



February 6, 2015

Ms. Susan Wilson
Director for Intellectual Property and Innovation
Office of the United States Trade Representative
600 17th Street NW
Washington, D.C. 20508

Re: USTR 2015 Special 301 Review, Request for Public Comment
(Docket No. USTR-2014-30312)

Dear Ms. Wilson,

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. COUNTRY-SPECIFIC CONCERNS

BRAZIL

Growing Patent and Trademark Application Backlogs

In Brazil, patent applications regularly remain pending for more than a decade, far longer than in most other patent offices around the world. The lengthy backlog hurts innovators by complicating investment decisions and often by impairing access to critical funding, especially for smaller companies. Additionally, the amount of time it takes to receive a patent affects the amount of money a patent owner may recover from potential infringers. Such delays hurt both would-be patent owners and potential competitors, adding to uncertainty in the market and increasing the cost of development.

The situation with respect to trademarks is similar. INPI's backlog is around 500,000.1

1 The New BPTO President's Backlog Challenge in Brazil. Managing IP. May 1, 2014. Available at: http://www.managingip.com/Article/3336726/The-new-BPTO-presidents-backlog-challenge-in-Brazil.html

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The resulting delays hurt brand owners, making it harder to penetrate the local market. With growing numbers of both patent and trademark applications, the related challenges are likely to continue into the foreseeable future.

INPI has taken definitive steps to reduce its backlogs. Over the past two years, a significant number of examiners were hired and the upgrading of INPI's IP infrastructure was completed. The introduction of a fast lane for applications related to green technology and participation in the PROSUR collaborative examination initiative show promise. Broader participation in work-sharing with other patent offices such as through a Patent Prosecution Highway (PPH) agreement may also prove helpful.

With respect to trademarks, accession to the Madrid Protocol could play an important role in improving the situation. Brazil has already taken important steps to pave the way for its adoption, but the treaty has not yet been sent to the country's Congress. INPI has even begun to initiate some of the changes necessary to comply. However, it is anticipated that beyond accession to the Protocol, several changes to legislation and further modifications to INPI's rules will be required.² Implementing the protocol would be a significant step towards reducing the backlog and the costs associated with trademark protection in Brazil.

ANVISA's Prior Consent for Patent Examination

While INPI takes steps to improve its backlog, a dual patent examination system complicates those efforts. Under Article 229-C of Brazil's Patent Law, the Health Surveillance Agency (ANVISA) must conduct a review of all pharmaceutical patent applications. Though in principle ANVISA's role is limited to reviewing issues related to public health and safety, in practice a secondary patent examination is conducted. This dynamic continues despite an opinion by Brazil's General Attorney that officially limited ANVISA's scope of review to assessing the safety and therapeutic efficacy of products.³

This additional scrutiny, which applies only to the pharmaceutical sector, raises significant questions of technology discrimination under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). It also further slows down an already sluggish system, where it can take INPI years to even forward an application to ANVISA for the initial analysis.

Technology Transfer Agreements, INPI's Right to Modify and Limitations

Under Brazil's Industrial Property Law, agreements that involve technology transfer

² As an illustrative example, in Brazil a trademark can only be registered in a single class and multiclass registrations are required by the Protocol.

³ Opinion 337/PGF/EA/2010. 10 January 2011

must be registered with and approved by INPI.⁴ In many cases, INPI modifies contract terms, encroaching on the freedom to contract. For example, INPI has limited the amount of royalties, restricted how such amounts are calculated and when they can begin to accrue. The terms of the agreements and the time during which exchanged information remains confidential are also controlled. Instead of promoting the transfer of technology, such policies may actually discourage these critical partnerships.

INPI's Efforts to Weaken Pharmaceutical Patents

INPI continues to pursue a series of lawsuits that seek to invalidate or shorten the term of 170 “mailbox patents” on primarily pharmaceutical inventions that were filed shortly after TRIPS went into effect in Brazil. The lawsuits allege that the products covered by those applications should not have been granted a minimum 10-year patent term as measured from the patent grant date. 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.

Potential Patent Reform May Weaken American IP Rights

In 2013 a study on Brazilian patent reform was released, concurrently with a bill on the same topic co-sponsored by the study’s coordinator.⁵ While there are certain positive proposals, for example investing in backlog reduction, other suggestions could impair the value of intellectual property. In particular, 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 year minimum term for patents. The study also proposes creating CODIPI under the Chief of Staff (Casa Civil), which would have binding decision-making authority. This would likely reduce the ability of INPI to use its expertise to properly apply Brazil’s patent law and further increase investor uncertainty.

Pursuit to Weaken IP at WIPO

In 2010 at the World Intellectual Property Organization’s Standing Committee on Patents (SCP), Brazil tabled a proposal for a work programme focused on exceptions and limitations to patents.⁶ The effort was designed in three phases. First, conduct a detailed exchange of experiences on exceptions and limitations. Second, determine the

⁴ Law No. 9,279/96

⁵ The Revision of the Patent Act: Innovation Towards Competitiveness. 2013. Available at: <http://bd.camara.gov.br/bd/handle/bdcamara/14797> and Congressional Bill PL 5402/2013

⁶ SCP/14/7. January 20, 2010. Available at: http://www.wipo.int/edocs/mdocs/patent_policy/en/scp_14/scp_14_7.pdf

most effective exceptions or limitations to patents. Finally, develop an “exceptions and limitations manual.” Brazil continues to pursue this agenda, and this proposal remains on the agenda of the SCP.

CANADA

Heightened Utility Requirement for Patents

Intellectual property rights are undermined in Canada by its distinct and impermissibly exacting 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 among developed countries 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.

Weak Patent Enforcement

The Canadian Patented Medicines (Notice of Compliance) Regulations include several key deficiencies that weaken Canada’s enforcement of patents, including the nature of patent dispute proceedings, lack of effective right of appeal for patent owners, and limitations on the listing of patents in the Patent Register.

Lack of Patent Term Restoration

Canada’s intellectual property regime currently provides no form of patent term restoration (PTR). Canada recently agreed to adopt a form of PTR in the context of the CETA, but concerns remain regarding the conditions and limitations within the agreed upon PTR mechanism.

