February 7, 2014

The Honorable Michael Froman
United States Trade Representative
Executive Office of the President
600 17th Street NW
Washington, DC 20508

Re: USTR 2014 Special 301 Review, Request for Public Comment (79 Fed. Reg. 420)

Dear Ambassador Froman:

These are comments on behalf of the Intellectual Property Owners Association (IPO) highlighting concerns with key issues surrounding the effective protection of intellectual property rights globally.

IPO is a trade association for companies, innovators, law firms and others who own or are interested in patents, trademarks, copyrights, and trade secrets. We have more than 200 corporate members from all major industries in the U.S. and more than 12,000 individuals who are involved in the association through corporate or other classes of membership.

I. IP-RELATED THREATS IN INTERNATIONAL AND MULTILATERAL FORA

The global framework of intellectual property rights and protections, particularly with respect to clean technology, energy, healthcare and advanced manufacturing rights, is continually challenged in a range of international fora. Without proper vigilance, decisions made within international bodies will have an adverse impact on American competitiveness.

UN Activities Relating to Clean Technology and Sustainable Development

Several countries, including India, Bolivia, the Philippines and Venezuela, along with outside stakeholders, continue to call for compulsory licensing or other forms of "flexibilities" in the context of global climate change negotiations that are taking place under the auspices of the United Nations Framework Convention on Climate Change (UNFCCC). These countries and others misrepresent IP rights as barriers to international technology transfer despite the proven positive effects of stable IP and legal regimes, such as enabling and encouraging innovation, development, dissemination and deployment of existing and new technologies. Calls to weaken IP and to make discussion of IP an agenda item have consistently been a negotiating tool that these countries have used against the United States and other developed countries.

Calls for intellectual property rights (IPR) weakening have been rejected repeatedly during several high-level Conferences of the Parties (COPs). We expect IPR issues to continue to cloud the negotiating agenda in the years ahead, and they may complicate the work of certain implementing bodies such as the Technology Executive Committee (TEC) and the Climate Technology Centers & Network (CTCN). We look forward to working with the U.S. Government to continue to address and neutralize such challenges to IPR.

We are also concerned with certain recommendations of the 2013 UN Report titled *A New Global Partnership: Eradicate Poverty and Transform Economies Through Sustainable Development*.[1] Although we share the broad goals of the report, we are concerned with its emphasis on exploiting "[f]lexibilities" in the WTO TRIPS agreement in order to promote technology transfer, as many countries have attempted to use TRIPS as a pretext for weakening IPR protections.

Clean technology IP rights are a key driver of U.S. exports, private sector investment, growth and jobs. They are also critical to achieving global climate change and energy-related objectives, and are exhaustively regulated in the WTO TRIPS Agreement. Weakening clean technology patent rights would be counterproductive and would stymie innovation and the development and diffusion of technology. Any efforts to alter or amend the IPR regime in an international context, moreover, would undermine the central role that the WTO TRIPS Agreement plays in this respect and would cause legal and political uncertainty for businesses, innovators, investors and consumers.

WIPO on Exceptions and Limitations

Publications and capacity-building activities of the World Intellectual Property Organization (WIPO) increasingly reflect IP-skeptic perspectives, despite its formal mandate and role as an IPR-focused organization. For example, WIPO has organized regional training sessions for government officials on the use of exceptions and limitations to patent rights. These sessions focus on public health, exploring the various possible ways that IPR for pharmaceuticals can be curtailed under national laws and regulations. Such training sessions could provide a basis for IP weakening and pose a threat to innovation and public health in the event that such policies are enacted. In addition to the training sessions, WIPO has also undertaken work to study "exceptions and limitations" to patents both within its Committee on Development & Intellectual Property (CDIP) and its Standing Committee on Patents (SCP).

At a minimum, it is crucial for WIPO to contextualize policies that would weaken patent rights by highlighting the negative impact that such policies have on innovation, partnership, investment, technology transfer, and other contributing factors to economic advancement, and by seeking evidence from a wide variety of stakeholders. Industry expressed concern on these issues as early as 2011, when the first training session on exceptions and limitations was organized in Bangkok; yet, sessions continue to be organized under WIPO's auspices with no particular improvements or change in

[1] http://www.un.org/sg/management/pdf/HLP_P2015_Report.pdf

direction in sight. In addition, industry participation is often very limited, making it very difficult to ensure that a more neutral, balanced view is heard.

