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February 7, 2019

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 2019 Special 301 Review, Request for Public Comment  
(Docket No. USTR-2018-0037)**

Dear Mr. Lee:

Intellectual Property Owners Association (IPO) appreciates the opportunity to provide comments regarding the U.S. Trade Representative's 2019 Special 301 Review. IPO's comments highlight concerns with key issues surrounding the effective protection of intellectual property (IP) rights globally.

IPO is an international trade association representing companies and individuals in all industries and fields of technology who own, or are interested in, intellectual property rights. IPO's membership includes about 200 companies and close to 12,000 individuals who are involved in the association either through their companies or as inventor, author, law firm, or attorney members. IPO membership spans over 30 countries.

IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; and disseminating information to the public on the importance of IP rights.

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

**I. COUNTRY-SPECIFIC CONCERNS**

**ARGENTINA**

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

The patent examination backlog in Argentina is challenging for innovators to manage. In general, the earliest that substantive examination begins is seven years after examination fees are paid. For most applications, examination takes place nearly a

decade after the filing date. Such delays in securing patent rights make it difficult for innovators to attract investors or support business plans. We welcome efforts by Argentina's Patent Office to reduce the backlog, including the enactment of Resolution 56/2016<sup>1</sup> and subsequent entry into a Patent Prosecution Highway (PPH) pilot program that started in 2017 and extends to 2020.<sup>2</sup> Some patents have already been granted under the pilot program, which is a positive step. However, we are concerned as this program explicitly excluded patents in several industries.<sup>3</sup> Unfortunately, a significant backlog remains. Argentina provides neither provisional nor supplemental protection to ameliorate the delays during prosecution.

### ***Shifts in the Legal Framework Creating Uncertainty for Innovators***

Argentina's Patent Office enacted Resolution P-107/2012 in May 2012.<sup>4</sup> This resolution introduced more restrictive patentability criteria for chemical and pharmaceutical inventions.<sup>5</sup> The criteria were applicable to both new and pending patent applications, which altered the legal framework in force when those patent applications were filed. Pending applications filed prior to the resolution are being rejected based on these restrictive criteria. When these changes are combined with the substantial backlog, significant uncertainty results for innovators in the chemical and pharmaceutical areas. In particular, restrictive guidelines refuse pharmaceutical patents for compositions and formulations, salts, esters and ethers, polymorphs, active metabolites and pro-drugs, enantiomers, selection patents, and certain Markush-type claims - almost 80% of all pharmaceutical applications.

### ***Proposed Amendment to Seeds Law Could Reduce Rights for Agricultural Innovations***

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

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<sup>1</sup> Resolución 56/2016, Instituto Nacional de la Propiedad Industrial.

<sup>2</sup> <https://www.uspto.gov/patents-getting-started/international-protection/patent-prosecution-highway/patent-prosecution-12>

<sup>3</sup> Resolución 125/2016, Instituto Nacional de la Propiedad Industrial.

<sup>4</sup> *Apruébanse las pautas para el examen de Patentabilidad de las solicitudes de Patentes sobre Invencciones Químico-Farmacéuticas* (May 2012), <http://www.wipo.int/edocs/lexdocs/laws/es/ar/ar109es.pdf>.

<sup>5</sup> 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.

<sup>6</sup> Ley De Semillas y Creaciones Fitogenéticas, Law No. 20.247; Bill 0030-PE.2016, Cámara de Diputados, <http://www4.hcdn.gob.ar/dependencias/dsecretaria/Periodo2016/PDF2016/TP2016/0030-PE-2016.pdf>.

## AUSTRALIA

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

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

Australia requires a patent to deliver all its “promised benefits,” despite the uncertainty of most types of innovation. If a patentee describes two potential advantages of an invention and only one turns out to be achievable, that resulting patent will be found invalid.<sup>8</sup> 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.”<sup>9</sup>

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*.<sup>10</sup> 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.

### *Market-Size Damages*

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

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

Biopharmaceutical innovators must be able to rely on and enforce patents issued by competent government authorities. Laws or policies that allow governments or other non-parties to a patent

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<sup>7</sup> 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](https://ustr.gov/sites/default/files/uploads/agreements/fta/australia/asset_upload_file148_5168.pdf).

