



January 28, 2021

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 2021 Special 301 Review, Request for Public Comment (Docket No. USTR–2020–0041)

Dear Mr. Lee:

Intellectual Property Owners Association (IPO) appreciates the opportunity to provide comments regarding the U.S. Trade Representative’s 2021 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 a “big tent” of diverse companies, law firms, service providers and individuals in all industries and fields of technology that own, or are interested in, intellectual property (IP) rights. IPO membership includes over 125 companies and 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 mission is to promote high quality and enforceable IP rights and predictable legal systems for all industries and technologies. Our vision is that this will result in the global acceleration of innovation, creativity, and investment necessary to improve lives.

The importance of the IP system is especially evident at this time, as the development of new ways to fight COVID-19 would not exist absent the IP system enabling companies to continue investing in new medical technologies. The ability to leverage and build upon scientific research conducted over many years, made possible by the IP system, enabled industry to expedite the vaccine development process. Beyond the tremendous impact our IP system has had on our ability to develop a COVID-19 vaccine, it has been instrumental in protecting us from the virus in the interim. Personal protective equipment, such as high-quality respirators, latex gloves, bio-suits, and goggles, offered frontline workers the protection necessary to safely treat patients and save lives. These products, too, were the result of years of investment in innovation. Innovative computer-implemented technologies have allowed us to stay connected for work, school, and socialization while in quarantine. During this unprecedented time that has required us as a global community to physically distance from each other, technologies that resulted from a balanced IP regime have allowed us to remain digitally connected.

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IPO's comments below highlight concerns with key issues affecting the effective protection of intellectual property rights globally, which impact foreign trade. IPO's comments areas are organized in three sections: (I) highlighted broad-based concerns, (II) country-specific concerns, in alphabetical order by country; and (III) concerns about the push to weaken IP rights within multilateral fora.

I. HIGHLIGHTED BROAD-BASED CONCERNS

IPO would first like to highlight a few high-level concerns with protection of intellectual property around the world, without intending to minimize problems not featured in this section. High among these concerns are (a) inadequate trade secret protection, (b) counterfeiting, (c) compulsory licensing, and (d) weak patent enforcement.¹

Trade Secret Protection

For years, Article 39 of TRIPS has required WTO members to ensure effective protection of trade secrets. In the years since TRIPS Article 39 has been agreed (December 15, 1993),² there has been an insufficient effort in many WTO member countries to bring the laws, regulations and enforcement environment up to compliance with the required standard.³ IPO suggests that improving the global environment for protection of trade secrets be one of the top priorities for the Special 301 Report and for further action. Further action should include, for example, setting high levels of trade secret protection as a requirement under bilateral or multilateral trade agreements, both in the negotiation and enforcement. For example, if negotiations are re-opened to reach a Trans-Pacific Partnership Agreement (TPP), IPO submits that trade secret protection be made one of the top negotiating priorities for the USTR. Elements of effective protection of trade secrets and undisclosed information include at least minimum standards to fully implement obligations under TRIPS Article 39, adequate and effective remedies (such as injunctions and criminal penalties) to stop misappropriation of trade secrets, and a prohibition against imposing compulsory licenses of trade secrets.⁴

As part of marketing authorization submissions of medicines, regulatory authorities require pre-clinical and clinical trial information demonstrating the safety and efficacy of a medicine, which includes trade secrets. Regulatory data protection (RDP) provides a minimum level of protection to innovators, during which time no unauthorized third party can rely on the data submitted by the innovator for regulatory approval. RDP recognizes the extensive time, effort,

¹ IPO also submitted a letter on October 29, 2020 to the USTR highlighting these concerns in its comments regarding the 2021 National Trade Estimate Report on Foreign Trade Barriers. See, IPO Comments Regarding Foreign Trade Barriers to U.S. Exports for 2021 Reporting (Docket Number USTR-2020-0034), <https://ipo.org/wp-content/uploads/2020/11/IPO-Comments-for-NTE-Report-on-Foreign-Trade-Barriers.pdf>.

² The Uruguay Round of negotiations created the World Trade Organization and negotiated the General Agreement on Trade-Related Aspects of Intellectual Property Rights, all of which became effective January 1, 1995. See, e.g., https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

³ Even in the case of the EU, for example, compliance was long delayed, with the EU Trade Secret Directive (adopted June 8, 2016) not requiring national laws to implement the directive until June 9, 2018. See "Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure."

⁴ IPO emphasized these trade secret protection elements in an IPO Board Resolution dated June 24, 2011: Protecting Trade Secrets Under the TPP, <https://ipo.org/index.php/protecting-trade-secrets-under-the-tpp/>.

and cost of clinical studies required to ensure that drugs developed are safe and effective for patients—and it provides critical incentives to engage in continued research and development of new innovative therapies. Unfortunately, several U.S. trading partners do not provide RDP or have inadequate RDP regimes. Examples include Argentina, Brazil, China, Egypt, India, and Turkey. IPO is encouraged by the recently released Decree 321 in the UAE, which could address some RDP deficiencies, among other issues, and IPO looks forward to meaningful implementation of the Decree that is consistent with international obligations (in particular the proposed exception in Article 5).

Counterfeiting

Counterfeiting is a global problem that affects more than a brand or brand owner. The sale and manufacture of counterfeit goods harms the public, consumers, patients, hospitals, governments, and more. Counterfeiting has well known links to organized crime and money laundering, and is a threat to public safety. IPO members have reported counterfeiting issues in countries such as, for example, Canada, China, Russia, Thailand, Turkey, the United Arab Emirates, Vietnam, and the United Kingdom.

Ecommerce and social media platforms have made it easier for counterfeiters to sell their products. These platforms provide counterfeiters with an opportunity to engage with consumers throughout the world anonymously with very little effort. Many ecommerce and social media platforms allow counterfeit products to be displayed next to authentic products. In many cases, consumers are not even aware they purchased a counterfeit product and only realize this after the product fails. The number of ecommerce platforms increase every year, making it easier for counterfeiters to move from one platform to another to avoid detection. Many brand owners engage with third party vendors to help enforce their brands on ecommerce and social media platforms. Other brand owners cannot afford to do this and must rely on internal resources and the cooperation of the platforms where they find counterfeit products. Some platforms cooperate well with brand owners, while others are more difficult in this regard. More action is needed by e-commerce platforms to prevent the sale of counterfeit goods on their platforms and provide information on the source of counterfeit goods.

