 2011 in a manner which effectively eliminates numerical thresholds or requirements of demonstrated harm to consumers in cases involving counterfeit pharmaceuticals. In conjunction with this change, local PSBs such as

²² Complete data for 2011 is not available as of this writing. For 2010 transfer statistics, see www.saic.gov.cn/zwgk/zyfb/qt/sbj/201104/P020110425607919983842.pdf. The official sources revealed that the sustained enforcement campaigns led by the Ministry of Public Security (MPS) throughout 2012, netting large-scale seizures of counterfeits and the arrests of suspects. During the period November 2010 to August 2012, police enforcement actions had led to the arrest of over 121,000 suspects in 72,000 cases.

Beijing, Chongqing and Liaoning, established specialized teams to exclusively deal with cases involving fake food and drugs and ramped up efforts to proactively deal with counterfeit drugs.²³

The Chamber is encouraged by China's approach to counterfeit pharmaceuticals and encourages the Chinese government to carefully study the results of these innovations as part of its research towards amendment of the intellectual property provisions in the Criminal Code and other enforcement reforms. The Chamber particularly looks forward to understanding how administrative authorities and the PSBs will allocate responsibility for investigations in the absence of formal numerical thresholds, as the standards adopted by local authorities should help to address key concerns of legislators and enforcement authorities focused on other types of goods.

Trademark Law Revision

The Chamber recognizes that new amendments to the Chinese Trademark law have been released, and we look forward to working with the U.S. Government and their Chinese counterparts on these new proposals.

In October 2011, the Chamber composed a position paper issued to the State Council regarding proposed amendments to the Trademark Law.²⁴ Among the main concerns expressed were: the lack of comprehensive provisions to address bad faith trademark piracy at the register; the need for clarity on the loopholes in the Trademark Law; the need for higher statutory damages and the clarification that a higher range of compensation may be awarded where the infringer is a counterfeiter, repeat offender, operating "underground" or otherwise engaged in more egregious behavior; the need for greater investigatory powers for local Administrations for Industry and Commerce (AICs); the need for concurrent revision of the PRC Criminal Code; and the need for new language to clarify the scope of secondary liability for landlords, trade boards, and other intermediaries, and in a manner consistent with decisions of Chinese civil courts. Such decisions,

²³ See http://www.chinaipr.gov.cn/newsarticle/news/government/201111/1265554_1.html. Similarly, it was reported on January 4, 2012 that police in the southwestern city of Nanning detained 39 people in a case involving fake drugs valued at RMB 46 million or US\$7.3 million. See http://www.chinaipr.gov.cn/newsarticle/news/local/201201/1274096_1.html.

²⁴ The U.S. Chamber of Commerce and the American Chamber of Commerce in China submitted comments to the State Council on the draft Trademark Law in September 2011:

<http://image.uschamber.com/lib/feed13797d6c06/m/1/US+Chamber+AmCham+Draft+TM+Law+Revision+Position+2011.pdf>

including recent appeal court decisions involving the infamous Silk Street Market, clarify the obligation of intermediaries to take timely measures to prevent repeat offences, and further clarify the duty of care of intermediaries to cover deemed knowledge, rather than just actual knowledge.

Physical Markets

The Chamber congratulates USTR for its publication on December 13, 2012, of an updated list of Notorious Markets, which includes the Buynow PC Malls, the Silk Street Market in Beijing, as well as markets in Yiwu, Putian, and Shenzhen.

Chinese courts have recently issued decisions which help to clarify the duty of care of landlords in physical markets to take action in monitoring and preventing infringements based on a deemed knowledge, rather than an actual knowledge standard. The Trademark Office and local AICs do not appear to have used these standards in their efforts to persuade landlords to take more aggressive action in addressing counterfeiting in the markets. The Chamber understands that some landlords have had success to reduce the number and scale of illicit vendors in some of the markets, while efforts in other market—including the Silk Street Market—have yielded little if any results. The Chamber therefore encourages greater dialogue and cooperation in dealing with these hot-spot markets, many of which are engaged in wholesale, as well as retail, trade.

