



By electronic submission

Stanford McCoy
Assistant U.S. Trade Representative for Intellectual Property and Innovation
Office of the U.S. Trade Representative
Chair of the Special 301 Committee
Washington, D.C.

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

2012 SPECIAL 301 SUBMISSION

TABLE OF CONTENTS

EXECUTIVE SUMMARY/LETTER.....	3
IMPORTANCE OF INTELLECTUAL PROPERTY TO JOBS, ECONOMIC DEVELOPMENT AND COMPETITIVENESS.....	6
CHALLENGES TO INTELLECTUAL PROPERTY PROTECTION AND ENFORCEMENT	7
Erosion of Intellectual Property Rights	7
<i>Public Perception and Trends.....</i>	<i>7</i>
Limitations of Multilateral Institutions.....	11
Importance of Bilateral and Regional Free Trade Agreements	13
Lack of Adequate Legal and Enforceable Standards in the Online Environment	14
<i>Rogue Sites/Notorious Markets.....</i>	<i>16</i>
<i>Pharmaceuticals – Distribution of Safe Medicines.....</i>	<i>17</i>
ENFORCEMENT	19
RESOURCES NEEDED TO FURTHER PROTECTION	22
COUNTRY ASSESSMENT.....	24
Brazil	24
Canada	27
China.....	29
India	38
Mexico	41
Russia.....	43
Turkey.....	45
Ukraine	47



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

Re: 2012 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 Special 301 report is a critical tool that shines a spotlight on countries that are threatening American jobs and economic growth by undermining the intellectual property rights (IPR) of our innovative and creative industries. Strong rules and effective enforcement regimes are an essential measure of the business climate for businesses small and large who wish to export their products to foreign markets, invest and conduct business with foreign countries, and buy from suppliers in those countries; this is why the Global Intellectual Property Center (GIPC) is pleased to submit written comments in response to the 2012 Special Review: *Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment and Announcement of Public Hearing*.

The GIPC was established in 2007 as an affiliate of the U.S. Chamber of Commerce, 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. Today, the GIPC is leading a worldwide effort to champion IPR as vital to creating jobs, saving lives, advancing global economic growth, and generating breakthrough solutions to global challenges.

The GIPC commends the U.S. Government and the Office of the U.S. Trade Representative (USTR) for continuing to urge for greater intellectual property protection and enforcement around the globe through the Special 301 process. The Special 301 process is an important mechanism for policymakers to assess who is playing by the rules of the global trading system, and more specifically, whether countries are adhering to their intellectual property obligations under trade agreements.

Our submission highlights areas in which we see major challenges to intellectual property protection and enforcement including, efforts to erode the protection of IPR globally, the lack of adequate legal and enforceable standards in the online environment, the need for additional resources legislatively and the systemic intellectual property challenges arising from bilateral or multilateral actions. In addition, we have provided an overall assessment of 8 countries that significantly deny adequate and effective intellectual property protections. These 8 countries are: Brazil, Canada, China, India, Mexico, Russia, Turkey and Ukraine. It should be noted that these country assessments solely reflect the views of the GIPC and contributing Member companies.

While we continue to see the Special 301 Report as a valuable tool and are pleased to be submitting comments, we believe that there are still ways in which the process must be improved. The GIPC urges Congress to enact legislation that will enhance the tools available to the administration to engage more effectively with countries that fail to respect and enforce the rights of American innovators and creators and live up to their international intellectual property obligations.

We commend USTR on the steps taken to provide countries the opportunity to respond to the Special 301 Report with specific action plans designed to lead to the country's removal from the list. We look forward to receiving an update on progress related to these action plans in this year's Special 301 report. We also believe, however, that in order to provide more meaningful consequences to those countries who fail to take action Congress must pass legislation requiring action plans for countries that include clear benchmarks to measure their performance.

Adequate and effective protection and enforcement of intellectual property abroad is vital to America's economy, and the U.S. Chamber's GIPC 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 that reads "David Hirschmann". The signature is written in a cursive style with a large, stylized initial "D".

David Hirschmann
President and CEO
U.S. Chamber's Global Intellectual Property Center

I. Importance of Intellectual Property to Jobs, Economic Development and Competitiveness

Today's global IPR system is designed to incentivize individuals and businesses small and large to invest in innovation and creativity that enrich our lives. The dollars applied to research and development (R&D) 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—stimulate the economy, create jobs, and enhance competitiveness.

Intellectual property-based industries account for more than \$7.7 trillion of the United States gross domestic output, drive 60 percent of U.S. exports, and employ more than 19 million Americans.¹ The global intellectual property system is designed to spur creativity and innovation and 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 IPR 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 IPR in their own countries and in multilateral institutions, thereby undermining the ability of businesses to innovate, to bring the newest and most effective technologies to market and to differentiate brands.

¹ Nam Pham, *Employment and Gross Output of Intellectual Property Companies in the United States*, NDP Consulting, January 2011.

II. Challenges to Intellectual Property Protection and Enforcement

Erosion of Intellectual Property Rights

Public Perception and Trends

The GIPC strongly advocates 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 to advance 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 market forces to create newer, improved innovations. Intellectual property rules both provide an incentive for individual innovation and serve the public interest by facilitating the creation and dissemination of knowledge and culture.

Recently, however, the public perception and debate on intellectual property rules has overlooked this careful balance. There are increasing calls to limit how innovators are able to protect their inventions and creations and even calls to limit the scope of what can be protected.

Opponents of strong intellectual property laws claim that these laws are fundamentally a barrier to the free development and distribution of new technologies and the protection of the environment and public health. However, there is little acknowledgment that these technologies could remain unknown or unavailable to the public were it not for the certainty and incentives provided by intellectual property law. Furthermore, this tunnel vision approach fails to recognize that the incentives provided by robust IPR serve as a primary engine of advances not only in business—a critical engine for growth and jobs—but also in providing solutions to many of the world's most pressing challenges.

The GIPC is concerned that intellectual property laws and norms are in danger of being eroded through these misrepresentations. In a number of multilateral organizations, including the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO), the World

Health Organization (WHO), and the United Nations Framework Convention on Climate Change (UNFCCC), a select number of governments have sought to undermine IPR in ways that are inconsistent with international treaty and trade agreement obligations.

