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February 6, 2020

Mr. Daniel Lee
Assistant U.S. Trade Representative for Innovation & Intellectual Property
Office of the U.S. Trade Representative
600 17th St., NW
Washington, DC 20508

Re: USTR 2020 Special 301 Review, Request for Public Comment (Docket No. USTR-2019-0023)

Dear Mr. Lee:

Intellectual Property Owners Association (IPO) appreciates the opportunity to provide comments regarding the U.S. Trade Representative's 2020 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, intellectual property rights. IPO's membership includes about 175 companies and close to 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 over 30 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.

I. COUNTRY-SPECIFIC CONCERNS

ARGENTINA

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 patent applications are resolved is five years, and for pharmaceutical and biotech inventions it can take up to ten to twelve years. Such delays in securing patent rights make it difficult for innovators to attract investors or support business plans. We welcome efforts by Argentina's Patent Office to reduce the backlog, including the enactment of

Resolution 56/2016¹ 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. Although Argentina's Patent Office efforts to reduce backlog during second half of 2019 led to increased number of patent applications examined, 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

Argentina's Patent Office enacted Resolution P-107/2012 in May 2012.³ This resolution introduced more restrictive patentability criteria for chemical and pharmaceutical inventions.⁴ The criteria were applicable to both new and pending patent applications, and thus altered the legal framework that had been in force when patent applications were previously filed. When these changes are combined with the substantial backlog, significant uncertainty results for innovators in the chemical and pharmaceutical areas. Restrictive guidelines refuse pharmaceutical patents for compositions and formulations, salts, esters and ethers, polymorphs, active metabolites and pro-drugs, enantiomers, selection patents, and certain Markush-type claims - almost 80% of all pharmaceutical applications.

Increased risk of Compulsory Licenses

In December 2019, Argentina passed an Emergency Economic Law that would increase the likelihood of the grant of compulsory licenses being required by the Ministry of Health.⁵ Compulsory licensing, however, undermines the economic incentives created by the IP system for innovation and investment in research and development.

AUSTRALIA

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

Several court decisions have highlighted two areas in which Australian law is out of line with the Australia-U.S. Free Trade Agreement⁶ and with international practice. Australia fails to offer certain patent protection that it agreed to provide, which harms innovators seeking patent protection in Australia.

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 *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>.

⁴ 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.

⁵ Article 70 of the December 2019 Emergency Economic Law.

⁶ 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.

Despite the uncertainty of most types of innovation, Australia requires a patent to deliver all its “promised benefits”: If a patentee describes two potential advantages of an invention and only one turns out to be achievable, the resulting patent will be found invalid.⁷ Besides serving as an 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.”⁸

Another unusual 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*.⁹ This would be the PCT filing date for a PCT application. It can complicate matters for applicants who do not update the first filed application before foreign filing. Such a requirement is inconsistent with international practice, and harms U.S. inventors seeking to protect their inventions in Australia.

Two recent cases have confirmed the continued applicability of the best method requirement. The Federal Court considered the best method requirement in *BlueScope Steel Ltd v Dongkuk Steel Mill Co., Ltd (No 2) [2019] FCA 2117 (17 December 2019)*. The Court found that the patents at issue were invalid for failing to disclose the best method known to the applicant at the date of filing. The Court also considered the best method requirement in *Domestic Australia Pty Ltd v Houghton Leisure Products Pty Ltd [2018] FCA 1573 (19 October 2018)*. In this case, the Court found that the best method requirement is based on what was known by the Applicant at the date of filing of the application (not the filing date of any earlier parent or priority application). In this case, the date of filing was the date on which a divisional was filed, not the date on which the parent PCT application was filed.

Patentable Subject Matter in Relation to Computer-Implemented Inventions

There are no exclusions or specific requirements in Australian legislation relating to computer-implemented inventions. Indeed, the Australian courts have made clear that computer-implemented inventions may be the subject of patent protection.

However, the Australian Patent Office Manual of Practice and Procedure¹⁰ assesses whether an invention is patentable subject matter by assessing whether the contribution of the invention (i.e., any novelty conferring feature of the invention) is patentable subject matter, rather than considering whether the claimed invention, considered as a whole, constitutes patentable subject matter. This approach has resulted in numerous examples of claims that have been found allowable in the U.S. being rejected in Australia, even when examined under the Patent Prosecution Highway.

⁷ *Streetworx Pty. Ltd. v. Artcraft Urban Group Pty. Ltd.*, FCA 1366 (2014), *aff'd*, *Ronneby Road Pty. Ltd. v. ESCO Corp.*, FCA 588 (2016).

⁸ Australia-U.S. Free Trade Agreement, Art. 17.9.13.

⁹ *Les Laboratoires Servier v. Apotex Pty. Ltd.*, FCAFC 27 (2016).

¹⁰ http://manuals.ipaustralia.gov.au/patents/Patent_Examiners_Manual.htm

Market-Size Damages

Australia's Department of Health has implemented a policy by which it seeks damages from biopharmaceutical innovators that commence proceedings to enforce their patents and obtain a preliminary injunction but are ultimately unsuccessful on the merits. Those damages are designed to compensate Australia's pharmaceutical reimbursement scheme (PBS) for any delay in the reduction in PBS prices during the period of the preliminary injunction. The PBS imposes automatic and irreversible price cuts on medicines as soon as a first competing brand enters the market, but the policy provides no corresponding mechanism for automatic compensation for innovators as a result of the PBS price cut if an infringing product is launched prematurely; the innovator must instead seek to recover those losses from the infringing generic as part of its damages claim.

This "market-size damages" policy is problematic. It unfairly tips the scales in commercial patent disputes by exposing them to significant compensation claims and thus discouraging innovators from enforcing their patents. It means that the same government that examined and granted a patent can seek damages from the patentee for unsuccessfully trying to enforce it.