WHO and Other Trade & Public Health Fora

Activities at the World Health Organization (WHO) deserve close scrutiny. The text that was adopted as part of the U.N. Global Strategy for the Prevention and Control of Noncommunicable Diseases (NCD) and NCD Action Plan suggested IPR could be a barrier to countries' and patients' access to NCD treatment, despite a lack of supporting evidence.[2] In general, the WTO should address IP-related trade issues, not the WHO or other non-specialized UN bodies. There is a lack of evidentiary support for IP-skepticism in the NCD context, and there is broad support for the positive role IPR plays in a range of WHO and other international publications and studies.[3]

WTO on Clean Technology

We continue to be concerned about suggestions by some countries at the WTO that IPR constitute a barrier to the development, dissemination, and deployment of "clean technology." In one paper presented by the Government of Ecuador at the TRIPS Council,[4] the overall conclusions lacked effective evidentiary support and are contradicted by a range of studies, papers and analyses. In contrast to the paper's conclusions, patents, trade secrets, and other forms of IPR allow U.S. innovators to capture the value of R&D activity, stimulating investment in innovation that might not otherwise occur.[5] They also provide private companies a means to distinguish their products from those of their competitors and offer commercial and economic incentives and assurances for firms and innovators to share technology and know-how. Trade, foreign direct investment, joint ventures, and other forms of commercial and public-private partnership play a particularly important role and allow developed, emerging and developing countries to become true partners in a global technology and advanced manufacturing value chain. We are encouraged by the recent U.S. intervention in the TRIPS Council pointing out the importance of strong intellectual property. However, we note that "Intellectual Property, Climate Change and Development" remains on the TRIPS Council Agenda.

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[2] The Declaration in that context called on members to consider the "full use of trade-related aspects of intellectual property rights (TRIPS) flexibilities" with respect to "affordable, safe, effective and quality medicines and diagnostics and other [medical] technologies."

[3] See, e.g., WHO, WIPO, and WTO, "Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property, and Trade" (2012); World Health Organization Report of the Commission on Intellectual Property Rights, Innovation and Public Health, "Public Health, Innovation and Intellectual Property Rights" (2006).

[4] Communication from Ecuador, "Contribution of Intellectual Property to Facilitating the Transfer of Environmentally-Sound Technology," IP/C/W/585, February 27, 2013.

[5] For the positive role IPR plays in this area, see, e.g., Daniel Johnson, Kristina Lybecker, "Innovating for an Uncertain Market: A Literature Review of the Constraints on Environmental Innovation," University of Colorado Working Paper 2009-06 (July 2009); Branstetter, Fishman, Foley, "Do Stronger Intellectual Property Rights Increase International Technology Transfer? Empirical Evidence from U.S. Firm-Level Panel Data" (July 2005), p. 2; UNFCCC, "Enabling Environments for Technology Transfer" (4 June 2003); World Trade Organization, "Trade and Transfer of Technology," Background Note by the Secretariat, WT/WGTTT/W/1 (2002).

II. COUNTRY-SPECIFIC CONCERNS

India

India is an important and growing market for U.S. companies. The country draws heavily on global investment and trade, and counts innovative industries including information and communications technology, infrastructure, services, healthcare, and entertainment as increasingly important contributors to economic growth. However, as described below, India is pursuing an agenda of forced technology transfer in contravention of a fundamental principle governing international trade – national treatment – while seeking to weaken IP rules and frameworks domestically and internationally. India is also systematically denying U.S. companies the protection and opportunities afforded its own industries, including with respect to IPR. These efforts not only threaten to diminish India's ability to innovate and attract investment, but they also unfairly disadvantage American businesses. The consistent use and threat of compulsory licensing and a continued lack of effective trade secrets protection are additional core issues of concern.

India's National Manufacturing Policy

The government of India is taking measures across sectors, including pharmaceuticals and green technologies, to advance a program to compulsory license foreign proprietary technology, in direct contravention of the more limited scope of compulsory license provisions in the WTO TRIPS Agreement. One primary purpose appears to be to enable domestic industries to avoid paying commercial rates for technologies. For example, India has announced its intention to engage in policies that would violate the intellectual property rights of foreign green technologies in order to favor domestic companies. Section 4.4 of India's National Manufacturing Policy (NMP), for example, states that India-based clean technology companies "have the option to approach the Government for issue of a Compulsory License for the technology which is not being provided by the patent holder at reasonable rates or is not being worked in India to meet the domestic demand in a satisfactory manner." The National Manufacturing Policy lists healthcare-related technology as another strategic industry, alongside clean technology.

Trade Secret Protection and India's National IPR Strategy

India released a draft National IPR Strategy in 2012,[6] which was broad in scope and appeared to represent an effort to tackle some of the important weaknesses that remain in India's IPR policy and enforcement. Publication of the Policy was a hopeful sign, but no concrete action has been taken thus far.