As noted, strong IPR are critical to incentivizing investments and creating innovations needed to advance economic growth and jobs, address global challenges, and meet the needs of the market and its evolving preferences. 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 IPR, destroying or undermining the protection of IPR will not help to achieve those goals. Rather, it will likely 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 and provide our recommended actions.

1. Copyrights

In the area of copyright protection, the biggest threat is the increasing piracy of digital media over the Internet. Ideally, the multilateral institutions that have the competency to address these issues, such as WIPO and the WTO, would give increased attention to the need for updated international norms and adequate and effective enforcement, one or both of which are conspicuously lacking in many countries.

Presently, the WIPO Standing Committee on Copyright and Related Rights (SCCR) is preparing for a Diplomatic Conference on the Protection of Audiovisual Performances. The SCCR has also spent a large portion, perhaps a majority, of its time over the past few years considering an International Instrument on Limitations and Exceptions for Visually Impaired Persons (VIPs). While these efforts have merit, it is important that they be considered carefully. After many years of negotiation, the agreement on Audiovisual Performances reflects the needs of many members of the copyright industry and will be a benefit in providing clarity to rights-holders, so long as the outstanding issues are resolved in a manner that promotes intellectual property protection and

enforcement. Consideration of the VIP issue should be equally careful and balanced, to ensure that a good-faith effort to enhance the availability of works in accessible formats is both of practical benefit and does not have the unintended consequence of facilitating digital piracy by those who would seek to misuse and abuse such exceptions in national laws in furtherance of illicit use of others' works and performances.

The SCCR has also provided international norms for the digital economy. The WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT) (collectively known as the "WIPO Internet Treaties") provide an essential baseline for copyright protection in the digital era. The GIPC supports the administration's efforts to continue to urge countries that have not yet done so to ratify and fully implement the WIPO Internet Treaties.

We also recognize that those treaties are now over fifteen years old and while they remain relevant, they do not address the contemporary business models and technology employed by professional pirates. The simple and obvious reality is that the age in which the Berne Convention can be sufficiently updated every few decades is over.

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.² 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 industries which could subsequently lead to less innovation of products to address global challenges.

The patent system provides important incentives for innovation in a wide variety of sectors. Recognizing the importance of patent protection, the Agreement on Trade Related Aspects of

² UNAIDS, WHO and UNDP, Using TRIPS Flexibilities to Improve Access to HIV Treatment: Policy Brief (2011) Fink, Carsten. "Intellectual Property and the WTO." (2004).

Intellectual Property Rights (TRIPS) requires WTO Members, as a general rule, to make patents available for inventions in all fields of technology. These rules include important provisions which, when properly implemented, both ensure incentives for innovators and protect the public interest against any possible abuse.

It is essential that the U.S. Government remains vigilant in international fora to ensure that patent rights are not weakened in order to avoid hindering innovation and the development and diffusion of technology. For example, efforts to bring TRIPS Doha Declaration language into the negotiations on climate change adaptation and mitigation technologies should continue to be resisted. We are also concerned about similar such efforts to undermine international property rights when world leaders meet in Rio de Janeiro, Brazil, in June 2012 for the twentieth anniversary of the United Nations Conference on Environment and Development (Rio+20).

Several country proposals have already sought to portray international 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 United States should seek to promote rules which provide adequate disclosure to competent national authorities and continue to resist rules which 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. For example, a patent amendment bill is currently pending in New Zealand which contains restrictions on the use of certain patents, inconsistent with New Zealand's obligations under the TRIPS agreement, and fails to include patent term restoration, inconsistent with the practice of many other developed countries and exacerbating already significant delays at the expense of effective market access. We urge the United States to continue to work with New Zealand to ensure that any patent amendments ultimately enacted are consistent with international obligations and best practices.

3. Trademarks

There have also been unwarranted efforts to weaken trademark protections in the name of public health. The GIPC is particularly concerned by government policies that reduce or eliminate the ability of manufacturers to distinguish their brands, especially when consumers are often reliant upon those brands to identify products they know and trust.

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. While the GIPC is supportive of advancing public health, we are deeply concerned about the approach taken in the bill and the unintended consequences it may create. First and foremost, we are concerned that the mandated elimination 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 IPR in the fashion underway in Australia is both unprecedented and unwarranted and will incentivize additional efforts to erode intellectual property protection. To make matters worse, 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. This bill could lead to 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 IPR in any sector, and to encourage Australia, in particular, to re-consider more narrowly tailored and evidence-based alternatives that would be more effective in protecting public health while not undermining the international system for protecting trademarks.

Limitations of Multilateral Institutions

Specialized multilateral institutions under the United Nations (UN) system can and should play an important role in developing policy and encouraging and facilitating the undertaking of international research. However, the effectiveness of these agencies is hindered by the

propagation, from various sources, of the counter-intuitive, counter-factual, and counter-productive view that intellectual property hinders economic growth and the development and distribution of new, innovative products and the solutions to global challenges.

When this view is held by a multilateral institution and it consequently drives that institution to pursue policies that seek to weaken intellectual property protection, it further complicates the mission of the multilateral institution whose mission and expertise is specifically focused on intellectual property protection. And when this unfortunate circumstance occurs without proper consultation with the companies and industries that will be prejudiced by such policies, it undermines the institution itself.

This view is all too frequently promoted by self-appointed guardians of public interest. The GIPC is actively working to provide a fact-based description of the realities of the marketplace to the relevant multilateral institutions. We believe it is critical that these institutions hear a more balanced and practical assessment of the current and future state of intellectual property protection and the economic growth and innovation it fuels.

We are also well aware that multilateral institutions are in most instances driven by the Member States and that some countries have also subscribed to this view of intellectual property. The GIPC is actively working to ensure that national governments understand the benefits of intellectual property protection and the consequences of disregarding IPR, which will ultimately result in long-term harm to their economies and to the innovation that drives development.

One of the most significant features of the multilateral institutions under the UN is that their rules affect the majority of the international community. The rules established there will be almost universally adopted, which can be positive for reducing transaction costs and disparate international standards. However, the consensus model of these institutions also means that those nations that are not ready to forge new rules may hold up progress for all.