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), including with respect to provisional measures and technology discrimination.

Lack of Regulatory Data Protection

Australia does not provide any regulatory data protection (RDP) relating to the registration of new formulations, combinations, indications, populations, or dosage forms of currently registered therapeutic goods. The absence of any such protection is in direct contravention of Australia's obligations under Article 17.10(2) of the AUSFTA, which mandates that the parties provide at least three years of RDP protection from the date of marketing approval in circumstances where new clinical information must be submitted to obtain regulatory approval of the relevant new therapeutic good (other than information relating to bioequivalence).

The lack of data protection for product changes supported by new clinical information, and the lack of protection for more than 5 years for biological products, potentially puts pharmaceutical innovators at a disadvantage in Australia in comparison to other developed countries. After expiry of the initial 5-year period, generic competitors can rely on innovators' clinical data to obtain abridged approvals without delay (subject to any patent protection). Thus, the Australian data protection system does not adequately reward innovators for the cost of obtaining the clinical data to support the approval of product changes for the benefit of Australian patients.

Shift Relating to Injunctions

There has been a recent shift in the Australian courts negatively impacting the likelihood an injunction would be granted. This is due to the perception that it would be more difficult to calculate potential losses for a generic company challenging a patent than to calculate patentee's losses. The Australian courts should make an assessment based on the facts of each specific case and not adopt the default position that it would be more difficult to calculate potential losses.

BRAZIL

Effort to Address the Severe Patent and Trademark Application Backlogs Is Underway

In Brazil, utility 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. Such delays hurt both would-be patent owners and potential competitors, adding to market uncertainty and increasing the cost of innovation. This situation, however, has seen recent improvement through the implementation of various strategies, such as hiring additional examiners, creating fast-track programs such as PPH agreements, and leveraging examination of foreign counterpart applications. The Brazilian National Institute of Industrial Property (INPI) has already significantly reduced the patent backlog, which went down from an average of 11.5 years to a little more than 8 years.

With respect to trademarks, both the backlog and the examination period has decreased substantially. Thanks to Brazil's accession to the Madrid Protocol in July 2019, INPI has implemented the changes necessary to comply with international standards. Trademarks are now being granted in less than 12 months on average.

IPO applauds these improvements, while recognizing also the need for further progress to reduce these backlogs.

ANVISA's Prior Consent for Patent Examination

As INPI is taking steps to improve its backlog, a seemingly dual patent examination system continues to impede 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. (It is worth mentioning that, after a recent agreement between ANVISA and INPI, an unfavorable opinion from ANVISA on patentability issues is no longer binding, *i.e.*, it no longer prevents INPI from granting patent rights.) This dynamic continues despite Brazil's General Attorney's opinion that ANVISA's scope is limited to assessing the safety and therapeutic efficacy of products¹¹ and appellate court decisions that have also

¹¹ Opinion 337/PGF/EA/2010 (Jan. 2011).

concluded that ANVISA's authority is limited to assessing public health risk.¹² Such dual examination thus continues to raise questions under TRIPS, although we must acknowledge the progress toward resolution.

Design Protection

In 2017, responsibility for registering and examining design patent applications in Brazil 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.

Lack of Regulatory Data Protection

Brazilian law (Law 10.603/02) provides data protection for veterinary, fertilizer, and agrochemical products, but does not provide similar protection for pharmaceutical products for human use, resulting in discriminatory treatment. Contrary to TRIPS Article 39, Brazil continues to allow government officials to grant marketing approval for pharmaceuticals to competitors relying on test and other data submitted by innovators to prove the safety and efficacy of their products. Additional efforts are needed to provide certainty that test data and other data will be fully protected against unauthorized use to secure marketing approval for a fixed period.

CANADA

Patented Medicines Price Review Board (PMPRB) Regulations

We have concerns about the *Regulations Amending the Patented Medicines Regulations*¹³ (the "*Regulations*") scheduled for implementation on July 1, 2020. We are particularly concerned about the changes to the list of comparator countries under section 4(1)(f)(iii) of the *Regulations* that remove the United States and Switzerland — and add Australia, Belgium, Japan, Netherlands, Norway, 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

¹² "The ANVISA has no statutory authority to deny prior approval to a patent application based on the argument that it does not meet the novelty and non-obviousness 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)).

¹³ <http://www.gazette.gc.ca/rp-pr/p1/2017/2017-12-02/html/reg2-eng.html>.

reporting requirements for patented generic medicines (approved by means of Abbreviated New Drug Submission (“ANDS”)). Generic medicines are exempt from the continual reporting of cost-utility analysis information unless requested by the Patented Medicine Prices Review Board (“PMPRB”). At the same time, innovative manufacturers have expansive reporting requirements satisfied by the “merest slender thread”¹⁴ and whereby the PMPRB will view any patent that “pertains to a medicine” as falling within its jurisdiction. The *Regulations* are thus lop-sided and, in fact, are unnecessary.

The *Regulations* unnecessarily discourage innovation and increase reporting requirements for innovative patent holders. When incentives for patent innovation are diminished, particularly in a major country like Canada, the value of intellectual property is negatively impacted for all types of patent owners everywhere. These concerns are heightened when reference to Canada’s patent statute is used as the basis for lowering prices for patent-protected technologies as it raises the likelihood that similar regulations could be extended to other consumer goods. Further, we are concerned that referencing a patent statute as a basis for placing patentees at an economic disadvantage compared to non-patent holders sets a troubling and disincentivizing precedent.

Weak Patent Enforcement

The 2017 *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*¹⁵ (the “2017 *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 (e.g., granting damages in excess of 100% of the total generic market), and a separate litigation track for some types of patents due to their ineligibility for listing on the Patent Register (e.g., arbitrary timing requirements).