<sup>8</sup> *Streetworx Pty. Ltd. v. Artcraft Urban Group Pty. Ltd.*, FCA 1366 (2014), *aff'd*, *Ronneby Road Pty. Ltd. v. ESCO Corp.*, FCA 588 (2016).

<sup>9</sup> Australia-U.S. Free Trade Agreement, Art. 17.9.13.

<sup>10</sup> *Les Laboratoires Servier v. Apotex Pty. Ltd.*, FCAFC 27 (2016).

dispute to collect market-size damages undermine legal certainty, predictability, and the incentives patents provide for investment in new treatments and cures. They also appear to be inconsistent with the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including with respect to provisional measures and technology discrimination.

### ***Lack of Regulatory Data Protection***

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

## **BRAZIL**

### ***Growing Patent and Trademark Application Backlogs***

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

For patent applications, the Brazilian PTO has proposed to clear the backlog by automatically granting (without examination) non-pharma applications that are already pending. However, this proposal seems to be on hold and is to be re-evaluated in March 2019. If the proposal is implemented, we are concerned that it would result in a vast number of low-quality patents being granted, which will require large scale filing of opposition and invalidation proceedings, potentially with a timeframe as short as 90 days. We are awaiting the effect of Resolution No. 2272018, published in November 2018, regarding the use of examinations of other jurisdictions.

With respect to trademarks, both the backlog and the examination period has decreased substantially, but delays hurt brand owners, making it harder to penetrate the local market. With growing numbers of patent and trademark applications, the related challenges are likely to continue into the foreseeable future.

With respect to trademarks, accession to the Madrid Protocol would help improve the situation. Following Brazil signaling its intention to accede to the Madrid Protocol, the treaty has been sent to the country's Congress—and the Brazilian National Institute of Industrial Property (INPI) has even begun to initiate some of the changes necessary to comply. It is anticipated, however, that beyond accession to the Protocol, several legislative changes and modifications to INPI's rules will be required.<sup>11</sup>

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<sup>11</sup> As an illustrative example, in Brazil, a trademark can only be registered in a single class. Multiclass registrations are required by the Protocol.

Implementing the Protocol would be a significant step towards reducing the backlog and the costs associated with Brazilian trademark protection.

### ***ANVISA's Prior Consent for Patent Examination***

Although INPI is taking steps to improve its backlog, a seemingly dual patent examination system is an impediment to those efforts. Under Article 229-C of Brazil's Patent Law, the Health Surveillance Agency (ANVISA) must review all pharmaceutical patent applications. Although ANVISA's role is limited to issues related to public health and safety, in practice a secondary patent examination is conducted. This dynamic continues despite Brazil's General Attorney's opinion that ANVISA's scope is limited to assessing the safety and therapeutic efficacy of products<sup>12</sup> and appellate court decisions that have also concluded that ANVISA's authority is limited to assessing public health risk.<sup>13</sup>

This additional scrutiny, which applies only to the pharmaceutical sector, raises significant questions of technology discrimination under TRIPS. It also further slows down an already sluggish system, under which it can take INPI years to even forward an application to ANVISA for the initial analysis.

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

Under Brazil's Industrial Property Law, agreements that involve technology transfer must be registered with and approved by INPI.<sup>14</sup> In many cases, INPI modifies contract terms, encroaching on the freedom to contract. For example, INPI has limited the amount of royalties and restricted how such amounts are calculated and when they can begin to accrue. The terms of the agreements and the time during which exchanged information remains confidential are also controlled. Instead of promoting the transfer of technology, such policies discourage critical partnerships.

### ***INPI's Efforts to Weaken Pharmaceutical Patents***

INPI continues to pursue lawsuits that seek to shorten the term of 170 "mailbox patents" on primarily pharmaceutical inventions filed shortly after TRIPS went into effect in Brazil. The lawsuits allege that the products covered by those applications should not have been granted a minimum ten-year patent term as measured from the patent grant date. The grounds alleged by INPI raise further questions about Brazil's commitment to the protection of IP rights.

### ***Design Protection***

In 2017, responsibility for registering and examining design patent applications in Brazil transitioned to a new team of examiners, who previously worked exclusively with trademark issues. The result has been very inconsistent examination, and some issues can only be solved with time consuming judicial

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<sup>12</sup> Opinion 337/PGF/EA/2010 (Jan. 2011).