This does not mean that the companies whose creative and innovative products are threatened can afford to allow erosion of their rights or fail to confront the ongoing and increasing violations of those rights. Similarly, the countries that recognize that their citizens' jobs and

consumers are threatened by unaddressed intellectual property violations have an unabated obligation to pursue the needed updates to international standards.

Importance of Bilateral and Regional Free Trade Agreements

One such example of a false assertion is the thought, by some, that TRIPS should be perceived as a global ceiling for IPR rather than a base. This notion has led not only to attempts by some WTO Members to implement minimally their requirements under TRIPS, but also an impasse in negotiating updated standards in a multilateral setting. Improved protection for IPR has, however, continued to grow under regional and bilateral trade agreements.

Countries who have implemented rules which go beyond TRIPS requirements have benefitted from increased trade and investment in innovative technologies. The impasse created in the multilateral space has left a number of nations behind as they wait for WTO negotiations to resume. As a result, this has become a lost opportunity for trade and the development of new technologies.

For that reason the GIPC is supportive of the negotiation of bilateral and regional free trade agreements (FTA) which can speed up the process of global trade integration and further unify and update intellectual property protections. The recent trade agreements between the United States and several of its trading partners mark significant success in moving global trade and intellectual property protection forward. In particular, the Korea-United States FTA (KORUS) includes provisions on intellectual property protection which should be seen as model text for future negotiations on intellectual property.³

The GIPC urges the U.S. Government to look to the KORUS intellectual property provisions as a benchmark when negotiating other bilateral or regional trade agreements. The Trans-Pacific Partnership Agreement (TPP) is the next opportunity where such standards should be pursued with important trading partners.

³ 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.

Lack of Adequate Legal and Enforceable Standards in the Online Environment

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 significant 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 attacked through counterfeiting or piracy, it is a direct threat to the other benefits that come with the strengths of intellectual property—global economic recovery, consumer protection, driving America’s competitiveness and export growth, and creating high-quality, high-paying American jobs. It follows that 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 environment as well as the brick-and-mortar world.

Intellectual property theft is a problem worldwide as counterfeiting and piracy have a significant influence on the global economy. In 2008, the Organization for Economic Co-operation and Development (OECD) estimated that the value of counterfeited and pirated goods in international trade totaled \$200 billion per year in the G20 economies.⁴ In 2009, they updated that estimate to \$250 billion.⁵ However, that analysis failed to include the domestically produced and consumed counterfeit and pirated products and pirated digital products being distributed via the Internet. If those metrics were included, the estimates would be “several hundred billion dollars more.”⁶ In February 2011, Frontier Economics updated OECD’s method of analysis to include those metrics, and concluded that the value of counterfeited and pirated goods would be

⁴ OECD, *The Economic Impact of Counterfeiting and Piracy* (2008).

⁵ OECD, *Magnitude of Counterfeiting and Piracy of tangible products: An Update* (Nov. 2009).

⁶ OECD, *The Economic Impact of Counterfeiting and Piracy*, p.4 (2008).

up to \$650 billion every year.⁷ That same study estimates that the value of counterfeited and pirated goods could reach \$1.77 trillion by 2015.

The effects of counterfeiting and piracy are serious. In the G20 economies, 2.5 million jobs have been lost to counterfeiting and piracy.⁸ That number will continue to rise if the tide is not stemmed. In some cases, it is hard to quantify the loss to the global economy, but it is clear that online counterfeiting and piracy cut into the sale of genuine products, force manufacturers to raise the prices of authentic products to cover costs, lower employment, deter investment in R&D as well as capital investment, reduce tax receipts, and raise law enforcement costs.

Both rights holders and the U.S. enforcement agencies recognize the need to protect these vital interests against theft. Rights holders spend untold millions of dollars in this effort. And the U.S. Government has become more active than ever before, as demonstrated by the seizure of nearly 300 domain names through Operation in Our Sites and the recent high-profile action against Megaupload. That case demonstrated again that international cooperation on intellectual property enforcement is possible and, when it occurs, is highly effective. Unfortunately, however it remains the exception rather than the rule.

Enforcement efforts online are complicated by numerous factors. The criminals are quite skilled 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, 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

⁷ Frontier Economics, Estimating the Global Economic and Social Impacts of Counterfeiting and Piracy (Feb.2011).

⁸ Frontier Economics, Estimating the Global Economic and Social Impacts of Counterfeiting and Piracy (Feb.2011).

result, they are able to continue to exploit American consumers and businesses. It is precisely that harm that has given rise to the widespread recognition among domestic stakeholders of the need for action against foreign rogue websites.

Rogue Sites/Notorious Markets

Physical markets continue to be an important consideration when considering the threat of piracy and counterfeiting, but fighting intellectual property theft on the Internet is imperative. Websites dedicated to trading in infringing copyrighted or trademarked 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 a safe and open online marketplace, and unfortunately the problem is growing.

The reach of rogue sites is significant. A study of only 138 rogue websites found that these websites generated over 53 billion visits annually.⁹ Approximately a quarter of all Internet bandwidth is used for digital theft.¹⁰

One of the problems is that it is difficult for consumers to determine what websites are legitimate. Rogue sites have the look and feel of legitimate sites. Indicia of legitimacy are counterfeited on a website, just as goods are counterfeited. Logos of payment processors are displayed even if in fact the site has no business relationship with the processor. Seals from consumer protection groups and federal agencies are often imitated. Images are directly copied from legitimate websites, and some rogue websites even display pictures of the presidents or CEOs of the companies from which they are stealing.

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 instantly know the safety and quality of the good they are purchasing. When that system is in danger, consumer confidence will rightfully fall.

⁹ MarkMonitor, Traffic Report: Online Piracy and Counterfeiting (Jan. 2011).

¹⁰ Envisional Report, “An Estimate of Infringing Use of the Internet” (Jan. 2011).

Rogue sites put customers at risk. Counterfeit goods are frequently produced in unregulated, unsuited, and sometimes unsanitary conditions and contain unknown and untested substances. Rogue sites have been found to be selling goods made from noxious materials. For example, perfumes, cosmetics, and even headphones are manufactured with disturbing and toxic substances. Counterfeit lighters, can explode 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.