Online Counterfeiting

The State Administration for Industry and Commerce (SAIC) announced last year that by the first half of 2013 it will launch its nationwide online commodities trading regulatory information system to monitor large online trading platforms. This information system has been discussed for at least the last two years, and we look forward to seeing how effective the system is. The Chamber notes that top officials in the Chinese Government have acknowledged that mere deletion of infringing information is insufficient to deter unlawful activities and that the government must step up penalties and raise the cost against pirates. It will be helpful that USTR continues its ongoing programs with the SAIC and press for more effective actions.²⁵

²⁵ See the Chinese media report at <http://finance.sina.com.cn/chanjing/cyxw/20121128/021913817821.shtml>.

As with physical markets, it is hoped that relevant ministries will carefully consider the decisions of Chinese courts in cases involving intermediary liability. As noted above, the Beijing courts have imposed clear duties on the Silk Street Market—a physical market—to prevent repeat offences based on a deemed knowledge standard. Similar standards have however not been issued against the online market Taobao.com.

The Chamber was happy to see Taobao sign an agreement with the Motion Picture Association of America (MPAA) to decrease piracy of movies. The Chamber is hopeful that Taobao will continue to 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.

Punitive Damages

The Chamber is pleased that the latest draft of the Trademark Law issued for comment by the National People’s Congress in 2013 includes provisions that would permit civil courts to impose punitive damages against willful infringement. The Chamber hopes that this provision will eventually be approved in the final version of the law.

On January 20, 2012, the State Council publicized two documents, which helped clarify the scope of the work of the Leading Group, ministries and judicial bodies participating therein.²⁶ While laudable, the action points set out therein are extremely broad and appear to break little, if any, new ground.

²⁶ The two State Council documents include the Opinion on Work Relating to the Fight against IP Infringement, Counterfeiting and Fake and Shoddy Goods, available at http://www.gov.cn/zwggk/2012-01/20/content_2049684.htm, issued on November 13, 2011, and a Notice intended to promote implementation of the Opinion, issued on December 28, 2011, available at http://www.gov.cn/zwggk/2012-01/20/content_2049677.htm.

Patent

Protection of Patented Pharmaceuticals

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 State Food and Drug Administration (SFDA) 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.

The Chamber views China's deference to these published material and regulatory decisions by agencies outside of China as an indicator that it is overly reliant on clinical data developed by originator companies. Published data merely summarizes the data included in the original filing; the original data is necessary to demonstrate the safety and efficacy of the product. Submitting the published data on its own is usually insufficient to prove the safety and efficacy of a product. Reliance on summary data or approvals in countries outside of China gives an unfair commercial advantage to non-originator companies because non-originator companies do not incur the cost of generating their own clinical data to prove safety and efficacy. Such reliance may also create safety concerns around non-originator products for which inadequate safety data are available to the Government of China.

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 views this commitment as a positive signal from Chinese authorities that can provide the basis for the achievement of substantial progress in 2013. The Chamber urges the U.S. Government to work closely with the Ministry of Health and other stakeholders in 2013 to ensure this commitment is implemented as soon as possible.

In 2006, China revised its patent examination guidelines regarding the disclosure required to claim pharmaceutical compounds (though the patent law was not changed). Examiners have been applying these new guidelines to all applications, regardless of when they were filed. They have been requiring a significant amount of biological data in the patent specification as filed, and they will not accept data submitted during patent prosecution. The adoption of this new guideline has caused concerns about the validity of existing patents granted prior to 2006.

The Government's practice under the guideline contravenes the practice used by the USPTO, JPO, and EPO, as well as the standard provided by the Patent Cooperation Treaty (PCT), of which China is a member. This has caused denials of patents in China to medicines that have received patents in other jurisdictions. China should ensure new patent disclosure obligation regulations will not automatically prevent grant of patents filed before the date of the new regulation. China should also reinstate patent applications that were adversely affected and consider relevant data generated after patent applications are filed, consistent with the practice in the United States, EPO, Japan, Korea, and as provided for in the PCT.