CHINA

Potential Negative Impact of Draft Service Inventions Regulations

China's State Intellectual Property Office continues to develop administrative Service Invention regulations with the intention to promote innovation. IPO commends SIPO's efforts to promote scientific advancement and technological innovation within China. However while we agree that inventors should be appropriately incentivized, in their current form the Draft Regulations have the potential to negatively affect the ability of U.S. companies to make commercial choices about how to best motivate their employees and use or dispose of the related assets.

For example, while the Draft Regulations make it appear possible for companies to create their own agreements or policies regarding inventor remuneration, an entity would do so at great risk. Policies or agreements that revoke an undefined set of inventor rights or attach "unreasonable conditions" are considered invalid. As a result the default rules, which for many commercial entities may be quite onerous, would retroactively apply. Rather than fostering a collaborative and harmonious relationship for innovation and development, the regulations could inadvertently create an adversarial relationship between companies and their inventors.

Variations among industry sectors, market conditions and corporate circumstances have led companies to pursue different ways to promote and reward innovation internally. The one-size-fits-all nature of the Draft Regulations, particularly with respect to calls for minimum financial compensation to inventors, would impair the carefully thought-out policies that many companies have established based on experience and knowledge of their industries. No single set of financial incentives works well for everyone, nor should it be applied to all inventors.

Several of the Draft Regulations are also likely to increase the cost of innovation and compel the disclosure of confidential business information, sometimes directly to competitors. For instance, inventors are entitled to know the "economic benefit" of their service inventions or when the company plans to abandon the related intellectual property rights. This would require businesses to track every patent used in every product, how much revenue is derived from the sale of every product using patented technology, and the portion of sales revenue that is traceable to each patented invention. Not only would this present an overwhelming administrative burden, but determining the value of each invention relative to the overall value of a product containing multiple inventions doubtless would give rise to many disputes. Similarly challenging logistics would be involved in notifying inventors of the intention to abandon their patents, making it difficult if not impossible to dispose of private property. On top of the practical concerns with complying with such a regulation, companies would be required to provide this information to inventors no longer in their employ. Given that it is not

unusual for ex-employee inventors to be hired by competitors, this could provide unusually strategic insight to their new employers.

Other provisions in the Draft Regulations put trade secrets at risk. The proposal covers both “unpatented inventions” and “technical secrets” in addition to those innovations that eventually become patented. Under such a construct, inventors would have an incentive to take employers to court when they are unhappy with remuneration received. If litigation is threatened, employers would face the difficult decision of agreeing to the employee’s terms or risking disclosure of their trade secrets. Both choices could have a significant impact on long-term competitiveness. To IPO’s knowledge, no other inventor remuneration system in the world covers unpatented inventions and technical secrets.

Similar concerns arise as a result of administrative oversight of the Draft Regulations, which empowers agencies to oversee and search work contracts, rules, regulations, financial and market data, and other business secrets relevant to service inventions. While administrative agencies are required to keep this information confidential, without limitations on the type of evidence considered relevant to such a search, confidential business information could be at risk.

Trade Secrets: Positive Developments and the Need to Upgrade

Trade secret law in China is fragmented, with protection provided under several different legal and administrative provisions including Anti-Unfair Competition, Contract, and Labor Law, among others. China is in the process of debating whether to implement a separate unified trade secret law with more expansive protections. It has recently agreed to conduct a legislative study on revising its law.⁷ However, no specific proposals have been formally submitted for discussion or public comment. Theft of trade secrets in China and by companies based in China has been and remains an escalating concern for IPO members.

China appears to agree generally that stronger enforcement is necessary, as evidenced by recent changes to its preliminary injunction law and court system. In August 2012 China’s civil procedure was amended to expand the availability of injunctive relief. The law became effective in January 2013. On August 2, 2013, Shanghai No. 1 Intermediate Court granted a preliminary injunction in a trade secret misappropriation case with an American plaintiff based on this change in law. That case was based on China’s Anti-Unfair Competition law and involved a former employee’s breach of a non-disclosure agreement. Prior to this ruling it was unusual to obtain a preliminary injunction for trade secret misappropriation in China. It is unclear whether this decision signals a

⁷ 25th U.S. China Joint Commission on Commerce and Trade. Fact Sheet. December 29 2014. Available at: <http://www.commerce.gov/news/fact-sheets/2014/12/29/us-china-joint-fact-sheet-25th-joint-commission-commerce-and-trade>

positive trend or if it is an isolated decision.

In August 2014, the Standing Committee of the 12th NPC issued a decision establishing Intellectual Property (IP) Courts in Beijing, Shanghai and Guangzhou. These separate IP courts will have jurisdiction over first-instance civil and administrative cases of IP rights that are of a strong professional and technical nature. The Ministry of Commerce (MOFCOM) has also named trade secret protection as one of its top priorities.

Significant progress was made through U.S. bilateral discussions with China throughout 2014, as was apparent at the most recent Strategic & Economic Dialogue and U.S.-China Joint Commission on Commerce and Trade.⁸ China has pledged to improve protection of trade secrets, particularly related to its administrative and legal processes. This includes accountability for government officials with access to confidential business information, limiting what information must be provided to the government, and enabling the shielding of confidential information from mandatory public disclosure by government agencies. Today, the Chinese government often requires companies to submit technical and functional features of their products as well as confidential test data to local authorities as a condition to access the Chinese market. These actions are particularly harmful, as receiving agencies have been generally willing to provide such confidential information to the public on request.

While recent developments are promising, trade secret owners still face significant challenges protecting their confidential information. High evidentiary burdens, limited discovery and minimal damages are considerable obstacles. Not only is the act of seeking relief difficult, but it can require waiting until additional damage transpires. Under criminal law, theft is determined by the consequences of the loss, as opposed to the act of misappropriation. Even if a trade secret owner knows a theft has taken place, a criminal investigation cannot begin until a more significant and possibly irreversible injury has taken place. There is also no guarantee that the injury will be readily detected, though the damage is no less harmful.