USTR has recognized the problem of rogue sites in the context of its two Special 301 Out-of-Cycle Reviews of Notorious Markets. We urge that the Notorious Market findings be factored into the annual Special 301 review and that USTR make action by foreign governments to address and fix any Notorious Markets in their jurisdiction a top priority.

Pharmaceuticals – Distribution of Safe Medicines

The counterfeiting of drugs perpetrated by illegitimate online pharmacies poses such an incredible and obvious threat to both legitimate companies and their brand names and public health and safety that it deserves special mention and attention. These illegal online pharmacies use professional-looking websites to lure unwitting consumers into believing the products they are purchasing are legitimate, when they are nothing of the sort. These illegitimate online pharmacies rely on the marks of well-known and trusted pharmaceutical brands to be able to sell counterfeit medicine online. These rogue websites make prescription drugs available without a prescription, or even a doctor's consultation. The harms to brand perception are only eclipsed by the direct physical threat to consumers.

According to the WHO, counterfeit medicines found on the Internet can kill or seriously harm consumers and result in treatment failure.¹¹ Counterfeit medicines, especially counterfeit painkillers sold online without a prescription, can contribute to drug abuse.

In April, 2011, White House Report identified prescription drug abuse as “the Nation’s fastest-growing drug problem” and identified the Internet as a new source of these drugs.¹²

¹¹ WHO, Factsheets (Jan. 2010) <http://www.who.int/mediacentre/factsheets/fs275/en/>

Counterfeiting of medicine on the Internet is shockingly widespread. LegitScript verifies and monitors online pharmacies, keeping an updated list of legitimate, potentially legitimate, and not legitimate online pharmacies. As of January 24th, 2012, LegitScript identified 276 online pharmacies as legitimate, 1,077 online pharmacies as possibly legitimate, and 39,222 as not legitimate.¹³ This means that less than .7% of online pharmacies are legitimate. As one in six Americans have purchased prescription medicine from the Internet,¹⁴ the likelihood that Americans are purchasing counterfeit medicine from illegal online pharmacies, even if they are do so unknowingly, is high.

These types of rogue sites deserve the highest attention of USTR in its Special 301 review and in its discussions with the governments of countries from which these sites are operated.

¹² Executive Office of the President of the United States, Epidemic: Responding To America's Prescription Drug Abuse Crisis (2011), http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx_abuse_plan.pdf.

¹³ LegitScript Blog, About the Update to LegitScript Homepage Data (Jan. 10, 2012), <http://legitscriptblog.com/2012/01/about-the-update-to-legitscript-homepage-data/>.

¹⁴ Alliance for Safe Online Pharmacies, ASOP Supports Legislation to Assist Consumers in Making Safe Online Drug Purchases (Dec. 16, 2011) <http://www.safeonlinerx.com/2011/12/asop-supports-legislation-to-assist-consumers-in-making-safe-online-drug-purchases.html> (noting a study by the Partnership at Drugfree.org).

III. Enforcement

It is important that the United States continue to work with foreign governments in order to promote the enforcement of existing FTAs and laws. In many cases there have been significant improvements, but in other cases we have seen considerable setbacks.

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

Free Trade Zones

Free Trade Zones (“FTZs”) are generally considered as: “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.”¹⁵ 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.¹⁶ “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.”¹⁷

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 unwilling authorities of customs to police the trade within them properly. The GIPC encourages the United States to work with these countries to make sure that the FTZs proper inventory controls, and that the customs agents should have the authority to confiscate, seize and destroy goods that are determined to be illicit.

¹⁵ World Customs Organization Glossary of International Customs Terms (May 2006), available at www.wcoomd.org/print/file.aspx?id=6652

¹⁶ WCO Guidelines on Controlling Free Zones in Relation to IPR Infringements, Para. 2 (January 12, 2005).

¹⁷ *Id.*

Transshipment

Overseas rogue websites 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.¹⁸ 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.¹⁹ Overseas remote sellers often misdeclare 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 ship in several small packages to avoid seizure or offer refunds for seized product to attract U.S. consumers.²⁰ 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.²¹

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.²²

An example of effective enforcement is Her Majesties Royal Customs (HMRC). HMRC started scanning all incoming mail parcels that originated in China due to the influx of counterfeit cigarettes arriving through customs. Since this enforcement method proved so successful,

¹⁸ 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).

¹⁹ *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.

²⁰ 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).

²¹ The Association of Convenience & Petroleum Retailing. *Remote Sales of Tobacco* (Retrieved March 19, 2010). www.nacsonline.com/NACS/Government/Tobacco/Pages/RemoteSalesofTobacco.aspx.

²² 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”).

HMRC continued to scan parcels for counterfeit goods from other countries on a targeted country-by-country basis. .²³

We recommend a similar approach to combating the problem by:

Increased Enforcement – In the case of the HMRC, the tactical redeployment of additional UK Border Agency (UKBA) staff to postal depots resulted in the substantial year on year increase in seizures.²⁴ Working closely with commercial stakeholders, UKBA 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 post offices we anticipate similar results.

Engagement with Foreign Law Officials – One of the biggest postal smuggling threats originates from inside China.²⁵ There has been some improvement through 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 Government of China’s Fiscal Crime Liaison Officers in devising strategies for tackling the illicit supply at its source.

It is equally as important that once these goods are seized they are destroyed in a proper manner. In USTR’s 2011 Special 301 Report, it 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.”²⁶ The GIPC urges the United States 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.

²³ Altria. "Countervailing Effects of a Potential Ban on Menthol Cigarettes." *Altria Client Services* (10 Feb. 2011. p6)

²⁴ www.hmrc.gov.uk

²⁵ United Kingdom. UK Boarder Agency. HM Revenue and Customs. *Tackling Tobacco Smuggling Together: An Integrated Strategy for HM Revenues & Customs and the Uk Border Agency*. London: HM Revenue & Customs, 2008 p 14.

²⁶ 2011 Special 301 Report, Office of the United States Trade Representative, p. 11.