Customs offices throughout the world play a key role in offline enforcement by helping brand owners stop product from entering a country. However, effective border enforcement is not available in many countries, including Brazil, Nigeria, Vietnam, India, Pakistan, and Indonesia. This lack of effective global border enforcement makes it easier for counterfeiters to ship counterfeit products throughout the world and focus their activities on countries with weak border and IP enforcement.

Compulsory Licensing

Patents drive and enable the research and development that delivers valuable new innovations to society. However, several countries, such as Argentina, Chile, Colombia, Egypt, Philippines, Russia, Thailand, Turkey, and Ukraine, have adopted or considered resolutions, laws, or regulations that promote or provide broad discretion to issue a compulsory license. Compulsory licenses have been issued in previous years in several countries, including India, Indonesia, Malaysia and Russia. IPO believes that licensing of IP rights is best accomplished through

voluntary efforts.⁵ An active compulsory licensing policy will not be helpful in promoting partnerships—and it undermines investment in innovative solutions that benefit society. Granting compulsory licenses undercuts the importance of a predictable and reliable patent system.

Weak Patent Enforcement

Effective, efficient, and fair means for enforcing patents are foundational principles for a legal system to deliver the intended benefits of patent rights. Unreasonable barriers to patent enforcement include excessive evidentiary burdens for the initial complaint, statutory caps or limited damage awards, slow resolution of legal disputes, failure of courts to understand technical issues or IP-specific legal concepts.

IPO urges legislative and administrative reforms that allow patent holders improved access to legal systems by adopting reasonable complaint pleading and evidentiary requirements, establishing standards of proof that are aligned with the parties' access to the relevant facts, and appointing experienced and competent judges to adjudicate patent matters. IPO further urges reforms to ensure patent proceedings in Court conclude within an appropriate timeline due to the time sensitivity of these claims, and adoption of appropriate legal changes to fully compensate patent holders for their losses in a case of proven infringement.

Additionally, early resolution mechanisms that provide for the timely resolution of patent disputes before marketing approval is granted for a generic or biosimilar product are important to continued investment in the research and development that leads to new medicines. The premature launch of a medicine that is later found to infringe a patent may disrupt patient treatment and also may cause commercial damage to the innovative company that is impossible to repair later. IPO welcomes efforts by China to implement such a mechanism and hopes that the draft measures being proposed in China will be revised further to provide clarity and meaningful protection for innovators' patent rights. Additional countries, such as India and Russia, among others, should also seek to implement such a mechanism.

II. 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 56/2016⁶ and subsequent entry into a Patent Prosecution Highway (PPH) pilot

⁵ See, e.g., IPO Board Resolution dated December 3, 2020: Resolution on Compulsory Licensing, <https://ipo.org/index.php/resolution-on-compulsory-licensing/>.

⁶ Resolución 56/2016, Instituto Nacional de la Propiedad Industrial.

program that started in 2017 and extends to 2020.⁷ Some patents have already been granted under the pilot program, which is a positive step. Although the efforts of Argentina's Patent Office to reduce the 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 2012.⁸ This resolution introduced more restrictive patentability criteria for chemical and pharmaceutical inventions.⁹ 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.

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.¹⁰ Compulsory licensing, however, undermines the economic incentives created by the IP system for innovation and investment in research and development.

Lack of Regulatory Data Protection

Argentina does not provide protection for regulatory test data, as required under TRIPS. Specifically, Law 24,766 and Decree 150/92 permit Argentine officials to rely on data submitted by originators to approve requests by competitors to market similar products.

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 Agreement¹¹ and with international practice. Australia fails to offer certain patent protections that it agreed to provide, which harms innovators seeking patent protection in Australia.

⁷See <https://www.uspto.gov/patents-getting-started/international-protection/patent-prosecution-highway/patentprosecution-12>.

⁸ *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>.

⁹ 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.

¹⁰ Article 70 of the December 2019 Emergency Economic Law.

¹¹ 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.¹² 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.”¹³

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*.¹⁴ 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.

Several recent cases have confirmed the continued applicability of the best method requirement. The Federal Court also 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 complete application. The Court also considered the best method requirement in *Dometic 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. More recently, *Dometic* was cited with approval in *Axent Holdings*.

The Federal Court in *Merck Sharp & Dohme Corporation v Wyeth LLC (No 3)* [2020] FCA 1477, recently construed the requirement of support in a manner that is inconsistent with Article 17.9(12) of the AUSFTA. Under the court's approach, unduly specific disclosures are required in the specification before a claimed invention can be said to be “sufficiently supported.”

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, recent Australian Full Court decisions in *Encompass Corporation Pty Ltd v InfoTrack Pty Ltd* [2019] FCAFC 161 and *Commissioner of Patents v Rokt Pty Ltd* [2020] FCAFC 86 confirm the need for the alleged invention to show that the computer is more than a generic intermediary in the invention in order to be patentable subject matter. The Australian

¹² *Streetworx Pty. Ltd. v. Artcraft Urban Group Pty. Ltd.*, FCA 1366 (2014), *aff'd*, *Ronneby Road Pty. Ltd. v. ESCO Corp.*, FCA 588 (2016).

¹³ Australia-U.S. Free Trade Agreement, Art. 17.9.13.

¹⁴ *Les Laboratoires Servier v. Apotex Pty. Ltd.*, FCAFC 27 (2016).

Patent Office Manual of Practice and Procedure¹⁵ assesses whether an invention is patentable subject matter by assessing, among other factors, whether the contribution of the invention (*i.e.*, any novelty conferring feature of the invention) is patentable subject matter. This approach may result in claims that have been found allowable in the U.S. being rejected in Australia, even when examined under the Patent Prosecution Highway.

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.¹⁶ The PBS imposes automatic and irreversible price cuts on medicines as soon as a first competing brand enters the market, but there is 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.

Nevertheless, in the recent case of *Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis) (No 5) [2020] FCA 543 (28 April 2020)*, the Department of Health was unsuccessful in seeking compensation as a result of a generic company being restrained from supplying products in Australia and obtaining a PBS listing of such products. This case turned on findings of fact that, but for the interlocutory injunction, the generic company would not have applied for PBS. Therefore, this finding does not prevent the Commonwealth from establishing that a relevant party would have sought and obtained PBS listing of its products in future cases – it will necessarily depend on the nature and strength of the evidence.