45 days for Action on Notice of Allegation

The 2017 *Regulations* provide that if a proceeding is not brought within the 45 days of timeline after a patent is listed on the Patent Register and a Notice of Allegation (NOA) has been sent, then one cannot bring a proceeding under the Patent Act, unless the innovator had a reasonable basis for not bringing the action in response to the NOA.¹⁶ This provision has the effect of revoking a statutorily granted patent right due to a missed deadline.

Excessive Damages

We are also concerned about the potential expansion of liability for pharmaceutical innovators. Innovative companies are potentially liable under section 8 and common law theories, including for treble damages, in cases proceeding within the provincial courts of Ontario and Quebec. Also, the 2017 *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

¹⁴ *ICN Pharms. Inc. v. Canada* (Staff of the Patented Medicine Prices Review Board)(C.A.)(1997) 1 F.C. 32 (ICN).

¹⁵ <http://www.gazette.gc.ca/rp-pr/p1/2017/2017-12-02/html/reg2-eng.html>.

¹⁶ Patented Medicines (Notice of Compliance) Regulations, sections 6(1) and 6.01.

“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 *2017 NOC Regulations*, as does happen in the real world. As a result, when innovators face multiple section 8 claims, there is a risk that the defendant (innovator) will be subject to a cumulative damage award based on what cannot possibly occur in the real world.¹⁷ Also, the *2017 Regulations* remove any limits to the period of a first person’s liability under section 8 of the Regulations. Thus, Second Persons under the *2017 Regulations* may be able to claim losses suffered beyond the date of any dismissal or discontinuance. Taken together, the common law and section 8 related amendments create a risk of “windfall” damage awards. Furthermore, such awards are contrary to the traditional compensatory function of damages and, in situations of section 8 damages in excess of 100% of the total generic market and/or potential treble damages, constitute a punitive award which is inconsistent with the limited remedy of declaratory relief currently provided for under Section 60(1) of the *Patent Act*, and would be an inequitable result.

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. Both of these restrictive requirements are unlike patent term restoration (“PTR”) requirements in other jurisdictions. Furthermore, Canada’s term is capped at 2 years of the possible 5 – an unduly restrictive time limit.

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 patent owners. Under the current CSP regime, one or more third parties are allowed to seek a CSP extension using the pharmaceutical innovator’s Notice of Compliance, or “NOC.” As Canadian law mandates only one CSP per drug, this “conflict” between one or more CSP applications citing the same NOC is resolved in an unnecessary and costly proceeding. Pharmaceutical innovators (the “NOC” holder) are concerned that the “conflict proceeding” may unjustly favor the third party. As a result, pharmaceutical innovators face a significant risk of losing the CSP to a third party thereby denying pharmaceutical innovators the incentive and reward for undertaking the costly and risky journey of drug development. IPO urges that third parties not be allowed to seek CSP extensions using a pharmaceutical innovator’s NOC without the permission of the innovator.

¹⁷ 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.

Lack of Interlocutory Relief

In the event a patentee pursues an action for infringement, it may apply for an interlocutory injunction to maintain its rights and, in particular, to prevent the market entry of the generic product or to seek its withdrawal from the market. These applications, however, rarely succeed in Canada, even when there is compelling evidence of infringement. This is because the extremely high standard applied by the Canadian courts for the necessary finding of “irreparable harm” is essentially impossible for innovative pharmaceutical companies to meet. It often takes at least two years before an action for patent infringement is tried—and even longer to obtain damages.¹⁸ 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. This lack of availability of interlocutory injunctions calls into question Canada’s compliance with Article 50 of TRIPS and Article 1716 of NAFTA, both of which call for “prompt and effective” provisional measures, *i.e.*, including interlocutory injunctions, to prevent an infringement of any intellectual property right and, in particular, to prevent the entry into the channels of commerce of allegedly infringing goods. IPO further notes that similar provisions will carry forward under the United States-Mexico-Canada Agreement (USMCA), Article 20.F.16, paragraph 1(c).¹⁹

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.²⁰ 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.

¹⁸ *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.)

¹⁹ If a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety and efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval by the Party or in another territory, that Party shall provide: (c) procedures, such as judicial or administrative proceedings, and expeditious remedies, such as preliminary injunctions or equivalent effective provisional measures, for the timely resolution of disputes concerning the validity or infringement of an applicable patent claiming an approved pharmaceutical product or its approved method of use. <https://usmca.com/intellectual-property-rights-usmca-chapter-20/>.

²⁰ Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, as amended, <http://www.laws-lois.justice.gc.ca/PDF/SOR-93-133.pdf>.

Overall, the Government of Canada should be more progressive in its approach, amending its laws to better define their boundaries in order to create greater business certainty. For example, Canada's policy of allowing transfer of prior user rights to third parties establishes an unstable foundation for reliable patent protection. Another example is Canada's recently enacted file wrapper estoppel rules,²¹ which have been unfairly applied retroactively and created a significant disruption in existing patent proceedings. Canada's data protection practices are also a concern due to court challenges calling into question the scope of protection provided for test data. Notably, when the Government of Canada has sought public comments on new proposals, the deadlines for comment are sometimes disturbingly short and do not allow sufficient time for a thoughtful perspective to be provided. Patent owners would like Canada to take steps to provide stronger protections for innovation.

CHILE

Pending Fármacos-II Bill

Chile, which has developed a leading health and innovation ecosystem, is at risk of reversing progress and developing anti-intellectual property laws and policies. The Health Committee of the Chamber of Deputies have proposed amendments under the Fármacos II bill to expand compulsory licenses and restrict use of brand names for medicines. These developments risk Chile's leading position and threaten continued innovation in Chile.