In addition, the Chamber is concerned about challenges related to counterfeit medicines that involve Active Pharmaceutical Ingredients (APIs). In an effort to ensure drug safety, the Chamber urges China to address unregulated APIs, including enacting new legislation to make chemical companies liable if they knowingly sell unregulated chemicals for use in counterfeit medicines or Traditional Chinese Medicines (TCMs).

Patent Protection and Enforcement

The Chamber, together with the American Chamber of Commerce in China, appreciated the opportunity to submit comments on the Amendments to the Patent Law of the People's Republic of China, for consideration by the State Intellectual Property Office (SIPO).²⁷ A number of the proposed amendments to the Patent Law can help to strengthen intellectual property rights in China. For example, it makes good sense to accelerate the announcement of Patent Reexamination Board (PRB) decisions on patent validity and clarify when they become effective

²⁷ The U.S. Chamber of Commerce and the American Chamber of Commerce in China jointly submitted comments on the Draft 4th Amendments to the Patent Law:

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

as long as (i) the right to judicial review is maintained, and (ii) any appeal must be exhausted before the infringing party is liable for damages and/or has an injunction issued against it in a separate infringement case.

Of most concern to industry, and the Chamber urges close monitoring by USTR in this regard, is the proposal to significantly expand the remedial powers of inexperienced administrative agencies so that they can impose not only injunctive relief, but also damages, fines, and penalties for patent infringement. This proposed dual system of enforcement -- with its expected increase in litigation, expense, conflicts with judicial actions, and options to forum shop for the most attractive venue -- 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 to include the authority to impose damages and fines for patent infringement, the Chamber urges USTR to work with SIPO to carefully consider study all of the positive and negative implications of such authority before SIPO moves forward.

Patent Quality and Utility Model Patents

As the Chamber noted in our submission to SIPO on the draft 4th Amendment to the Patent Law, the Chamber is concerned about “(i) the reality that an increasing number of lower quality patents are being filed in China, (ii) an administrative officer, often with little or no patent dispute experience, would have the authority to initiate its own actions, confiscate illegal earnings and then impose an additional fine of up to four times the illegal earnings and (iii) patent holders would be able to receive three times the profits, losses, or royalties for willful infringement.” In response to rising concerns from our members regarding the threat that the proliferation of low quality, utility model patents present to foreign companies and Chinese innovation goals, the Chamber commissioned a comprehensive report and recommendations on the utility model patent system in China, which it released in late 2012.²⁸ The report concluded that while the utility model patent system has both strengths and weaknesses, the meteoric rise in

²⁸ 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

filings of utility model patent applications pose a risk to innovation in China. Among its key recommendations, the report urged 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.

The Chamber has taken note of the Chinese State Intellectual Property Office report “The Development of China UMPs” that was released at the end of 2012.²⁹ Furthermore, SIPO has just released new draft patent examination guidelines that appear to address certain aspects of concern related to the quality UMPs.³⁰ The Chamber looks forward to the opportunity to comment on the measures and appreciates the ongoing work of SIPO to address patent quality concerns. The Chamber urges the U.S. Government to continue to engage SIPO on patent quality challenges for our members, and we look forward to working closely with the U.S. Government and Chinese authorities in 2013 to enhance meaningful dialogue on the recommendations contained in our 2012 report.

Inventor Remuneration

One of the most controversial legislative actions among industry in 2012 was the draft Regulations on Employment Invention prepared by SIPO. The subject matters of the Draft Regulations directly stipulate the ownership of inventions and employment relationship as well as companies’ operations to commercialize their inventions. The Chamber provided detailed comments to SIPO on the measures in December of 2012.³¹

If implemented as drafted, the provisions in the Draft Regulations would have a significant impact on the way companies own and dispose of intellectual property assets, unduly exceeding the scope of the Patent Law and its Implementing Rules now in force. More broadly, the measures 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

²⁹ SIPO website publishes the entire report in Chinese: http://www.sipo.gov.cn/yw/2012/201212/t20121221_781008.html.