One key problem in India continues to be the lack of an effective trade secrets protection regime. Although the National IPR Strategy recognizes that a "predictable and recognizable trade secret regime will improve investor confidence," it fails to call for greater protection of trade secrets and asserts that they are already "protected through the contract law in India and [are] part of the concept of protection against unfair

[6] http://dipp.nic.in/English/Discuss_paper/draftNational_IPR_Strategy_26Sep2012.pdf

competition." To ensure full market access and non-discriminatory treatment of Indian and non-Indian companies, and in order to ensure full TRIPS-compliance, it is critical that India adopt an effective, codified, trade secret act. This would reduce the uncertainty now often faced by companies and the difficulties companies face protecting their proprietary technologies and confidential data. It would also incentivize U.S. companies to invest in India and to collaborate, share technology and know-how, and engage in mutually beneficial technology supply and partnership contracts with Indian partners and customers.

Other Instances of India's Forced Technology Transfer, Compulsory Licensing, and Lack of Effective IP Protection

India's National Manufacturing Policy and its draft IPR Policy demonstrate a lack of effective IPR protection and enforcement. Another example includes a 2010 discussion paper published by a department in the Ministry of Commerce (DIPP), which argued that "compulsory licensing has a strong and persistent positive effect on domestic invention" and encouraged India's Controller General of Patents to grant a compulsory license if, among other things, he was satisfied that the patented invention is not being worked (i.e., manufactured) in India.[7]

Additionally, India's patent statute requires every patentee and licensee to furnish periodic statements that include significant details of how they are working each patented invention on a commercial basis in India or, if not worked, the reasons why and the steps being taken to work the invention.[8] Not only is this "Form 27" process highly burdensome from an administrative point of view, but we are concerned that the information that is provided could be eventually used to justify compulsory licenses in a variety of industries, as specifically contemplated in the Form. Recently, submissions of Form 27 have become publicly available, which is likely to result in even greater pressure on Indian authorities to compulsory license the covered products.[9] Moreover, a majority of the questions in Form 27 are only directly answerable in a one-patent-one-product context and cannot clearly be answered for information technologies, for example. Notwithstanding the impracticality of attributing a specific commercial value to one patented feature of a complex technology, the form calls for criminal and civil penalties for submission of false information.

Since 2012, India has also infringed, overridden, or revoked nearly a dozen pharmaceutical patents held by foreign firms, in part because the patented product was manufactured outside of India. These and other instances of broad compulsory licensing are based on Section 84 of India's Patent Act[10] and pose a clear risk not only to U.S.

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[7] *See* http://dipp.nic.in/English/Discuss_paper/CL_DraftDiscussion_02September2011.doc

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

[9] *See* http://ipindiaservices.gov.in/workingofpatents/

[10] Some of these actions have been based on Section 84 of India's Patent Act that states: "(1) At any time after the expiration of three years from the date of the [grant] of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely:— (a) that the reasonable requirements of the public with respect to the patented invention have

pharmaceutical industries, but to advanced manufacturing, industrial, and other innovative U.S. businesses.

Finally, the Indian Government not yet passed the National Innovation Act,[11] which would have been a positive step towards providing a more robust IPR environment. The Innovation Act would include a range of measures to promote innovation (including an annual "Science and Technology Plan" and provisions to aid public/private partnerships, promote innovation financing and establish special innovation zones). It would also codify rules on the protection of confidential information. Because protection to date relies on common law principles, the scope of protection is often unpredictable.

Third Party Access to Essential Facilities in India

We commend efforts of the Indian Government's Committee of the Ministry of Corporate Affairs to formulate a National Competition Policy for India that has evolved into a comprehensive and helpful framework for fair competition. One particular issue, however, is a serious cause for concern. Section 5.1(vi) of the Competition Policy contains a blanket requirement for dominant infrastructure *and IPR owners* to grant third party access to "essential facilities" on "agreed reasonable and nondiscriminatory terms," without providing more specifics about the situations in which this requirement may or may not be justified.[12]

Experts have heavily criticized blanket application of an "essential facilities" doctrine to IPR owners, and such application has been severely curtailed around the world. A broad international consensus exists that the unconditional, unilateral refusal to license a technology rarely raises competition concerns. In addition, the decision not to license a technology is considered to be the most fundamental right conveyed under the IP rights laws – namely, the right to exclude. To impose a blanket duty to license on IPR owners could effectively nullify IP rights and impair or remove the economic, cultural, social and educational benefits created by them, ultimately hurting American innovators. The blanket inclusion of IP rights currently foreseen in the Policy is directly at odds with international competition standards and fundamentally irreconcilable with TRIPS. Although industry consultations with the Minister and Joint Secretary yielded a solution in which the Ministry agreed to review the essential facilities language, the final National Competition Policy has still not been passed or made public.