The way a misappropriator uses a trade secret can also affect the ability to obtain relief under civil law. For example, under the Anti-Unfair Competition Law, action can only be taken against a “business undertaker.” If the trade secret is used outside a commercial context, the owner has no recourse. Like its criminal counterpart, the current civil law prevents early intervention to minimize damages.

⁸Sixth Meeting of the U.S-China Strategic and Economic Dialogue Fact Sheet – Economic Track. July 11 2014. Available at <http://www.treasury.gov/press-center/press-releases/Pages/jl2563.aspx> and 25th U.S. China Joint Commission on Commerce and Trade. Fact Sheet. December 29 2014. Available at: <http://www.commerce.gov/news/fact-sheets/2014/12/29/us-china-joint-fact-sheet-25th-joint-commission-commerce-and-trade>

We are hopeful that as China studies its existing trade secret protections, a plan to address these concerns will emerge.

Challenges Create by Recent Amendments to Chinese Trademark Law

Several amendments to China's Trademark law became effective last year. The new legislation makes significant improvements to the law, such as the addition of a good-faith requirement when applying for new marks. While the legislative update was aimed at curbing bad-faith registration of trademarks, brand owners still face substantial challenges. For example, failed oppositions result in immediate registration of challenged marks. The intent is to deter bad-faith oppositions. However, brand owners must initiate separate invalidation proceedings before the Trademark Review and Adjudication Board (TRAB). While the brand owner waits, a bad faith registrant may build up years of use, improving its chances for using the mark permanently based on current Chinese jurisprudence. Bad faith registrants may even be able to take enforcement action against a brand owner's own use of its trademark.

Draft IP Abuse Rules Impose Restraints on IP Enforcement

China's State Administration of Industry and Commerce (SAIC) recently released a new draft of its Regulations on the Prohibition of Abuse of Intellectual Property Rights to Eliminate and Restrict Competition (IP Abuse Rules).⁹ The latest draft contains some improvements, such as eliminating several presumptions that certain forms of conduct involving IPR are anticompetitive. However, in its current form, it has the potential to significantly damage the incentive to innovate. The draft IP Abuse Rules explicitly extend the "essential facilities" doctrine to intellectual property rights, prohibiting a business operator in a "dominant market position" from refusing to license its IP.¹⁰ The right to exclude is a key feature of IP protection. Such a policy could greatly undermine the IP rights that serve as an incentive to invest in innovation. Adding to the potential challenge are the unclear definitions of "essential facilities" and "dominant market positions." As currently drafted, almost any new technology could be interpreted as essential and the market could be construed equally broadly. Without clear guidance, inconsistent application of the rules by regulators is likely, causing innovators to use an overabundance of caution when enforcing their IP rights.

Patents and Technical Standards

The draft IP Abuse Rules also restrain the use of IP in the context of standard setting.¹¹ For example, a business operator in a dominant market position would be required to

⁹ 工商行政管理机关禁止滥用知识产权排除、限制竞争行为的规定(征求意见稿). June 11 2014.

Available at: <http://www.saic.gov.cn/gzhd/zqyj/201406/W020140610434051285346.doc>

¹⁰ IP Abuse Rules, Article 7

¹¹ IP Abuse Rules, Article 13

license patents required to implement the standard on fair, reasonable, and non-discriminatory terms (FRAND), regardless of participation in the standard setting process. With an emphasis on creating national standards within China, coupled with the lack of participation by non-Chinese entities in the related processes, the implications for non-Chinese patent holders could be significant. China continues to develop indigenous standards that diverge, in some cases intentionally, from international norms based on limited consultation with industry stakeholders. Foreign invested companies can only participate in China's standard setting process by invitation, leading to the exclusion of many U.S. companies and their Chinese subsidiaries. The effects go beyond potentially delayed entry into the market. Such standards, by nature of the design process, are likely to incorporate mostly local technologies. When these standards become mandatory, some U.S. innovators may be completely blocked from the Chinese market.

Incomplete Delinking of Indigenous Innovation from Government Procurement

Since 2011, China has committed to delink its innovation policies from government procurement preferences. Much progress has been made since then, with a number of provinces and sub-provincial units issuing notices to comply with a State Council notice requiring the policy change. However, it is clear that a relationship between indigenous innovation and government procurement still exists today. As illustrative examples, several local governments have promulgated “Rules to support local enterprises” after the State Council Notice. These notices encourage government procurement of high tech and software products¹² or the use of an indigenous innovation product catalog to support local firms¹³.

Patent Enforcement and the Fourth Amendment to Chinese Patent Law

The high and growing volume of utility models in China,¹⁴ combined with the lack of examination with respect to patentability, creates substantial uncertainty for U.S. companies in 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 innovative American and Chinese companies. One such measure might be to require, rather than leave to the discretion of a court or administrative agency, that the owner of a utility model or design patent in every case

¹²扬州市政府采购优先购置我市省级以上高新技术产品和软件产品的操作规程. 19 August 2013. Available at: http://www.gyzfcg.gov.cn/show_news.asp?News_Class=126&Nid=1223

¹³关于开展工业企业增产增效专项行动的实施意见 June 2012. Available at: http://www.zhenjiang.gov.cn/xxgk/zfwj/bgsjw/201207/t20120706_776945.htm

¹⁴ In 2013, utility model applications grew by over 20%. 2013 SIPO Annual Report published June 6, 2014, pg. 86 Available at: <http://english.sipo.gov.cn/laws/annualreports/2013/201406/P020140609548419315217.pdf>

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.

In 2013, China issued a revised draft Fourth Amendment to its Patent Law. The draft amendment includes 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 for 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.

Unique Challenges to Pharmaceutical Protection

With respect to patent examination, China recently changed its patent examination guidelines to allow patent applicants to file additional biological data after filing their applications and confirmed that its patent examination guidelines would no longer be applied retroactively. This is a welcome step. However, concerns remain that SIPO appears to be imposing new – and unfair or inappropriate – limitations on the use of post-filing data to satisfy inventive step requirements.

