February 5, 2016

Mr. Probir Mehta
Acting Assistant United States Trade Representative for
Intellectual Property and Innovation
Office of the United States Trade Representative
600 17th Street NW
Washington, D.C. 20508

Re: USTR 2016 Special 301 Review, Request for Public Comment (Docket No. USTR-2015-0022)

Dear Mr. Mehta,

Intellectual Property Owners Association (IPO) appreciates the opportunity to provide comments regarding the U.S. Trade Representative's 2016 Special 301 Review. IPO's comments highlight the concerns with key issues surrounding the effective protection of intellectual property (IP) rights globally.

IPO is an international 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 and more than 12,000 individuals who are involved in the association through corporate or other classes of membership.

IPO's comments address three main areas: country-specific concerns, in alphabetical order by country; the push to weaken IP rights within multilateral fora; and the trends that discourage investment in pharmaceutical innovation.

I. COUNTRY-SPECIFIC CONCERNS

ARGENTINA

Backlog Leading to Reduced Patent Value and Lack of Clarity of Rights

The patent examination backlog in Argentina is one of the most challenging for innovators to manage. Delays in securing patents makes it more challenging to attract investors or support business plans. In general, the earliest substantive examination starts is seven years after examination fees are paid. For most applications, examination takes place nearly a decade from the filing date. Moreover, Argentina provides neither provisional protection, nor supplemental protection due to the delays during prosecution.

Shifts in the Legal Framework Creating Uncertainty for Innovators

In May, 2012, Argentina's Patent Office enacted resolution P-107/2012.[1] The resolution introduced more restrictive criteria for patentability of inventions in the chemical and pharmaceutical areas.[2] The changes were applicable to both new and pending patent applications, changing the legal framework in force when those patent applications were filed. In our experience, pending applications filed prior to the change are being rejected based on this new guidance. When these changes are combined with the substantial backlog, significant uncertainty results for innovators in the chemical and pharmaceutical areas.

AUSTRIA

Gaps in Austria's Trade Secret Regime

Although Austria offers protection for trade secrets, improvements are needed to ensure a broader range of theft can be addressed and would-be infringers sufficiently deterred. For example, one significant gap in criminal liability relates to the disclosure of non-technical, but commercially sensitive information. If a third party entrusted with such information reveals it, there is no criminal recourse, even when the discloser intentionally reveals the information knowing it is confidential commercial information and the disclosure causes substantial harm.[3] Our members also use trade secrets to protect a wide variety of confidential business information. Many commercially sensitive details are non-technical in nature, yet their disclosure can be equally, if not more, damaging than disclosure of technical trade secrets.

The almost nominal criminal penalties available also concerns us. The maximum prison term for a trade secret breach under Austria's Act Against Unfair Competition is a mere three months, compared to ten- to fifteen-year terms for similar crimes available under U.S. law. These low penalties are even out of step with penalties for other IP crimes, for which violators can face up to two-year imprisonment for violations.

Even when remedies exist for trade secret theft, it can be extremely difficult to gather the necessary evidence. Under Austrian law, public prosecutors lack the authority to prosecute trade secrets *ex officio*. Although private prosecutions are available, investigations prior to filing a complaint are not. Just getting into court can be challenging. And when trade secret owners manage to kick off an investigation, getting the necessary proof remains difficult. Private parties cannot provide input into police investigations, or request a search of an alleged violator's premises or the seizure of goods, all of which could provide critical evidence. The U.S. should encourage Austria to reintroduce the right of private individuals to appoint an investigating judge

[1] *Apruébanse las pautas para el examen de Patentabilidad de las solicitudes de Patentes sobre Invenciones Químico-Farmacéuticas*, (May 2, 2012), http://www.wipo.int/edocs/lexdocs/laws/es/ar/ar109es.pdf.
[2] *See* IPO Committee Newsletter, INTELLECTUAL PROPERTY OWNERS ASSOCIATION ((Dec., 2012), http://www.ipo.org/wp-content/uploads/2013/03/122012committeenewsletter.pdf (For example, polymorphs, hydrates, and solvates of known compounds are not allowed and single enantiomers are not patentable when the racemic mixture is already known. There are also restrictions of Markush-type claims, selection patents, active metabolites, pro-drugs, etc.).
[3] *See* Federal Act Against Unfair Competition, §§ 11- 12 (2007), http://www.wipo.int/edocs/lexdocs/laws/en/at/at117en.pdf.

in criminal prosecutions for alleged violations of trade secrets under Austria's Act Against Unfair Competition or the Criminal Code, in addition to providing some authority for public prosecutors to launch their own investigations.

Trade secret owners also face even more barriers in Austria's courts. Criminal prosecutions of trade secrets are heard by District Courts that generally handle low-value criminal matters. Cases involving trade secret misappropriation involve a more complex set of technical and commercial issues. The U.S. should encourage these cases to be handled by more experienced judges, such as those in the Regional Courts. Civil cases are no less complex and should be heard by specialized judges as well.