This “market-size damages” approach has issues. It tips the scales in commercial patent disputes by exposing them to significant compensation claims and thus may discourage innovators from enforcing their patents. It means that the same government (albeit through different government entities) 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.

IPO recognizes the Australian Government has committed to take steps to increase the period of notification a patent holder receives of entry of a generic competitor, in an effort to reduce the need for emergency injunctive action. Nonetheless, the ongoing existence of the market-sized

¹⁵ See http://manuals.ipaustralia.gov.au/patents/Patent_Examiners_Manual.htm.

¹⁶ The claimed damage must have "necessarily and naturally flowed" from the interlocutory injunction for it to be recoverable.

damages policy remains an obstacle to innovation and investment, and a challenge to the principle of fair and reasonable governance of IP protections.

Shift Relating to Injunctions

There has been a recent shift in the Australian courts negatively impacting the likelihood an interlocutory injunction would be granted. This is partly due to the perception that it would be more difficult to calculate potential losses for a generic company challenging a patent than to calculate a patentee's losses. The primary consideration in determining whether to grant an injunction is where the balance of convenience lies. This looks at the detriment caused by granting or not granting the injunction on each party and whether damages would be an inadequate remedy to compensate for that detriment. Patentees, in recent cases, have been required to demonstrate the strength of their validity case. This approach in Australian courts is inconsistent with the provisional measures in Article 17.11(18) of the AUSFTA which provide that there is a rebuttable presumption that a patent is valid.

Weak Regulatory Data Protection

Australia provides regulatory data protection (RDP) of 5 years for small molecule and biologic products; however, Australia does not provide RDP relating to the registration of new formulations, combinations, indications, populations, or dosage forms of currently registered therapeutic goods. 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.

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 decreased from an average of 11.5 years to a little more than 8 years.

The program to combat the patent backlog was launched in October 2019 with the promise to reduce the backlog by 80% over the following 2 years – after which INPI estimates it will take

less than 24 months to examine new applications. In December 2020, the program achieved the successful mark of nearly 50% in reduction of the backlog.

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 6 months on average.

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

Supreme Court to Decide on Statutory Provision Granting a Minimum of 10 Years of Patent Protection in May 2021

Section 40, sole paragraph, of the 1996 Brazilian patent statute sets forth that patents are valid for 20 years counted from filing or 10 years counted from grant, whichever is the longest. Considering that the Brazilian PTO might often take more than a decade to examine and grant a patent, this legal provision was conceived to guarantee that the patentee will be able to effectively enforce its patent for at least 10 years. This provision is currently under review by the Supreme Court. IPO supports retaining Art. 40 of Brazil's Patent law to help offset some of the patent examination delays.

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 products¹⁷ and appellate court decisions that have also concluded that ANVISA's authority is limited to assessing public health risk.¹⁸ Such dual examination thus continues to raise questions under TRIPS, although we must acknowledge the progress toward resolution.

¹⁷ Opinion 337/PGF/EA/2010 (Jan. 2011).

¹⁸ "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)).

Brazil's Design Examination is Inconsistent

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 slow and inconsistent examination, and some issues can only be solved with time consuming and costly 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. In addition, Brazil should be encouraged to allow for an administrative re-opening or reexamination at the Patent Office for the cases that have been rejected during this transition time, rather than requiring an appeal before the courts.

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*¹⁹ (the “*Regulations*”) scheduled for implementation on July 1, 2021. 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 in the benefits of that research, but not in paying for or incentivizing the research necessary to create the benefits.

We are also concerned about the reduction in reporting requirements for patented generic medicines (approved by means of 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, including any patent that

¹⁹ See <http://www.gazette.gc.ca/rp-pr/p1/2017/2017-12-02/html/reg2-eng.html>.

“pertains to a medicine” as falling within the jurisdiction of the PMPRB, while the PMPRB continues to support an even more expansive patent reporting scope,²⁰ and pharmacoeconomic factors as per the upcoming Amendments. The *Regulations* are 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*²¹ (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.²² 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 “first

²⁰ See <https://www.canada.ca/content/dam/pmprb-cepmb/documents/hearings/decisions-and-orders/redetermination-decision-galderma-en.pdf>. The PMPRB found that the phrase “pertains to a medicine” in section 79(2) of the *Patent Act* should be given a broad interpretation, whereby an invention that is the subject of a patent may “pertain to a medicine,” and therefore come under PMPRB jurisdiction, even if the invention does not encompass the medicine.

²¹ See <http://www.gazette.gc.ca/rp-pr/p1/2017/2017-12-02/html/reg2-eng.html>.

²² Patented Medicines (Notice of Compliance) Regulations, sections 6(1) and 6.01.

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.²³ 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 Canada has recently provided for restoration of patent terms under certain circumstances, by means of a Certificate of Supplementary Protection (“CSP”), 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 result in the exclusion of otherwise worthy patents from receiving a CSP and discourage 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 requirements in other jurisdictions. Furthermore, Canada’s term for a CSP 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 CSP regime for unnecessary conflicts between patent owners. Under the current CSP regime, one or more third parties are allowed to seek a CSP 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” holders) 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

²³ An example of this is seen in the cases of *Apotex v. Sanofi-Aventis*, 2014 FCA 68 and *Teva Canada v. SanofiAventis*, 2014 FCA 67.

urges that third parties not be allowed to seek CSPs using a pharmaceutical innovator's NOC without the permission of the innovator.

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.²⁴ 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 20.50, paragraph 1(c).²⁵

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.²⁶ 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.

²⁴ 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.)

²⁵ “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.” See

<https://usmca.com/intellectualproperty-rights-usmca-chapter-20/>.

²⁶ 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,²⁷ 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 extremely 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, developing anti-intellectual property laws, and suggesting modifications to regulatory affairs process. The Health Committee of the Chamber of Deputies have proposed amendments under the Fármacos II bill to expand compulsory licenses, restrict use of brand names for medicines, and suggest modifications to regulatory affairs for bioequivalent drugs and in the process for regulatory registration of drugs. These developments risk Chile's leading position and threaten continued innovation in Chile.