IV. Resources Needed to Further Protection

In order to have truly effective intellectual property protection, the necessary framework and legislation needs to be funded and supported. The GIPC 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 comprehensive intellectual property protections abroad.

Strengthen the Special 301 Process

The GIPC recommends improvements to the USTR's "Special 301" process by enhancing the tools available to the administration to engage more effectively with nations that fail to respect or enforce the rights of America's innovators and/or live up to their international intellectual property obligations. This legislation should build off the actions that USTR has already taken and requires an action plan for countries that includes clear benchmarks to measure performance, and meaningful consequences for nations that fail to perform.

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

In November 2009, the Senate confirmed the first-ever U.S. Intellectual Property Enforcement Coordinator (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 IPR.²⁷ While the GIPC is pleased with the IPEC's work so far, successful implementation of the 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 reform.

Expand Intellectual Property Assistance to U.S. Businesses Operating Abroad

A critical component to America's economic growth and competitiveness is the ability of United States businesses to penetrate 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 are an

²⁷ Intellectual Property Enforcement Coordinator. *2010 JOINT STRATEGIC PLAN ON INTELLECTUAL PROPERTY ENFORCEMENT*. By Victoria A. Espinel. 2010 p2

important asset 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 an embassy, and help to provide technical assistance to law enforcement agencies and judges within the host country on intellectual property legal issues. The current Attaché program has been hugely successful in advancing intellectual property protection and enforcement for U.S. businesses abroad. As such, the GIPC urges the enactment of funding and legislation that expands and improves the program.

Preserve a Strong International Intellectual Property Legal Framework

The GIPC urges the Administration to continue to promote and defend a robust international system of IPR and norms and oppose any efforts to weaken or expropriate IPR in international institutions, whether in WIPO, WTO, WHO, UNFCCC, or any other multilateral institution. It is also important that the administration remains 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.

The U.S. Government should also be a vocal supporter of strong IPR in regional fora, such as the Asia Pacific Economic Forum (APEC), and the OECD. These fora provide important opportunities to engage like-minded partners and emerging powers to ensure the development of strong IPR frameworks that drive innovation. In addition, the GIPC looks forward to seeing the entry into force of the Anti-Counterfeiting Trade Agreement (ACTA).

V. Country Assessment

Brazil

Over the past fifteen years, Brazil has made some steady improvements in its intellectual property protection and enforcement regime. There are, however, a number of specific challenges faced by United States businesses in protecting and enforcing their IPR in Brazil. There seems to be a growing perception both in the Brazilian private sector and among the economic policy-related agencies of the Government of Brazil (GOB) that higher intellectual property protection and enforcement standards play a key role in fostering innovation, growth, and social and economic development. Although rapidly growing, this perception is not necessarily shared by some GOB agencies as well as by certain constituencies in Brazilian society. These groups keep calling for a halt – or even a roll back – to intellectual property protection and enforcement initiatives. In order to support the ongoing effort in Brazil to improve the intellectual property regime, we encourage the U.S. Government to pursue the following specific goals with its counterparts in the GOB.

Patent

Prior Consent

The GIPC encourages the United States to support the position of the Office of the Brazilian Attorney General (AGU) and the Brazilian National Industrial Property Institute (INPI), linked to the Brazilian Ministry of Development, Industry, and Foreign Trade (MDIC), to clarify the so-called “prior consent” clause of the Industrial Property Act of 1996. According to Opinion no. 2010 (2009) from AGU, the Brazilian National Health Surveillance Agency (ANVISA) does not have authority to review patent requirements in pharmaceutical patent applications filed with INPI. AGU has 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 should be enforced and supported by GOB as a whole.

Data Protection

The GIPC is concerned that the Brazilian Government has not made sufficient efforts to provide certainty that tests 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 biologics, similar to U.S. law.

Patent Prosecution Highway Agreement (PPH)

The United States should work with GOB to negotiate and implement 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

We encourage the U.S. to continue to engage the GOB on the benefits of a strong intellectual property protection and enforcement regime in order to avoid the use of compulsory licensing by Brazil, particularly by helping facilitate dialogue between stakeholders.

Copyright

Piracy

The GOB needs to strengthen the Brazilian National Anti-Piracy Council (CNCP) human resources infrastructure and focus on increasing its resources to adequately enforce its broad mandate. The U.S. should also engage the GOB with regard to the implementation of Brazilian President Dilma Rousseff's recently launched Frontiers Strategic Plan, an intended comprehensive border management initiative. Both CNCP and the Strategic Plan offer an opportunity for the United States to focus Brazil's attention and resources to fight piracy.

Pending Federal Legislation

The United States should work to structure a dialogue with both the MDIC and the Brazilian Ministry of External Relations (MRE) to discuss current intellectual property regime reform in Brazil, particularly in the fields of copyrights and the Internet. There are a number of intellectual property-related bills pending before the Brazilian National Congress. While most of them are piecemeal reforms of the current legal framework proposed by representatives and senators alike, a few are omnibus Brazilian Executive Branch-sponsored legislation such as the Internet Civil Framework Act and the Copyrights Amendment Act, respectively sponsored by the Brazilian Ministry of Justice (MJ) and the Brazilian Ministry of Culture (MinC). It is imperative that these initiatives do not erode the current intellectual property protection and enforcement regime.

WTO Cotton Dispute

Finally, there needs to be a definitive solution to the WTO cotton dispute, particularly through the regular consultations process structured by the 2010 United States-Brazil Framework Agreement, in order to avoid nearly one billion in Brazilian trade retaliation and “cross-retaliation” respectively against United States goods and IPR.²⁸

²⁸ *Talking Points to BRAZTAC Members*. 2 Nov. 2011. WTO COTTON CASE OVERVIEW.

Canada

The GIPC 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. 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 fora, we recommend the following reforms.

Patent

Canada's intellectual property regime suffers from a lack of certainty and stability for innovators. One of the most significant challenges facing innovators in Canada is the lack of an equitable right of appeal under The Patent Medicines (Notice of Compliance) (PMNOC) regulations. These regulations create a patent enforcement mechanism to prevent infringements that might arise as the result of the "early working" exception under Canada's Patent Act. 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. We urge the United States to encourage Canada to correct this significant regulatory inequity by providing a meaningful and effective right of appeal to patent holders, thereby avoiding significant harm to innovative pharmaceutical and biotechnology companies operating in Canada.