With respect to enforcement, transparent mechanisms are needed in China to ensure that patent issues can be resolved before potentially infringing pharmaceutical products are launched on the market. Neither China's Drug Administration Law nor the Provisions for Drug Registration provide an effective mechanism for enforcing patent rights vis-à-vis regulatory approval of follow-on products.

The situation has improved somewhat with respect to counterfeit medicines, as China has implemented its plans to improve drug safety and severely crack down on the production and sale of counterfeit medicines. However, the production, distribution and sale of counterfeit medicines and unregulated APIs remain rampant in China and continue to pose a threat to China and its trading partners.

Concerns also remain that despite China's commitment to provide a 6-year period of protection against unfair commercial use for clinical test and other data submitted to secure approval of products containing a new chemical ingredient, in practice the protection has not been effective.

Requirements for Foreigners to Hire Local Patent Agencies

In China, domestic applicants may file their patent applications directly with SIPO. Foreign applicants who want to directly own their patent assets must to appoint a patent agency to represent them before SIPO.¹⁵ Hiring a third party can both increase expenses and risk that confidential information is lost in the process. For companies with significant operations in foreign countries, it is not uncommon to have in-house operations that manage the patent application process. However, this is not possible under the current Patent Law.

While companies can avoid filing through a third party by establishing a Chinese business unit, relevant patent applications must be assigned to a Chinese entity. This complicates patent ownership by splitting up a potential family of assets among several entities, may disqualify the applicant from receiving incentives in other countries, and may not be allowed based on contractual obligations. U.S. companies should be allowed to file patent applications in their own names, as long as facilitated by an attorney or agent qualified by SIPO.

ECUADOR

Advances to Weaken the Global IP Infrastructure

Ecuador has granted "mandatory licenses" at an alarming rate, including at least nine since the country expanded the ability to pursue compulsory licenses in 2009.¹⁶ A number of applications for such licenses are pending. While these licenses are limited to "public health" priorities, Ecuador has also sought to weaken patent protection for green technology. In 2013, Ecuador introduced a discussion paper at the TRIPS Council, which included proposals to reduce the patent term and expand flexibilities to weaken the related IP.¹⁷ Ecuador has suggested similar policies during negotiations at the UN Framework Convention on Climate Change (UNFCCC).¹⁸ This preference

¹⁵ Patent law of the People's Republic of China. Article 19. Available at: http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244.html

¹⁶ Executive Decree No. 118. Available in English at: <http://www.wipo.int/edocs/lexdocs/laws/en/ec/ec035en.pdf>

¹⁷ TRIPS Council. Contribution of Intellectual Property to Facilitating the Transfer of Environmentally Rational Technology. 27 February 2013. IP/C/W/585

¹⁸ .e.g. Submission of Ecuador. Durban Platform. 1 March 2013., pg. 5 Available at: http://unfccc.int/files/documentation/submissions_from_parties/adp/application/pdf/adp_ecuador_workstr_eam2_20130301.pdf and proposals for an international mechanism on IPR, as referenced in the proposal

towards accessing technology outside of market channels, often in a forced manner, damages the incentive to invest. It can also slow down the process of technology dissemination.

INDIA

Over the last year a number of positive developments have helped shape the landscape for U.S. innovators operating in India. An annual high-level Intellectual Property Working Group was established as part of the U.S.-India Trade Policy Forum.¹⁹ This move is anticipated to open a more constructive dialogue at both a technical and political level. India created an IPR Think Tank to draft a new IP Policy and advise on IP issues.²⁰ As discussed in detail below, the recently released draft IP Policy includes many promising proposals that can improve India's intellectual property regime. In addition, the "Make in India" initiative, designed to facilitate investment in Indian manufacturing, includes a specific objective to improve the IP regime.²¹

The Office of the Controller General of Patents and Trademarks also took noteworthy steps towards improving its application backlog and improving patent quality. Among them are hiring additional examiners, launching a new electronic payment gateway and the introduction of the Stack and Flow System to monitor the progress of patent applications.

There are many positive signs that India wants to attract foreign direct investment and potentially strengthen intellectual property to accomplish its objective. However, other actions and policies tell a different story. Over the last few years India has demonstrated a preference for more proactively using compulsory licenses instead of reserving them as tools of last resort. This increases uncertainty for innovators, calling into question the value of the intellectual property that should support Indian technology investment. Ultimately the approach makes it more uncertain and expensive to invest, hurting both India and the U.S. economy.

India aims to be one of the top five global scientific powers by 2020.²² Expanding the country's capabilities in science and technology cannot be accomplished in a vacuum. Collaboration with innovators across the globe must be an integral component of the

from the Like-Minded Developing Countries in Climate Change. Elements for a Draft Negotiating Text of the 2015 ADP Agreed Outcome of the UNFCCC. 3 June 2014, pg. 7-8. Available at: http://unfccc.int/files/documentation/submissions_from_parties/adp/application/pdf/adp2-5_submission_by_malaysia_on_behalf_of_the_lmhc_crp.pdf

¹⁹ U.S.-India Joint Statement. September 30 2014. Available at: <http://www.whitehouse.gov/the-press-office/2014/09/30/us-india-joint-statement>

²⁰ DIPP Constitutes IPR Think Tank to Draft National Intellectual Property Rights Policy . 24 Oct 2014. <http://pib.nic.in/newsite/PrintRelease.aspx?relid=110790>

²¹ <http://www.makeinindia.com/policy/intellectual-property-rights/>

²² For example, see India's Science, Technology and Innovation Policy, 2013. Ministry of Science and Technology, pg. 4. Available at: <http://dst.gov.in/sti-policy-eng.pdf>

country's strategy. Policies that weaken intellectual property put technology providers on the defensive, making them less likely to partner and exchange the knowledge that India will need to support its growth.

Draft National IP Policy

Overall the draft IP Policy provides a valuable roadmap for realizing the potential of India's creativity and recognizes the central role intellectual property plays in this regard. It includes many positive recommendations, such as a focus on attracting foreign investment, improving enforcement of IP, building cooperation with counterpart IP offices around the world, upgrading trade secret protection and improving the efficiency of its patent and trademark operations.

