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Milbank Tweed

Executive Director
Mark W. Lauroesch

8 February 2018

Sue Chang
Director for Innovation and Intellectual Property
Office of the U.S. Trade Representative
600 17th St., NW
Washington, DC 20508

Re: USTR 2018 Special 301 Review, Request for Public Comment (Docket No. USTR-2017-0024)

Dear Ms. Chang:

Intellectual Property Owners Association (IPO) appreciates the opportunity to provide comments regarding the U.S. Trade Representative's 2018 Special 301 Review. IPO's comments highlight concerns with key issues surrounding the effective protection of intellectual property (IP) rights globally.

IPO is an international trade association representing companies and individuals in all industries and fields of technology who own, or are interested in, IP rights. IPO's membership includes about 200 companies and more than 12,000 individuals who are involved in the association either through their companies or as inventor, author, law firm, or attorney members. IPO membership spans 50 countries. IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; and disseminating information to the public on the importance of IP rights.

IPO's comments address two main areas: country-specific concerns, in alphabetical order by country; and concerns about the push to weaken IP rights within multilateral fora.

ARGENTINA

I. COUNTRY-SPECIFIC CONCERNS

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

The patent examination backlog in Argentina is challenging for innovators to manage. In general, the earliest that substantive examination begins is seven years after examination fees are paid. For most applications, examination takes place nearly a decade after the filing date. Such delays in securing patent rights make it difficult for innovators to attract investors or support business plans.

We welcome the recent efforts by Argentina's Patent Office to reduce the backlog, including the enactment of Resolution 56/2016[1] and subsequent entry into a Patent Prosecution Highway (PPH) pilot program that started in 2017 and extends to 2020.[2] Some patents have already been granted under the pilot program, which is a positive step. However, we are concerned as this program explicitly excluded patents in several industries.[3] Unfortunately, a significant backlog remains. Argentina provides neither provisional nor supplemental protection to ameliorate 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.[4] This resolution introduced more restrictive patentability criteria for chemical and pharmaceutical inventions.[5] The criteria were applicable to both new and pending patent applications, which altered the legal framework in force when those patent applications were filed. Pending applications filed prior to the resolution are being rejected based on these new restrictive criteria. When these changes are combined with the substantial backlog, significant uncertainty results for innovators in the chemical and pharmaceutical areas.

Proposed Amendment to Seeds Law Could Reduce Rights for Agricultural Innovations

Inventors in the agricultural sector might soon face a new and disastrous paradigm with respect to their IP rights if a pending amendment to Argentina's Seed Law passes.[6] The bill introduces new limitations on the use of patents related to agricultural biotechnology. For example, it would limit royalty collections to periods much shorter than a patent's term. The draft also excludes IP rights enforcement against certain users altogether, without compensating IP owners for the use. These, and other proposed changes, would effectively deny patent protection for these critical inventions.

AUSTRALIA

Australia's Heightened Utility and Onerous Best Method Requirements for Patents

A number of court decisions have highlighted two areas for which Australian law is out of line with the Australia-U.S. Free Trade Agreement[7] and with international practice. As a consequence, Australia fails to offer certain patent protection that it agreed to provide, which harms U.S. innovators seeking patent protection in Australia.

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[1] Resolución 56/2016, Instituto Nacional de la Propiedad Industrial
[2] https://www.uspto.gov/patents-getting-started/international-protection/patent-prosecution-highway/patent-prosecution-12
[3] Resolución 125/2016, Instituto Nacional de la Propiedad Industrial
[4] *Apruébanse las pautas para el examen de Patentabilidad de las solicitudes de Patentes sobre Invenciones Químico-Farmacéuticas* (May 2012), http://www.wipo.int/edocs/lexdocs/laws/es/ar/ar109es.pdf.
[5] 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.
[6] Ley De Semillas y Creaciones Fitogeneticas, Law No. 20.247; Bill 0030-PE.2016, Cámara de Diputados, http://www4.hcdn.gob.ar/dependencias/dsecretaria/Periodo2016/PDF2016/TP2016/0030-PE-2016.pdf
[7] Australia-U.S. Free Trade Agreement, 118 Stat. 919 (May 2004). https://ustr.gov/sites/default/files/uploads/agreements/fta/australia/asset upload file148 5168.pdf.

Australia requires a patent to deliver all its "promised benefits," despite the uncertainty of most types of innovation. If a patentee describes two potential advantages of a new invention and only one turns out to be achievable, that resulting patent will be found invalid.[8] Besides serving as inequitable ground for denying a patent, the outcome is inconsistent with the Free Trade Agreement, which requires Australia to protect inventions with "a specific, substantial, and credible utility."[9]

Another unusual and onerous feature of Australian law is its "best method" requirement. An independent ground for invalidity, patent applicants must describe the best method known to them at the time of the *complete application.*[10] This complicates matters for applicants who first file for patent protection in another country. During the time between that first foreign filing and the subsequent filing in Australia, innovation continues, and the best method known to the applicant might evolve. However, the inventor is unable to update the Australian application to reflect those changes. Such a requirement is fundamentally impractical, inconsistent with international practice, and harms U.S. inventors seeking to protect their inventions in Australia.

Market-Size Damages

Australia's Department of Health has implemented a policy in which it seeks damages from biopharmaceutical innovators that pursue unsuccessful patent claims. Those damages are designed to compensate Australia's pharmaceutical reimbursement scheme (PBS) for any higher price paid for a patented medicine during the period of a provisional enforcement measure. The PBS imposes automatic price cuts on medicines as soon as competing versions enter the market, but the policy provides no corresponding mechanism to compensate innovators for losses if an infringing product is launched prematurely.

This "market-size damages" policy is problematic. It unfairly tips the scales in commercial patent disputes by encouraging competitors to launch at risk — and discouraging innovators from enforcing their patents. It creates an inappropriate conflict of interest by permitting the same government that examined and granted a patent to seek damages if that patent is later ruled invalid or not infringed. And it exposes innovators to additional, unquantifiable, and significant compensation claims that were not agreed at the time provisional enforcement measures were granted.

Biopharmaceutical innovators must be able to rely on and enforce patents issued by competent government authorities. Laws or policies that allow governments or other non-parties to a patent dispute to collect market-size damages undermine legal certainty, predictability, and the incentives patents provide for investment in new treatments and cures. They also appear to be inconsistent with the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) intellectual property rules, including with respect to provisional measures and technology discrimination. USTR and other federal agencies should prioritize actions to address and resolve this challenge in Australia.

[8] *Streetworx Pty. Ltd. v. Artcraft Urban Group Pty. Ltd.*, FCA 1366 (2014), *aff'd, Ronneby Road Pty. Ltd. v. ESCO Corp.*, FCA 588 (2016).
[9] Australia-U.S. Free Trade Agreement, Art. 17.9.13.
[10] *Les Laboratoires Servier v. Apotex Pty. Ltd.*, FCAFC 27 (2016).