More specifically, IPO is concerned about the doctor's obligation to prescribe medications exclusively by their International Common Name in the prescription, not designating the trademark, and that the medicine packaging must include the name of the product in question, according to its international common name, in letters of a size that, as a whole, uses at least one third of one of its main faces. Medicines may only have a "fantasy" name on the container, in a size that, as a whole, does not exceed one fifth of the size used for the international common name. Requiring qualified professionals to prescribe drugs using the International Common Name of the drug will then lead the pharmacy to dispense any version of the drug, including bioequivalent drugs, without any input or benefit of the judgment of the qualified professional.

These measures would also excessively broaden the scope of compulsory licenses, incorporating vague and discretionary elements such as the "shortage" or the "economic inaccessibility" of pharmaceutical products. They are not consistent with internal legislation or with the international treaties that Chile has signed, which promote the protection of these rights in order to encourage innovation.

²⁷ Section 53.1 of the Patent Act (R.S.C., 1985, c. P-4), last amended on 2019-10-30. See <https://laws-lois.justice.gc.ca/eng/acts/P-4/page-13.html#docCont>.

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. 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. IPO has monitored the implementation of the agreement and continues to do so.

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 laws, among others. In these differing regimes, there have been several promising developments.

For example, China recently amended its Anti-Unfair Competition Law.²⁸ The State Administration for Market Regulation published Draft Rules on Trade Secret Protection for public comments.²⁹ The Supreme People's Court also published Interpretations on Several Issues Concerning the Application of Law in the Trial of Civil Cases of Trade Secret Infringement Disputes.³⁰ These amendments, new rules, and judicial interpretations indicate 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 significant³¹ 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, where the misappropriator benefits from a trade secret by virtue of accelerated development rather than actual profits or other unjust gains, such a concept is not

²⁸ See Anti-Unfair Competition Law (as amended April 2019),

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

²⁹ See Rules on Trade Secret Protection (Draft for Solicitation of Comments), published on September 4, 2020,

http://www.moj.gov.cn/news/content/2020-09/04/zlk_3255345.html

³⁰ See the Supreme People's Court published Interpretations on Several Issues Concerning the Application of Law in the Trial of Civil Cases of Trade Secret Infringement Disputes, published on August 24, 2020 and implemented on September 12, 2020, <http://www.court.gov.cn/zixun-xiangqing-254751.html>.

³¹ 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).

formally recognized in the determination of damages to the trade secret owner. 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, 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.³² 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 might be 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.³³

In summary, in China, our members face high burdens of proof, limited discovery, and damages issues when seeking to enforce their trade secrets. While preliminary injunctions in the form of conduct preservations are more recently being granted in trade secret actions, such relief remains uncommon and unpredictable particularly in view of the high threshold of proof, and thus a trade secret owner usually 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.

China Lacks a Meaningful General Period for Design Applications

China is 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, Japan, South Korea and Canada, and under consideration in Australia — provide applicants the time and flexibility to consider the

³² The Patent Law of the People's Republic of China Draft Revision dated 4 January 2019, Article 69.

³³ 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>.

need for 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.

Abusive Anti-Suit Injunctions

Beginning in August 2020, Chinese courts appear to have embarked on efforts to seize control of global standard essential patent (SEP) rate-setting cases. Chinese courts took very aggressive positions in a number of FRAND cases, rendering decisions that should concern not only patent owners around the world but governments as well. These anti-suit injunctions have arguably tipped the scales in favor of state-owned businesses, preventing non-Chinese entities from obtaining a fair resolution of disputes relating to non-Chinese patents. These efforts have included purporting to effect service of process by sending emails to foreign defendants; issuing unlawful anti-suit injunctions, without notice, having broad extra-territorial effect; and accepting generic complaints requesting declaratory judgments purporting to set royalty rates for foreign, non-Chinese patents. Each of these actions, now taken by several Chinese courts, raises concerns of due process, fundamental rights to defenses, and the rule of law.

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 nonregistrant 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 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 Yingzhou 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.³⁴

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, as well as biopharmaceutical companies conducting research in China, 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 Fourth Amendment to the Patent Act, effective June 1, 2020, increases the power of administrative agencies to investigate patent infringement and seize confidential information including trade secrets, which

³⁴ 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-andchinese-delegations>.

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 require improvements in the protection of trade secrets and confidential business information from unauthorized disclosure by government authorities and prohibit forced technology transfer through administrative and licensing requirements.

Patent Enforcement and the Amendment to Chinese Patent Law

Language in China's 4th Amendment to its Patent Law³⁵ raises concerns that, in some instances, valid patent rights might not be enforced. Article 20 of the Patent Law requires those who apply for and exercise patent rights to act in good faith and not misuse patents to "damage public interests or other's legal rights."³⁶ Little detail has been given to explain this principle or guide the courts and administrative agencies that will ultimately be tasked with enforcing it. 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,³⁷ 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 companies. One such measure would be to automatically stay infringement proceedings until timely invalidation requests have been resolved.

The 4th Amendment to the Patent Law 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

³⁵ The 4th Amendment to Patent Law of the People's Republic of China, published on November 19, 2020, effective June 1, 2021, <http://www.npc.gov.cn/npc/c30834/202011/82354d98e70947c09dbc5e4eeb78bdf3.shtml>.

³⁶ *Id.* at Art. 20.

³⁷ 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%).

effects of the 4th Amendment Patent Law 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. This change would fragment enforcement, interpretations, and procedures regarding patent laws and the related rights, making enforcement in China less predictable and extremely difficult to navigate.

To be more effective, China's patent system should allow for appropriate recourse to civil litigation for patent infringement to the exclusion of administrative enforcement remedies, which can be political, unprofessional, and discriminatory. This would help rights-holders 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 January 15, 2021,³⁸ whereby supplementary data could be conditionally accepted to prove both sufficient disclosure and inventive step, even if the applications as filed do not provide any data. 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, and await to see whether the amendments will make a substantial impact in practice. 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 to improve 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 to the Examination Guidelines (Second Batch of Draft for Solicitation published on November 10, 2020).³⁹ However, this amendment introduces confusion as to patentable subject matter for computer programs, and further clarity is needed on whether an invention includes a "technical means." We are concerned about these changes, which are being made at a relatively low level (via Examination Guidelines), substantively impacting the patentability standards for computer programs and causing broader confusion on how to apply patentability standards, without the changes being coherently addressed in higher-order changes to the laws or regulations.