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 impairing access to critical funding, especially for smaller companies. Additionally, the amount of time it takes to receive a patent reduces the patent's term. Such delays hurt both would-be patent owners and potential competitors, adding to uncertainty in the market and increasing the cost of innovation.

The situation for trademarks is similar. Brazil's IP Office (INPI) has a backlog of around 500,000 trademark applications.[4] The resulting delays hurt brand owners, making it harder to penetrate the local market. With growing numbers of both patent and trademark applications, these challenges are likely to continue into the foreseeable future.

INPI has taken definitive steps to reduce its backlogs. Over the past two years, INPI hired a significant number of examiners and completed the upgrade of its IP infrastructure. The introduction of a fast lane for applications related to green technology and participation in the WIPO's "PROSUR" collaborative examination initiative show promise. We are also encouraged by the ongoing collaboration between the USPTO and INPI,[5] and the resulting pilot Patent Prosecution Highway (PPH).[6] Although this is a helpful first step, expanding the program to other technology areas for Brazilian patent applications will be important to enable the program to have maximum impact on the backlog.

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[4] Michael Loney, *The New BPTO President's Backlog Challenge in Brazil*, MANAGING INTELLECTUAL PROPERTY. (May 1, 2014), http://www.managingip.com/Article/3336726/The-new-BPTO-presidents-backlog-challenge-in-Brazil.html.

[5] *Joint Statement Between the Government of the United States and the Government of the Federative Republic of Brazil on Patent Work Sharing Between Patent Offices* (June 30, 2015), http://www.uspto.gov/sites/default/files/documents/VI.%20U.S.-Brazil%20Joint%20Statement%20on%20Patent%20Work%20Sharing.pdf.

[6] *Memorandum of Understanding Between the United States Patent and Trademark Office and the National Institute of Industrial Property of Brazil on a Patent Prosecution Highway Pilot Program*, INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL (Nov., 2015), http://www.uspto.gov/sites/default/files/documents/PPH_MOU_and_Workplan_USPTO-INPI.pdf.

With respect to trademarks, accession to the Madrid Protocol could help improve 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. We are pleased that INPI has begun to initiate some of the changes necessary to comply. It is anticipated, however, that beyond accession to the Protocol, several changes to legislation and further modifications to INPI's rules will be required.[7] 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

Although INPI is taking steps to improve its backlog, a seemingly dual patent examination system has complicated those efforts. Under Article 229-C of Brazil's Patent Law, the Health Surveillance Agency (ANVISA) must review all pharmaceutical patent applications. Though in principle ANVISA's role is limited to 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.[8]

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, under which 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 must be registered with and approved by INPI.[9] In many cases, INPI modifies contract terms, encroaching on the freedom to contract. For example, INPI has limited the amount of royalties, restricted how royalties 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 polices might 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 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 ten-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.

[7] As an illustrative example, in Brazil, a trademark can only be registered in a single class, and multiclass registrations are required by the Protocol.
[8] Opinion 337/PGF/EA/2010 (Jan., 10, 2011).
[9] Law No. 9,279/96 of May 14, 1996, World Intellectual Property Organization.

Potential Patent Reform Might Weaken Brazilian 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.[10] Although 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 a Counsel of Intellectual Property Rights 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

Brazil continues to advance IP-weakening agendas within international fora. For example, Brazil continues to push for creation of a World Intellectual Property Organization (WIPO) manual on exceptions and limitations to guide developing countries in setting aside IP rights.[11] At one recent WIPO meeting, Brazil suggested that compulsory licensing is the most powerful tool in its arsenal to improve public health. Such positions make it difficult for innovators to invest in solutions that will solve health-related challenges and other societal concerns, as well as collaborate with governments in IP-based research efforts.

CANADA

Heightened Utility Requirement for Patents

IP rights are undermined in Canada by its distinct and impermissibly exacting standards for patentability of inventions. For example, 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 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."

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[10] Brazil's Patent Reform: Innovation Towards National Competitiveness (2013), http://bd.camara.gov.br/bd/handle/bdcamara/14797; *see also* Congressional Bill PL 5402/2013.

[11] *See* Standing Committee on the Law of Patents, Fourteenth Session, WORLD INTELLECTUAL PROPERTY ORGANIZATION,. SCP/14/7 (Jan. 20, 2010), http://www.wipo.int/edocs/mdocs/patent_policy/en/scp_14/scp_14_7.pdf.

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 on the patentability of biopharmaceutical inventions than on other inventions, in violation of TRIPS, which requires that there be no discrimination in patentability standards by fields 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) (PM (NOC)) Regulations include several key deficiencies that weaken Canadian patent enforcement, including lack of effective right of appeal for patent owners and limitations on the listing of patents in the Patent Register.