Studies Aimed at Restricting Patentability of Pharmaceuticals

A large number of reviews of the Australian IP system appear to focus on weakening IP protections for pharmaceuticals. These include a review of compulsory licensing and "Crown- Use" provisions,[11] a review of patentable subject matter (aimed primarily at the issue of the patentability of genetic and biological materials),[12] a review of the innovation patent system,[13] and a root-and-branch review of Australia's patent system as it relates to pharmaceutical products.
In 2016, the Productivity Commission proposed reducing Patent Term Extensions.[14] Such proposals should be closely monitored, to ensure consistent incentives for the development of life saving pharmaceuticals and related products. We are encouraged that the "Crown-Use" provisions are currently being reviewed to clarify the purposes for which these may be invoked and to introduce transparency and accountability measures for their use,[15] while the Government has no plans to proceed with the recommendation on the Patent Term Extension in the form proposed by the Productivity Commission. The Government will discuss ways to improve the patent term extension system with the sector.[16]

BRAZIL

Growing Patent and Trademark Application Backlogs

In Brazil, both utility and design 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 time it takes to receive a patent might reduce the patent's term, which ultimately affects the damages a patent owner could recover from potential infringers. Such delays hurt both would-be patent owners and potential competitors, adding to market uncertainty and increasing the cost of innovation.

The situation for trademarks is similar. Notwithstanding increasing the number of examiners and improving the IT infrastructure several years ago, Brazil's IP Office (INPI) continues to have a large backlog of trademark applications. 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.

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[11] *Balancing Access to Technology and Innovation*, Joint Media Release, No. 059 (June 2012), http://ministers.treasury.gov.au/DisplayDocs.aspx?doc=pressreleases/2012/059.htm&pageID=003&min=djba&Year=&Doc%20Type=.
[12] Australian Government Advisory Council on Intellectual Property, *Review of Patentable Subject Matter* (2008), https://www.ipaustralia.gov.au/about-us/public-consultations/archive-of-ip-reviews/ip-reviews/issues-paper-patentablesubject-matter.
[13] Australian Government Advisory Council on Intellectual Property, *Review of the Innovation Patent System* (2015), https://www.ipaustralia.gov.au/sites/g/files/net856/f/final report.pdf.
[14] Productivity Commission, *Intellectual Property Arrangements*, Chapter 10.2 (2016), http://www.pc.gov.au/inquiries/completed/intellectual-property/report/intellectual-property.pdf.
[15] https://www.ipaustralia.gov.au/sites/g/files/net856/f/public_consultation_crown_use_of_patents_and_designs.pdf
[16] https://www.industry.gov.au/innovation/Intellectual-Property/Documents/Government-Response-to-PC-Inquiry-into-IP.pdf.

For patent applications, the Brazilian PTO has proposed to clear the backlog by automatically granting (without examination) non-pharma applications that are already pending. The measure would not encompass applications that were subject to pre-grant opposition proceedings. Also, applicants would be able to opt-out and remove part or all of their own applications from the automatic grant program. We are concerned that this will result in a vast number of low quality patents being granted, which will require large scale filing of opposition and invalidation proceedings, potentially with a timeframe as short as 90 days.

With respect to trademarks, accession to the Madrid Protocol would help improve the situation. Following Brazil signaling its intention to accede to the Madrid Protocol, the treaty has been sent to the country's Congress[17] and INPI has even begun to initiate some of the changes necessary to comply. It is anticipated, however, that beyond accession to the Protocol, several legislative changes and modifications to INPI's rules will be required.[18] Implementing the Protocol would be a significant step towards reducing the backlog and the costs associated with Brazilian trademark protection.

ANVISA's Prior Consent for Patent Examination

Although INPI is taking steps to improve its backlog, a seemingly dual patent examination system is an impediment to those efforts. Under Article 229-C of Brazil's Patent Law, the Health Surveillance Agency (ANVISA) must review all pharmaceutical patent applications. Although 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 Brazil's General Attorney's opinion that ANVISA's scope is limited to assessing the safety and therapeutic efficacy of products[19] and appellate court decisions that have also concluded that ANVISA's authority is limited to assessing public health risk.[20]

This additional scrutiny, which applies only to the pharmaceutical sector, raises significant questions of technology discrimination under 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.[21] In many cases, INPI modifies contract terms, encroaching on the freedom to contract. For example, INPI has limited the amount of royalties and restricted

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[18] As an illustrative example, in Brazil, a trademark can only be registered in a single class and multiclass registrations are required by the Protocol.
[19] Opinion 337/PGF/EA/2010 (Jan. 2011).
[20] "The ANVISA has no statutory authority to deny prior approval to a patent application based on the argument that is does not meet the novelty and nonobviousness requirements." (Court of Appeals for the 1st Federal Circuit, 6th Panel, Reporting Appellate Judge Hon. Jirair Meguerian, Appeal # 1001081-59.2015.4.01.3400 (Dec. 2016). Other appellate courts have also decided that ANVISA has no statutory authority to examine pharmaceutical applications for patentability requirements (*see* Court of Appeals for the 2nd Federal Circuit, 2nd Panel, Reporting Appellate Judge Hon. Simone Schreiber, Interlocutory Appeal # 0005084-51.2016.4.02.5101 (Sept. 2016)).
[21] 22 Law No. 9,279/96 of May 14, 1996, WIPO.

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 polices discourage critical partnerships.

INPI's Efforts to Weaken Pharmaceutical Patents

INPI continues to pursue lawsuits that seek to 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 raise further questions about Brazil's commitment to the protection of IP rights.

Design Protection

In the past year, responsibility for registering and examining design patent applications in Brazil has transitioned to a new team of examiners, who previously worked exclusively with trademark issues. The result has been very inconsistent examination, and some issues can only be solved with time consuming judicial review. Brazil should be encouraged to remedy this situation as soon as possible, perhaps through immediate supplemental training of the new examiners or by returning design examination to its former place with the patent department.

Potential Patent Reform Might Weaken U.S. IP Rights

Although a study on Brazilian patent reform released concurrently with a bill on the same topic co-sponsored by the study's coordinator[22] had certain positive proposals, for example investing in reducing backlogs, other suggestions could impair the value of IP. 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, 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 has pushed for creation of a WIPO manual on exceptions and limitations to guide developing countries in setting aside IP rights.[23] At a 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 to improve the existing toolset.

[22] *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.
[23] *See* Standing Committee on the Law of Patents, Fourteenth Session, SCP/14/7 (Jan. 2010), http://www.wipo.int/edocs/mdocs/patent policy/en/scp 14/scp 14 7.pdf.

Throughout various WIPO technical meetings discussing best practices for implementation, Brazil champions eroding the international IP regime and dismisses the facilitating role IP plays in encouraging innovation.