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 help bring transparency and predictability to enforcement of IP

³⁸ Amendment to the Guidelines of Patent Examination According to the CNIPA Announcement No. 391 (effective January 15, 2021) .

³⁹ Notification to Solicit Public Comments on the *Draft Amendments to the Patent Examination Guidelines (Second Batch of Draft for Solicitation of Comments)* published on 10 November 2020.

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.

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.⁴⁰ 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 in 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 Laws and Regulations Regarding Service Inventions

Article 15 of the Patent Law lists 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.⁴¹ Article 15 already required 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 listed examples of incentive mechanisms in Article 15 could be misinterpreted as requiring share-based awards as the only acceptable type of remuneration, and thereby as limiting the employer’s freedom in remunerating its employees. We would like to see clarification that the obligation under Article 15 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, preferably in the final Implementing Regulations of the Patent Law. We note that currently the Draft Amendments to the Implementing Regulations (Published for Comments November 27, 2020)

⁴⁰ <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/>

⁴¹ The Patent Law of the People’s Republic of China Draft Revision dated 4 January 2019, Art. 6.

acknowledges in Article 76-1 that employers and employees may agree to reward and remuneration as required under Article 15.

Unique Challenges to Pharmaceutical Protection

Our members welcome the patent term extension for pharmaceutical products in Article 42 of the 4th Amendment to the Patent Law. The National Medical Products Administration and CNIPA published Draft Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes (“Draft Measures”) on September 11, 2020. The Supreme People’s Court also published the Provisions on Several Issues Concerning the Application of Law in the Trial of Patent Civil Cases Involving Drug Marketing Review and Approval (Draft for Solicitation of Comments) (“Draft Provisions”) on October 29, 2020.

The patent linkage provisions are new for China. A fair and effective linkage system for China will not only need to balance the interests of generics and innovators, but also will need consistency between the courts and the range of concerned administrative agencies. Synchronous reforms to the relevant laws and regulations are necessary to enable stakeholders to consider the proposed scheme fully and holistically. Furthermore, rules and judicial interpretations should be harmonized with higher level laws and regulations.

Article 76 of the Patent Law is directed to drug marketing applications. We would like to see a broad definition of “drug” (e.g., to include both chemicals and biologics) to reflect the current state of the art in the field. Similarly, the applicable patents should broadly include those directed to chemical compounds, chemical compositions, pharmaceutical composition or formulation, method of manufacturing of the active ingredient, specific medical use, etc. The current version of the Draft Measures and Draft Provisions needs to be revised to reflect the broad definition of “drug” and the wide range of patents.

We are concerned about the absence of a time limit for the court to issue a decision in the Draft Measures. The current version of the NMPA/CNIPA’s Draft Measures has a 9-month time limit for litigation to conclude, which the Draft Provisions do not. Failure to conclude the litigation within 9 months allows the NMPA to end the moratorium on approval. As the NMPA does not suspend evaluation during the moratorium, it is possible that the NMPA could issue marketing approval before the litigation concludes. The NMPA will not revoke marketing approval even if the Beijing IP Court rules against the generic manufacturer, rendering the patent linkage litigation moot. Furthermore, the 9-month time limit applies only to small molecules and not biologics.

We are also concerned about the lack of notification requirement by a generic drug applicant to notify the Marketing Authorization Holder when it makes a patent statement in its generic drug application. The Phase One Agreement in Art. 1.11(a) sets out that China shall provide “a system to provide notice to a patent holder, licensee, or holder of marketing approval, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use.” However, the process proposed in the current version of the NMPA/CNIPA’s Draft Measures does not require a generic drug applicant to notify the Marketing Authorization Holder. The patentee or interested party opposing such a patent statement is given a 45-day window from the date when NMPA makes

the generic drug application public to bring an action. Without notification, the patentee or interested party may have very limited time to prepare for a litigation by the end of the 45-day window.

In addition, the requirement of simultaneous market approval applications in China and abroad 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 and Invalidation Department) level on the use of post-filing data to satisfy inventive step requirements.

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.⁴² 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. This is not possible under China's current Patent Law.

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

⁴² Patent Law of the People's Republic of China, at Art. 19,
http://www.sipo.gov.cn/zhfwp/zlsqzn_pt/zlfssxzjsczn/1063062.htm.

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.⁴³ 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.⁴⁴ 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. Further items whose implementation will be interesting to observe include: 3.9 for guidelines on technology transfer, know-how and licensing of SEPs; 4.15 for India's accession to Hague System; 4.16.1 on timelines for grant of registrations and disposal of opposition matters; 6.8 for strengthening protection mechanisms for protection of IP rights; and 6.10 for effective adjudication of IP disputes.

Some of the Policy objectives are implemented through different vehicles. Item 4.13 of the Policy has been implemented, wherein a Cell for IPR Promotion and Management (CIPAM) has been set up with the guidance of the DPIIT (Department for Promotion of Industry and Internal Trade). CIPAM facilitates programs and initiatives for IPR awareness, promotion, creation and commercialization of IP assets as per the Policy. CIPAM prepared and released "*Draft Model Guidelines on Implementation of IPR Policy for Academic Institutions*"⁴⁵ with the objective to frame a uniform IP Policy for licensing and commercialization of IP rights for academic institutions on national level. The provisions are primarily based on the *Guidelines on Developing Intellectual Property Policy for Universities and R&D Organizations, WIPO*, and introduces, for the first time, an 'incentive model' for allocation of royalties to inventors. This is related to implementation of at least two objectives under the Policy – Generation of IPRs and Commercialization of IPRs.

Immediately after the Policy, a *Scheme for Facilitating Startups Intellectual Property Protection* (SIPP) was launched in May 2016, which has been currently extended until March 2023. It is appreciated that the benefits of the scheme, such as concession (of up to 80%) on the official charges payable at IP Offices by start-ups and small entities have been extended to

⁴³ National Intellectual Property Rights Policy, Government of India (May 2016) (National IPR Policy), https://dipp.gov.in/sites/default/files/National_IPR_Policy_English.pdf.

⁴⁴ *Id.* at ¶ 3.8.4.