We are concerned, however, with references that appear to indicate a relaxation of IP protection. Throughout the IP Policy there are calls for using flexibilities "judicially to keep IP laws updated" as well as studies on topics such as exceptions and limitations and exhaustion of IP rights.

There is also a recommendation to add utility model protection to support the informal segment of India's economy. While there may be some benefits, this may also lead to increased litigation and uncertainty for innovators operating in India, as has been the case with a similar system in China.

Additional Patentability Criteria

India's Patent Act adds an additional criterion for patentability, beyond what was agreed upon in TRIPS. Known as 3(d), it requires enhanced efficacy for substances in order for an invention to be eligible for patent protection. The law makes it difficult to secure patent protection for certain types of pharmaceutical inventions and chemical compounds.

Recent Policies that Mandate or Encourage Compulsory Licensing

Section 4.4 of India's National Manufacturing Policy discusses the use of compulsory licensing to help domestic companies "access the latest patented green technology."²³ It creates the "Technology Acquisition and Development Fund" (TADF) to help in situations where a patent holder is unwilling to license, either at all or "at reasonable rates" or when an invention is not being "worked" within India.²⁴ The TADF is empowered to request compulsory licensing from the Government of India.²⁵ The

²³ National Manufacturing Policy, 2011. Available at:

http://dipp.nic.in/English/policies/National_Manufacturing_Policy_25October2011.pdf

²⁴ National Manufacturing Policy, ¶4.4.1

²⁵ National Manufacturing Policy, ¶¶4.2, 4.4.3

recent draft National IP Policy references the TADF, recommending its efforts be promoted.²⁶

Similarly, India's National Competition Policy requires intellectual property owners to grant access to "essential facilities" on "agreed and nondiscriminatory terms" without reservation.²⁷ The concept of essential facilities appears to cover a broad range of technologies including at least "electricity, communications, gas pipelines, railway tracks, ports, IT equipment." The unconditional application of the essential facilities doctrine to such a broad technology landscape substantially decreases the value of the underlying intellectual property and can undermine incentives for innovation.

While other motives may be at play, the impetus to use compulsory licensing appears directly tied to industrial policy. While not adopted, a 2011 discussion paper produced by the Ministry of Commerce (DIPP) provides some insights. It explains that "compulsory licensing has a strong and persistent positive effect on domestic invention."²⁸ The objective of the paper was "to develop a predictable environment" for compulsory licensing to be used.²⁹

Lack of Regulatory Data Protection

The Indian Regulatory Authority relies on test data submitted by originators to another country when granting marketing approval to follow-on pharmaceutical products. This indirect reliance results in unfair commercial use prohibited by TRIPS and discourages the development of new medicines that could meet unmet medical needs.

Local Working Requirements

In addition to the policies discussed above, patent holders risk compulsory licensing if they fail to "work" their inventions in India within three years of grant.³⁰ This appears to include situations where patent holders import the related technology into the country but do not locally manufacture it. It is difficult to understand how this squares with TRIPS, which requires patents and their associated rights to be available "without discrimination as to the place of invention, the field of technology and whether products

²⁶ National IPR Policy (draft). December 24, 2014. ¶5.4.1, Available at:

http://dipp.nic.in/English/Schemes/Intellectual_Property_Rights/IPR_Policy_24December2014.pdf

²⁷ National Competition Policy, 2011, Section 5.1(vi). Available at:

http://www.mca.gov.in/Ministry/pdf/Revised_Draft_National_Competition_Policy_2011_17nov2011.pdf

²⁸ Discussion Paper on Compulsory Licensing. DIPP. 2011. ¶70. Available at

http://dipp.nic.in/English/Discuss_paper/CL_DraftDiscussion_02September2011.doc

²⁹ Discussion Paper on Compulsory Licensing, ¶2

³⁰ The Patents Act, 1970. (Patent Act) Section 84(1)(c). Available at:

http://ipindia.nic.in/ipr/patent/eVersion_ActRules/sections/ps84.html

are imported or locally produced.”³¹ Among those rights is the ability to exclude others from making, using or selling their invention.³²

To facilitate potential forced licensing activity, the Controller of Patents is empowered to require patent holders and any licensees to provide details on how the invention is being worked in India.³³ In 2009, a public notice was issued indicating this requirement would now be enforced. Statements of Working, (Form 27)³⁴, must be provided annually.³⁵ Failure to provide the requested information is punishable by fine or imprisonment.³⁶

The recent push to enforce the submission of Statements of Working is thought to increase the availability of compulsory licensing. The subsequent publication of the statements in a standalone database is further evidence of that intention. Form 27 is also extremely burdensome, including requests concerning the value of the products worked. Not only may this be impossible to provide on a per patent basis, but it also forces patent holders and their licensees to potentially provide confidential business information to both the government and the public.

India clearly intends to impose working requirements on users of its patent system. India issued its first compulsory license in 2012, which survived several legal challenges including most recently at the Supreme Court of India. Most troubling about the decision was the interpretation that at least in some circumstances, the working requirement may not be fully satisfied through importation.³⁷ In many cases it would be impractical, if not impossible for patent holders or licensees to manufacture in every country around the world. The ability to make commercial choices with respect to manufacturing is imperative, both in terms of preserving competitiveness and reducing the cost of critical technologies.