We have also seen Brazil work to stop WIPO initiatives that could improve the functioning of patent systems relating to efforts to study work sharing and patent quality.

CANADA

Patented Medicines Price Review Board (PMPRB) Regulations

We have concerns about the proposed *Regulations Amending the Patented Medicines Regulations*[24] (the "*Proposed Regulations*") that are slated to come into force on the 1st of January 2019. We are particularly concerned about the changes to the list of comparator countries under section 4(1)(f)(iii) of the *Proposed Regulations* that remove the United States and Switzerland — and add Australia, Belgium, Japan Netherlands, Norway, Republic of Korea and Spain. The removal of the U.S. and the absence of other countries such as Mexico, another one of Canada's largest trading partners, is concerning. Also troubling is the selection of countries for the list that in general have lower drug prices than Canada — without considering the impact this has on accessibility to new medicines in those jurisdictions. Furthermore, the U.S. and Switzerland are home to many of the world's pharmaceutical and biotechnology research companies, sending a message that Canada is interested only in the benefits of that research and not in paying for or incentivizing the research necessary to create the benefits. We are also concerned about the reduction in reporting requirements for patented generic medicines (approved by means of ANDS). Generic medicines are exempt from the continual reporting of cost-utility analysis information unless requested by the Board. At the same time, innovative manufacturers have expansive reporting requirements under the "merest slender thread"[25] basis for jurisdiction by the PMPRB. The *Proposed Regulations* are thus lop-sided and, in fact, are unnecessary when the market includes generic competition. The *Proposed Regulations* unnecessarily discourage innovation and increase reporting requirements for innovative patent holders.

Canada's Heightened Utility Requirement for Patents

For more than a decade, Canada had applied a heightened patent utility standard, known as the Promise Doctrine, which significantly weakened patent rights for the innovative pharmaceutical industry. This standard was inconsistent with Canada's international obligations and the practices of other countries, including the United States, and fundamentally at odds with the innovative life cycle for pharmaceuticals.

On June 30, 2017, in *AstraZeneca Canada Inc. v. Apotex Inc,*[26] the Supreme Court of Canada rejected Canada's "Promise Doctrine" in a unanimous decision. This decision, if implemented fully, represents a significant step forward toward restoring certainty and predictability to Canada's patent system. At the same time, how issues relating to the doctrine will be interpreted in the future remains uncertain. Canada should completely implement the decision *in AstraZeneca Canada, Inc. v. Apotex, Inc.*,

[24] http://www.gazette.gc.ca/rp-pr/p1/2017/2017-12-02/html/reg2-eng.html.
[25] *ICN Pharms. Inc. v. Canada* (Staff of the Patented Medicine Prices Review Board)(C.A.)(1997) 1 F.C. 32 (ICN).
[26] *AstraZeneca Canada Inc. v. Apotex Inc.*, (2017) SCC 36.

including abolition of Canada's promise doctrine, to restore greater certainty and predictability with respect to patentability requirements for Canadian patent applications.

Lack of Patent Term Restoration

Canada's IP regime currently provides no form of patent term restoration. Canada agreed to adopt some form of patent term restoration in the context of the CETA,[27] but the procedure has not yet been fully implemented. As more implementation details are released, its execution should be monitored to ensure that patent rights are adequately protected.

Weak Patent Enforcement

The recent *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*[28] (the "*Amended NOC Regulations*") include deficiencies that weaken Canadian patent enforcement, including insufficient time for final patent determinations in a single proceeding, increasing liability for damages under section 8, and a separate litigation track for some types of patents due to their ineligibility for listing on the patent register.

24-Month Stay Is Insufficient

In moving to a one-track system whereby section 6 proceedings will now all proceed by way of patent actions, we are concerned that the pre-existing 24-month stay will be insufficient to accommodate the more lengthy and complicated proceedings. To date there have been few procedural or Federal Court staffing changes addressed in the *Amended NOC Regulations* that would lead to increased confidence that the timeliness requirements may be met, which leaves the process at the discretion of Court. Given that the streamlining provisions are very limited, we are concerned that there might be unforeseen complications leading to increased litigation. In this context, innovative manufacturers must choose between the surrender of procedural rights and a meaningful injunction while the merits of the patent rights could be determined in an inadequate system. Canada should consider providing discretion for extension of the stay beyond the 24-month period where an action is not completed in time.

Section 8 Damages

We are also concerned about the potential expansion of liability for pharmaceutical innovators. As has been articulated as a concern in a 2016 IPO Resolution on section 8 damages, the *Amended NOC Regulations* explicitly consider all plaintiffs in the infringement action to be jointly and severally liable for losses suffered by the second person as opposed to only the "first person" under the previous regulations. However, there is no requirement for all second persons in NOC proceedings related to the same patented medicine to bring their section 8 claim together. Furthermore, there has been no amendment to allow the Court to consider multiple section 8 claims together and make findings related to multiple generic companies entering the market in the absence of the *Amended NOC Regulations*, as does happen in the real world. As a result, when innovators face multiple section 8 claims, there is a

[27] Article 20.27 of CETA refers to sui generis protection for pharmaceuticals, http://www.international.gc.ca/tradecommerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/20.aspx?lang=eng.
[28] http://www.gazette.gc.ca/rp-pr/p1/2017/2017-12-02/html/reg2-eng.html.

risk that the defendant (innovator) will be subject to a cumulative damage award based on what cannot possibly occur in the real world.[29] Secondly, the *Amended NOC Regulations* remove any limits to the period of a first person's liability under section 8 of the Regulations. Thus, Second Persons under the *Amended NOC Regulations* may be able to claim losses suffered beyond the date of any dismissal or discontinuance. Taken together, the section 8 related amendments create a risk of "windfall" damage awards. Such awards are contrary to the traditional compensatory function of damages.

Restrictive Certificate of Supplementary Protection (CSP) Eligibility Criteria

Although it is positive that there are now Regulations granting restoration of patent terms under certain circumstances, we are concerned that there remains a bar to certain types of innovation being CSP eligible, including, for example, process and formulation patents. Overly restrictive eligibility criteria, which limits otherwise worthy CSP patents, discourages innovation. Furthermore, the requirement that the innovator file their complete new drug submission in Canada within a year of filing in the U.S or Europe (or several other smaller markets) is overly restrictive, especially with respect to smaller companies who do not have the resources to file in multiple jurisdictions before they receive an indication of whether their submission is sufficient to receive approval.

Multiple and Conflicting Certificate of Supplementary Protection (CSP) Applications

We are concerned that there remains a significant risk under the current Regulations for unnecessary conflicts between innovative manufacturers and third parties because a third party may seek a CSP extension even if it is not the market authorization holder.

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 might 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.[30] 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.

[29] An example of this is seen in the cases of *Apotex v. Sanofi-Aventis*, 2014 FCA 68 and *Teva Canada v. Sanofi-Aventis*, 2014 FCA 67.
[30] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FCA 359.