Canada could also secure greater stability and certainty for innovative pharmaceuticals by providing Patent Term Restoration (PTR) and clarifying certain restrictions in its data protection regulations. Many major economies, including the United States, the European Community and Japan, generally provide some form of PTR to compensate for patent life lost due to clinical trials and regulatory approval processes. Canada, however, does not provide any such similar mechanism to allow patent holders to recoup some portion of lost time off the patent term.

While we appreciate Canada's publication of regulations in 2006 to implement eight years of protection for data submitted to obtain marketing approval²⁹, we are also concerned about the requirement that innovative products must be "marketed in Canada" in order to receive and maintain this protection. This marketing requirement does not appear to be supported by either

²⁹ Canada. Minister of Health. *Regulations Amending the Food and Drug Regulations (Data Protection)*. 2006. p4.

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.

Copyright

Canada remains an outlier among developed economies for its failure to implement the WIPO Internet Treaties, which it signed more than 14 years ago. While we welcome the June 2011 introduction of a new copyright reform bill (C-11), at the time of this writing, Canada has yet to enact modern-day copyright legislation that addresses online piracy effectively. Moreover, while the GIPC fully supports the stated objectives of C-11, we have significant concerns that the Bill as drafted will not meet the objectives of combating copyright theft and targeting commercial-scale infringers. In particular, we urge that important fixes be made to this legislation to: ensure that the safe harbor regime provided in the bill is an effective tool for reducing online infringements and protects only appropriately good faith entities; ensure that exceptions, including those related to new works, are consistent with Canada's WTO TRIPS obligations; ensure clear rights of making available online as contemplated in the WPPT and provide effective statutory damages as a deterrent to the infringement of copyright.

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 without a court order and greater resources to combat intellectual property rights infringements to both its customs and law enforcement authorities. We have viewed with alarm the ongoing and substantial illicit trafficking in goods across some segments of the United States – Canada border, which only serves to enrich organized criminals at the expense, in many instances, of public security, safety, and brand owners. Much greater efforts need to be undertaken by United States and Canadian authorities to address this illegal activity.

In addition, Canada as a negotiating party to ACTA should ratify and fully implement that agreement without delay.

China

The GIPC continues to work closely with the Government of the People’s Republic of China (“PRC” or “China”) to protect and enforce IPR. The GIPC applauds the Chinese government for its work to emphasize the protection of IPR as a basic regime in igniting innovation and working to improve transparency. In particular, we welcome the announcement to make permanent China’s 2010 Special IPR Campaign and to continue high-level involvement that will enhance its ability to crack down on IPR.

In late 2011, China’s central government leaders announced plans to adopt a range of reforms to address concerns over a perennially weak enforcement of IPR. Premier Wen Jiabao offered the first indications of reforms in a speech given on November 9, 2011, which also announced the re-creation of an IPR “Leading Group” within the State Council.³⁰ In particular, Premier Wen identified a few critical areas for action, notably, the reduction of liability thresholds for criminal prosecution against intellectual property violators and the introduction of punitive damages for willful infringements undertaken for commercial purposes.³¹ The GIPC welcomes the commitment of China’s Leaders at the highest levels to address the substantial protection and enforcement challenges in the country. The GIPC encourages the United States Government to work with the new Leading Group to promote intellectual property reforms that will benefit domestic and U.S. rights holders.

In addition, the GIPC eagerly awaits the Supreme People’s Court’s (SPC) Judicial Interpretation to address online piracy and counterfeiting, and the expansion of software legalization programs to local government departments. The GIPC is particularly concerned over current policy directives that seem intended to protect local enterprises—including internet service providers (ISPs), online trade platforms, and original equipment manufacturers (OEM)—from having to

³⁰ A summary of Wen Jiabao’s November 9, 2011, speech is available in Chinese at http://www.gov.cn/ldhd/2011-11/09/content_1989241.htm.

³¹ In his speech, Premier Wen also noted in broad terms the need for police to commence investigations into criminal cases on a more timely basis, to shift the burden of proof to infringers, and to address online infringements through further regulation. *Ibid.*

implement more substantial changes in the way they protect IPR; only time will tell whether overdue legal reforms will move forward in a timely manner and be effectively implemented.

The GIPC recommends continued monitoring of the implementation of China's policy plans, as well as close engagement with relevant ministries, the National People's Congress ("NPC") 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, China remains a country of concern to the GIPC, due to a full range of intellectual property concerns—counterfeiting (both domestic and exports), copyright piracy, including online infringement, patents, and trade secrets – which we have 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.³² However, these statistics suggest that there are still continuing flaws in existing transfer procedures. The GIPC 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.

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

³² 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.

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.³³

The GIPC lauds China's innovative and comprehensive measures in handling 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 GIPC 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 GIPC echoes the concerns laid out by the U.S. Chamber in a position paper issued to the State Council in October 2011 over proposed amendments to the Trademark Law. 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, 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.

³³ 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.

Physical Markets

The GIPC lauds USTR's publication on December 20, 2011, of an updated list of Notorious Markets, which includes the Silk Street Market in Beijing, as well as markets in Yiwu and Shenzhen.

Chinese courts have recently issued decisions which help 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 GIPC understands that some landlords have had varied success in some of the markets, while efforts in others—including the Silk Street Market—have yielded little if any results. The GIPC 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

As noted above, the Special Enforcement Campaign of the central government has focused the much overdue attention on the online trading platforms and the ISPs in China. The Government of China has imposed broad pressure on online operators to provide a minimum level of protection for intellectual property rights, mainly by offering reasonably prompt take-downs of infringing items, and without the need for the purchase of samples by the intellectual property owner.

Some Provincial AICs, including those in Jiangsu, Zhejiang, Shanghai, Fujian, and Guangdong, have reportedly issued rules to implement Order No. 49 of the State Administration for Industry and Commerce (SAIC), to promote the registration of complete and accurate details of the identities of online traders and the linking of infringement data to corporate registration records. Experience has shown that online markets that allow sellers of intellectual property-protected products to operate anonymously have significantly higher problems with counterfeiting and piracy. However, the net effect of these new rules in helping local AICs to monitor and control counterfeiting remains to be seen.