CHINA

Phase I Economic and Trade Agreement

The United States and China entered into Phase I of the Economic and Trade Agreement on January 15, 2020, which promises improvements in intellectual property and tech transfer in China. The Phase I Agreement will have China prepare an Action Plan within 30 days including measures that China will take to implement its obligations and the date by which each measure will go into effect. IPO looks forward to seeing the Action Plan and to full implementation of Chapter 1 (Intellectual Property) and Chapter 2 (Tech Transfer) of the Phase I Agreement. IPO notes, in particular, that provisions in Chapter 1 promise needed improvements in trade secret protection, measures against bad faith trademarks, and the protection of patents relating to pharmaceuticals.

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.

²¹ New Section 53.1 of the Patent Act (R.S.C., 1985, c. P-4), last amended on 2019-10-30. <https://laws-lois.justice.gc.ca/eng/acts/P-4/page-13.html#docCont>

For example, China recently amended its Anti-Unfair Competition Law.²² 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.

Although recent developments are promising, trade secret owners still face significant challenges protecting their confidential information. High evidentiary burdens, limited discovery, and damages issues 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 significant²³ 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. Further, the most recent draft revision of China’s Patent Law would give local and provincial patent administration and enforcement IP offices new powers to investigate patent infringement cases, including giving them broad authority to inspect the sites where the alleged infringement takes place and to review and copy relevant documents.²⁴ Our members are concerned with the significant risk of trade secret disclosure that could result from administrative investigations. Absent proper safeguards, such administrative enforcement of patents could result in disclosure of confidential information.

The consequences of such disclosures to government agencies can be 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 accountable and otherwise shield the details from public disclosure, the impact of any changes has yet to be felt.²⁵

²² See Anti-Unfair Competition Law (as amended April 2019),

<http://www.npc.gov.cn/npc/c30834/201905/9a37c6ff150c4be6a549d526fd586122.shtml>.

²³ A threshold of 500,000 RMB needs to be met. See The Supreme People’s Procuratorate and Ministry of Public Security’s Regulations on Standards for Initiating a Criminal Case under the Jurisdiction of Public Security (Part 2), Rule 73 (May 2010).

²⁴ The Patent Law of the People’s Republic of China Draft Revision dated 4 January 2019, Article 69.

²⁵ 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>.

In summary, in China, our members face high burdens of proof, limited discovery, and damages issues when seeking to enforce their trade secrets. Especially distressing, a trade secret owner must wait until a significant and possibly irreversible injury has taken place before seeking relief. Our members also face requirements to submit confidential details to government agencies. 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. We are encouraged by Section B (Articles 1.3-1.9) of the Phase I Economic and Trade Agreement between the U.S. and China, which if fully implemented, will substantially improve trade secret protection in China.

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

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.²⁶ A recent decision²⁷ confirms the reduced availability and worth of graphical user interface (GUI) and icon design patents in China, particularly for companies that produce software alone, and for software that is usable on a variety of devices or platforms.

The inability to claim partial designs is not only a problem for GUI designs. Much of today's innovation is incremental, building on existing ideas and products, and certain elements of a product's design often carry through to later generations. Because new designs for a product may build on or incorporate portions of designs of previous product generations, novel features within those goods with respect to look and feel can have significant commercial relevance separate and apart from the overall product. 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 U.S. should encourage China to make changes to permit partial designs to be claimed, which would provide enhanced protections for manufacturers.

China should also be encouraged to allow 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. The U.S. should also encourage China to clarify that design patent applications can contain broken lines.

China is also one of the few modern countries not to have a meaningful grace period during which a design owner can file a design application after disclosing the design publicly anywhere in the world. Unsophisticated designers may not appreciate the need to file a design application before disclosing their design, at which point protection will be unavailable in China. Further, grace periods — like those adopted in the U.S., Europe, and under consideration in Australia — provide applicants the time and flexibility to consider the need for

²⁶ The Draft Revision of the Patent Law (4 January 2019) does not include amendments to Article 2 which were included in previous versions of the Draft Revision that would enable protection for partial designs.

²⁷ *Beijing Qihu Technology Co., Ltd. and Qizhi Software Co., Ltd. v. Beijing Jiangmin New Sci. Tech. Co.*

protection and to prepare quality applications. China should be encouraged to adopt a generally applicable grace period of at least 6 months, and preferably 1 year.

Challenges Created by Chinese Trademark Law

Several amendments to China's trademark law became effective on November 1, 2019. These amendments, together with those made in 2013, improved the law, such as with the addition of a good-faith requirement when applying for new marks and the rejection of bad faith trademark registrations without an intent to use. Yet, brand owners still face substantial challenges. For example, failed oppositions result in immediate registration of challenged marks in the absence of a right to appeal, forcing brand owners to 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 Chinese jurisprudence. Bad faith registrants might even be able to take enforcement action against a brand owner's use of its own trademark.

The 2014 PRC Trademark Law dropped the Opposition Review, depriving both parties of their rights of action. As the success rate of opposition in China is very low, the removal of Opposition Review from the PRC trademark framework can only make things worse. Once bad faith registrants get their registration certificates, the brand owners will bear a heavy burden to invalidate them, not to mention the infringement risks caused by the registration if the non-registrant brand owner continues using their unregistered mark. Even if the invalidation action goes well, the process takes about one year, and the bad faith registrant might continue to appeal to the courts at three levels, which takes at least an additional three years, delaying resolution of the dispute, to the detriment of the brand owner.

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 to rein in trademark abuse.

Bad faith trademark filings include "trademark squatters" who file trademark applications and obtain registrations on the internationally established trademarks of brand owners, either to sell them back to the brand owner or to confuse the public and consumers. Establishing bad faith in these circumstances is too difficult and the standard for establishing the brand owner's trademark as "well known" is excessively high (even beyond famous), particularly where the bad faith trademark filing is made before launch of the legitimate branded product in China. Moreover, to avoid abuse, we believe that China should look to evidence outside China of the fame and whether a trademark is well known, rather than limiting such inquiry to fame within China. We look forward to seeing more rejection of bad faith trademark applications the under the newly amended Article 4, and to implementation of Section H (Article 1.24) of the Phase I Economic and Trade Agreement between the U.S. and China.