⁴⁵ See https://dipp.gov.in/sites/default/files/Draft_Model_Guidelines_on_Implementation_of_IPR_Policy_for_Academic_Institutions_09092019.pdf.

foreign companies as well. Also, item 4.14 has been implemented by enabling expedited examination of patent applications for at least selected applicants (such as start-ups and small entities.).

Taken as a whole, the Policy includes many positive actions for improving India's IP systems, and while there have been efforts towards implementation of several objectives to varying degrees, we have yet to see a sustained and organized implementation of several key objectives. The U.S. should continue to monitor the implementation of the Policy as it unfolds.

IPO was pleased to learn about the bilateral Memorandum of Understanding on IP cooperation, which was signed in December 2020, and we encourage increased IP dialogue between the two countries.

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. It appears that Section 3(d) is discriminatory against pharmaceutical inventions and the law makes it difficult to secure patent protection for certain types of pharmaceutical inventions and chemical compounds. Further, India law 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.

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."⁴⁶ 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.⁴⁷ TADF is empowered to request compulsory licensing from the Government of India.⁴⁸

Similarly, India's National Competition Policy requires IP owners to grant access to "essential facilities" on "agreed and nondiscriminatory terms" without reservation.⁴⁹ 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."⁵⁰ 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.

⁴⁶ 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.

⁴⁷ *Id.* at ¶ 4.4.1.

⁴⁸ *Id.* at ¶¶ 4.2, 4.4.3.

⁴⁹ National Competition Policy, § 5.1(vi) (2011), <http://www.mca.gov.in/Ministry/pdf/RevisedDraftNationalCompetitionPolicy201117nov2011.pdf>.

⁵⁰ *Id.*

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.”⁵¹ The objective of the paper was “to develop a predicable environment” for compulsory licensing to be used.⁵²

Within the life sciences arena, the grounds for issuing a CL in India under the Patents Act, 1970 are broad, vague and appear to include criteria that are not clearly related to legitimate health emergencies. Moreover, some Indian pharmaceutical companies routinely initiate requests for voluntary licenses under Section 84(6)(iv) of the Patents Act as a precursor to seeking a compulsory license, reducing compulsory licenses to a commercial tool rather than a measure of last resort. Internationally, in various multilateral forums, India has advocated for the broad adoption and implementation of legislation that facilitates the use of compulsory licenses, contrary to the spirit of the TRIPS Agreement. A market with ongoing threats of compulsory licenses perpetuates an unreliable environment for patent protection and investment.

Lack of Regulatory Data Protection and Patent Linkage

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.

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.

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.⁵³ This appears to include situations when patent holders import the related technology into the country, but do not locally manufacture it. It is difficult to understand how this complies with TRIPS, which requires patents and their associated rights to be available “without discrimination as to the place of invention, the field of technology and whether products are *imported or locally*

⁵¹ Discussion Paper on Compulsory Licensing, ¶70, DIPP (2011), <http://dipp.nic.in/English/Discusspaper/CLDraftDiscussion02September2011.doc>.

⁵² *Id.* at ¶ 2.

⁵³ The Patents Act, 1970, Section 84(1)(c).

produced.”⁵⁴ Among those rights is the ability to exclude others from making, using, or selling their invention.⁵⁵

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.⁵⁶ Statements of Working (Form 27) must be provided annually.⁵⁷ Failure to provide the requested information is punishable by fine.⁵⁸ Although the Form-27 has recently been amended to relax certain details required to be furnished, the Statement is still very much required to be filed on annual basis.⁵⁹

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 difficult to provide 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.⁶⁰ Although this is a welcome move, the electronic version of Form 27 has not been amended as per the Patent Amendment Rules 2020 and still requires mandatory submission of information which otherwise is not required to be submitted as per the amended Rules. This inconsistency causes a great deal of hardship to patentees.

The emphasis on Form 27 suggests that India intends to impose working requirements on users of its patent system. India issued its first compulsory license in 2012, which survived several legal challenges including at the Supreme Court of India. Most troubling about the decision was the interpretation that, at least in some circumstances, the working requirement might not be fully satisfied through importation.⁶¹ 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.

⁵⁴ TRIPS, Art. 27.1 (emphasis added).

⁵⁵ TRIPS, Art. 28(1).

⁵⁶ The Patents Act, 1970, Section 146.

⁵⁷ The Patents Rules, § 131, Intellectual Property India (2003).

⁵⁸ The Patents Act, 1970, Section 122 (1).

⁵⁹ See http://ipindia.nic.in/writereaddata/Portal/Images/pdf/patents_amendment_rules_2020.pdf.

⁶⁰ Public Notice No.CG/F/Public Notice/2016, published in Pt. II, Section 3, Sub-Section (i) of the Gazette of India (May 2016), http://www.ipindia.nic.in/writereaddata/Portal/IPORule/1_42_1_Patent_Amendment_Rules_2016_16May2016.pdf.

⁶¹ 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.

Patent Examination

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. The Delhi High Court, while affirming patentability of a computer related invention in a decade long litigation,⁶² observed that if the invention demonstrates a “technical effect” or a “technical contribution” it is patentable even though it may be based on a computer program and acknowledged that the legal position in India is similar to that in EU.

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,⁶³ 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.

It is a positive development that India entered into its first ever PPH (Patent Prosecution Highway) Program last year with the Japan Patent Office. We hope that India enters into PPH arrangements with other IP Offices.

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,”⁶⁴ 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.

⁶² *Ferid Allani V. Union of India and Ors.*, 2019 SCC Online Del 11867

⁶³ 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

⁶⁴ 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>.

Moves by the Indian government indicate that the country might value such an approach. We are encouraged by the commitment at the 2015 U.S. and India Trade Policy Forum to deepen cooperation on trade secrets.⁶⁵ There is also a recommendation included in India's National IPR Policy to study trade secret protection, with an aim for further policy development.⁶⁶ Earlier recognition of the need to improve trade secret protection can be found in the 2014 draft National Innovation Act⁶⁷ and 2012 draft National IPR Strategy.⁶⁸ There is also a growing body of academic literature originating within India that agrees such initiative is critical.⁶⁹ The 2012 draft National IPR Strategy made the point when it explained that a "predictable and recognizable trade secret regime will improve investor confidence,"⁷⁰ 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."⁷¹ 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.⁷² 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.⁷³ Furthermore, in absence of clarity on "*substantially the same*

⁶⁵ 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>.