The Need to Upgrade Trade Secret Protection

India lacks statutory protection for trade secrets, either civilly or criminally. Contractual obligations provide the primary vehicle for protecting trade secrets. While other means

³¹ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Article 27.1 (emphasis added)

³² TRIPS. Article 28(1)

³³ Patent Act. Section 146. Available at:

http://ipindia.nic.in/ipr/patent/eVersion_ActRules/sections/ps146.html

³⁴ Statement Regarding the Working of the Patented Invention on Commercial Scale in India, available at:

http://patinfo.nic.in/pdf/form_27.pdf

³⁵ The Patents Rules, 2003. Section 131. Available at:

http://ipindia.nic.in/ipr/patent/eVersion_ActRules/rules/pr131.html

³⁶ Patent Act. Section 146

³⁷ Intellectual Property Appellate Board, Bayer Corporation v. Union of India through the Secretary & Ors., Order No. 45 of 2013, issued March 4, 2013., ¶52. Available at: <http://www.ipab.tn.nic.in/045-2013.htm> and Bayer v. Union of India, Writ Petition No.. 1323 of 2013. pg.48

of protection may exist, such as the tort of “breach of confidence,”³⁸ each has a common shortcoming – requiring a close relationship between the trade secret owner and the would-be misappropriator. Unfortunately bad actors who choose to steal information rather than innovate are often not in privity with trade secret owners. There are significant benefits to collaborating with Indian firms, especially in light of the country’s highly skilled services sector. Yet the industries for which it makes the most sense to join forces rely on trade secrets to protect competitiveness. The U.S. and India would mutually benefit from stronger and more transparent trade secret protection, covering a broader range of actors.

Recent moves by Indian government indicate that the country sees value in such an approach. A recommendation to pursue legislation on trade secrets to “fill in gaps” in their IP regime was included in the draft National IPR Policy.³⁹ Earlier recognition of the need to improve trade secret protection can be found in the 2014 draft National Innovation Act⁴⁰ and 2012 draft National IPR Strategy.⁴¹ There is also a growing body of academic literature originating within India that agrees such initiative is critical.⁴² The 2012 draft National IPR Strategy made the point quite clearly when it explained that a “predictable and recognizable trade secret regime will improve investor confidence.” We agree that a national trade secret law that provides sufficient protection against all potential misappropriators, injunctive relief, preservation of evidence, the ability to secure damages, and effective deterrence to prevent acts of theft in the first place, is an important step.

³⁸ Normani & Rahman. Intellection of Trade Secrets and Innovation Laws in India. Journal of Intellectual Property Rights. Vol. 16, July 2011., 346 Available at:

<http://nopr.niscair.res.in/bitstream/123456789/12449/1/IJPR%2016%284%29%20341-350.pdf>

³⁹ National IPR Policy (First Draft). December 19 2014, ¶3.2 Available at:

http://dipp.nic.in/English/Schemes/Intellectual_Property_Rights/IPR_Policy_24December2014.pdf

⁴⁰ The National Innovation Act of 2008 (Draft). Chapter VI. Available at:

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

⁴¹ Invitation of Views on the draft National IPR Strategy. ¶¶50-52. Available at:

http://dipp.nic.in/English/Discuss_paper/draftNational_IPR_Strategy_26Sep2012.pdf

⁴² e.g. Hariani. The Draft National Innovation Act, 2008. India Law Journal, Volume 3. Available at:

http://indialawjournal.com/volume3/issue_1/article_by_anirudh.html

Kumar et al. Legal Protection of Trade Secrets. Journal of Intellectual Property Rights. Vol 11. November 2006, pg. 379. Available at:

[http://nopr.niscair.res.in/bitstream/123456789/3604/1/JIPR%2011\(6\)%20397-408.pdf](http://nopr.niscair.res.in/bitstream/123456789/3604/1/JIPR%2011(6)%20397-408.pdf)

Normani & Rahman. Intellection of Trade Secrets and Innovation Laws in India. Journal of Intellectual Property Rights. Vol. 16, July 2011., 341 Available at:

<http://nopr.niscair.res.in/bitstream/123456789/12449/1/IJPR%2016%284%29%20341-350.pdf>

Roy. Protection of Intellectual Property in the Form of trade Secrets. Journal of Intellectual Property Rights. Vol. 11, May 2006. 192 Available at:

<http://nopr.niscair.res.in/bitstream/123456789/3577/1/JIPR%2011%283%29%20192-200.pdf>

Singh et. Al. Need for a Separate Trade Secret Act with Required Law. The Practical Lawyer, 2011 (PL) June 44. Available at:

http://www.supremecourtcases.com/index2.php?option=com_content&itemid=1&do_pdf=1&id=24329

Disclosure of Foreign Filings

Section 8 of India’s Patent Act requires disclosure and regular updates on foreign applications that are substantially “the same or substantially the same invention.” The original purpose of the requirement was to ensure high quality patents were issued by India, in light of patent examinations around the world. While this may have been necessary when the Patent Act was originally enacted almost 50 years ago, patent examiners now have access to file histories for applications in many jurisdictions. In fact, given India’s appointment as an International Search Authority for the Patent Cooperation Treaty (PCT), it is possible that the requirement to furnish examination results for co-pending applications conflicts with PCT rules.⁴³ However, failure to provide the required information can result in devastating consequences to the patent applicant. Non-compliance provides an independent ground for pre- and post- grant opposition, as well as revocation.⁴⁴

Failure to comply with Section 8 is now a commonly cited ground to invalidate patents. Patentees must worry about co-pending family members as well as other similar patents.⁴⁵ The requirements set forth by Section 8 are antiquated and create unnecessary uncertainty and expense for patent applicants.

India’s Stance Within Multilateral Fora

Just in the past year at the TRIPS Council, India has insisted there is “no evidence to prove that strong IP could deliver on development or innovation.”⁴⁶ In the same forum, India has also insisted on several occasions that “there is not direct linkage between IP and innovation.”⁴⁷ At WIPO, India pursues further efforts to expand patent flexibilities⁴⁸, including supporting the development of an instruction manual on how best to adopt exceptions and limitations to patents. At the UNFCCC, India has promoted “a facilitative IPR regime,”⁴⁹ including by creating an “international mechanism on IPR.”⁵⁰

⁴³ Patent Cooperation Treaty. Article 42. Available at: <http://www.wipo.int/pct/en/texts/articles/a42.htm>

⁴⁴ Patent Act, Sections 25(1)(h), 25(2)(h), and 64(1)(m) respectively.

⁴⁵ See *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.* FAO (OS) 188/2008. Decision April 24, 2009

⁴⁶ TRIPS Council. Minutes of Meeting held 25-26 February. IP/C/M/75/Add.1, ¶¶398-399. See also ¶399

⁴⁷ TRIPS Council. Minutes of Meeting held 11 June 2014. IP/C/M/76/Add.1, ¶347; See also June 2013.