³⁰ SIPO website releases draft Patent Examination Guidelines for public comment: http://www.sipo.gov.cn/tz/gz/201302/t20130206_785294.html

³¹ 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, the Chamber recommended a number of changes to the text of the draft regulations and we urge USTR to closely follow this process.

The Chamber understands that SIPO is carefully weighing input it has received from all stakeholders on the draft measures, including foreign associations like the Chamber. In particular, we are hopeful that provisions related to the questionable superiority of existing company policy or agreements, the calculation of the value of patents in determining remuneration, and right of first refusal will be revised

Intellectual Property Misuse

The Chamber has a long-standing record of robust engagement with Chinese authorities on all aspects of the implementation of China's 2008 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.³²

The Chamber harbors serious concerns regarding numerous provisions of the draft guidelines, and we urge close consideration of all possible impacts these proposal could have on competitiveness and innovation.

Competition law should view intellectual property rights as being 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 in its final guidelines, and we urge USTR to track this process closely.

³² 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

National Standards and Patents

Following years of deliberation and consultation with industries and professionals, the Standardization Administration Commission (SAC) published the Draft Administrative Measures on National Standards Involving Patents (Interim) for comments in December 2012. The Chamber submitted comments to SAC on the Draft Measures in January 2013.³³

The Chamber appreciates that SAC removed several controversial provisions, including compulsory licensing and low royalty fee licensing from the earlier draft back in 2009. If implementation proceeds in a manner consistent with the removal of these provisions, this would constitute a significant step forward in China's recognition of markets to appropriately price intellectual property rights incorporated into standards as well as international best practice in standard setting activities.

At the same time, the Chamber noted several areas require further clarification and predictability, and we look forward to working with USTR to ensure these provisions are appropriate.

The Chamber will continue to actively monitor the SAC Measures out of concern that the concepts of compulsory and low-royalty fee licensing may be reintroduced in the future.

Civil Procedure Law

The Chamber was pleased that the newly amended Civil Procedure Law offers improved rules in enforcement of court judgments, wider availability of preliminary injunctive relief in all types of intellectual property cases including those for unfair competition and trade secret cases, while it remains unclear whether the courts will indeed progressively issue injunctive relief in intellectual property cases. We are hoping that the maturing civil procedures will eventually result in more effective evidence collection measures, including adoption of civil discovery proceedings, lowering the thresholds around accepting and conducting evidence preservation, and reducing the burden of proof on right holders.

³³ 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>

Copyright

Online Piracy

With respect to online piracy, there has been some progress in government enforcement against infringements, including when several major Chinese video sharing sites purchased licenses from content owners after their IPO and Taobao signed an agreement with the MPAA.

However, much more still needs to be done including increased criminal actions against online infringers and additional measures against internet service providers and online platforms that knowingly host infringing content.

Judicial Opinions

As discussed before, the Chamber was extremely pleased with the transparency of the SPC in its efforts to draft a new judicial interpretation to clarify the duty of online operators in protecting copyright in the context of civil enforcement. The JI included key issues such as inducement and contributory liability, constructive knowledge, red-flag tests, and take-down notices, which are all positive steps forwards. The Chamber urges USTR to work closely with the Chinese government and Judicial organs to implement the JI in a manner that provides vibrant and effective level of intellectual property rights.

Criminal Code Revision

The Chamber looks forward to the schedule of hearings 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 an intensified enforcement campaign. 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. Additionally, Chinese authorities appeared to have some success in persuading online entities to be more responsive to take-down requests from intellectual property owners.³⁴ 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.

³⁴ Intellectual Property Protection in China. http://www.chinaipr.gov.cn/newsarticle/news/government/201107/1240884_1.html

India

In the last two decades, India has experienced dramatic economic growth. Much of this success has been a product of domestic and foreign investment in India. Unfortunately, due to inadequate protections for intellectual property, many of the companies investing capital in India face serious challenges that undermine the companies' ability to compete and succeed in this vital market and to grow even faster. In addition, the lack of intellectual property protections limits the growth and opportunities for India's domestic creative and innovative industries.