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not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India." Section 84 of India's Patent Act violates the WTO TRIPS Agreement's national treatment provision in Article 3, which mandates that WTO members protect IP regardless of its origin, as well as TRIPS Article 27.1, which explicitly prohibits discrimination in national patent laws based on "whether products are imported or locally produced." Section 84 also exceeds several TRIPS compulsory licensing restrictions, for instance Article 31(h) requiring pricing to be based on the "economic value of the authorization."

[11] http://www.dst.gov.in/draftinnovationlaw.pdf

[12] http://www.mca.gov.in/Ministry/pdf/Revised_Draft_National_Competition_Policy_2011_17nov2011.pdf

India's Positions in International Fora

In addition to domestic policy actions such as those outlined above, we continue to be very concerned about India's policy position on intellectual property in a range of international fora. India has played a leading role in driving an IP weakening agenda at the UNFCCC, WTO, and WIPO, where government officials consistently represent intellectual property rights as a barrier to economic advancement and access to technology for developing countries despite a lack of evidence supporting this view. These claims threaten to undermine not only U.S. innovation and industries, but economic development and innovation in India, where domestic companies are in the process of maturing their capabilities in the IP generation and policy advocacy space. They also continue to distract negotiators in these and other fora from the real technology, trade, environmental and healthcare-related issues that they are or should be seeking to address.

Unfortunately, India's influence with respect to intellectual property policy may be expanding. In May 2013, the BRICS IP Offices agreed on a roadmap for collaboration.[13] The roadmap identifies India as the lead IP office to improve the influence of BRICS offices within WIPO and other fora.

China

China has made major improvements to its intellectual property laws in recent years, but much room for progress remains. Further action is needed for China to achieve an open, fair, and non-discriminatory innovation policy that does not discriminate against non-indigenous companies or give substantive or procedural advantages to companies that develop or own their IP locally within China. Examples of discriminatory or otherwise harmful policies that are currently in place include indigenous innovation accreditation; China's current treatment of remuneration for "service inventions"; continued government-driven standard setting that often includes discriminatory elements; and onerous government-driven technology transfer and licensing policies, such as through MOFCOM's Technology Import-Export Rules. Additional critical concerns include the ability for brand owners to protect their trademarks against piracy, enforcement concerns emanating from the Fourth Amendment of China's Patent Law, as well as China's continued need for effective trade secret protection.

China's Innovation Policy

We were encouraged by the agreement at the 2013 Strategic and Economic Dialogue (SED) to foster an open and fair trade and investment relationship and, particularly, to recognize the importance of trade secret protection (discussed separately below) in developing an innovative Chinese economy. We also welcome recent efforts by China to limit the use of indigenous innovation policies in government procurement and to liberalize foreign company access to government-run or semi-governmental projects including, for example, in the wind power sector. We are further encouraged by China's

[13] http://www.rupto.ru/rupto/nfile/786b6c92-696b-11e3-731c-9c8e9921fb2c/SIGNED-BRICS-IP-OFFICES-COOPERATION-ROADMAP.pdf

commitment to "delink its innovation policies" from government procurement preferences. We note that this commitment has been implemented from national to local level through a State Council directive and notices issued by the Ministry of Science & Technology, National Development & Reform Commission and the Ministry of Finance.

Despite these positive developments, U.S. companies continue to face innovation policy-related difficulties. For example, Indigenous Innovation Product Accreditation systems impose onerous and discriminatory requirements on companies seeking to sell into the Chinese government procurement market and contravene multiple commitments of China's leadership to resist trade and investment protectionism and promote open government procurement policies. Another example is forced disclosure of trade secrets in a regulatory context. We believe it is important that China follows through on its SED commitments in this and other related areas.

Chinese Service Inventions

China's State Intellectual Property Office has been developing a new administrative Regulation intended to increase employer payments for "service inventions" that are created during an inventor's employment, apparently in the belief it will increase innovation. The draft Regulation, if passed, will negatively affect the ability of companies to determine how best to incentivize innovation by its own employees and will increase legal and financial risks of conducting R&D in China. For example, under the second paragraph of Article 19, any agreement or policy reasonably implemented by an employer regarding inventor remuneration could be subject to repeated challenge as somehow "limiting" an inventor's rights and could be retroactively supplanted by SIPO's onerous default rules. Employers are also required to make a decision about how best to protect an asset very quickly, even if an invention has not been fully conceived or formed by the inventor.