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 several 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 or the budget notice from Nanxian County, Hunan stipulating the same preferences. 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.²⁸

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.

Forced Technology Transfer

The new Foreign Investment Law has provisions that, if effective, could constitute substantial progress in dismantling policies, laws, regulations, and practices that force technology transfer. Article 22 of the law provides, among other things, that “administrative organs and their employees must not force the transfer of technology through administrative measures.” The concern is that this language might prove open to loopholes that would prevent it being fully effective. For example, if a transfer is mandated other than “through administrative measures” it might not be considered a violation of the law.

In addition, there are many other laws, regulations, and practices outside the Foreign Investment Law that would serve to undermine the restriction against forced technology transfer. For example, joint venture requirements and data localization requirements for Internet and Cloud companies mean that foreign companies are, as a practical matter, forced to hand over their IP to local PRC companies in order to participate in the Chinese market. Moreover, the draft Patent Act, dated 4 January 2019, would increase the power of administrative agencies to investigate patent infringement and seize confidential information including trade secrets (Article 69), which might result in the disclosure of such trade secrets to others, including competitors. Regulatory laws such as environmental, pharmaceutical, and medical device approval requirements can also result in concerning disclosures of confidential information, particularly where information is sought more broadly than reasonably necessary to accomplish regulatory review or where the regulatory agencies share submitted information with competitors (such as technical experts employed by or affiliated with competitors) or share submitted information with later regulatory applicants (or use it on their behalf). We look forward to implementation of Articles 1.9 and 2.3 of the Phase I Economic and Trade Agreement, which requires improvements in the protection of trade secrets and confidential business information from unauthorized disclosure by government authorities and prohibits forced technology transfer through administrative and licensing requirements.

²⁸ *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-delegations>.

Patent Enforcement and the Amendment to Chinese Patent Law

Language in China's current draft revision to its Patent Law²⁹ 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 misuse patents to "damage public interests or exclude or restrict competition."³⁰ 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,³¹ combined with the lack of examination with respect to patentability, creates substantial uncertainty for U.S. companies in the Chinese market. Although China's National Intellectual Property Administration (CNIPA) 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. 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 CNIPA 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 revision continues to expand administrative enforcement of patent rights. It would give hundreds of inexperienced local and provincial patent administration and enforcement offices new powers to investigate and inspect, 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 willful. 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,

²⁹ The Patent Law of the People's Republic of China Draft Revision dated 4 January 2019.

³⁰ *Id.* at Art. 20.

³¹ See 2017 SIPO Annual Report at 45 (June 2018), <http://english.sipo.gov.cn/lawpolicys/annualreports/2017a/> (in 2017, utility model applications grew by over 22%).

which can be political, unprofessional, and discriminatory. This would help rights-holders demonstrate the value of their patents or other IP, by addressing, among other issues, the problem of insufficiently examined rights by adjudication before more experienced, technical trained, competent, and less political courts.

One positive development is that the revisions to the Patent Examination Guidelines, implemented by CNIPA on April 1, 2017,³² 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, including allowing the submission of supplemental data to satisfy requirements for patentability, such as sufficiency of disclosure and inventive step, as now required in Article 1.10 of the Phase I Economic and Trade Agreement between the U.S. and China. 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 are glad to see CNIPA's effort in improving patent quality and examination process of invention patent applications containing algorithm or business rule and method features, as indicated by the Draft of the Amendment of the Examination Guidelines Regarding Chapter 9, Part II published on November 12, 2019.³³ We are concerned, though, about several revisions to the Patent Examination Guidelines implemented on November 1, 2019.³⁴ For example, the revision to Part 2, Chapter 4, Section 6.4 regarding inventive step determination could unnecessarily limit innovators' ability to obtain patent claims with appropriate scope.

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 a system of guiding cases can be adopted by more IP courts.

A centralized tribunal for hearing appeals in IP cases – the Supreme Peoples' Court Intellectual Property Court – began operating on January 1, 2019. By the end of 2019 the Court reported that it had closed 1433 cases but only about 20-30 had been published. The establishment of the IP Court of the Supreme Peoples' Court may bring predictability to enforcement of IP rights in China, but the relatively few decisions published to date raises concerns about the transparency of such enforcement.

³² Decision on Amending the Patent Examination Guidelines (Feb. 2017), <http://www.sipo.gov.cn/zcfg/zcfgflfg/flfgzl/zlbmgz/1020135.htm> .

³³ Notification to Solicit Public Comments on the Draft of the Amendment of the Examination Guidelines Regarding Chapter 9, Part II (Nov. 2019), <http://www.sipo.gov.cn/gztz/1143646.htm>.

³⁴ Decision on Amending the Patent Examination Guidelines (Sep. 2019), <http://www.cnipa.gov.cn/zfgg/1142481.htm>.

Judicial Transparency

Judicial transparency is critical to ensure fairness to parties and consistent case law development. Lack of judicial transparency continues to pose challenges for parties using the Chinese court system. In 2014, China mandated public access to all judicial decisions via a database called China Judgments Online.³⁵ Although this mandate increased the availability of judicial decisions, courts in China are not consistently publishing decisions. Additionally, some parties have observed delays of one year or more from the decision to publication. We recommend that China implement measures to ensure that all courts comply with the mandate to publish decisions in a timely manner.

Additionally, unlike the U.S., courts in China are not required to publish intermediate decisions, such as decisions on preliminary injunction requests. There is also no requirement to publish administrative patent enforcement decisions. To improve transparency during all stages of IP adjudication, we recommend that China implement a rule requiring publication of intermediate and patent enforcement decisions.