The Chamber commends the Government of India (GOI) for recognizing the importance of intellectual property in their National IPR strategy and taskforce, but to date has not seen demonstrable progress in confronting or overcoming the issues around intellectual property protection, particularly as they affect pharmaceutical and copyright industries. In fact, on the Index³⁵, which identified significant areas of concern, India ranked last out of all the countries that were examined.

The Chamber is a strong advocate for the fundamental rights of innovative thinkers and inventors to protect the economic and cultural benefits resulting from any scientific, literary, or artistic work, and other innovations and creativity they produce. A robust intellectual property regime based in law provides an incentive for individual innovation and serves the public interest by facilitating the creation and dissemination of knowledge and culture. Recently, in India, the public debate on intellectual property rules has overlooked this careful balance of the benefits derived from protection of intellectual property, thus skewing the public understanding of the careful balance that characterizes modern intellectual property regimes around the world.

Patent

Court Decisions

With respect to pharmaceutical patent protection, three recent cases have done significant damage to the overall IP protection environment. The first is the decision by the Indian Patent Office to issue India's first-ever compulsory license to allow for generic manufacturing of a

³⁵ U.S. Chamber of Commerce. (2012). GIPC International IP Index: *Measuring Momentum*, p. 54-57

patented anti-cancer drug. Although governments have recognized that certain occasions call for issuing compulsory licenses, especially in the case of pandemics or other health care emergencies, this case was not one of those occasions. This decision weakens patent protection for innovative pharmaceuticals, and thus may impede the development of new life-saving solutions. Relying on compulsory licenses in general is bad for innovation and bad for overall health policy.

The second was the revocation by the Indian Patent Office of a patent covering a kidney cancer drug. The explanation for this revocation was that the drug lacked inventiveness, yet the same drug was patented without challenge in 90 other countries. The Chamber commends the Supreme Court of India for overturning this ruling and sending it back to the Indian Patent Office for further review.

The third recent decision is a ruling by the Delhi High Court finding that a generic drug manufacturer did not infringe a compound patent claiming the active ingredient of the drug when the generic manufacturer sold a single polymorphic form (form B) of the drug. The court found non-infringement on the grounds that since the patentee had sought a separate patent on form B, the patentee's original compound patent should be interpreted to exclude form B. The court's interpretation is contrary to well-established principles of patent law.

These decisions may set a precedent for future cases, threatening to further erode the intellectual property environment. In addition, the Indian Supreme Court is expected to issue a decision on a case regarding Section 3(d) of the Indian patent law, which could significantly weaken patent rights in India. In its current form, the patent law imposes an additional hurdle for the protection of incremental innovation and does not recognize that incremental innovation provides benefits beyond enhanced efficacy in terms of patient safety and compliance, manufacturing efficiency (affecting product cost), and product stability during storage and transport. This decision is an important marker in determining whether the Indian courts are going to continue to erode intellectual property via the judicial system or whether they are going to reverse this trend.

Regulatory Data Protection/Data Exclusivity

There is a critical need to underscore the 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 such 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 recognizes the considerable effort required to create these products. India also has not yet implemented any meaningful protection for the data that must be generated to prove that pharmaceutical and agricultural chemical products are safe and effective.

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

Patent Linkage

Currently, in India, no system is in place to prevent the health authorities from providing marketing authorization for patent-infringing products. We urge the United States to continue to press India to provide an effective mechanism to enforce patents prior to the issuance of marketing approval.

Copyright

India has large copyright industries: The country produces more feature films than any other country in the world and has major music, publishing, and software industries. Although one might look at the size of these industries and assume that the situation is fine in India, the reality is that there is significant untapped potential for generating foreign investment, creating jobs, and promoting exports in these sectors because they are held back by inadequate laws and rampant piracy, both physical and via the Internet. The legal environment must be significantly improved and piracy levels must be curbed to create a climate for increased investment and increased growth that benefit India's citizens with greater choices and creative industries with greater opportunities.