⁶⁶ National IPR Policy, at ¶3.8.4.

⁶⁷ The National Innovation Act of 2008 (Draft), Ch. VI, http://www.prsindia.org/uploads/media/vikas_doc/docs/1241500117~~Draftinnovationlaw.pdf.

⁶⁸ Invitation of Views on the Draft National IPR Strategy, ¶¶ 50-52, <http://dipp.nic.in/English/Discusspaper/draftNationalIPRStrategy26Sep2012.pdf>.

⁶⁹ 82 See e.g., Hariani, *The Draft National Innovation Act*, India L.J. (2007), http://indialawjournal.com/volume3/issue_1/articlebyanirudh.html; 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.

⁷⁰ Draft National IPR Strategy, ¶ 52 (2012).

⁷¹ Indian Patents Act, § 8(1) (1970), http://www.wipo.int/wipolex/en/text.jsp?file_id=128091.

⁷² Patent Cooperation Treaty, Art. 42, <http://www.wipo.int/pct/en/texts/articles/a42.htm>.

⁷³ Indian Patent Act, §§ 25(1)(h), 25(2)(h), and 64(1)(m) respectively.

invention,” in many cases, it is difficult to be certain about full compliance with this requirement.

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.⁷⁴ The requirements set forth by section 8 are antiquated and create unnecessary uncertainty and expense for patent applicants.

Foreign Filing Permissions and the 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.⁷⁵ Non-compliance with this requirement results in monetary fine or a jail term or both.⁷⁶ 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 its 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 Oppositions and Enforcement

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, as well as litigation matters on the merits, still take a few years. Additionally, pre-grant opposition procedures under Section 25 of India’s Patent Act, 1970, have created uncertainty and delayed the introduction of new inventions by delaying patent prosecution and undermining patent office efficiency.

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.

In a positive development, however, the Delhi High court, in a patent litigation,⁷⁷ laid out guidelines for Patent Office functioning during post-grant oppositions to patents. Among other clarifications, the guidelines spelled out the timelines and nature of documents permitted to be filed during the opposition proceedings.

⁷⁴ See *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.* FAO (OS) 188/2008, (Apr. 2009).

⁷⁵ Indian Patents Act, § 39.

⁷⁶ *Id.* at § 118.

⁷⁷ *Pharmacyclics LLC v. Union of India.*

Drug Price Control

In 2019, Drug (Prices Control) Amendment Order 2019 was released according to which 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 exemption to include drugs patented outside India.

Some pharmaceutical companies have received notices from National Pharmaceutical Pricing Authority's (NPPA) for invoking self-exemption from price caps (after having been granted a patent for their drugs), without first seeking the authority's approval. Some of these pharma companies (including Lupin, Abbot Healthcare, Sun Pharma and Glenmark) have filed different petitions in High Courts concerning the interpretation of invocation of exemption clause. In parallel, the All India Drug Action Network (AIDAN) has also challenged the exemption provided under the Drug (Prices Control) Amendment Order, 2019. Clarification should be provided to remove the ambiguities with respect to the exemption.

Unnecessary Administrative Burdens Imposed on U.S. Design Patent Applicants

Under Indian law, an assignment is not required to be filed in a design application if, when a priority is claimed, the applicant of the priority application is the same as that of the Indian application. Yet, Indian examiners often require that an original certified copy of a recorded assignment be submitted for design applications that claim priority to a U.S. application, even where the applicant is the same. This is a significant cost and administrative burden on U.S. applicants. If the problem is that the Indian law is unclear, it should be clarified to eliminate this burden. Otherwise, Indian examination practices should be updated to align with the law so that an assignment copy need not be submitted where the applicant is the same as in the priority application.

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. In July 2020, Indonesia issued Presidential Regulation No. 77/2020, on government use of compulsory licenses without consulting stakeholders and the final form contains various concerning provisions.

IPO, however, welcomes the recently issued Omnibus Law that aligns Indonesia's patent working requirements with international rules and practices. Furthermore, the Minister of Law and Human Rights 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 improve the innovative environment in Indonesia.

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

Under the enactment of the new Federal Law for the Protection of Industrial Property (FLPIP) that entered into force on November 5, 2020, previous concerns about the ineffectiveness of preliminary injunctions in IP cases that should result in the seizure of infringing goods have not been definitively corrected. 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. Under the new law, the criteria for establishing the amount should include consideration of the public interest and the relative damages of the seizure relative to the infringement. The new law applicable for the counterbond might be effective depending on the criteria that IMPI establishes in practice but, in principle, the ease of lifting an injunction and continuing the infringing behavior remains a concern.

Another challenge in patent proceedings is that IMPI uses its examiners to act as expert witnesses, in effect serving as both judge and party.

The law for recovery of damages for trademark and patent infringement has also changed in Mexico under the new FLPIP, but its effectiveness remains to be seen. Under the FLPIP, damages can be claimed now either before IMPI or civil courts, instead of previously when this could only be done after administrative proceedings were final. The lack of experience of civil courts in patent cases, and the fact that both the administrative and court routes are available, make it uncertain whether the timeliness and effectiveness associated with enforcing damages claims will improve.

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 announced the intention to improve the availability of information on patented drugs, which is now mandated by the FLPIP

without restriction on the kind of patent. However, the health regulations have not been updated, thus limiting the scope and effectiveness of the system, as COFEPRIS may limit patent linkage to patents covering active compounds even though there may be other patents listed in the Patent Linkage Gazette by statute.

Data exclusivity laws are also a pending task and uncertainty regarding enforcement and compliance by COFEPRIS is unclear. Moreover, despite USMCA commitments, innovative pharmaceutical and 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. In addition, there are serious concerns regarding the observance of the patent linkage system and data exclusivity obligations under a new equivalency ruling that will allow fast-track grant of marketing authorizations by COFEPRIS based on foreign health authority assessments, without observing the timeframes and procedures for verification of patent linkage.

IPO does, however, applaud IMPI for implementing the Parallel Patent Grant Initiative,⁷⁸ which allows IMPI to leverage USPTO search and examination results when granting a counterpart patent, resulting in an expedited timeline for obtaining a patent in Mexico if one already has a corresponding U.S. patent.