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, and based on a deemed knowledge standard. Similar standards have however not been issued against the most notorious online market of all, Taobao.com.

Taobao itself is regarded as one of the single largest online sources of counterfeits, and the GIPC applauds USTR's decision to include it in the latest list of Notorious Markets. The GIPC 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 GIPC 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 latest draft of the Trademark Law issued for comment by the State Council in 2011 did not include provisions that would permit civil courts to impose punitive damages. However, this law is still subject to further changes by the NPC, which is likely to review and enact the law before the end of 2012, and the GIPC strongly encourages the insertion of punitive damages into the next draft of the Trademark 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.³⁴ While laudable, the action points set out therein are extremely broad and appear to break little, if any, new ground.

³⁴ 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 GIPC 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. Current law is ambiguous as to how data protection is implemented; for example, certain key concepts such as "new chemical ingredient" and "unfair commercial use," are left undefined.

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 GIPC views China's deference to these published material and regulatory decisions by agencies outside of China as an indicator that they are overly reliant on clinical data developed by originator companies. Published data merely summarizes the data included in the original filing; however, 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.

In addition, the GIPC is concerned about challenges related to counterfeit medicines that involve Active Pharmaceutical Ingredients (APIs). In an effort to ensure drug safety, the GIPC 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).

Copyright

Online Piracy

With respect to online piracy, there has been noticeable progress in government enforcement against infringements. This progress was evident in 2011, when several major Chinese video sharing sites purchased licenses from content owners after their IPO. Even with this, more still needs to be done including increased criminal actions against online infringers and additional measures against ISPs and online platforms that knowingly host infringing content.

Judicial Opinions

The GIPC has been extremely pleased with the transparency of the SPC in its current efforts to draft a new judicial interpretation to clarify the duty of online operators in protecting copyright in the context of civil enforcement. While much of the relevant paragraphs of the Opinion issued by the SPC on December 16, 2011 set out a reasonable framework,³⁵ we are concerned that it leaves unstated whether online platforms have a duty to act where they have actual or deemed knowledge of the existence of pirated content.

Criminal Code Revision

The GIPC looks forward to the schedule for 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.

³⁵ The SPC document is entitled the “Opinion on How to Exploit Intellectual Property Trials to Further and Enrich Socialist Culture and Develop a Self-reliant and Balanced Economy”. http://rmfyz.chinacourt.org/paper/html/2011-12/21/content_37879.htm (in Chinese). A summary in English is available at www.zypartners.com/zjys/Blog/show_e.asp?newsid=31.

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 GIPC 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. It is also critical to address increasing concerns over trade secret violations in China.

Copyright Law Revision

On July 13, 2011, the National Copyright Administration of China ("NCAC") announced the commencement of work towards a further amendment of the PRC Copyright Law, which was last amended in February 2010. Among the many opportunities for improvement of the law in this process is the ability of right holders to prevent the unauthorized Internet retransmission of live sporting event broadcasts.

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 that lasted from 2010 to 2011. Our members reported that intellectual property enforcement bodies across China were noticeably more active in conducting raids, seizures, and arrests during this campaign. 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, during the campaign, Chinese authorities appeared to have some success in persuading online entities to be more responsive to take-down requests from intellectual property

owners.³⁶ 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.

³⁶ http://www.chinaipr.gov.cn/newsarticle/news/government/201107/1240884_1.html

India

U.S. companies continue to face enormous challenges that undermine their ability to compete and win in this vital market. Despite raising these challenges with the Government of India (GOI) over the last several years, the GIPC has not seen demonstrable progress.

Patent

Compulsory licensing

While India has not issued any compulsory licenses, the environment for pharmaceutical innovation is plagued with uncertainty. We remain concerned about the 2010 Department of Industrial Policy and Promotion (DIPP) paper³⁷ which erroneously suggested that compulsory licenses may be an effective means of improving access to health care. We believe the GOI must remain vigilant in resisting unauthorized compulsory licensing, ensuring that procedures set forth under the TRIPS agreement to allow government flexibility in exceptional circumstances are not misused. The issuance of compulsory licenses for anything other than such exceptional circumstances and in any manner inconsistent with the TRIPS agreement would set a terrible precedent that would do irreparable harm to the innovative biopharmaceutical industry and send a chilling message to those companies in India attempting to conduct research into new and effective medicines.

Regulatory Data Protection/Data Exclusivity

There is a critical need to underscore the importance of regulatory data protection to the biopharmaceutical and agrochemical industry. 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. The standard that the GIPC supports is a twelve-year period from the date of first commercial sale, and we encourage

³⁷ India. ORGANISATION OF PHARMACEUTICAL PRODUCERS OF INDIA. *Views and Suggestions on the DIPP 'Discussion Paper' on Compulsory Licensing*. By Tapan Ray. 2010. p5.

India to uphold the same standard. During that period, the test and clinical trial data of one company should not be used, referred to, or in any way relied upon in an application by another company to obtain marketing authorization consistent with Article 39.3 of the TRIPS agreement. 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 GIPC encourages the United States to work with India to prevent the unauthorized disclosure of data submitted for marketing approval.

Patent Linkage

Currently in India, there is no system 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 a thriving film and entertainment sector and has the potential to become a significant market for foreign investment. However, the growth of the domestic and foreign creative industries is being hampered by rampant piracy, both physical and over the internet. While we acknowledge that certain states have made progress in combating piracy, more needs to be done overall to combat this problem.

Copyright law reform

India has yet to implement the WIPO Internet Treaties. We commend the GOI for seeking to move forward with intellectual property reform with the introduction of a copyright reform bill in April 2010. However, we are concerned that this legislation as introduced contains a number of deficiencies that would cause the bill to fall short of its intended purpose to implement the Internet Treaties, as well as a number of provisions that would inappropriately and unproductively interfere with the free market for copyrighted works. While we hope to see copyright reform legislation passed soon in India, the United States should urge India to ensure that any legislation ultimately enacted is consistent with its international treaty obligations.