Moreover, the draft Regulation vastly expands the scope of the Patent Law to require under Article 25 payment of compensation for simple technical know-how the employer elects to keep secret, which will greatly increase the administrative costs for the technical secret owner. This expansion would also create disputes between the inventor and the employer over the patentability and scope of the technical secret. We were encouraged by the Shanghai High Court's promulgation of Guidelines on Trial of Disputes over Rewards and Remunerations for Inventors or Designers of Creation of Service Inventions (《职务发明创造发明人或设计人奖励、报酬纠纷审理指引》) in June 2013, which were meant to clarify elements of existing State Council-passed Implementing Rules. The guidelines more appropriately recognize the presumptive reasonableness and priority of company agreements or polices over statutory standards than do the Regulation, so we believe the further modification of the Regulation based upon the guidelines merits close ongoing scrutiny.

These are just a few illustrations of how the Regulations would create unpredictability to the detriment of all rights-holders in China's business environment.

Patents and Technical Standards in China

China's standard-setting practices continue to be a cause of significant concern. As part of its National IP Strategy, China has focused on improving its standards-related policies, including regulating "the process of turning patents into standards." In 2012, the Standardization Administration of China (SAC) issued its revised draft Disposal Rules for Patents in National Standards (《国家标准涉及专利的处置规则》) (draft Disposal Rules) and requested comments from stakeholders. The draft Disposal Rules remove some problematic articles such as free licensing due to failure to disclose patents involved. The key remaining issues are whether the patent applications that are required to be disclosed include non-published applications, and a lack of clarity regarding legal liabilities for failure to disclose. Separately, since foreign invested companies can participate in the standard setting process by invitation only, most American companies and their Chinese subsidiaries are unable to participate in the standard setting process. This impacts their ability to be heard as part of the standard-setting process, and their competitive opportunities in the Chinese market due to possible noncompliance with (future) product standards or the setting of standards that are specifically geared towards a Chinese competitor's technology advantage.

China's Trademark Laws Give Pirates a Competitive Edge

China's recent amendments to its Trademark Law, which will become effective shortly, on May 1, 2014, increase the risk that brand owners will be held hostage to pirates registering marks in bad faith. For example, under the amended law, if a brand owner opposes a preliminary approved mark and loses, the mark will be *immediately* registered before Trademark Review and Adjudication Board (TRAB) can invalidate it. As a result, a bad-faith registrant may freely use a mark for years while waiting for a TRAB decision without infringing on the brand owner's rights. This problem is exacerbated by a Chinese judicial policy that allows marks that are confusingly similar to co-exist after a certain period of use. To add insult to injury, a bad faith registrant may also be able to take enforcement action against the brand owner's own use of the trademark. These policies weaken the value of American brands by allowing bad actors to capitalize on our U.S. investments.

China's MOFCOM Import-Export Rules

China's Ministry of Commerce (MOFCOM) Technology Import-Export Administrative Regulations impose greater risks and liabilities on foreign technology licensors than what China's Contract Law imposes on domestic licensors. For example, a foreign licensor must indemnify against infringement of a third party's rights due to the licensee's use of the licensed technology and cannot negotiate rights to improvements made by the licensee. This paternalistic approach by the State is at odds with both the Contract Law's normal deference to contract terms negotiated by parties at arms-length and common international licensing practices. The de facto result, whether expressly intended to promote indigenous innovation or not, is to unjustifiably place foreign-owned technologies and licensors at an unfair disadvantage.

Patent Enforcement and the Fourth Amendment to the Chinese Patent Law

China's patent system includes the issuance of IP assets, including utility models and design patent rights, without sufficient examination of the substance. Unlike other rights like invention patents, the quality of these assets is routinely low, creating substantial uncertainty for U.S. companies who want to sell products to the Chinese market. Although SIPO has recently acknowledged the extent of the problem by rejecting some utility model applications that are "obviously unpatentable," more safeguards are needed to ensure these patents are not inappropriately used against innovation-driven American (and Chinese) companies. One such measure might be to require, rather than leave it to the discretion of a court or administrative agency, that the owner of a utility model or design patent in every case obtain a search report from SIPO supporting the validity of the patent prior to asserting it, and to automatically stay infringement proceedings until timely invalidation requests have been resolved.