No Effective Right of Appeal in PM (NOC) Proceedings

The restrictive nature of the PM (NOC) regime means that a patent owner, unlike a generic drug producer, does not have an effective right of appeal. The PM (NOC) Regulations provide that a generic product may be approved for marketing (through the issuance of a Notice of Compliance, or "NOC") following a decision by the court in the first instance in favor of the generic producer. Regulations only allow for the prohibition against the issuance of a NOC and not its revocation. Therefore, once the NOC issues, an appeal filed by the patent owner becomes moot.[12] The patent owner is then left with no alternative but to start a new proceeding outside of the framework of the PM (NOC) Regulations, i.e., commencing an action for patent infringement once the generic product enters the market, essentially having to restart a case it had already spent up to two years litigating under the Regulations. Moreover, irreparable harm can result by the time the patent owner obtains a favorable decision in such a separate infringement case.

In contrast, a right of appeal is available to the generic producer under the PM (NOC) Regulations if the patent owner prevails in the first instance. The U.S. should strongly encourage Canadian authorities to rectify this discriminatory imbalance in legal rights and due process in a way that will ensure there is a meaningful and effective right of appeal for patent owners while maintaining other patent enforcement tools.

Although a patent owner may separately choose to proceed later by way of a patent infringement action, and may apply for an interlocutory injunction to maintain its patent rights and to prevent the market entry of the generic product or to seek its withdrawal from the market, these interlocutory injunction motions rarely succeed in Canada even if there is compelling evidence of infringement.

Additionally, it often takes at least two years before an action for patent infringement is tried, and far longer to obtain damages once a generic has been successfully sued for infringement.[13] By

[12] Eli Lilly Canada Inc. v. Novopharm Ltd., 2007 FCA 359.

[13] *See, e.g.*, Merck & Co., Inc. v. Apotex Inc. (2013 FC 751) (On July 16, 2013, the Federal Court released a decision granting the largest award of damages for patent infringement in Canadian history. Although the award

then, the marketing of the generic product can almost completely erode the innovative company's market share. Provincial and private payer policies mandating the substitution of generics for brand-name products guarantee rapid market loss.

These various deficiencies frequently result in violations of the patent rights of pharma companies operating in Canada with attendant, and often irreparable, economic losses. There are indications, however, that the situation might change. We understand the unratified final text of the Comprehensive Economic Trade Agreement (CETA)[14] negotiated between Canada and the European Union contains a commitment to provide all litigants equivalent and effective rights of appeal. The Canadian government has yet to provide any clarity with respect to how it will implement this commitment, however.

Limitation of Listing of Valid Patents and Inequitable Listing Requirements

Patent owners continue to be prevented from listing their patents on the Patent Register established under the PM (NOC) Regulations if the patents do not meet certain, seemingly arbitrary timing requirements. These timing restrictions are not present in the U.S. under the Hatch-Waxman Act. The effect of this is to deny pharmaceutical innovators access to enforcement procedures in the context of early working for any patent not meeting these listing requirements.

Lack of Patent Term Restoration

Canada's IP regime currently provides no form of patent term restoration (PTR). Canada agreed to adopt some form of PTR in the context of the CETA, but no movement towards implementation has taken place. As more implementation details are released, the USTR should monitor to ensure that patent rights are adequately protected.

CHINA

Potential Negative Impact of Draft Service Inventions Regulations

China's State Intellectual Property Office (SIPO) continues to develop administrative service invention regulations with the intent to promote innovation. IPO commends SIPO's efforts to promote scientific advancement and technological innovation within China. Although we understand the policy that inventors should be appropriately incentivized, the current form of 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 IP assets their employees have been compensated to create.

The latest draft of the administrative service invention regulations, however, contained several improvements. In particular, we appreciate the removal "technical secrets" in Article 4, which could have put trade secrets at risk. Other references to trade secrets or know-how remain. These

quantum was widely reported, less reported was that the case dated back to 1993 when Apotex first served a Notice of Allegation in which it undertook not to infringe Merck's patent if it obtained a Notice of Compliance (NOC). This judgment has also been appealed, further delaying any eventual damages award.).

[14] *See Comprehensive Economic Trade Agreement*, EUROPEAN COMMISSION (Sept. 26, 2014), http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc_152806.pdf.

should be removed to prevent uncertainty of their treatment in the service invention context. Similarly, we are also encouraged to see the removal of the entitlement for inventors to know the "economic benefit" of their service inventions. Such a requirement could have required companies to reveal confidential information to ex-employees hired by competitors. Unfortunately, in a dispute between inventors and their employers, entities still bear the burden of showing the "economic benefit" received. This requirement could lead to a strategy in which competitors purposely hire inventors and encourage them to dispute their remunerations to learn strategic insights.

The current draft could improve in several areas. For example, although 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. A finding that prior policies or agreements are invalid would result in the draft regulation default rules retroactively applying, which for many commercial entities might be quite onerous. 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 respective industries. No single set of financial incentives works well for everyone, nor should it be applied to all inventors.

Another practical challenge involves the requirement that to abandon a patent, the inventor must be notified,[15] which makes 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 ex-employees. Given that it is not unusual for ex-employee inventors to be hired by competitors, this could provide unusually strategic insight for their new employers.