A patentee might separately choose to proceed later by way of a patent infringement action. In doing so, a patentee might 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. However, these interlocutory injunction motions rarely succeed in Canada, even when there is compelling evidence of infringement.

Additionally, it often takes at least two years before an action for patent infringement is tried — and even longer to obtain damages.[31] By 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 pharmaceutical 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)[32] 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 certainty 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 per PM (NOC) Regulations when the patents do not meet certain, seemingly arbitrary timing requirements.[33] These timing restrictions are not present in the U.S. under the Hatch-Waxman Act. The effect is to deny pharmaceutical innovators access to enforcement procedures in the context of early working for any patent not meeting these listing requirements.

CHINA

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 those involving Anti-Unfair Competition, Contract, and Labor Law, among others. In these differing regimes, there have been several promising developments.

For example, China has amended its Anti-Unfair Competition Law.[34] The amendment indicates that China desires stronger enforcement against trade secret misappropriation. This continues a trend of expanded enforcement of trade secret rights in China.

[31] *See, e.g., Merck & Co. v. Apotex Inc*. (2013 FC 751) (On 16 July 2013, the Federal Court released a decision granting the largest award of damages for patent infringement in Canadian history. Although the award 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. This judgment has also been appealed, further delaying any eventual damages award.).
[32] *See* Comprehensive Economic Trade Agreement, European Commission (Sept. 2014), http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc 152806.pdf.
[33] Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, as amended, http://www.laws-lois.justice.gc.ca/PDF/SOR-93-133.pdf.
[34] *See* Anti-Unfair Competition Law, (Nov. 2017), http://www.npc.gov.cn/npc/xinwen/2017-11/04/content_2031432.htm.

China's civil procedure was amended to expand the availability of injunctive relief. Based on this change in law, the Shanghai No. 1 Intermediate Court was able to grant a preliminary injunction to a U.S. plaintiff in a trade secret misappropriation action involving 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. The Ministry of Commerce (MOFCOM) has named trade secret protection as one of its top priorities. We hope this decision and MOFCOM commitment is a positive trend. The U.S.-China Joint Commission on Commerce and Trade (JCCT) reflects progress on trade secret protection in China; China has stated its intention to issue model or guiding court cases for trade secrets, and to clarify rules on preliminary injunctions, evidence preservation orders, and damages.[35] We are also encouraged by the Asia-Pacific Economic Cooperation (APEC) endorsement of Best Practices for Trade Secret Protection and Enforcement, which the U.S. should encourage China to implement expediently.[36]

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

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[35] *U.S.-China Joint Fact Sheet for the 27th U.S.-China Joint Commission on Commerce and Trade* (Jan. 2017), https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2017/january/us-china-joint-fact-sheet-27th-us.
[36] *AMM Joint Statement*, APEC Peru (2016), http://mddb.apec.org/Documents/2016/MM/AMM/16_amm_jms.pdf; *Best Practices in Trade Secret Protection and Enforcement Against Misappropriation* (Nov. 2016), https://ustr.gov/sites/default/files/11202016-US-Best-Practices-Trade-Secrets.pdf.
[37] *See U.S.-China Joint Fact Sheet on 25th Joint Commission on Commerce and Trade* (Dec. 2014), https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2014/december/us-china-joint-fact-sheet-25th-us.

The Standing Committee of the 12th National People's Congress established IP Courts in Beijing, Shanghai, and Guangzhou with jurisdiction over first-instance civil and administrative cases of IP rights that are of a strong professional and technical nature. These courts have taken an increasing workload of IP cases, bringing improved expertise and uniformity to IP cases.

In China, our members face high burdens of proof, limited discovery, and minimal damages when seeking to enforce their trade secrets. Especially distressing, a trade secret owner has to wait until a significant and possibly irreversible injury has taken place before seeking relief. Our members also face regulatory requirements to submit confidential details as a condition of market access. Although we are encouraged with recent upgrades, such as the expanded availability of injunctive relief in China's amended civil procedure framework, more needs to be done to protect trade secrets.

Challenges Created by Chinese Trademark Law

Several amendments to China's trademark law became effective in 2014. These amendments improved the law, such as with the addition of a good-faith requirement when applying for new marks, yet brand owners still face substantial challenges. For example, failed oppositions result in immediate registration of challenged marks, forcing brand owners to initiate separate invalidation proceedings before the Trademark Review and Adjudication Board in the absence of a right to appeal. As the brand owner waits, a bad faith registrant can build up years of use, improving its chances to use the mark permanently under Chinese jurisprudence. Bad faith registrants might even be able to take enforcement action against a brand owner's use of its own trademark.

We also note that, in late 2015, the Chinese Trademark Office began invoking the Article 7 good faith requirement to invalidate abusive trademark registrations. Although this represents needed progress, China should be encouraged to continue its efforts to rein in trademark abuse.

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 within the last few years, such as the catalogue of indigenous innovation products established by the Economic and Information Technology Bureau of Yingzou District[38] or the budget notice from Nanxian County, Hunan stipulating the same preferences.[39] Therefore, although we are encouraged by China's renewed commitment at the 27th JCCT to build on the country's 2011 commitment, the U.S. should encourage implementation to move at a more rapid pace.[40]

[38] *See* Notice on the Organization to Report to the Yinzhou District Government on the Priority Procurement of Independent Innovative Products and High Quality Products Catalog in 2015, http://www.yzjx.gov.cn/html/gonggaotongzhi/20150209/2136html.
[39] *See* Notice of the Finance Bureau of Nanxian County on Clarifying the Relevant Matters Concerning the Preparation of Departmental Budget, http://www nxczw.gov.cn/tongzhigonggao/2015/0127/309 html.
[40] *U.S. and Chinese Delegations Conclude the 27th Session of the U.S.-China Joint Commission on Commerce and Trade* (Nov. 2016), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2016/november/us-and-chinese-

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

Discriminatory Technology Transfer Regulations

Regulations on Technology Import and Export Administration of the People's Republic of China[41] place onerous obligations on foreign licensors that are not applied to domestic licensors. These include Articles 24 and 25, which require that a company licensing a foreign technology indemnify a Chinese licensee against third parties who sue for infringement. Article 27 forbids the use of invention grantback clauses in which the licensee grants a license back to the licensor for improvements. These regulations do not allow parties to contractually agree to a different allocation of risk. No similar obligations are placed on domestic licensors. These difficulties are exacerbated by the ability of MOFCOM to require modification of license agreements before allowing payment of royalties. These matters should be negotiated by the contracting parties at arm's length, rather than dictated by regulation in a manner that deprives foreign companies of "national treatment."[42]

Patent Enforcement and the Amendment to Chinese Patent Law

Language in China's original revision to its Patent Law[43] 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."[44] Little detail has been 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 government-sanctioned restriction on competition. Under the proposed law, 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 the legitimate interests of third parties.