<sup>13</sup> "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 nonobviousness requirements." (Court of Appeals for the 1st Federal Circuit, 6th Panel, Reporting Appellate Judge Hon. Jirair Meguerian, Appeal # 1001081-59.2015.4.01.3400 (Dec. 2016). Other appellate courts have also decided that ANVISA has no statutory authority to examine pharmaceutical applications for patentability requirements (*see* Court of Appeals for the 2nd Federal Circuit, 2nd Panel, Reporting Appellate Judge Hon. Simone Schreiber, Interlocutory Appeal # 0005084-51.2016.4.02.5101 (Sept. 2016)).

<sup>14</sup> 22 Law No. 9,279/96 of May 14, 1996, WIPO.

review. Brazil should be encouraged to remedy this situation as soon as possible, perhaps through immediate supplemental training of the new examiners or by returning design examination to its former place with the patent department.

### ***Potential Patent Reform Might Weaken IP Rights***

Although a study on Brazilian patent reform released concurrently with a bill on the same topic co-sponsored by the study's coordinator<sup>15</sup> had certain positive proposals, for example investing in reducing backlogs, other suggestions could impair the value of IP. In particular, the study and the Patent Law Reform bill propose to limit patent rights by (1) excluding from patentability certain pharmaceutical inventions; (2) providing for pre-grant opposition proceedings; (3) barring regulatory data protection; (4) explicitly granting ANVISA the role of patentability examination of pharmaceutical inventions; (5) expanding the use of compulsory licensing; and (6) revoking the ten-year minimum term for patents. The study also proposes creating a Counsel of Intellectual Property Rights under the Chief of Staff, which would have binding decision-making authority. This would likely reduce the ability of INPI to use its expertise to properly apply Brazil's patent law and further increase investor uncertainty.

### ***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 of time.

### ***Pursuit to Weaken IP at WIPO***

Brazil continues to advance IP-weakening agendas within international fora. For example, Brazil has pushed for creation of a WIPO manual on exceptions and limitations to guide developing countries in setting aside IP rights.<sup>16</sup> Brazil has suggested that compulsory licensing is the most powerful tool in its arsenal to improve public health. Such positions make it difficult for innovators to invest in solutions that will solve health-related challenges and other societal concerns, as well as to collaborate with governments to improve the existing toolset.

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

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

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<sup>15</sup> *Brazil's Patent Reform: Innovation Towards National Competitiveness* (2013), <http://bd.camara.gov.br/bd/handle/bdcamara/14797>; see also Congressional Bill PL 5402/2013.

<sup>16</sup> See Standing Committee on the Law of Patents, Fourteenth Session, SCP/14/7 (Jan. 2010), [http://www.wipo.int/edocs/mdocs/patent\\_policy/en/scp\\_14/scp\\_14\\_7.pdf](http://www.wipo.int/edocs/mdocs/patent_policy/en/scp_14/scp_14_7.pdf).

## CANADA

### *Patented Medicines Price Review Board (PMPRB) Regulations*

We have concerns about the proposed *Regulations Amending the Patented Medicines Regulations*<sup>17</sup> (the “*Proposed Regulations*”). We are particularly concerned about the changes to the list of comparator countries under section 4(1)(f)(iii) of the *Proposed Regulations* that remove the United States and Switzerland — and add Australia, Belgium, Japan Netherlands, Norway, Republic of Korea, and Spain. The removal of the U.S. and the absence of other countries such as Mexico, another one of Canada’s largest trading partners, is concerning. Also troubling is the selection of countries for the list that in general have lower drug prices than Canada — without considering the impact this has on accessibility to new medicines in those jurisdictions. Furthermore, the U.S. and Switzerland are home to many of the world’s pharmaceutical and biotechnology research companies, sending a message that Canada is interested only in the benefits of that research and not in paying for or incentivizing the research necessary to create the benefits. We are also concerned about the reduction in reporting requirements for patented generic medicines (approved by means of ANDS). Generic medicines are exempt from the continual reporting of cost-utility analysis information unless requested by the Board. At the same time, innovative manufacturers have expansive reporting requirements under the “merest slender thread”<sup>18</sup> basis for jurisdiction by the PMPRB. The *Proposed Regulations* are thus lop-sided and, in fact, are unnecessary when the market includes generic competition. The *Proposed Regulations* unnecessarily discourage innovation and increase reporting requirements for innovative patent holders.