Concerns also 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. Although 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 the Anti-Unfair Competition, Contract, and Labor Law, among others. China is debating whether to implement a separate unified trade secret law with more expansive protections. It has recently decided to conduct a legislative study on revising its

[15] Draft Service Invention Regulations, Art. 15; *See* http://images.chinalaw.gov.cn/www/201504/20150402081956918.doc

law.[16] 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 a serious and escalating concern for IPO members.

China appears to agree generally that stronger enforcement against trade secret misappropriation 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, the 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 positive trend or if it is an isolated decision.

We are pleased that in August, 2014, the Standing Committee of the 12th National People's Congress issued a decision establishing 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 has also named trade secret protection as one of its top priorities.

Progress also was made through U.S. bilateral discussions with China throughout 2015, as apparent at the U.S.-China Joint Commission on Commerce and Trade (JCCT).[17] China clarified its intention to issue model or guiding court cases for trade secrets, and to clarify rules on preliminary injunctions, evidence preservation orders, and damages.

Although 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 significant and possibly irreversible injury has taken place.

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.

The requirements for many businesses to submit technical and functional features of their products, as well as confidential test data, as a condition for access to the Chinese market present

[16] U.S.-China Joint Fact Sheet on 25th Joint Commission on Commerce and Trade, COMMERCE.GOV (Dec. 29 2014), http://www.commerce.gov/news/fact-sheets/2014/12/29/us-china-joint-fact-sheet-25th-joint-commission-commerce-and-trade.

[17] U.S. Fact Sheet: 26th U.S.-China Joint Commission on Commerce and Trade, COMMERCE.GOV (Nov. 23 2015), https://www.commerce.gov/news/fact-sheets/2015/11/us-fact-sheet-26th-us-china-joint-commission-commerce-and-trade.

further challenges for protecting confidential business information. These requirements are particularly harmful because receiving agencies have been generally willing to provide such confidential information to the public on request. In some cases, the information provided is reviewed by expert panels that include employees of local businesses and institutions that might benefit financially from having access to another company's trade secrets. Although at the 2014 JCCT China promised to hold government officials with access to confidential business information more accountable and otherwise shield the details from public disclosure, the impact of any changes has yet to be felt.[18] We are hopeful that as China studies its existing trade secret protections a plan to address these concerns will emerge.

Challenges Created by Recent Amendments to Chinese Trademark Law

Several amendments to China's trademark law recently became effective. The new legislation makes significant improvements to the law, such as the addition of a good-faith requirement when applying for new marks. Although 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. As the brand owner waits, a bad faith registrant can build up years of use, improving its chances to use the mark permanently under current Chinese jurisprudence. Bad faith registrants may even be able to take enforcement action against a brand owner's own use of its trademark.

IP Abuse Rules Impose Restraints on IP Enforcement

China's State Administration of Industry and Commerce finalized its Regulations on the Prohibition of Abuse of Intellectual Property Rights to Eliminate and Restrict Competition (IP Abuse Rules).[19] The Regulations have the potential to significantly damage the incentive to innovate. The draft IP Abuse Rules explicitly extend the "essential facilities" doctrine to IP rights, prohibiting a business operator in a "dominant market position" from refusing to license its IP.[20] The right to exclude is an essential 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 in a way that results in a dominant position. 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.[21] For example, a business operator in a dominant market position would be required to license patents

[18] U.S.-China Joint Fact Sheet on 25th Joint Commission on Commerce and Trade, *supra* note 15.
[19] *See* http://www.saic.gov.cn/zwgk/zyfb/zjl/fld/201504/t20150413_155103.html.
[20] IP Abuse Rules, Art. 7.
[21] IP Abuse Rules, Art. 13.

for implementing the standard on fair, reasonable, and non-discriminatory terms, 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.

In addition, China continues to develop indigenous innovation 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 might 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. It is clear, however, that a relationship between indigenous innovation and government procurement still exists today. There were several examples just last year, such as the catalogue of indigenous innovation products established by the Economic and Information Technology Bureau of Yingzou District[22] or the budget notice from Nanxian County, Hunan stipulating the same preferences.[23]

Along similar lines, there are indications that China might be establishing sovereign patent funds to provide an advantage to Chinese companies in the market.

Patent Enforcement and the Amendment to Chinese Patent Law

Language in China's draft revision to its Patent Law[24] raises concerns that in some instances valid patent rights might not be enforced. The draft revision would require those who apply for and exercise patent rights to act in good faith and not use patents to "damage public interests or unreasonably exclude or restrict competition."[25] Little detail is given to explain this principle or guide the courts and administrative agencies that will ultimately be tasked with enforcing it. Every patent, on some level, is a time-limited government-sanctioned restriction on competition. Under the proposed revision, there is too much risk and uncertainty that patents might be deemed improper and thus invalidated. Although well intentioned, such a position would create significant uncertainty and impede the legal exploitation of patents. This also raises questions regarding consistency with TRIPS Article 30, which provides that the exceptions to the exclusive rights conferred by a patent should not unreasonably conflict with a normal exploitation of the patent and unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

[22] *See* http://www.yzjx.gov.cn/html/gonggaotongzhi/20150209/2136 html
[23] *See* http://www nxczw.gov.cn/tongzhigonggao/2015/0127/309 html
[24] Draft Revision of the Patent Law of the People's Republic of China (Dec. 2, 2015), http://images.chinalaw.gov.cn/www/201512/20151202075620423.doc
[25] *Id.* Art.14.