China issued a revised draft Fourth Amendment to its Patent Law in March 2013. In the draft amendment, there is a significant focus on administrative enforcement of patent rights putatively in order to provide lower cost remedies for small businesses and individual rights holders. The Amendment would give hundreds of inexperienced local and provincial intellectual property offices new powers to grant injunctive relief and to impose compensatory damages, fines and penalties for patent infringement and even enhance them if deemed intentional. One of the effects of the draft Fourth Amendment will be to allow (primarily Chinese domestic) entities or individuals to assert their rights before local and administrative officials, who may not be technologically and legally qualified, without clear guidance tying any award to the value of the patent. Currently, such proceedings are entrusted only to certain courts selected by the Supreme People's Court due to concerns about the complexity of patent cases.

To be more effective, China's patent system should allow for effective recourse to civil litigation for patent infringement to the exclusion of administrative enforcement remedies, which can be political, unprofessional, or commercial and discriminatory in nature. This would help rights-holders who can demonstrate the innovative nature of their patents or other intellectual property to address, among other issues, the problem of insufficiently examined rights in competent and less political fora. Finally, China's patent system should be reformed so as to ensure that infringement litigation that is based on these insufficiently examined rights cannot proceed until the validity of the utility model and design patent involved is finally determined through the Patent Reexamination Board's examination and judicial review.

Trade Secret Protection in China

The U.S. International Trade Commission has estimated the value of U.S. IP stolen by Chinese entities to total $48 billion, including lost sales (76 percent of the total) and lost

royalties and license fees (24 percent).[14] Civil and administrative protection for trade secrets in China relies on the 1993 Anti-Unfair Competition Law (AUCL). The AUCL applies only to trade secret theft by a "business undertaking." This is problematic, because the AUCL does not provide for enforcement actions against current or former employees who misappropriate the company trade secrets without actually conducting a business. It also applies only to information with "practical applicability," which imposes an evidentiary burden inconsistent with strong protections of trade secrets.

We note that even though the AUCL does not provide for preliminary injunction, in a positive step, the newly amended Civil Procedure Law at Art. 100 provides for preliminary injunction in civil cases whenever warranted. In August 2013, the Shanghai First Intermediate Court issued the first preliminary injunction in a trade secret theft case in which the plaintiff was a non-Chinese company. With respect to criminal protection, according to Art. 219 of the Chinese Criminal Law, the crime of trade secret theft is focused on consequences, not conduct (i.e., causing direct economic loss in the amount of RMB500,000 (USD83,000); or causing bankruptcy of the trade secret owner; or the infringer receiving illegal benefits in the above-mentioned amount). This focus fails to communicate a serious commitment to protecting trade secrets.

Additionally, without a criminal investigation a trade secret owner can rarely secure the evidence needed to prove any of these criminal thresholds; but without such evidence, the police cannot start a criminal investigation. This Catch-22 creates a serious challenge for criminal trade secrets prosecution in China.

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

Forced Regulatory Disclosure of Trade Secrets

Chinese regulations sometimes require companies to submit technical and functional features of their product, as well as the testing method adopted in the companies' "enterprise standards" to local quality and technical supervision authorities. This allows the authorities and interested parties to understand these enterprise standards to ensure compliance. Failure to provide the information may prevent access to the Chinese market. The information furnished, however, is often unprotected from further disclosure. In fact, in many circumstances, local agencies will provide the information to anyone who requests it. This requirement and practice puts companies' technical secrets at risk of leaking into the public domain.

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

China's Position in International Fora

China continues to support IP-weakening agendas in a range of international fora, including the UNFCCC, WIPO, and WTO.

Brazil

Overall, Brazil's position on IPR issues, both domestically and globally, has improved over the past few years. The Government of Brazil has recognized the importance of effective intellectual property protection to incentivize innovation and drive the development of viable innovative industries. Nonetheless, areas of real concern continue to exist. Such polices are being undermined through efforts and policies to weaken IP protection.

ANVISA's "Prior Consent" for Patent Examination

One area of concern is the "prior consent" provision of the Patent Law (Article 229-C) which applies to the Health Surveillance Agency (ANVISA). Brazil's General Attorney (AGU) has clarified that Article 229-C limits ANVISA's patent review role to issues of health and safety, distinct from the patent examination role of the Brazilian Patent Office (INPI). The AGU opinion has been ignored and ANVISA is now effectively the gatekeeper in patentability determinations of pharmaceutical inventions.

This dual system of patent examination is reserved only for the pharmaceutical sector and raises questions of discrimination, for example, under Article 27.1 of the World Trade Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). ANVISA and INPI do not apply their patentability standards equally and such a system will generate uncertainty for patent applicants and undermine incentives for innovation.