### *Canada’s Heightened Utility Requirement for Patents*

The Supreme Court of Canada rejected Canada’s “Promise Doctrine” in a unanimous decision on 30 June 2017 in *AstraZeneca Canada Inc. v. Apotex, Inc.*<sup>19</sup> This decision, if implemented fully, represents a significant step forward toward restoring certainty and predictability to Canada’s patent system. At the same time, how issues relating to the doctrine will be interpreted in the future remains uncertain. Canada should completely implement the decision in *AstraZeneca Canada, Inc. v. Apotex, Inc.*, including abolition of Canada’s Promise Doctrine, to restore greater certainty and predictability with respect to patentability requirements for Canadian patent applications.

### *Weak Patent Enforcement*

The recent *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*<sup>20</sup> (the “*Amended NOC Regulations*”) include deficiencies that weaken Canadian patent enforcement, including insufficient time for final patent determinations in a single proceeding, increasing liability for damages under section 8, and a separate litigation track for some types of patents due to their ineligibility for listing on the Patent Register.

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<sup>17</sup> <http://www.gazette.gc.ca/rp-pr/p1/2017/2017-12-02/html/reg2-eng.html>.

<sup>18</sup> *ICN Pharms. Inc. v. Canada* (Staff of the Patented Medicine Prices Review Board)(C.A.)(1997) 1 F.C. 32 (ICN).

<sup>19</sup> *AstraZeneca Canada Inc. v. Apotex Inc.*, (2017) SCC 36.

<sup>20</sup> <http://www.gazette.gc.ca/rp-pr/p1/2017/2017-12-02/html/reg2-eng.html>.

### ***24-Month Stay Is Insufficient***

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

### ***45 days for Action on Notice of Allegation***

The amended *Patented Medicines (Notice of Compliance) Regulations* provides 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.<sup>21</sup> 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, including for treble damages, under section 8 and common law theories in cases proceeding within the provincial courts of Ontario. Also, the *Amended NOC Regulations* explicitly consider all plaintiffs in the infringement action to be jointly and severally liable for losses suffered by the second person as opposed to only the “first person” under the previous regulations. However, there is no requirement for all second persons in NOC proceedings related to the same patented medicine to bring their section 8 claim together. Furthermore, there has been no amendment to allow the Court to consider multiple section 8 claims together and make findings related to multiple generic companies entering the market in the absence of the *Amended NOC Regulations*, as does happen in the real world. As a result, when innovators face multiple section 8 claims, there is a risk that the defendant (innovator) will be subject to a cumulative damage award based on what cannot possibly occur in the real world.<sup>22</sup> Also, the *Amended NOC Regulations* remove any limits to the period of a first person’s liability under section 8 of the Regulations. Thus, Second Persons under the *Amended NOC Regulations* may be able to claim losses suffered beyond the date of any dismissal or discontinuance. Taken together, the common law and section 8 related amendments create a risk of “windfall” damage awards. Such awards are contrary to the traditional compensatory function of damages.

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<sup>21</sup> Patented Medicines (Notice of Compliance) Regulations, sections 6(1) and 6.01.

<sup>22</sup> An example of this is seen in the cases of *Apotex v. Sanofi-Aventis*, 2014 FCA 68 and *Teva Canada v. Sanofi-Aventis*, 2014 FCA 67.

### ***Restrictive Certificate of Supplementary Protection (CSP) Eligibility Criteria***

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

### ***Multiple and Conflicting Certificate of Supplementary Protection (CSP) Applications***

We are concerned that there remains a significant risk under the current Regulations for unnecessary conflicts between pharmaceutical innovators. Under the current CSP regime, one or more third parties are allowed to seek a CSP extension using the pharmaceutical innovator's Notice of Compliance, or "NOC." As Canadian law mandates only one CSP per drug, this "conflict" between one or more CSP applications citing the same NOC is resolved in an unnecessary and costly proceeding. Pharmaceutical innovators 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.

### ***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.<sup>23</sup> 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

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<sup>23</sup> 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.).

infringing goods. (Similar provisions will carry forward under the United States-Mexico-Canada Agreement (USMCA), Article 20.F.16, paragraph 1(c).)