Moreover, the high and growing volume of utility models in China,[26] 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 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.

The draft amendment continues to include significant focus on administrative enforcement of patent rights to provide lower cost remedies for small businesses and individual rights holders. The draft amendment would give hundreds of inexperienced local and provincial IP offices new powers to grant injunctive relief and to impose compensatory damages, fines, and penalties for patent infringement -- and even to enhance damages if the infringement is deemed intentional. One of the effects of the draft amendment will be to allow primarily Chinese domestic entities or individuals to assert their rights before local and administrative officials, who might 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. Implementing the proposed draft would fragment enforcement, interpretations, and procedures regarding patent laws and the related rights, making enforcement in China less predictable and extremely difficult to navigate.

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 IP to address, among other issues, the problem of insufficiently examined rights in more experienced, technically trained and competent, and less political courts.

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. Concerns remain, however, 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

[26] *See* 2013 SIPO Annual Report at 86 (June 6, 2014), http://english.sipo.gov.cn/laws/annualreports/2013/201406/P020140609548419315217.pdf. In 2013, utility model applications grew by over 20%).

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 plans to improve drug safety and severely crack down on the production and sale of counterfeit medicines. The production, distribution, and sale of counterfeit medicines and unregulated active pharmaceutical ingredients, however, 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 six-year period of protection against unfair commercial use of 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 appoint a patent agency to represent them before SIPO.[27] 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. Yet this is not possible under China's current Patent Law.

Although 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, can disqualify the applicant from receiving incentives in other countries, and might not even be allowed based on contractual obligations. U.S. companies should be allowed to file patent applications in their own names, as long as subsequent prosecution is facilitated by an in-house or outside 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.[28] A number of applications for such licenses are pending. Although 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.[29] This preference towards accessing technology outside of market channels, often in a forced manner, damages the incentive to invest. It can also slow down or halt technology dissemination.

[27] Patent Law of the People's Republic of China, SIPO, Art. 19, http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244 html.
[28] Executive Decree No. 118, http://www.wipo.int/edocs/lexdocs/laws/en/ec/ec035en.pdf.
[29] TRIPS Council, *Contribution of Intellectual Property to Facilitating the Transfer of Environmentally Rational Technology*,IP/C/W/585 (Feb. 27, 2013)

INDIA

Draft National IPR Policy

Overall, India's draft IPR Policy provides a valuable roadmap for realizing the potential of India's creativity and recognizes the central role IP plays. The draft Policy includes many positive recommendations, including 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 patent and trademark examination operations.

We are concerned, however, with references in the draft Policy that appear to indicate a relaxation of IP protection. Throughout the draft Policy, there are calls for flexibility to "judicially … keep IP laws updated" as well as for studies on topics such as exceptions, 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. Although there might be some benefits, this might 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 criteria for patentability beyond the TRIPS requirements. 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 unduly 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."[30] This section creates the "Technology Acquisition and Development Fund" (TADF) to help in situations when a patent holder is unwilling to license, either at all or "at reasonable rates," or when an invention is not being "worked" within India.[31] TADF is empowered to request compulsory licensing from the Government of India.[32] The recent draft National IPR Policy references the TADF, recommending its efforts be promoted.[33]

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[30] National Manufacturing Policy, GOVERNMENT OF INDIA MINISTRY OF COMMERCE & INDUSTRY DEPARTMENT OF INDUSTRIAL POLICY & PROMOTION (2011), http://dipp nic.in/English/policies/National_Manufacturing_Policy_25October2011.pdf.
[31] *Id*. at ¶ 4.4.1.
[32] *Id*. at ¶¶ 4.2, 4.4.3
[33] National IPR Policy (draft) at ¶ 5.4.1, IPR THINK TANK (Dec. 24, 2014), http://dipp nic.in/English/Schemes/Intellectual_Property_Rights/IPR_Policy_24December2014.pdf.

Similarly, India's National Competition Policy requires IP owners to grant access to "essential facilities" on "agreed and nondiscriminatory terms" without reservation.[34] The concept of essential facilities appears to cover a broad range of technologies, including, at least, "electricity, communications, gas pipelines, railway tracks, ports, [and] IT equipment."[35] The unconditional application of the essential facilities doctrine to such a broad technology landscape substantially decreases the value of the underlying IP and can undermine incentives for innovation and market-based technology dissemination.