Moreover, the high and growing volume of utility models in China,[45] combined with the lack of examination with respect to patentability, creates substantial uncertainty for U.S. companies in the Chinese market. Although SIPO has 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.

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delegations.

[41] http://www.wipo.int/edocs/lexdocs/laws/en/cn/cn125en.pdf.

[42] *See, also*, starting at page 7 of the testimony of Mark Cohen to the U.S.-China Economic and Security Review Commission, at the Hearing on the Foreign Investment Climate in China: Present Challenges and Potential for Reform, on January 28, 2015, https://www.uscc.gov/sites/default/files/Mark%20Cohen_testimony.pdf..

[43] Draft Revision of the Patent Law of the People's Republic of China (Dec. 2015), http://www.chinalaw.gov.cn/article/cazjgg/201512/20151200479591.shtml.

[44] *Id.* at Art. 14.

[45] *See* 2016 SIPO Annual Report at 47 (June 2014), http://english.sipo.gov.cn/laws/annualreports/20163/ (in 2016, utility model applications grew by over 30%).

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 another might be 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. It 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 appropriate recourse to civil litigation for patent infringement to the exclusion of administrative enforcement remedies, which can be political, unprofessional, and discriminatory. This would help rights-holders who can demonstrate the value of their patents or other IP to address, among other issues, the problem of insufficiently examined rights in more experience, technical trained, competent, and less political courts.

One positive development is that the revisions to the Patent Examination Guidelines, implemented by SIPO on April 1, 2017,[46] include provisions in section 3.5 requiring patent examiners to consider post-filing data provided by patent applicants in support of their applications. We believe these changes will foster timely filing of applications for new drugs by allowing applicants to later submit additional information consistent with the drug development process. Further amendments would be useful to clarify that such data can be submitted in response to various kinds of rejections. We also note changes in sections 4.2 and 4.3.1 harmonizing Chinese patent practice with U.S. patent practice in allowing invalidity petitioners to submit new evidence of invalidity when patent owners seek to amend their claims during the invalidity proceeding.

We note that the Beijing IP Court has embarked upon an initiative to use guiding cases in deciding new IP cases, including establishing a database of guiding cases and a research organization for identifying guiding cases to add to the database. Such efforts reveal a desire on the part of China's judiciary to bring some transparency and predictability to enforcement of IP rights in China. We believe transparency and predictability in IP enforcement in China will be improved if the Beijing IP Court applies guiding cases in its review of new cases.

Much Needed Upgrades to China's Design Patent Protection Under Consideration

The proposed amendments to China's Patent Laws could provide a critical upgrade to the

[46] Decision on Amending the Patent Examination Guidelines (Feb. 2017), http://www.sipo.gov.cn/zwgg/201712/t20171220_1322147.html.

availability of design protection. Currently, China's patent law only offers design protection for an overall product, as opposed to protection for individual parts or portions of a larger design. Yet, much of today's innovation is incremental, building on existing ideas and products. So, although we might see relatively few new designs for an automobile or mobile phone, for example, novel features within those goods with respect to look and feel can have significant commercial relevance. Additionally, it might be necessary to separately protect individual parts of a product to safeguard against specific infringers in a supply chain or to preserve revenue for spare parts. The proposed amendment to Article 2 of China's Patent Law would enable protection for both the design of an overall product or part of a product.[47] The U.S. should encourage this necessary improvement, which would provide enhanced protections for American manufacturers.

China should also be encouraged to interpret the potentially amended law as allowing the use of broken lines in design patents. Broken lines enable the applicant to provide critical context for their design without overly limiting what is protected by a design patent. Broken lines also allow the applicant to focus on just the novel features of the design. In other countries, including the U.S., such lines allow the applicant to depict non-essential features to clarify the novel aspect being claimed. Although the proposed amendment would be an improvement over China's current design regime, its impact would be significantly limited without also allowing the use of this widely accepted convention. The U.S. should also encourage China to clarify that design patent applications could contain dotted lines.

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 has the potential to negatively affect the ability of 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.

We have previously noted improvements to the service invention regulations in the latest draft, released in April 2015.[48] Specifically, reference to "technical secrets" in Article 4, which could have put trade secrets at risk, has been removed. The entitlement for inventors to know the "economic benefit" of their service inventions, which could have required companies to reveal confidential information to ex-employee inventors hired by competitors, has also been removed. Other references to trade secrets or know-how remain, however, and the requirement for entities to show "economic benefit" in disputes with inventors also remains. This requirement could lead to a strategy in which competitors purposely hire inventors and encourage them to dispute their remunerations to learn strategic insights from their competitors.

The current draft could be improved in several additional 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

[47] Draft Revision of the Patent Law of the People's Republic of China, at Art. 2.
[48] Notice of the Office of Legislative Affairs of the State Council on Public Consultation on the Draft of Service Invention Regulation (Draft for review) (Apr. 2015), http://zqyj.chinalaw.gov.cn/readmore?listType=1&id=143.

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. For example, fixed remuneration arrangements, currently in wide use by entities and by far the simplest way to reward inventors, cannot satisfy the requirements in the latest draft of the regulations. Rather than fostering a collaborative and harmonious relationship that encourages 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 structure 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 or should be applied to all inventors.

Another practical challenge involves the requirement that, to abandon a patent, the inventor must be notified,[49] which makes it difficult, if not impossible, to dispose of private property. Beyond the practical concerns attending compliance with such a regulation, companies would be required to provide this information to former employees. Given that it is not unusual for former employee inventors to be hired by competitors, this could provide unique 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.

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 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

[49] *Id* at Art. 15.

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 own their patent assets must appoint a patent agency to represent them before SIPO.[50] Hiring a third party, however, can increase both expense 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.[51] 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. Ecuador has also supported discussions in international fora to reduce the patent term and expand flexibilities to weaken the related IP.[52] This preference 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

National IPR Policy

Overall India's IPR Policy (Policy) unveiled in May 2016 provides a valuable roadmap for

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

realizing the potential of India's creativity and recognizes the central role IP plays in this regard.[53] The Policy lays down seven objectives with action points for each objective to stimulate a dynamic, vibrant, and balanced IP rights system in India. Among other positive recommendations, we are encouraged by the Policy's recommendation to further study the protection of trade secrets.[54] As discussed below, improving India's trade secret regime is critical to ensuring a level playing field for non-Indian innovators.

Although much of the Policy is still being implemented, some recommendations should be closely monitored. For example, item 2.16 in the Policy proposes statutory incentives, like tax benefits linked to IP creation, for the entire value chain from IP creation to commercialization. Although incentivizing the pursuit of IP protection and its use is a laudable objective, caution should be exercised to prevent frivolous filings being made just to benefit from this initiative. Regarding the tax benefits, clarity is needed on how to value IP creation. Additionally, considering that IP can arise from a variety of actors, we suggest that such benefits should be extended to all IP being created or commercialized in India by individuals, small entities, or companies.