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.⁷⁹ 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.

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 —

⁷⁸ USPTO December 7, 2020 Press Release (20/27): USPTO and Mexican Institute of Industrial Property announce launch of Parallel Patent Grant Initiative, <https://www.uspto.gov/about-us/news-updates/uspto-and-mexican-institute-industrial-property-announce-launch-parallel>.

⁷⁹ Federal Law on Commercial Secrecy No. 98-FZ, 32 SZ RF item 3283 2004 (July 2004) (as amended).

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.⁸⁰ Similarly, patent enforcement remains a concern and Russian courts rarely grant preliminary injunctions in patent infringement cases.

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. 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 by the appellate court, the IP Court.

Additionally, on November 22, 2019, the Russian Government submitted to the State Duma the draft Federal Law "On Amendments to Article 1360 of the Civil Code of the RF" (considering the use of an invention, utility model, or industrial design in the interests of national security). That amendment would expand the government's discretion to issue a compulsory license "to ensure national security or protect human lives or health, in case of emergency" with a notice and compensation to the patent holder as approved by the Government. On December 15, 2020 the State Duma passed the draft Federal Law in the 1st reading and sent it to other state authorities for comment. The term for the 2nd reading has not yet been determined.

In addition, on December 31, 2020 the Russian Government adopted Decree No. 3718-p, which in accordance with the current provisions of Article 1360 of the Russian Civil Code, granted a compulsory license to a local generic company, Pharmasyntez, to produce a patent protected product.⁸¹

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.

⁸⁰ 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>.

⁸¹ See <https://www.cms-lawnow.com/ealerts/2021/01/russian-government-issues-first-compulsory-pharmaceutical-licence>.

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.

In April 2020, Saudi Authority for Intellectual Property (SAIP) issued damaging final regulations on the compulsory licensing of patents, which have the potential to frustrate Saudi Arabia's efforts to promote innovation and economic growth. The final regulations largely disregard comments pharmaceutical innovators provided on draft regulations SAIP published in July 2019.

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.⁸² Although the policy included positive language recognizing the value of IP in promoting innovation and economic growth, it 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 regulatory process for adjudicating these rather than referring these disputes directly to the courts as is currently the case). These policies would require an amendment of the current Patents Act, which to our understanding is underway. IPO is also concerned by South Africa's role in multilateral fora to broaden the uses and scope of TRIPS flexibilities, and IPO is particularly concerned by South Africa's role in championing efforts at the WTO to suspend countries' obligations to protect IP.

UKRAINE

Amendments to the Ukrainian Patent Act

Ukraine's amendments to the Ukrainian Patent Act effective 21 July 2020 (Law 816-IX) appear to limit the scope of patent protection for certain inventions, and several of the amendments seem contrary to Ukraine's commitment to TRIPS.⁸³ The amended law now excludes from patentability surgical or therapeutic ways of human or animal treatment, ways of diagnosing a human or animal organism,⁸⁴ and has eliminated the novel use of a known product or process from the definition of invention.⁸⁵

⁸² <https://www.gov.za/documents/intellectual-property-policy-south-africa-%E2%80%93-phase-i-2018-13-aug-2018-0000>

⁸³ See <https://www.lexology.com/library/detail.aspx?g=be8bf55f-f7fa-4b67-ba5a-422ac5116a4e>; <https://www.pazellentin.de/artikel/changes-in-ukrainian-patent-law-and-spc-practice.html>.

⁸⁴ Article 6(3) of the Ukrainian Patent Law, as amended effective 21 July 2020.

⁸⁵ Article 6(2) of the Ukrainian Patent Law, as amended effective 21 July 2020.

Contrary to Article 27(1) of TRIPS, which requires that patents be available “without discrimination as to ... the field of technology,” the Ukrainian Patent Act was amended to prevent patenting of new forms of a known medicine, including salts, esters, ethers, compositions, combinations and other derivatives, polymorphs, metabolites, pure form, particle size, isomers, considering such new forms as being obvious in light of the state of the art if they do not differ significantly with regard to efficacy.⁸⁶ The introduction of this additional restrictive patentability criteria (improved efficacy) is contradictory to the Ukraine’s obligations.

The amendments introduced in the new Ukrainian patent law further limit the ability to obtain Supplementary Protection Certificates (SPCs), requiring the patent owner to apply for market authorization in the Ukraine within one year of the first marketing authorization application in any other country. Granted SPCs in the Ukraine will not apply to product to be exported from the Ukraine or to manufacture of product in the last 6 months of the SPC to build up inventory.

The 2020 amendments of the Ukrainian Patent Law also introduced new oppositions procedures into Ukrainian law, including both a pre-grant opposition procedure and a post-grant opposition procedure. The pre-grant opposition procedure is problematic under Article 62.2 of TRIPS, which requires the grant of patents (subject to compliance with substantive examination) “within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.”⁸⁷ The new pre-grant opposition procedure can be filed within 6 months of publication of the application.

III. PUSH TO WEAKEN IP RIGHTS WITHIN MULTILATERAL FORA

IP protection continues to come under fire in multilateral fora. 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.⁸⁸

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

⁸⁶ Article 7(7) of the Ukrainian Patent Law, as amended effective 21 July 2020.

⁸⁷ See https://www.wto.org/english/docs_e/legal_e/27-trips_06_e.htm

⁸⁸ 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>.

continued effort is based, at least in part, on a 2010 proposal.⁸⁹ 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.

Concerning efforts are also underway at the World Trade Organization, where India and South Africa are driving a proposal calling for the temporary elimination of various IP rights on a wide range of COVID-related technologies. Such dangerous proposals that incorrectly portray intellectual property as a barrier to rapid innovation and R&D collaboration are counterproductive to responding to this and future pandemics. This does not correspond to the experience of IPO members; on the contrary, the IP system has enabled an unprecedented amount of innovation—in all sectors—and has facilitated collaboration.

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 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

⁸⁹ Standing Committee on the Law of Patents at n. 24.

developing the 2021 Special 301 Report.

Sincerely,

A handwritten signature in blue ink, appearing to read "Daniel J. Staudt". The signature is fluid and cursive, with a prominent horizontal line crossing through the middle of the name.

Daniel J. Staudt
President