Although other motives might be at play, the impetus to use compulsory licensing appears directly tied to industrial policy. Even though not adopted, a 2011 discussion paper produced by the Ministry of Commerce provides some insights. It explains that "compulsory licensing has a strong and persistent positive effect on domestic invention.[36] The objective of the paper was "to develop a predicable environment" for compulsory licensing to be used.[37]

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 patent grant.[38] This appears to include situations when patent holders import the related technology into the country, but do not locally manufacture it. This is inconsistent 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 are *imported or locally produced*."[39] Among those rights is the ability to exclude others from making, using, or selling their invention.[40]

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.[41] In 2009, a public notice was issued indicating this requirement would now be enforced.

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[34] National Competition Policy, 2011, § 5.1(vi), http://www.mca.gov.in/Ministry/pdf/Revised_Draft_National_Competition_Policy_2011_17nov2011.pdf
[35] *Id*.
[36] Discussion Paper on Compulsory Licensing, ¶ 70, DIPP (2011), http://dipp nic.in/English/Discuss_paper/CL_DraftDiscussion_02September2011.doc.
[37] *Id*. at ¶ 2.
[38] The Patents Act, 1970 § 84(1)(c), INTELLECTUAL PROPERTY INDIA (1970), http://ipindia nic.in/ipr/patent/eVersion_ActRules/sections/ps84 html.
[39] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Art. 27.1 (emphasis added)
[40] TRIPS. Art. 28(1).
[41] The Patents Act, *supra* n. 38 at § 146, http://ipindia.nic.in/ipr/patent/eVersion_ActRules/sections/ps146.html.

Statements of Working, (Form 27),[42] must be provided annually.[43] Failure to provide the requested information is punishable by fine or imprisonment.[44]

The recent push to enforce the submission of Statements of Working is intended 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 might 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 the government and public.

This suggests that India 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 at the Supreme Court of India. Most troubling about the decision was the interpretation that at least in some circumstances, the working requirement might not be fully satisfied through importation.[45] 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 civil and criminal statutory protection for trade secrets. Contractual obligations provide the primary vehicle for protecting such IP. Although other means of protection may exist, such as suing under the tort of "breach of confidence," [46] such means have 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 are the same industries which 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 the Indian government indicate that the country might value such an approach. We are encouraged by the commitment at the recent U.S. and India Trade Policy Forum to deepen

[42] Statement Regarding the Working of the Patented Invention on Commercial Scale in India, http://patinfo.nic.in/pdf/form_27.pdf.
[43] The Patents Rules, § 131, INTELLECTUAL PROPERTY INDIA (2003), http://ipindia nic.in/ipr/patent/eVersion_ActRules/rules/pr131.html.
[44] The Patents Act, *supra* n. 41.
[45] Intellectual Property Appellate Board, Bayer Corporation v. Union of India Through the Secretary & Ors., Order No. 45 of 2013, issued Mar. 4, 2013, ¶ 52, http://www.ipab.tn.nic.in/045-2013.htm; *see also* Bayer v. Union of India, Writ Petition No. 1323 of 2013 at 48.
[46] Zafar Mahfooz Normani & Faizanur Rahman, *Intellection of Trade Secrets and Innovation Laws in India*, 16 J. INTELL. PROP. RTS. 346 (July, 2011), http://nopr.niscair.res.in/bitstream/123456789/12449/1/IJPR%2016%284%29%20341-350.pdf.

cooperation on trade secrets.[47] There is also a recommendation included in India's draft National IPR Policy to pursue legislation on trade secrets to "fill in gaps" in the IP regime.[48] Earlier recognition of the need to improve trade secret protection can be found in the 2014 draft National Innovation Act[49] and 2012 draft National IPR Strategy.[50] There is also a growing body of academic literature originating within India that agrees such initiative is critical.[51] The 2012 draft National IPR Strategy made the point when it explained that a "predictable and recognizable trade secret regime will improve investor confidence." [52] 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 a critical step.

Disclosure of Foreign Filings

Section 8 of India's Patent Act requires disclosure and regular updates on foreign applications that are "the same or substantially the same invention." [53] The original purpose of the requirement was to ensure high quality patents were issued by India, in light of patent examinations around the world. Although this might 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.[54] 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.[55]

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.[56] The requirements

[47] United States and India Joint Statement on the Trade Policy Forum, (Oct., 2015), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/october/united-states-and-india-joint.
[48] National IPR Policy, *supra* n. 33 at ¶ 5.4.1.
[49] The National Innovation Act of 2008 (Draft), Chap. VI, http://www.dst.gov.in/draftinnovationlaw.pdf.
[50] Invitation of Views on the draft National IPR Strategy, ¶¶ 50-52, http://dipp nic.in/English/Discuss_paper/draftNational_IPR_Strategy_26Sep2012.pdf.
[51] *See, e.g.*, Hariani, *The Draft National Innovation Act*, 3 India L.J. __, http://indialawjournal.com/volume3/issue_1/article_by_anirudh.html; Kumar et al., *Legal Protection of Trade Secrets*, 11 J. Intell. Prop. Rts. 379 (Nov., 2006),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*, 16 J. Intell. Prop. Rts. 341 (July, 2011), 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*, 11 J. Intell. Prop. Rts. 192 (May, 2006), 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*, Prac. Law. 44, (June, 2011), http://www.supremecourtcases.com/index2.php?option=com_content&itemid=1&do_pdf=1&id=24329).
[52] 2012 Draft National IPR Strategy, ¶ 52; Invitation of Views on the Draft National IPR Strategy, *supra* n. 50, at ¶ 52.
[53] India Patent Act, 1970 at § 8(1).
[54] Patent Cooperation Treaty, Art. 42, http://www.wipo.int/pct/en/texts/articles/a42 htm.
[55] Patent Act at §§ 25(1)(h), 25(2)(h), and 64(1)(m) respectively.
[56] *See* F. Hoffmann-La Roche Ltd. v. Cipla Ltd. FAO (OS) 188/2008 Decision (Apr. 24, 2009).