Taken as a whole, the Policy includes many positive actions for improving India's IP systems. The U.S. should continue to monitor the implementation of the Policy as it unfolds.

Additional Patentability Criteria

India's Patent Act adds an additional criterion 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 difficult to secure patent protection for certain types of pharmaceutical inventions and chemical compounds.

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."[55] 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.[56] TADF is empowered to request compulsory licensing from the Government of India.[57]

Similarly, India's National Competition Policy requires IP owners to grant access to "essential facilities" on "agreed and nondiscriminatory terms" without reservation.[58] The concept of essential facilities appears to cover a broad range of technologies including at least "electricity,

[53] National Intellectual Property Rights Policy, Government of India (May 2016) (National IPR Policy), http://dippnic.in/English/Schemes/IntellectualPropertyRights/NationalIPRPolicy08.08.2016.pdf.
[54] National IPR Policy at ¶ 3.8.4.
[55] 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.
[56] *Id.* at ¶ 4.4.1.
[57] *Id.* at ¶¶ 4.2, 4.4.3.
[58] National Competition Policy, § 5.1(vi) (2011), http://www mca.gov.in/Ministry/pdf/Revised DraftNationalCompetition Policy201117nov2011.pdf.

communications, gas pipelines, railway tracks, ports, [and] IT equipment."[59] 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.

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."[60] The objective of the paper was "to develop a predicable environment" for compulsory licensing to be used.[61]

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 the respective patent grant.[62] This appears to include situations when patent holders import the related technology into the country, but do not locally manufacture it. It is difficult to understand how this complies 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*."[63] Among those rights is the ability to exclude others from making, using, or selling their invention.[64]

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.[65] Statements of Working, (Form 27),[66] must be provided annually.[67] Failure to provide the requested information is punishable by fine or imprisonment.[68]

The 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

[59] *Id.*
[60] Discussion Paper on Compulsory Licensing, ¶70, DIPP (2011), http://dipp nic.in/English/Discusspaper/CL DraftDiscussion 02September2011.doc.
[61] *Id.* at ¶ 2.
[62] The Patents Act, § 84(1)(c), Intellectual Property India (1970), http://ipindia nic.in/ipr/patent/eVersion ActRules/sections/ps84html.
[63] TRIPS, Art. 27.1 (emphasis added).
[64] TRIPS, Art. 28(1).
[65] The Patents Act, § 146, http://ipindia nic.in/ipr/patent/eVersion ActRules/sections/ps146html.
[66] 72 Statement Regarding the Working of the Patented Invention on Commercial Scale in India, http://patinfo nic.in/pdf/form 27.pdf.
[67] The Patents Rules, § 131, Intellectual Property India (2003), http://ipindia nic.in/ipr/patent/eVersion ActRules/rules/pr131html.
[68] 74 The Patents Act at n.57.

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.

In addition, Patent Rules, as amended in 2016, require all Forms, including Form 27, to be submitted electronically by the agents or representatives of the patentees.[69] Although this is a welcome move, the electronic version of Form 27 requires mandatory submission of information which otherwise is not required to be submitted in the manual version of Form 27. This inconsistency causes a great deal of hardship to patentees.

The emphasis on Form 27 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.[70] 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 trade secrets. Although other means of protection might exist, such as suing under the tort of "breach of confidence,"[71] each has a common shortcoming: requiring a close relationship between the trade secret owner and the would-be misappropriator. 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 with 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.

Moves by the Indian government indicate that the country might value such an approach. We are encouraged by the commitment at the 2015 U.S. and India Trade Policy Forum to deepen cooperation on trade secrets.[72] There is also a recommendation included in India's National IPR

[69] Public Notice No.CG/F/Public Notice/2016, published in Pt. II, Section 3, Sub-Section (i) of the Gazette of India (May 2016), http://www.ipindia nic.in/writereaddata/Portal/IPORule/1 42 1 Patent Amendment Rules 2016 16May2016.pdf.
[70] Intellectual Property Appellate Board, *Bayer Corporation v. Union of India through the Secretary & Ors.*, Order No. 45, ¶ 52 (Mar. 2013), http://www.ipabindia.in/Pdfs/Order-45-2013.pdf; *see also Bayer v. Union of India*, Writ Petition No. 1323 of 2013, at 48.
[71] 77 Zafar Mahfooz Normani & Faizanur Rahman, *Intellection of Trade Secrets and Innovation Laws in India*, 16 J. Intell. Prop Rpts. 346 (July 2011), http://nopr niscair res.in/bitstream/123456789/12449/1/IJPR%2016%284%29%20341-350.pdf.
[72] *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.

Policy to study trade secret protection, with an aim for further policy development.[73] Earlier recognition of the need to improve trade secret protection can be found in the 2014 draft National Innovation Act[74] and 2012 draft National IPR Strategy.[75] There is also a growing body of academic literature originating within India that agrees such initiative is critical.[76] The 2012 draft National IPR Strategy made the point when it explained that a "predictable and recognizable trade secret regime will improve investor confidence,"[77] although this was not included in the approved version of the National IPR Strategy. 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.

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."[78] 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.[79] 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.[80]

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.[81] The requirements set forth by section 8 are antiquated and create unnecessary uncertainty and expense for patent applicants.

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[73] National IPR Policy, at ¶3.8.4.
[74] The National Innovation Act of 2008 (Draft), Ch. VI, http://www.prsindia.org/uploads/media/vikas doc/docs/1241500117~~Draftinnovationlaw.pdf.
[75] Invitation of Views on the Draft National IPR Strategy, ¶¶ 50-52, http://dipp nic.in/English/Discuss paper/draftNational IPR Strategy26Sep2012.pdf.
[76] 82 *See e.g.*, Hariani, *The Draft National Innovation Act*, India L.J. (2007), http://indialawjournal.com/volume3/issue 1/articlebyanirudhhtml; Kumar *et al.*, *Legal Protection of Trade Secrets*. 11 J. Intell. Prop. Rpts. 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. Rpts 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. Rpts. 192 (May 2006), http://nopr niscair.res.in/bitstream/123456789/3577/1/JIPR%2011%283%29%20192-200.pdf); Singh, *Need for a Separate Trade Secret Act with Required Law*, Prac. L. 44 (2012), http://www.supremecourtcases.com/index2.php?option=com content&itemid=1&do pdf=1&id=24329.
[77] Draft National IPR Strategy, ¶ 52 (2012).
[78] Indian Patents Act, § 8(1) (1970), http://www.wipo.int/wipolex/en/text.jsp?file id=128091.
[79] Patent Cooperation Treaty, Art. 42, http://www.wipo.int/pct/en/texts/articles/a42 htm.
[80] Indian Patent Act, §§ 25(1)(h), 25(2)(h), and 64(1)(m) respectively.
[81] *See F. Hoffmann-La Roche Ltd. v. Cipla Ltd.* FAO (OS) 188/2008, (Apr. 2009).