INPI's Efforts to Weaken Pharmaceutical Patents

Recently, INPI filed a series of lawsuits which seek to invalidate or shorten the term of "mailbox patents" for pharmaceutical inventions that were filed shortly after TRIPS went into effect in Brazil. The grounds alleged by INPI have no basis in the law and raise further questions about Brazil's commitment to the protection of IP rights.

Brazil's Patent Law Reform May Weaken American IP Rights

The Center for Strategic Studies and Debates of the Brazilian Chamber of Deputies, which is affiliated with the Brazilian Parliament, recently produced a study entitled The Revision of the Patent Act: Innovation Towards National Competitiveness,[15] which coincided with the introduction of Congressional Bill PL 5402/2013 (the "Patent Law Reform"). The study and the Patent Law Reform bill propose to limit patent rights by (1) excluding from patentability certain pharmaceutical inventions, (2) providing for pre-grant opposition proceedings, (3) barring regulatory data protection, (4) explicitly granting ANVISA the role of patentability examination of pharmaceutical inventions, (5) expanding the use of compulsory licensing, and (6) revoking the ten (10) year

[15] Available at: http://bd.camara.gov.br/bd/bitstream/handle/bdcamara/14797/brazils_patent_reform.pdf?sequence=2

minimum term for patents. In addition, the study proposes the creation of an administrative entity called CODIPI, under the Chief of Staff (Casa Civil), which would enjoy binding authority. If established, Brazil's patent office (INPI) would become subject to this new body instead of using its expertise to apply Brazil's patent law. The proposals in this study, if implemented, would drastically reduce the ability of U.S. companies to achieve a return on their investments made in Brazil.

INPI's Right to Modify Contracts

INPI's role in approving all IP licensing and technology transfer agreements potentially impinges on the freedom of companies to contract freely for goods and services and may result in the destruction of trade secrets in exchange for market access. Specifically, INPI's policies prevent any temporary license of non-patented technology. In addition, INPI frequently establishes limits on royalties and confidentiality clauses and prevents the return of technology upon the conclusion of contracts. INPI's authority to interfere dates back to the 1970s and Law 5648/70, which established INPI and granted it the authority to regulate technology transfer. While the law changed in 1996, formally ending INPI's power to interfere in licensing agreements, INPI continues the practice today.

Brazil's Patent and Trademark Application Backlog

INPI continues to maintain a significant backlog in its review of patent applications, with an average patent pendency of 8 to 9 years. The inability to timely obtain patents in Brazil impairs innovation and the ability to commercialize research and development. At the same time, we commend recent efforts to improve delivery of IP services through INPI's hiring of examiners and enhancement of internal processes to reduce patent and trademark application backlogs. For example, the recent Resolution No. 295/12 to foster the first examination of patents was a positive measure. Moreover, although more examiners are needed, seventy examiners have already been hired. We also commend the U.S. Patent Office's efforts to cooperate with INPI including on training examiners.

Still, additional measures are needed to address the application backlog and to support patent quality, including putting government resources towards INPI's core missions and eliminating interference by non-INPI government agencies in the patent examination process. In that regard, ANVISA's continued ability to duplicate the patent examination itself remains a very serious concern.

Similarly, INPI's trademark backlog would be greatly improved by the country's accession to the Madrid Protocol. Implementation of the Protocol would also reduce costs for both U.S. and Brazilian companies to protect their marks within the country. Brazil and INPI have recently taken steps to pave the way for its adoption. The U.S. should strongly support Brazil's efforts in this regard.

Canada's Utility Requirement for Patents

Intellectual property rights are being undermined in Canada through unique standards for patentability of inventions. In particular, Canada's heightened utility requirements,

also known as the "promise of the patent doctrine," have weakened patent rights, in particular for pharmaceuticals. In Canada, innovators are required to "demonstrate" or "soundly predict" the effectiveness of an invention "promised" at the time of filing the patent application in order to meet the utility requirement. Such a standard is fundamentally inconsistent with TRIPS. To meet the utility requirement, TRIPS, and all developed countries, require only that an invention be "useful" or "capable of industrial application." It is not reasonable or financially feasible to require patent applicants to undertake substantial risks and possibly spend millions of dollars on clinical drug development before a patent application is even filed. Ironically, the Canadian courts have deemed patents covering drug products that have been approved as "safe and effective" by Health Canada to "lack utility."

The promise doctrine as applied by the Canadian courts is unique in the world and is inconsistent with the patentability standard Canada committed to apply under TRIPS. The promise doctrine also effectively imposes a higher utility standard to the patentability of biopharmaceutical inventions than to other inventions. TRIPS requires that there be no discrimination as to the field of technology. Furthermore, this heightened utility standard is fundamentally incompatible with the lifecycle of biopharmaceutical development.