set forth by Section 8 are antiquated and create unnecessary uncertainty and expense for patent applicants.

India's Stance Within Multilateral Fora

India regularly intervenes in committee meetings at WIPO to stop or slow initiatives that could result in practical work programs, analysis, or recommendations that could enhance the functioning of patent systems. For instance, India has opposed work on patent quality, though it is a topic of interest for many emerging countries as their offices struggle to deliver high-quality IP assets amidst rising volumes of applications and backlogs. India also opposes information sharing or analysis about work-sharing programs among IP offices, incorrectly characterizing such programs as sovereignty-threatening. Given the rising number of patent filings in India, including by domestic innovators, it is not clear why India opposes WIPO work to improve and fine-tune patent systems. On the contrary, India's Draft National IPR Policy contains references to improving the operation of its own patent system, including a dedicated section on IP Administration and Management.

In the TRIPS Council, India regularly questions the utility of IP systems. At a recent TRIPS Council, India stated there is "no evidence to prove that strong IP could deliver on development or innovation."[57] In the same forum, India has also insisted on several occasions that "there is not direct linkage between IP and innovation."[58] And at the recent negotiations on the Paris Outcome as part of the UN Framework Convention on Climate Change (UNFCCC), India continually pushed for a variety of measures that could have resulted in weakening IP rights for clean technology solutions needed to accomplish the convention's goals.

India's activities in these fora might be especially influential, considering a 2013 collaboration agreement by IP offices in Brazil, Russia, India, China, and South America (BRICS countries).[59] 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 IP within India and beyond.

MEXICO

Challenges to Enforcement of Patent and Trademark Rights

Although preliminary injunctions that result in the seizure of infringing goods are possible in patent and trademark infringement proceedings in Mexico, as a practical matter this tool is often ineffective. After seizure, defendants can post a bond that causes the Mexican Institute of Industrial Property (IMPI) to release the goods in question without any additional requirements or obligations. This state of affairs makes it easy to lift injunctions and continue the infringing behavior. Another challenge in patent proceedings is that IMPI uses its examiners to act as expert witnesses, which leads to conflicts of interest.

[57] TRIPS Council Meeting Minutes, Feb. 25-26, 2014, IP/C/M/75/Add.1, ¶ 398-399; *see also id*.at ¶ 399.
[58] TRIPS Council Meeting Minutes, June, 11-12, 2014, IP/C/M/76/Add.1, ¶ 347; *see also id.* at ¶ 423
[59] BRICS Intellectual Property Offices Cooperation Roadmap, Magaliesburg, BRICS (May, 2013), http://www.ip-watch.org/weblog/wp-content/uploads/2013/11/SIGNED-BRICS-IP-OFFICES-COOPERATION-ROADMAP.pdf .

Recovery of damages for trademark and patent infringement is also challenging in Mexico. Damages cannot be claimed until after proceedings are final. In patent cases, it can take more than ten years to exhaust the four potential stages of litigation in the administrative arena, and remands from higher to lower courts are common.

IP owners also face challenges enforcing their patent and trademark rights at the border. Authorities act inconsistently regarding stopping shipments in transit at the border that contain infringing goods. Some Officers will stop and seize the shipments, but others will not because Mexico is not their final destination.

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' value. 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, Bridgestone sent a "reservation of rights" letter to the users of RIVERSTONE and later filed an opposition motion for its mark in Panama. Although 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 and awarded over $5 million in damages to the owners of RIVERSTONE.[60] In essence, the Supreme Court's decision penalized a brand owner for using a mechanism designed to challenge potential trademark infringement. The policy undermines the intent of TRIPS[61] and the U.S.-Panama Trade Promotion Agreement[62] designed to protect brand owners.

[60] Muresa Intertrade, S.A.,Tire Group of Factories Ltd., Inc. v. Bridgestone Corp., and Bridgestone Licensing Servs., Inc. (Supr. Ct. Panama May, 2014).
[61] TRIPS, Art. 15.5.
[62] U.S.-Panama Trade Promotion Agreement, Art. 15.2(6)(c), 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 published a draft National Policy on Intellectual Property,[63] which we understand is still under review. 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 IP system.