Computer Related Invention (CRI) Guidelines

The Indian Patent Office issued guidelines for examination of patent applications involving Computer Related Inventions (CRI) on 21 August 2015 which were acceptable to many stakeholders and were the product of extensive discussions since 2013.[82] Over two years, the Indian Patent Office solicited written comments from all interested stakeholders and held numerous public meetings to discuss all aspects of the proposed CRI Guidelines. Indian Patent Office officials carefully reviewed the relevant statutory language of the 1970 Patent Act, the legislative history and intent behind the statute, and all relevant precedents before publishing the CRI Guidelines.

However, in December 2015, the Indian Patent Office abruptly suspended the August 2015 CRI Guidelines. As a sharp turn in policy, the Indian Patent Office issued revised CRI Guidelines on 19 February 2016 (currently in force) without taking the same deliberative, multi-stakeholder engagement approach.[83] The revised CRI Guidelines, which require a novel hardware element rather than a further technical effect, will prevent most software enabled inventions from receiving patent protection in India.[84] This result would be contrary to the 1970 Patent Act, and inconsistent with international practice. The speed with which such contradiction has emerged and lack of any legal basis in issuing revised CRI guidelines is extremely worrisome and goes against the very objective of National IPR Policy of providing a stable IP Policy regime.

Foreign Filing Permissions and Ministry of Defense

India's Patent Act requires that an invention having a resident Indian inventor should not make or cause to make any patent application outside India unless a Foreign Filing Permission (FFP) is obtained from the Indian Patent Office.[85] Non-compliance with this requirement results in monetary fine or a jail term or both.[86] Although India's Patent Rules require disposal of the FFP within 21 days from the request, in our experience, the process takes at least several months.[87]

Further, if the Indian Patent Office concludes that the subject matter of an invention is relevant for defense purposes or atomic energy, it refers the FFP application to Ministry of Defense (MoD) for their prior consent. We understand that the MoD can take up to two years to grant consent. This delay is extremely detrimental to FFP. Applicants might lose their application priority date and have no ability to contest the Patent Office's decision.

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

[82] Guidelines for Examination of Computer Related Inventions (CRIs), Government of India (Aug. 2015).
[83] Guidelines for Examination of Computer Related Inventions (CRIs), Government of India (Feb. 2016), http://tematelecom.in/pdf/GuidelinesExamination CRI 19February2016.pdf.
[84] *Id.* at § 5(3).
[85] Indian Patents Act, § 39.
[86] *Id.* at § 118.
[87] India Patent Rule 71 (2003), http://www.wipo.int/edocs/lexdocs/laws/en/in/in067en.pdf; India Patent Amendment Rules, ¶15 (2016), http://www.ipindia.nic.in/writereaddata/Portal/IPORule/1421PatentAmendment Rules201616May2016.pdf.

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 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. At WIPO's Standing Committee on Patents (SCP), India continued to suggest that "work sharing has nothing to do with the quality of patents.[88] Given the rising number of 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 National IPR Policy contains references to improving the operation of its own patent system, including a dedicated section on IP Administration and Management.[89]

In the TRIPS Council, India regularly questions the utility of IP systems. At one TRIPS Council, India stated there is "no evidence to prove that strong IP could deliver on development or innovation."[90] In the same forum, India has also insisted on several occasions that "there is not direct linkage between IP and innovation."[91] India, along with other countries, has requested a dedicated agenda item within the TRIPS Council to discuss the UN High Level Report on Access to Medicines, which includes a number of recommendations aimed at weakening the IP framework around health related innovations.[92] India supports similar work programs at WIPO. India also continues to push for a variety of measures to weaken IP rights for energy technologies, as part of the elaboration of the technology framework that will be implemented as part of the Paris Agreement of the UN Framework Convention on Climate Change.[93]

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 Africa (BRICS countries).[94] 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

[88] Opening Statement by India at the 25th Session of SCP (Dec. 2016), http://www.ipindia.nic.in/writereaddata/Portal/News/295 1 SCP25 OpeningStatementorGeneralStatement.pdf; Opening Statement by India at the 24th Session of SCP (June 2016), http://pmindiaun.org/pages.php?id=1336.
[89] National IPR Policy, Objective 4.
[90] TRIPS Council Meeting Minutes, IP/C/M/75/Add.1, ¶¶ 398-399 (Feb. 2014).
[91] TRIPS Council Meeting Minutes, IP/C/M/76/Add.1, ¶ 347 (June 2014).
[92] TRIPS Council Communication from Brazil, China, India, and South Africa, IP/C/W/61 (Oct. 2016), https://docs.wto.org/dol2fe/Pages/FE Search/FE S S009-DP.aspx?language=E&CatalogueIdList=232341&CurrentCatalogueIdIndex=0&FullTextHash=371857150&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True.
[93] Views from the Government of India on Subsidiary Body for Scientific and Technological Advice Agenda Item No 4: Technology Framework Under 10(4) of the Paris Agreement (Sept. 2016), http://www4.unfccc.int/Submissions/Lists/OSPSubmissionUpload/176 256 131183211609661690-Submission%20on%20Technology%20Framework%20-%20India.docx.
[94] BRICS Intellectual Property Offices Cooperation Roadmap (May 2013), http://www.ip-watch.org/weblog/wp-content/uploads/2013/11/SIGNED-BRICS-IP-OFFICES-COOPERATION-ROADMAP.pdf).

Although preliminary injunctions that result in the seizure of infringing goods are possible in patent and trademark infringement proceedings, 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 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, in effect serving as both judge and party.

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.

RUSSIA

Russian Law Fails to Provide Adequate Trade Secret Protection

Russia offers nominal, weak, and unpredictable protection for trade secrets, leaving little protection for U.S. innovators doing business in the country. Russian law requires a trade secret holder to introduce a "regime of commercial secrecy" to protect its know-how.[95] Although this law sounds similar to the "reasonable steps" in TRIPS, which exist in many countries, in reality it is a rigid regime that places an unrealistic burden on the people it is meant to protect. Russian law only provides protection to trade secret holders that have complied with a specific set of obligations, including a specific inventory of the information to be protected, an up-to-date record of those with access to the information, and the trade secret has to be marked as both confidential and with the full name and address of the owner. Such prerequisites for protection fail to match the commercial realities. For example, an inventory might be impossible to create considering new trade secrets might be created on a daily basis and many types of trade secrets might be difficult or impossible to mark as required by the law. In practice, these formalities would cause many businesses to grind to a halt instead of offering any meaningful protection.