South Africa

The South African Ministry of Trade and Industry recently published a draft National Policy on Intellectual Property (National IPR Policy).[16] While we welcome many positive perspectives and positions reflected in the draft National IPR Policy, it contains a number of positions and observations on IPR that would be counterproductive and should be removed or qualified. Problematic positions include endorsement of weaker IPR in certain fields; suggestions that weak IP protections can be an effective part of a country's industrial policy (as opposed to being reserved for extraordinary circumstances); and adoption of a broader narrative that developing countries have gained little from the protection of IPR, despite evidence of the profound benefits that such protections bring by way of increased FDI and technology diffusion. We understand that the Ministry is currently reviewing the policy and we are hopeful that problematic elements will be removed from the document.

The Netherlands and the Borderless Nature of Piracy

What is widely known as "The Pirate Bay" is the world's largest bit torrent tracker. Bit torrent is a file sharing protocol that enables large file transfers. The Pirate Bay (TPB) is an open tracker, where anyone can download torrent files. To be able to upload torrent files, one must register at the site. TPB exists for wholesale downloading of content, and much of it is registered copyright digital content. Examples of these copyrighted works include movies, software, video games and music.

[16] Draft National Policy on Intellectual Property, September 4, 2013, accessed at http://www.thedti.gov.za/invitations/36816_4-9_TradeIndustry.pdf

TPB was founded by the Swedish anti-copyright organization Piratbyrån in the late 2003. Today, it is run by an organization registered in the Seychelles. In 2010, after considerable pressure was exerted on it by the Swedish government, TPB moved to Greenland (Denmark), then Iceland, and now it resides in the Caribbean island of Saint Maarten (Netherlands).

In early 2013, Swedish prosecutors sought to seize two of Pirate Bay's Swedish domains (thepiratebay.se and piratebay.se) and filed a complaint in Iceland threatening seizure of TPB's Icelandic domain. In response, in April 2013, TPB sought refuge for their servers on the Caribbean island of Saint Maarten (one of four countries that comprise the Kingdom of the Netherlands), thereby enabling TPB to offer their services (up to the present day) with a new .sx domain name.

Because so much counterfeiting/piracy of digital content takes place by the infringement-enabling bit torrent software of TPB, we request the USTR to exert pressure on the Netherlands by listing it as a country on either the Priority Watch List or on the Watch List as it did with Sweden a few years ago when TPB was based there. Such pressure may cause the Netherlands to either shut down TPB's torrent search tracker software or greatly restrict the company's ability to induce and facilitate copyright infringement and piracy within its borders.

III. OPPORTUNITIES TO IMPROVE GLOBAL IPR PROTECTION AND ENFORCEMENT

Apart from the challenges highlighted above, we see some additional near-term opportunities to strengthen the global framework for advanced manufacturing and industrial IPR.

Unique opportunities currently exist to raise the profile of trade secrets and IPR protections generally within the Trans-Pacific Partnership (TPP) and the Transatlantic Trade and Investment Partnership (TTIP). The issue of trade secrets has already been included in draft negotiating agendas for both U.S. and EU negotiators in the TTIP negotiations. Including trade secrets in a future TTIP Agreement will provide additional leverage towards both the U.S. and EU policy process, and allow the U.S. and EU to set the "gold standard" for trade secrets protection worldwide. Trade secrets language has already been included in the TPP negotiations. Japan's entry into the negotiations provides a further opportunity to strengthen trade secrets protection in the agreement and throughout the Asia-Pacific region. Finally, the TTIP negotiations in particular offer a unique framework for the U.S. and EU to further codify existing bilateral IPR-related cooperation.

Beyond the WTO, TPP and TTIP efforts, we also welcome and support the U.S. Government's ongoing efforts to encourage and improve global IPR policymaking, protection, and enforcement, and to drive innovation policies and market-based technology development, deployment, and dissemination at home and abroad. A key

challenge in the area of IPR is the continued lack of a broad, global understanding of the positive role patents, trade secrets, and other forms of advanced manufacturing and industrial IPR play – for businesses, workers, consumers, and even the environment, global health, and our economies as a whole. In this regard, we fully support the findings reflected in the President's U.S. Trade Secrets Strategy presented earlier this year. The findings pointed out the critical importance of diplomatic efforts, education, training, and global capacity building alongside domestic and foreign legislation, trade negotiations and other forms of policymaking and enforcement.

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Respectfully submitted,

Philip S. Johnson
President