TRIPS Council. Minutes of meeting held 11-12 June. IP/C/M/73/Add.1, ¶423

⁴⁸ e.g. SCP/20/13 PROV.2 ¶¶32, 99

⁴⁹ Submission by India on the Work of the Ad-Hoc Working Group on the Durban Platform for Enhance Action: Workstream 1., pg. 3. Available at:

http://unfccc.int/files/documentation/submissions_from_parties/adp/application/pdf/adp_india_workstream_1_20130913.pdf

⁵⁰ pg.8-9. Submission on Elements of the 2015 Agreed Outcome. 8 March 2014. Available at:

http://unfccc.int/files/documentation/submissions_from_parties/adp/application/pdf/adp_lmdc_ws1_2014_0309.pdf

India's activities in these fora may be especially influential, considering a 2013 collaboration agreement by intellectual property offices in the BRICS countries.⁵¹ The agreement named India as the lead office to coordinate the exchange of views on the international IP agenda. India's stances in the multilateral arena raise questions for investors as to the long-term value of their intellectual property within India and beyond.

PANAMA

Sanctions for Protection of Famous Marks

Brand owners must vigilantly monitor the use of trade names that are similar to their famous marks in order to preserve their marks' values. A recent decision by the Supreme Court of Panama resulted in surprising and severe consequences for a U.S. company attempting to protect its famous mark. The ramifications of the decision are likely to make brand owners rethink efforts to enforce their marks in Panama, potentially impairing the value of their intellectual property.

In 2004, Bridgestone became aware that a Panamanian tire company was using the trademark RIVERSTONE. Concerned about confusion with its brand, the company sent a "reservation of rights" letter to the users of RIVERSTONE and later filed an opposition motion for its mark in Panama. While the opposition motion was unsuccessful, a Panamanian civil court found that Bridgestone was legitimately concerned about confusion.

Nonetheless, the owners of RIVERSTONE sued Bridgestone for monetary damages, alleging that its "reservation of rights" letter and opposition action caused them to halt the sale of their tires. Two lower courts ruled in favor of Bridgestone. However, the Supreme Court of Panama reversed the decision and awarded over \$5 million in damages to the owners of RIVERSTONE.⁵² In essence, the Supreme Court's decision penalized a brand owner for justifiably using a mechanism designed to challenge potential trademark infringement. The policy undermines the procedures foreseen in the TRIPS agreement⁵³ and the U.S.-Panama Trade Promotion Agreement⁵⁴ designed to protect brand owners.

⁵¹ BRICS Intellectual Property Offices Cooperation Roadmap. Magaliesburg May 2013. Available at: <http://www.ip-watch.org/weblog/wp-content/uploads/2013/11/SIGNED-BRICS-IP-OFFICES-COOPERATION-ROADMAP.pdf>

⁵² *Muresa Intertrade, S.A. and Tire Group of Factories Ltd., Inc. v. Bridgestone Corporation and Bridgestone Licensing Services, Inc.* May 2014.

⁵³ TRIPS. Article 15.5

⁵⁴ U.S.-Panama Trade Promotion Agreement. Article 15.2(6)(c). Available at: http://www.ustr.gov/sites/default/files/uploads/agreements/fta/panama/asset_upload_file131_10350.pdf

SOUTH AFRICA

Proposed National IPR Policy

In 2013, South Africa's Department of Trade and Industry (dti) published a draft National Policy on Intellectual Property (National IP Policy).⁵⁵ We understand that the draft is still under review by the dti. Highlights include recognition of the importance of trade secret protection and the importance of incentivizing technology dissemination and deployment. However, among these positive signals to investors are indications of an intention to weaken the existing intellectual property system.

For example, the draft appears to encourage and broaden compulsory licensing and similar flexibilities. While the stated objectives of increasing access to technology and medicine are clearly important, the preference for accomplishing this by eroding intellectual property is troublesome. Advocating expropriative solutions rather than commercial pathways degrades the incentives to invest in innovation. Such policies increase uncertainty that successful investments in technology can ever be recouped, making it harder and more expensive to finance the necessary research and development. Promoting a preference for IP flexibilities may also have the unintended effect of making it more difficult to access the underlying know-how often necessary to implement technology, ultimately slowing down further innovation and technology dissemination.

II. TRENDS THAT DISCOURAGE INVESTMENT IN PHARMACEUTICAL INNOVATION

In the name of increased access to medicines, a number of countries have implemented a variety of measures, from limiting regulatory data protection, to heightening patentability requirements and expanding the availability of compulsory licensing. Unfortunately many of these policies actually increase the cost of investing in innovative medicines, a field characterized by lengthy development cycles and significant capital expenditures. These necessary steps are critical to transforming advances from the laboratory into medicines that can be delivered to those who need them most. Below we highlight a few of the challenges faced when developing these critical goods.

⁵⁵ Draft National Policy on Intellectual Property (IP) of South Africa. 4 September 2013. Available at: <http://ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf>

Limits and Restrictions on Patentability

Whether through additional patentability criteria like India's 3(d) or Canada's heightened utility requirement known as the "promise doctrine," several countries are making it increasingly difficult to obtain patent protection for pharmaceuticals. In Brazil, a secondary patent examination is conducted by the health regulatory agency for related application, sometimes applying patentability requirements that conflict with Brazil's patent authority. In other jurisdictions, such as Argentina⁵⁶ and the Andean Community⁵⁷, patent protection for several types of innovation has been foreclosed.

Other jurisdictions, such as Australia, may be following suit. A large number of recent reviews of the Australian IP system appear to focus on pharmaceuticals, including a review of compulsory licensing and Crown-Use provisions in Australia⁵⁸; a review of patentable subject matter (aimed primarily at the issue of the patentability of genetic and biological materials)⁵⁹; a review of the innovation patent system⁶⁰; and a root-and-branch review of Australia's patent system as it relates to pharmaceutical products.