Enforcement tends to be inadequate as well. Although preliminary remedies such as injunctions and seizures are theoretically available, there is little available evidence that indicates they are ever used. Criminal penalties are similarly lacking, often limited to community service — despite significant losses for the trade secret owner. Considering these shortcomings, the U.S. should encourage the implementation of the APEC Best Practices for Trade Secret Protection and Enforcement, which Russia endorsed as part of a 2016 APEC declaration.[96]

[95] Federal Law on Commercial Secrecy No. 98-FZ, 32 SZ RF item 3283 2004 (July 2004) (as amended).
[96] *AMM Joint Statement*, APEC Peru (2016), http://www.apec.org/Meeting-Papers/Annual-Ministerial-Meetings/Annual/2016/2016 amm.aspx; *Best Practices in Trade Secret Protection and Enforcement Against Misappropriation* (Nov. 2016), https://ustr.gov/sites/default/files/11202016-US-Best-Practices-Trade-Secrets.pdf .

SOUTH AFRICA

Proposed National IPR Policy

South Africa's Department of Trade and Industry published a draft National Policy on Intellectual Property in 2013,[97] 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, there are also indications of an intention to weaken the existing IP system.

For example, the draft appears to encourage and broaden compulsory licensing and similar flexibilities. 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 ever be recouped, making it harder and more expensive to finance the necessary research and development. Promoting a preference for IP flexibilities 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.

This course of actions appears to be under active consideration. In 2016, the Department of Trade and Industry issued an Intellectual Property Consultative Framework,[98] which contains a number of similar positions compared to the draft National Policy. For example, the Framework references making "full use of the flexibility within international law" to boost local manufacturing.[99] And in international bodies, such as WIPO, TRIPS Council, and the UN Framework Convention on Climate Change, South Africa pushes for discussions on exceptions and limitations to patent rights.[100]

II. PUSH TO WEAKEN IP RIGHTS WITHIN MULTILATERAL FORA

Within the UN system, IP protection continues to come under fire. Such efforts are largely based on misinformation about the impact of IP rights on innovation and technology diffusion. The principal argument is that IP systems are a barrier that needs to be dismantled if developing countries are to advance. Yet this argument does not accurately reflect the contribution of IP to innovation and technology diffusion in the real world. It ignores that the IP system has supported life-changing innovations across all sectors for decades and that there is no empirical evidence that IP rights are a barrier to advancement.[101]

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

[98] *Intellectual Property Consultative Framework*, South Africa International Trade and Economic Development Division (July 2016); http://www.thedti.gov.za/news2016/IPConsultativeFramework.pdf

[99] *Id.* at § 4.1.

[100] TRIPS Council Communication from Brazil, China, India, and South Africa, IP/C/W/619 (Oct. 2016), https://docs.wto.org/dol2fe/Pages/FE Search/FE S S009-DP.aspx?language=E&CatalogueIdList=232341&CurrentCatalogueIdIndex=0&FullTextHash=371857150&HasEnglishRec ord=True&HasFrenchRecord=True&HasSpanishRecord=True.

[101] K. Lybecker & S. Lohse, *Innovation and Diffusion of Green Technologies: The Role of Intellectual Property and Other*

A variety of proposals aimed at weakening the global IP framework are regularly raised including: compulsory or concessional licensing; the elimination of IP rights for certain technologies; technology buyouts, or other international IP mechanisms; 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.[102] Designed in three phases, this proposal involves a detailed exchange of experiences on exceptions and limitations, a determination of the most effective exceptions and limitations, and the development of an "exceptions and limitations manual." Similar discussions are ongoing as part of WIPO's Committee on Development as well.

These agendas were bolstered by the UN High Level Panel (HLP) on Access to Medicines.[103] The mandate for the HLP focused only on IP systems, in national laws and enshrined in global treaties, as the critical barrier to healthcare delivery and thus, fulfilment of human rights. No other factors influencing healthcare delivery – funding, health infrastructure, public and private health investment, and numbers of trained health personnel – were considered by the Panel, which also ignored submissions from innovators and other IP users. The report called on countries to drastically reduce IP protection. To support its recommendations, it cited inapposite cases, for instance inadequate R&D for neglected diseases, a problem resulting from market factors, but which is unrelated to IP.

Now developing countries, notably Brazil, India, and certain African nations, are pushing for discussion and implementation of the HLP's IP recommendations in every multilateral forum, including the WTO, WHO, and WIPO.[104] U.S. leadership is required to push back on this negative agenda, while at the same time making the case for innovation, which will be a key driver of Sustainable Development Goals' achievement, and working to improve enabling environments for technological advancement.

UN bodies, notably WIPO, but also WTO and WHO, play an important role in ensuring the existence of robust evidence about the contribution of IP systems to innovation and technology diffusion. They also have the responsibility to push back on erroneous and misleading statements about how IP works in practice. However, this has become extremely difficult due to intense political engagement by several countries in these "member-driven" organizations. Many

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Enabling Factors, WIPO Global Challenges Report (2015), https://www3.wipo.int/wipogreen/docs/en/globalchallengesreportlybeckerlohse.pdf.

[102] Standing Committee on the Law of Patents at n. 24.

[103] The *United Nations Secretary-General's High-Level Panel on Access to Medicines Report* (Sept. 2016), http://www.unsgaccessmeds.org/final-report/.

[104] TRIPS Council Communication from Brazil, China, India, and South Africa, IP/C/W/619 (Oct. 2016), https://docs.wto.org/dol2fe/Pages/FE Search/FE S S009-DP.aspx?language=E&CatalogueIdList=232341&CurrentCatalogueIdIndex=0&FullTextHash=371857150&HasEnglishRec ord=True&HasFrenchRecord=True&HasSpanishRecord=True; Statement by India on the Provisional Agenda Item 2, Adoption of the Agenda at the Executive Board Meeting of the WHO (Jan. 2016), http://pmindiaun.org/adminpart/uploadpdf/geneva.pdf; Proposal by the African Group for a WIPO Work Program on Patents and Health SCP/24/4 (June 2016), http://www.wipo.int/edocs/mdocs/scp/en/scp 24/scp244.pdf.

countries aggressively orient work programs and discussions towards IP weakening. They seek technical assistance, analysis, and recommendations in favor of compulsory licensing, unduly restrictive patentability criteria, and lack of enforcement. Such efforts align with their industrial strategies, aimed at obtaining proprietary technologies at reduced cost.

Activities in these bodies can influence legislation. Unfortunately, misguided modifications of IP systems, like those discussed in many of these bodies, can lead to significant uncertainty and ultimately, severe disadvantages for U.S. industry. Considering the wide range of bodies attempting to chip away at the global IP framework that is needed to enable a level playing field for our innovations, a robust U.S. interagency process is necessary to effectively monitor U.S. interests in this regard. And more importantly, sustained U.S. leadership is critical to preventing the mandates of these agencies from eroding the IP system our members depend on, to take the leap that turn ideas into the products and services that will generate innovative products, exports, and American jobs.

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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 2018 Special 301 Report.

Sincerely,

Mark W. Lauroesch
Executive Director