Potential Negative Impact of Draft Laws and Regulations Regarding Service Inventions

The current draft revision of the Patent Law proposes amendments to Article 6 to list specific examples of incentive mechanisms for employers to share innovation profit with service inventors. We believe that the list of incentive mechanisms is unnecessary and might cause confusion.³⁶ Article 16 of the Patent Law already requires an employer entity to give the inventor or designer (of a service invention) a reasonable amount of remuneration (but without specifying exactly how). We are concerned that the proposed amendments to Article 6 could be misinterpreted as requiring share-based awards as the only acceptable type of remuneration, and thereby limiting the employer's freedom in remunerating its employees. We would like to see clarification that the obligation under Article 16 of the Patent Law to give inventors remuneration shall be considered satisfied by compliance with an employer's invention remuneration rules, regulations, plan, policy, or compliance with an agreement between employer and inventor regarding inventor remuneration.

CNIPA continues to develop administrative service invention regulations with the intent to promote innovation. IPO commends CNIPA'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.

³⁵ <http://wenshu.court.gov.cn/>. See, also, Jeffrey Langer, Rapid changes in the Chinese legal system, an increasingly attractive venue for IP litigation, IPWatchDog.com (May 7, 2018), <https://www.ipwatchdog.com/2018/05/07/rapid-changes-chinese-legal-system-attractive-venue-ip-litigation/id=96099/>

³⁶ The Patent Law of the People's Republic of China Draft Revision dated 4 January 2019, Art. 6.

We have previously noted improvements to the service invention regulations in the draft released in April 2015.³⁷ 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 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 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 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 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,³⁸ 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.

³⁷ 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://www.sipo.gov.cn/docs/pub/old/ztzl/ywzt/zwfmtlzl/tlcayj/201504/t20150413_1100584.html.

³⁸ *Id* at Art. 15.

Unique Challenges to Pharmaceutical Protection

Our members welcome the patent term extension for pharmaceutical products in Article 43 of the draft revision of Patent Law. The requirement of simultaneous market approval applications in China and abroad, however, is burdensome to innovative pharmaceutical companies.

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 CNIPA appears to be imposing new and unfair or inappropriate limitations and interpretations of the new amendment, especially at the PRB (Patent Reexamination Board) level 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. Section C (Articles 1.10 and 1.11) of the Phase I Economic and Trade Agreement, if fully implemented, should go a long way to addressing these challenges.

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.

Requirements for Foreigners to Hire Local Patent Agencies

In China, domestic applicants may file their patent applications directly with CNIPA. Foreign applicants who want to own their patent assets must appoint a patent agency to represent them before CNIPA.³⁹ 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 including filing applications. 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

³⁹ Patent Law of the People's Republic of China, at Art. 19,
http://www.sipo.gov.cn/zhfwp/zlsqzn_pt/zlfssxzjsczn/1063062.htm.

own names, as long as subsequent prosecution is handled by an in-house or outside attorney or agent qualified by CNIPA.

INDIA

National IPR Policy

Overall India's IPR Policy (Policy) unveiled in May 2016 provides a valuable roadmap for realizing the potential of India's creativity and recognizes the central role IP plays in this regard.⁴⁰ 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.⁴¹ 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, but we have not yet seen much in the way of implementation. 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 new forms of known 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. Section 3(d) is thus clearly discriminatory against pharmaceutical inventions, and does not afford the availability of post-patent filing data that could be used as evidence to support novelty and inventiveness of such new compound forms.

⁴⁰ National Intellectual Property Rights Policy, Government of India (May 2016) (National IPR Policy), <http://dippnic.in/English/Schemes/IntellectualPropertyRights/NationalIPRPoly08.08.2016.pdf>.

⁴¹ National IPR Policy at ¶ 3.8.4.

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."⁴² 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.⁴³ TADF is empowered to request compulsory licensing from the Government of India.⁴⁴

Similarly, India's National Competition Policy requires IP owners to grant access to "essential facilities" on "agreed and nondiscriminatory terms" without reservation.⁴⁵ 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."⁴⁶ 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."⁴⁷ The objective of the paper was "to develop a predicable environment" for compulsory licensing to be used.⁴⁸

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.⁴⁹ 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

⁴² 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.

⁴³ *Id.* at ¶ 4.4.1.

⁴⁴ *Id.* at ¶¶ 4.2, 4.4.3.

⁴⁵ National Competition Policy, § 5.1(vi) (2011), <http://www.mca.gov.in/Ministry/pdf/RevisedDraftNationalCompetitionPolicy201117nov2011.pdf>.

⁴⁶ *Id.*

⁴⁷ Discussion Paper on Compulsory Licensing, ¶70, DIPP (2011), <http://dipp.nic.in/English/Discusspaper/CLDraftDiscussion02September2011.doc>.

⁴⁸ *Id.* at ¶ 2.

⁴⁹ The Patents Act, § 84(1)(c), Intellectual Property India (1970).

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*.”⁵⁰ Among those rights is the ability to exclude others from making, using, or selling their invention.⁵¹

To facilitate potential 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.⁵² Statements of Working (Form 27)⁵³ must be provided annually.⁵⁴ Failure to provide the requested information is punishable by fine or imprisonment.⁵⁵

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 further evidence of that intention. Form 27 is also extremely burdensome, including requests concerning the value of the products worked and the licenses or sub-licenses that are granted for a given patent. Not only might this be impossible or at least difficult to provide on a per patent basis (in part because IP holders often have many complex licensing agreements that may not explicitly enumerate specific patents, and because such agreements may restrict disclosure of such information), but it also forces patent holders and their licensees to potentially provide confidential business information to the government and public. Currently, there is no mechanism to submit the information with request for confidentiality and to avoid the information from going public after filing.

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.⁵⁶ 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. While there are some promising amendments published with respect to Form 27 under the Draft Patent Amendment Rules in May 2019,⁵⁷ these are pending Parliament’s approval.