### ***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.<sup>24</sup> 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.

Overall, the Government of Canada should be more progressive in its approach, amending its laws more regularly 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, which have been unfairly applied retroactively and created a significant disruption in existing patent proceedings. Canada's data protection practices are also a concern due to court challenges calling into question the scope of protection provided for test data. Notably, when the Government of Canada has sought public comments on new proposals, the deadlines for comment are sometimes disturbingly short and do not allow sufficient time for a thoughtful perspective to be provided. Patent owners would like Canada to take steps to provide stronger protections for innovation.

## **CHINA**

### ***Trade Secrets: Positive Developments and the Need to Upgrade***

Trade secret law in China is fragmented, with protection provided under several different legal and administrative provisions, including those involving Anti-Unfair Competition, Contract, and Labor Law, among others. In these differing regimes, there have been several promising developments.

For example, China amended its Anti-Unfair Competition Law in 2017.<sup>25</sup> The amendment indicates that China desires stronger enforcement against trade secret misappropriation. This continues a trend of expanded enforcement of trade secret rights in China.

China's civil procedure was amended to expand the availability of injunctive relief. Based on this change in law, the Shanghai No. 1 Intermediate Court was able to grant a preliminary injunction to a U.S. plaintiff in a trade secret misappropriation action involving a former employee's breach of a non-disclosure agreement. Prior to this ruling, it was unusual to obtain a preliminary injunction for trade secret misappropriation in China. The Ministry of Commerce (MOFCOM) has named trade secret protection as one of its top priorities. We hope this decision and MOFCOM commitment are signs of a positive trend. The U.S.-China Joint Commission on Commerce and Trade (JCCT) reflects progress on trade secret protection in China; China has stated its intention to issue model or guiding court cases for trade secrets, and to clarify rules on preliminary injunctions, evidence preservation orders, and

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<sup>24</sup> Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, as amended, <http://www.laws-lois.justice.gc.ca/PDF/SOR-93-133.pdf>.

<sup>25</sup> See Anti-Unfair Competition Law, (Nov. 2017), [http://www.npc.gov.cn/npc/xinwen/2017-11/04/content\\_2031432.htm](http://www.npc.gov.cn/npc/xinwen/2017-11/04/content_2031432.htm).

damages.<sup>26</sup> We are also encouraged by the Asia-Pacific Economic Cooperation (APEC) endorsement of Best Practices for Trade Secret Protection and Enforcement, which the U.S. should encourage China to implement expediently.<sup>27</sup>

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 significant and possibly irreversible injury has taken place.

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

The requirements for many businesses to submit technical and functional features of their products, as well as confidential test data, as a condition for access to the Chinese market present further challenges for protecting confidential business information. Further, the most recent draft revision of China’s Patent Law would give local and provincial patent administration and enforcement IP offices new powers to investigate patent infringement cases, including giving them broad authority to inspect the sites where the alleged infringement takes place and to review and copy relevant documents.<sup>28</sup> Our members are concerned with the significant risk of trade secret disclosure that could result from administrative investigations. Absent proper safeguards, such administrative enforcement of patents could result in disclosure of confidential information.

The consequences of such disclosures to government agencies can be particularly harmful because receiving agencies have been generally willing to provide such confidential information to the public on request. In some cases, the information provided is reviewed by expert panels that include employees of local businesses and institutions that might benefit financially from having access to another company’s trade secrets. Although at the 2014 JCCT, China promised to hold government officials with access to confidential business information accountable and otherwise shield the details from public disclosure, the impact of any changes has yet to be felt.<sup>29</sup>

In summary, in China, our members face high burdens of proof, limited discovery, and damages issues when seeking to enforce their trade secrets. Especially distressing, a trade secret owner must wait until a significant and possibly irreversible injury has taken place before seeking relief. Our members also face requirements to submit confidential details to government agencies. Although we are encouraged

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<sup>26</sup> *U.S.-China Joint Fact Sheet for the 27th U.S.-China Joint Commission on Commerce and Trade* (Jan. 2017), <https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2017/january/us-china-joint-fact-sheet-27th-us>.