Copyright Law Reform

Although we commend the GOI for taking steps 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.

This legislation also fails to provide adequate and effective protections to prevent the unauthorized copying of movies in theaters and optical disc piracy. 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.

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

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.

Mexico

The Chamber has previously commended 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 welcomes their entrance into the TPP negotiations. However, a number of key areas remain to be addressed regarding intellectual property protection and enforcement and the Index³⁶ identifies significant areas of concern where intellectual property industries seek progress from Mexico in 2013.

Patent

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 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

³⁶ U.S. Chamber of Commerce. (2012). GIPC International IP Index: *Measuring Momentum*, p. 61-64

extend to include biologics. The Chamber urges clarity on this protection to ensure that biologics will be included under these new guidelines.

Copyright

It is important that Mexico 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. We also urge Mexico to strengthen its criminal laws against the unauthorized camcording of films in theaters and to take steps to strengthen the enforcement of its copyright laws.

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.

Trade Secrets

We commend 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 the industrial espionage cases go unpunished and of the cases that are brought to court only 56% result in damages or fines.

Russian Federation

The Chamber welcomes the United States' extension of permanent normal trade relations (PNTR) to the Russian Federation as part of its accession to the WTO. We remain cautiously optimistic that Russia will take swift and effective actions to implement the critical commitments to protect and enforce intellectual property rights as outlined in the intellectual property Action Plan developed with the United States. The Index³⁷ identifies significant areas of concern where intellectual property-intensive industries seek progress from Russia in 2013.

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 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 protection for biologic drugs. Adopting the U.S. standard for biologics would help resolve innovator and generic launch patent issues in Russia.

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.

³⁷ U.S. Chamber of Commerce. (2012). GIPC International IP Index: Measuring Momentum, p. 65-68

Copyright

Online copyright infringement continues to be a significant problem in Russia. Indeed, sites and services based in Russia play an outsized role in the global criminal piracy ecosystem. An ineffective legal framework for fighting piracy means that Russia-based infringing websites such as vKontakte and Rutracker continue to be large contributors to global piracy and continue to grow, based in part on their status as providers of access to infringing products. The Chamber encourages USTR to work with Russia to make amendments to its laws to provide for effective copyright enforcement on the Internet, including modifying the Civil Code to create clear liability for acts that induce or promote infringement, to include an efficient notice and takedown system that does not require judicial review (as well as takedown staydown), and creating a liability regime that includes legal incentives for ISPs and other intermediaries to cooperate with rights holders in taking action against infringement. Additionally, USTR should encourage Russia to narrow its limitations and exceptions, which currently are incompatible with the Berne three-step test. Finally, USTR should work with Russia to secure enactment of legislation to ensure against circumvention of technical protection measures used to secure access to and the integrity of protected works.

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 a 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

Although Russian law provides for civil and procedural remedies against intellectual property infringement, the availability and enforcement of these remedies – injunctions, for example – remain weak. Statutory damages, while provided for under Russian law, are usually too small to serve as an effective deterrent for illegal behavior. Overall customs enforcement is inefficient, bureaucratic, and cumbersome, which means that stopping the flow of counterfeit goods into the Russian market is problematic for rights owners. Customs seizures require the filing of an administrative action, which can last up to two years and cost \$1,000 - \$3,000 per shipment. Implementing an expedited summary procedure would alleviate much of the delay and expense in enforcement.

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

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

Piracy rates across industries in Ukraine are ever increasing and are among the highest in Europe.³⁸ In addition, there is evidence to suggest that the enforcement of intellectual property laws and regulations has weakened over the past year and will continue to erode over this next year unless urgent and decisive action is taken by the Government of Ukraine.. 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.

³⁸ International Intellectual Property Alliance (IIPA). (2011). *International Intellectual Property Alliance (IIPA) 2011 Special 301 Report on Copyright Enforcement and Protection: Ukraine*, p130

Legislation

As reported in our 2012 report, Ukraine's intellectual property laws are 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.

In addition, 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.