Limits on Regulatory Data Protection

Pharmaceuticals undergo rigorous regulatory review before they can be introduced to the market. As part of the process, pharmaceutical producers must submit proprietary information to the appropriate agencies that demonstrate the safety and efficacy of a proposed product. Companies spend tremendous resources to compile this information. To facilitate this process, TRIPS requires WTO members to protect the supplied confidential details.⁶¹ However, this protection varies significantly between countries.

⁵⁶ Argentina's patentability guidelines restrict the possible patentability of compositions, dosages, salts, esters and ethers, polymorphs, analogous processes, active metabolites and pro-drugs, enantiomers, selection patents and Markush-type claims. Joint Regulation No 118/2012, 546/2012 and 107/2012. Guidelines for Patentability Examination of Patent Applications on Chemical and Pharmaceutical Inventions. Issued May 2, 2012.

⁵⁷ Second use patents are not permitted by Andean law. Decision 486, Article 21; Decision 344, Article 16. Members of the Andean Community include Bolivia, Colombia, Ecuador and Peru.

⁵⁸ Balancing Access to Technology and Innovation. Joint Media Release. No. 059. June 29, 2012. Available at:

<http://ministers.treasury.gov.au/DisplayDocs.aspx?doc=pressreleases/2012/059.htm&pageID=003&min=djba&Year=&DocType=>

⁵⁹ Review of patentable subject matter, available at <http://www.acip.gov.au/reviews/all-reviews/review-patentable-subject-matter/>

⁶⁰ Review of the Innovation Patent System. Available at: <http://www.acip.gov.au/reviews/all-reviews/review-innovation-patent-system/>

⁶¹ TRIPS. Article 39.3

Several countries, such as Brazil⁶² and Argentina, do not currently provide adequate regulatory protection for pharmaceuticals. Other countries, like China and Ecuador, have included protection for the related data but in practice, the protection remains inadequate. In India, the local regulatory authority relies on test data submitted by originators to another country when granting marketing approval to follow-on pharmaceutical products, in effect denying protection for the underlying data that may be available in other countries. Similarly, in Canada, the scope of regulatory data protection is narrow, such that there are concerns about drugs marketed outside the country.

III. PUSH TO WEAKEN IPR WITHIN MULTILATERAL FORA

At the UNFCCC, calls to weaken the global intellectual property framework protecting the related innovations have been a regular theme. Intellectual property rights (IPR) have been unfairly portrayed by some as a barrier to the necessary technology transfer, either by limiting the availability of the technology altogether or making it more expensive to secure.

However, there is limited, if any, evidence that IPR is a barrier.⁶³ A variety of proposals to weaken IPR have been raised within the UNFCCC, including: compulsory or concessional licensing; the elimination of IPR for climate related technologies; technology buyouts, or other international IPR mechanisms; and non-assertion pledges for patents for technology used by developing countries. There are also efforts to implement these types of measures at the national level.

In parallel, negotiations to establish the UN's Sustainable Development Goals (SDGs) demonstrate similar cause for concern. The Open Working Group's proposal contained specific provisions to "encourage the full use of TRIPS flexibilities" or licensing on concessional terms.⁶⁴ The text also calls for the establishment of a Technology Bank that would facilitate such concessional licensing of intellectual property.⁶⁵ While the promotion of broad access to technology is certainly a laudable objective, it is best achieved through existing, market-based mechanisms and competition, combined with effective global financing mechanisms, and a focus on key enabling factors. If adopted,

⁶² Although Brazil has enacted federal laws to ensure adequate data protection for veterinary and crop products, Brazilian law still does not provide adequate regulatory data protection (RDP) for pharmaceuticals.

⁶³Lohse. Incentivising the adoption of green technology on a global scale. WIPO Global Challenges Brief. November 2014. Available at:

http://www.oapi.wipo.net/export/sites/www/policy/en/climate_change/pdf/wipo_lohse_brief.pdf

⁶⁴ Open Working Group proposal for Sustainable Development Goals. ¶3.b and ¶17.7 respectively Available at: <https://sustainabledevelopment.un.org/sdgsproposal>

⁶⁵ *Id.* ¶¶17.6-17.8 *See also*. A Technology Bank and Science, Technology and Innovation Supporting Mechanism. 3 July 2013. Available at:

<http://www.unohrrls.org/UserFiles/File/LDC%20Documents/Tech%20Bank%20-%20Background%20Note%20for%203%20June%202013%20Event.pdf>

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such provisions would undermine U.S. technology interests, exports, and jobs, as well as the clean technology and sustainable development goals that they are purported to pursue.

Another related dialogue is taking place under the auspices of the WTO at the TRIPS Council. In early 2013, a discussion on the role of intellectual property in transferring environmentally friendly technology was launched.⁶⁶ Among other proposals, the paper included recommendations to reaffirm existing flexibilities in the TRIPS Agreement for environmentally sound technologies and reduce the term for related patented inventions.⁶⁷

At the World Health Organization (WHO), there was a recent proposal to extend the work of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) through 2022.⁶⁸ The extension would likely lead to further study of weakening IP protection, without the benefit of expertise from key stakeholders such as industry, whose participation tends to be limited within the organization.

At WIPO's Standing Committee on Patents (SCP), several countries continue to pursue a work programme that would promote exceptions and limitations to patents. The continued effort is based, at least in part, on a 2010 proposal.⁶⁹ Designed in three phases, it involves a detailed exchange of experiences on exceptions and limitations, a determination of the most effective exceptions or limitations, and finally the development of an "exceptions and limitations manual." Similar discussions are ongoing as part of the Committee on Development (CDIP).

* * *

Respectfully submitted,



Philip S. Johnson
President

⁶⁶ TRIPS Council. Contribution of Intellectual Property to Facilitating the Transfer of Environmentally Rational Technology. 27 February 2013. IP/C/W/585

⁶⁷ *Id.* ¶17

⁶⁸ WHO. EB136/CONF./7

⁶⁹ SCP/14/7. January 20, 2010. Available at:

http://www.wipo.int/edocs/mdocs/patent_policy/en/scp_14/scp_14_7.pdf