For example, the draft appears to encourage and broaden compulsory licensing and similar exceptions to the property rights of IP owners. Although the stated objectives of increasing access to technology and medicine are clearly important, the preference for accomplishing this by eroding IP 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 be recouped, making it harder and more expensive to finance the necessary research and development. Promoting a preference for IP exceptions might 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. PUSH TO WEAKEN IP RIGHTS WITHIN MULTILATERAL FORA

In an increasingly growing number of international fora, calls to weaken the global IP framework protecting innovation have been a regular theme. IP rights have been unfairly portrayed by some as a barrier to technology transfer, either by limiting the availability of the technology altogether or making it more expensive to secure.

The empirical evidence shows that IP rights are not a barrier to technology availability.[64] To the contrary, strong and clear IP protection facilitates technology transfer and sharing. Thus, it is regrettable and concerning that a variety of proposals to weaken IP rights have been raised, including: compulsory or concessional licensing; the elimination of IP rights for certain technologies; technology buyouts; and non-assertion pledges for patents on technology used by developing countries. There have also been efforts to implement these types of measures at the national level.

For example, at WIPO, within the Standing Committee on Patents, several countries continue to pursue a work program that would promote exceptions and limitations to patents. The continued effort is based, at least in part, on a 2010 proposal.[65] Designed in three phases, this proposal involves a detailed exchange of experiences on exceptions and limitations to IP rights, a determination of the most effective exceptions and limitations, and the development of an

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[63] Draft National Policy on Intellectual Property of South Africa (Sept. 4, 2013), http://ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf.

[64] Kristina M. Lybecker & Sebastian Lohse, *Innovation and Diffusion of Green Technologies: The Role of Intellectual Property and Other Enabling Factors*, WIPO GLOBAL CHALLENGES REPORT (2015), https://www3.wipo.int/wipogreen/docs/en/globalchallengesreport_lybecker_lohse.pdf).

[65] Standing Committee on the Law of Patents, *supra* n. 11.

"exceptions and limitations manual." Similar discussions are ongoing as part of WIPO's Committee on Development as well.

III. 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 which is characterized by lengthy development cycles and significant capital expenditures. Strong IP protection for these investments 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 innovators face when developing these critical goods.

Limits and Restrictions on Patentability

Through additional patentability criteria, like India's 3(d) or Canada's heighted utility requirement known as the "promise doctrine," several countries are making it increasingly difficult to obtain patent protection for pharmaceutical innovations. In Brazil, a secondary patent examination is conducted by the health regulatory agency, sometimes applying patentability requirements that conflict with Brazil's patent authority. In other jurisdictions, such as Argentina[66] and the Andean Community,[67] patent protection for several types of innovation has been foreclosed.

Other jurisdictions might be following suit. In Australia, for example, a large number of recent reviews of the Australian IP system appear to focus on pharmaceuticals. These include a review of compulsory licensing and Crown-Use provisions,[68] a review of patentable subject matter (aimed primarily at the issue of the patentability of genetic and biological materials),[69] a review of the innovation patent system,[70] 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

[66] Guidelines for Patentability Examination of Patent Applications on Chemical and Pharmaceutical Inventions, May 2, 2012 (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).
[67] Decision 486, Art. 21; Decision 344, Art. 16. Members of the Andean Community include Bolivia, Colombia, Ecuador and Peru.(Second use patents are not permitted by Andean law.).
[68] Balancing Access to Technology and Innovation. Joint Media Release. No. 059. (June 29, 2012), http://images.chinalaw.gov.cn/www/201504/20150402081956918.doc).
[69] *Review of Patentable Subject Matter*, AUSTRALIAN GOVERNMENT ADVISORY COUNCIL ON INTELLECTUAL PROPERTY, http://www.acip.gov.au/reviews/all-reviews/review-patentable-subject-matter/.
[70] Review of the Innovation Patent System, AUSTRALIAN GOVERNMENT ADVISORY COUNCIL ON INTELLECTUAL PROPERTY, http://www.acip.gov.au/reviews/all-reviews/review-innovation-patent-system/.

appropriate agencies and demonstrate the safety and efficacy of their proposed product. Companies spend tremendous resources to compile this information. To facilitate this process, TRIPS requires WTO members to protect the supplied confidential details.[71] Yet, this protection varies significantly between countries.

Several countries, including Argentina, Brazil,[72] and Mexico,[73] do not currently provide adequate regulatory protection for pharmaceutical information. Other countries, like China and Ecuador, have included protection for such 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.

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We again thank the USTR for permitting IPO to provide comments and would welcome any further dialogue or opportunity to provide additional information to assist your efforts in developing the Special 301 Report.

Sincerely,

Mark Laureosch
Executive Director

[71] TRIPS, Art, 39.3.
[72] 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 for pharmaceuticals.
[73] Despite Mexico's membership in both NAFTA and TRIPS, Mexico still lacks domestic legislation. In addition, the Federal Commission Against Sanitary Risks (COFEPRIS) refuses to protect biologics, orphans, new formulations and indications.