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

⁵⁰ TRIPS, Art. 27.1 (emphasis added).

⁵¹ TRIPS, Art. 28(1).

⁵² The Patents Act, § 146.

⁵³ 72 Statement Regarding the Working of the Patented Invention on Commercial Scale in India, [http://patinfo.nic.in/pdf/form 27.pdf](http://patinfo.nic.in/pdf/form%2027.pdf).

⁵⁴ The Patents Rules, § 131, Intellectual Property India (2003).

⁵⁵ 74 The Patents Act at n.57.

⁵⁶ 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/1421PatentAmendmentRules2016May2016.pdf>.

⁵⁷ Draft Patents (Amendment) Rules, 2019 (May 31, 2019), https://dipp.gov.in/sites/default/files/Draft_Patents_Rules_2019.pdf.

be fully satisfied through importation.⁵⁸ 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.

Patent Examination Consistency

The July 2017 “Guidelines for Examination of Computer Related Inventions” provided additional certainty for software inventions by, for example, aligning the patent eligibility approach more closely to Europe’s problem-solution approach.

Additionally, the Indian Patent Office has reduced application pendency by, among other measures, hiring additional patent examiners. Given its rapid hiring rate, however, the average patent examiner now only has 3.8 years of experience,⁵⁹ which has anecdotally had a negative impact on examination consistency. We suggest that the Indian Patent Office implement measures to improve patent quality, including additional examiner training and closer supervision of junior examiners by more experienced examiners.

Some patentees have also observed inconsistencies in examination between regional offices based on different interpretations of examination policies and guidelines. Any training implemented by the Indian Patent Office should also address this issue.

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,”⁶⁰ 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

⁵⁸ 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.

⁵⁹ : WIPO (2019). World Intellectual Property Indicators 2019. Geneva: World Intellectual Property Organization, page 51. https://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2019.pdf

⁶⁰ 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>.

cooperation on trade secrets.⁶¹ There is also a recommendation included in India's National IPR Policy to study trade secret protection, with an aim for further policy development.⁶² Earlier recognition of the need to improve trade secret protection can be found in the 2014 draft National Innovation Act⁶³ and 2012 draft National IPR Strategy.⁶⁴ There is also a growing body of academic literature originating within India that agrees such initiative is critical.⁶⁵ The 2012 draft National IPR Strategy made the point when it explained that a "predictable and recognizable trade secret regime will improve investor confidence,"⁶⁶ 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 "the same or substantially the same invention."⁶⁷ 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.⁶⁸ 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.⁶⁹ Furthermore, in absence of clarity on "*substantially the same invention*," in many cases, it is difficult to be certain about full compliance with this requirement.

⁶¹ 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>.

⁶² National IPR Policy, at ¶3.8.4.

⁶³ The National Innovation Act of 2008 (Draft), Ch. VI, http://www.prindia.org/uploads/media/vikas_doc/docs/1241500117~Draftinnovationlaw.pdf.

⁶⁴ Invitation of Views on the Draft National IPR Strategy, ¶¶ 50-52, <http://dipp.nic.in/English/Discusspaper/draftNationalIPRStrategy26Sep2012.pdf>.

⁶⁵ 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](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.

⁶⁶ Draft National IPR Strategy, ¶ 52 (2012).

⁶⁷ Indian Patents Act, § 8(1) (1970), http://www.wipo.int/wipolex/en/text.jsp?file_id=128091.

⁶⁸ Patent Cooperation Treaty, Art. 42, <http://www.wipo.int/pct/en/texts/articles/a42.htm>.

⁶⁹ Indian Patent Act, §§ 25(1)(h), 25(2)(h), and 64(1)(m) respectively.

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.⁷⁰ The requirements set forth by section 8 are antiquated and create unnecessary uncertainty and expense for patent applicants.

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.⁷¹ Non-compliance with this requirement results in monetary fine or a jail term or both.⁷² 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.

IP Enforcement

State regulatory authorities in India can grant marketing approval for a generic version of a new medicine after four years have passed since the new medicine was first approved. State regulatory authorities are not required to verify or consider the remaining term of any existing patents. IPO supports development of a notification and early resolution mechanism for patent disputes to give innovators security in knowing that their efforts in creating a new drug will be respected for the duration of the patent period, similar to patent linkage in the U.S.

While the timeframes for prosecution and grant of patents as well as trademarks have shrunk, disposal of contentious proceedings, such as opposition and cancellation proceedings, on the merits of the case still take few years. Also, while the IP appellate body, the Intellectual Property Appellate Board (IPAB) has been nominated as adjudicating body for copyright matters as well, it continues to face a deficiency of adjudicating members, and the timeframes for disposal of patent and trademark appeal matters are still long.

Drug Price Control

In a positive move, under the Drug (Prices Control) Amendment Order 2019, any patented new drug would be exempt from all forms of price control that exist in India for a period of five years from the start of the drug's commercial marketing. Earlier, such exemption was only available to a manufacturer of a patented new drug which was developed through indigenous research and development in India and which was not produced elsewhere. Also, all orphan drugs would also be exempt from all forms of price control that exist in India, irrespective of their patent status or new drug status. IPO submits that India should not limit the price control exemption to "drugs" patented under the Indian Patent Act, but rather should extend the

⁷⁰ See *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.* FAO (OS) 188/2008, (Apr. 2009).

⁷¹ Indian Patents Act, § 39.

⁷² *Id.* at § 118.

exemption to include drugs patented outside India.

Draft National E-commerce Policy

India published its Draft National E-commerce Policy in February 2019. The policy provides positive action points to address the issue of sale of counterfeits on e-commerce portals. The policy, however, provides certain limitations related to FDI in e-commerce, wherein any e-commerce portals in which foreign investments have been made cannot exercise ownership or control over the inventory sold on its platform.