It is also critical that India provides 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 anti-camcording provisions are adopted either separately or as part of 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 copyright piracy in India. 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 without a court order and to destroy these goods, once judged illegal, so that they do not reenter the marketplace.

Mexico

The GIPC commends Mexico for making advancements in improving its intellectual property protection and enforcement regime in recent years; for example, by enacting legislation granting *ex officio* authority to its law enforcement officials in 2010. However there remain a number of key areas to be addressed.

Patent

While a positive step forward, the Patent Linkage Decree of 2003, which mandates coordination between the health regulatory agency (COFEPRIS) and the Patent Office (IMPI), is not being 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 time-consuming court actions by patent holders.

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.

Copyright

Mexico's legislative copyright protections should be enhanced in order to better address physical and online piracy. For example, although Mexico acceded to the WIPO Internet Treaties in 2002, they have not yet implemented these treaties.

In addition, currently the police in Mexico has no legal recourse over an individual camcording in a theater unless they can prove that the person intended on distributing the film. This law makes it incredibly difficult to curb camcording and provides almost no deterrent for any person wanting to illegally film movies. We encourage Mexico to strengthen their camcording laws and allow for stronger enforcement powers for the police.

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 such 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 without a court order.

In addition, Mexico, as a negotiation party to ACTA, should ratify and fully implement the agreement without delay.

Russian Federation

The GIPC commends the Russian government for the successful conclusion of Russia's WTO Accession process in December 2011 but remains concerned about a number of issues.

Patent

The Government of Russia took the first steps in passing legislation in September 2010 that provides for data protection for a period of six years. We encourage the United States to work with Russia to ensure the effective implementation of these data protection provisions. In addition, 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.

Copyright

Russia is one of the few countries that allows for pay-for-download of piracy of music and film as well as functions as the source for BitTorrent systems, which are one of the major channels for peer-to-peer downloading. We urge the United States to continue to press the Russian Government to address online piracy effectively, particularly the mechanisms to take down websites hosting illegal material and remove the infringing content.

Russia has also 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 effective measures against illegal camcording of motion pictures in theaters, adopting optical disc regulations, and ensuring proper enforcement actions against these and other production facilities of hard copy materials.

Bilateral Agreements

The IPR Agreement reflects Russia's acknowledgment of the numerous legal reforms and enforcement steps it needs to undertake to accede to the WTO, and to modernize and improve its intellectual property protection system. As the United States has consistently noted, Russia must

meet the IPR Agreement obligations on protection and enforcement as part of its entry into the WTO.

Enforcement and the Rule of Law

On November 17, 2011, the State Duma of the Russian Federation adopted a draft Federal law “on the introduction of the changes into the Criminal Code of the Russian Federation and certain enactments dd. 08.06.2011”. The GIPC is concerned that the draft law eliminates Article 188 related to smuggling in the Russian Criminal Code, which criminalizes contraband, i.e., the attempted import and/or export of goods by concealment or without customs control, and replaces it with a significantly narrower definition that encompasses only dangerous products or other products under special regulation (e.g., poisons, radiant matter, drugs, or firearms). The smuggling of all other goods will be decriminalized and treated as administrative offenses. This change is inconsistent with efforts to strengthen the rule of law. It will also undermine existing protections in the legal enforcement structure and adversely implicate the environment for IP rights holders.

We strongly urge the United States to encourage Russia to either keep Article 188 without any changes, or to extend the scope of the new contraband definition to include goods subject to excise tax.

Turkey

While Turkey has made some progress on intellectual property in the copyright sector, there still remain problems in the overall structure of Turkey's intellectual property system, particularly in their judicial and legal system.

Patent

Data and Regulatory Protection

In Turkey, the period of data protection begins on the first date of marketing authorization in any country of the European Customs Union yet regulatory approval times can last almost two years in Turkey. This combined regulatory waiting period means that new products will receive no more than one to two years of exclusivity in practical terms. This undermines much of the incentive for innovators to introduce new medicines in the Turkish market.

Linkage between authorities responsible for intellectual property enforcement and the marketing authorization of new medicines also remains a problem. An effective patent environment requires that questions about patent rights be resolved prior to the issuance of marketing approval for follow-on products.

Judicial Review

Currently, Turkey does not provide an effective mechanism for resolving patent issues before the marketing of follow-on products, such as generics. Effective mechanisms would help eliminate the concern by fostering early resolution of patent issues prior to marketing approval of the generic product. In order to be able to create an effective patent environment, it will be necessary to recognize up to five years' of additional protection for patented products per the adoption of Council Regulation No. 1768/92 (June 18, 1992), concerning the Creation of a Supplementary Protection Certificate for Medicinal Products and EC Regulation No. 1902/2006.

Copyright

Legislation was expected to implement the WIPO Internet Treaties was expected in 2011. We encourage Turkey to implement this legislation in 2012 and encourage the United States Government to work with Turkey to ensure smooth implementation.

Enforcement

To encourage effective intellectual property enforcement, the United States Government should work with Turkey to: improve coordination and cooperation between authorities, police, judiciary and anti-piracy commissions in cities other than Istanbul, Ankara and Izmir; increase the number of specialized intellectual property courts throughout Turkey to ensure courts issue preliminary court injunctions in a timely and effective manner; and ensure that Police and Inspection Committee members have *ex officio* authority to seize copyrighted materials on streets and in public places.

Ukraine

The GIPC commends Ukraine for taking the steps necessary to pass legislation designed to strengthen intellectual property but remains concerned that there is a lack of enforcement ability across sectors in 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 amongst 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.

Ukraine is one of the few countries that allows for pay for download of music and film, and it is the source of some of the world's top BitTorrent systems.

Legislation

Laws agreed 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 have grown in the period since the original discussions.

³⁸ INTERNATIONAL INTELLECTUAL PROPERTY ALLIANCE (IIPA). *INTERNATIONAL INTELLECTUAL PROPERTY ALLIANCE (IIPA) 2011 SPECIAL 301 REPORT ON COPYRIGHT ENFORCEMENT AND PROTECTION: UKRAINE*. 2011. p130

In addition, Ukraine should enact legislation to implement the WIPO Internet Treaties.

Enforcement

The GIPC commends Ukraine for granting full *ex officio* authority but are 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.