INDONESIA

Compulsory Licensing

Indonesia has granted compulsory licenses on several patent-protected pharmaceutical products in recent years. These licenses were granted in a manner inconsistent with Indonesia's international obligations. Although the Ministry of Law and Human Rights (MLHR) revised compulsory license Regulation No. 30/2019 is an improvement over Regulation 39, there are further concerns and fundamental issues that need to be addressed. The MLHR has initiated a process to amend the existing Patent Law, which provides an opportunity for Indonesia to work collaboratively with the U.S. and patentees to address unmet medical needs while at the same time respecting its international obligations.

MALAYSIA

Compulsory Licensing

In 2019, Malaysia's intellectual property office published a "consultation paper" on proposed amendments to the Patents Act 1983 that raises concerns about compulsory licensing and related issues. This continued a trend as, in 2017, Malaysia granted a compulsory license for a breakthrough medicine despite the manufacturer's efforts to negotiate a voluntary license. These actions undermine incentives for innovation.

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, 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, except for posting a counterbond which tends to cost between \$15,000 and \$20,000. 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. Although damages can be claimed, this can only be done 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 if Mexico is not their destination.

Mexico's health regulatory agency (COFEPRIS) and IMPI have committed to improve the application of Mexico's 2003 linkage decree which mandates coordination between COFEPRIS and IMPI and to provide protection for data generated to obtain marketing approval for pharmaceutical products. Limiting the scope and effectiveness of these commitments, COFEPRIS may limit patent linkage to patents covering active compounds even though there may be other patents listed in the Patent Linkage Gazette. Moreover, despite these commitments, innovative biopharmaceutical companies are unable to obtain accurate and timely information from COFEPRIS prior to marketing authorization being granted on a generic or biosimilar drug where the innovator product is used as a reference. As a result, companies have little to no notice that a potentially patent infringing product is entering the market. Further, obtaining effective preliminary injunctions or final decisions on cases regarding infringement within a reasonable time (as well as collecting adequate damages when appropriate) remains challenging. Recent cases which allow the lifting of a preliminary injunction by simply posting a higher counterbond without other evidence is problematic for patentees.

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.⁷³ 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 requirements, including a specific inventory of the information to be protected and an up-to-date record of those with access to the information. The trade secret must 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 daily, and many types of trade secrets might be difficult or impossible to mark as required by the law. In practice, these formalities could cause businesses to grind to a halt instead of offering any meaningful protection.

⁷³ Federal Law on Commercial Secrecy No. 98-FZ, 32 SZ RF item 3283 2004 (July 2004) (as amended).

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.⁷⁴

Challenges to Patent Protection

The Russian Government is pursuing draft legislation and other measures that would prevent inventors from securing patents on many types of innovative medicines and, in addition, would facilitate the compulsory licensing of patents. In 2019, a Russian court granted a compulsory license under the Russian Patent Statute to a generic company which owns a dependent patent for an innovative cancer medicine developed in the United States. The decision was based on an extremely low evidence test and standard of proof but was upheld on appeal. Review by the Supreme Court of the Russian Federation has been sought.

SAUDI ARABIA

Patent Enforcement and Regulatory Data Protection

Companies continue to face challenges with respect to weak patent enforcement in Saudi Arabia. For example, the Saudi Food and Drug Administration (SFDA) recently granted marketing approval to a generic version of an innovative medicine during the patent term of that product. SFDA's approval and related price listing of a generic product corresponding to a patented innovator medicine undermines the integrity of Saudi Arabia's patent linkage system.

In addition, Saudi Arabia does not provide regulatory data protection from the date of marketing authorization of innovator products in Saudi Arabia, contradicting the country's own regulations and WTO commitments.

SOUTH AFRICA

Proposed National IPR Policy

South Africa's Department of Trade and Industry released in July 2018 the first phase of the long-awaited Intellectual Property Policy.⁷⁵ The policy could result in a number of concerning amendments to the Patents Act including permitting parallel importation of pharmaceuticals (so that pharmaceuticals bought in a foreign country can be imported into South Africa without approval of the patent holder in some circumstances), restrictive patentability criteria, and increasing the accessibility of current compulsory licensing provisions (possibly by creating a

⁷⁴ 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>.

⁷⁵ http://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf

regulatory process for adjudicating these rather than referring these disputes directly to the courts as is currently the case). These polices would require an amendment of the current Patents Act, which is expected to take a few years.

UNITED ARAB EMIRATES

Challenges to Pharmaceutical Protection

The UAE Ministry of Health has registered generic pharmaceutical products for sale in the UAE that appear to infringe the patents of innovative medicines. At that time, the patents in the countries of origin remained in force and, thus, should have been honored in the UAE as required by Decree 404.⁷⁶ This is a troubling development.

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, socio-economic growth, 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.⁷⁷

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.⁷⁸ 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.

UN bodies, notably WIPO, but also the World Trade Organization (“WTO”) and World Health Organization (“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

⁷⁶ Ministry of Health Decree No. 404, issued on 30 April 2000 (MOH Decree).

⁷⁷ K. Lybecker & S. 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/globalchallengesreportlybeckerlohse.pdf>.

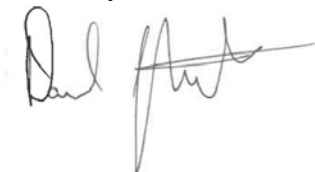
⁷⁸ Standing Committee on the Law of Patents at n. 24.

practice. However, this has become extremely difficult due to intense political engagement by several countries in these “member-driven” organizations. Many 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 encourage these bodies to recognize that IP turns ideas into innovative products, exports, and jobs.

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 2020 Special 301 Report.

Sincerely,

A handwritten signature in black ink, appearing to read "Daniel J. Staudt", with a long horizontal flourish extending to the right.

Daniel J. Staudt
President