<sup>27</sup> *AMM Joint Statement*, APEC Peru (2016), [http://mddb.apec.org/Documents/2016/MM/AMM/16\\_amm\\_jms.pdf](http://mddb.apec.org/Documents/2016/MM/AMM/16_amm_jms.pdf); *Best Practices in Trade Secret Protection and Enforcement Against Misappropriation* (Nov. 2016), <https://ustr.gov/sites/default/files/11202016-US-Best-Practices-Trade-Secrets.pdf>.

<sup>28</sup> The Patent Law of the People’s Republic of China Draft Revision dated 4 January 2019, Article 69.

<sup>29</sup> 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>.

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.

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

Currently, China's patent law only offers design protection for an overall product, as opposed to protection for individual parts or portions of a larger design. A recent decision<sup>30</sup> confirms the reduced availability and worth of graphical user interface (GUI) and icon design patents in China, particularly for companies that produce software alone, and for software that is usable on a variety of devices or platforms.

The inability to claim partial designs is not only a problem for GUI designs. Much of today's innovation is incremental, building on existing ideas and products, and certain elements of a product's design often carry through to later generations. Because new designs for a product may build on or incorporate portions of designs of previous product generations, novel features within those goods with respect to look and feel can have significant commercial relevance separate and apart from the overall product. Additionally, it might be necessary to separately protect individual parts of a product to safeguard against specific infringers in a supply chain or to preserve revenue for spare parts. The most recent draft revision of China's Patent Law deleted a proposed amendment to Article 2 in the previous draft that would enable protection for the design of part of a product. The U.S. should encourage China to amend Article 2 as previously proposed to include this necessary improvement, which would provide enhanced protections for American manufacturers.

China should also be encouraged to allow the use of broken lines in design patents. Broken lines enable the applicant to provide critical context for their design without overly limiting what is protected by a design patent. Broken lines also allow the applicant to focus on just the novel features of the design. In other countries, including the U.S., such lines allow the applicant to depict non-essential features to clarify the novel aspect being claimed. The U.S. should also encourage China to clarify that design patent applications can contain dotted lines.

### ***Challenges Created by Chinese Trademark Law***

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

The 2014 PRC Trademark Law dropped the Opposition Review, depriving both parties of their rights of action. As the success rate of opposition in China is very low, the removal of Opposition Review from the PRC trademark framework can only make things worse. Once bad faith registrants get their registration certificates, the brand owners will bear a heavy burden to invalidate them, not to mention the infringement risks caused by the registration if the non-registrant brand owner continues using their

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<sup>30</sup> *Beijing Qihu Technology Co., Ltd. and Qizhi Software Co., Ltd. v. Beijing Jiangmin New Sci. Tech. Co.*

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, particularly where the bad faith trademark filing is made before launch of the legitimate branded product in 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<sup>31</sup> or the budget notice from Nanxian County, Hunan stipulating the same preferences.<sup>32</sup> Therefore, although we are encouraged by China’s renewed commitment at the 27<sup>th</sup> JCCT to build on the country’s 2011 commitment, the U.S. should encourage implementation to move at a more rapid pace.<sup>33</sup>

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

### ***Discriminatory Technology Transfer Regulations***

Regulations on Technology Import and Export Administration of the People's Republic of China<sup>34</sup> place onerous obligations on foreign licensors that are not applied to domestic licensors. These include Articles 24 and 25, which require that a company licensing a foreign technology indemnify a Chinese licensee against third parties who sue for infringement. Article 27 forbids the use of invention grant-back clauses in which the licensee grants a license back to the licensor for improvements. These regulations do not allow parties to contractually agree to a different allocation of risk. No similar

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<sup>31</sup> See Notice on the Organization to Report to the Yinzhou District Government on the Priority Procurement of Independent Innovative Products and High Quality Products Catalog in 2015, <http://www.yzjx.gov.cn/html/gonggaotongzhi/20150209/2136.html>.

<sup>32</sup> See Notice of the Finance Bureau of Nanxian County on Clarifying the Relevant Matters Concerning the Preparation of Departmental Budget, <http://www.nxczw.gov.cn/tongzhigonggao/2015/0127/309.html>.

<sup>33</sup> *U.S. and Chinese Delegations Conclude the 27th Session of the U.S.-China Joint Commission on Commerce and Trade* (Nov. 2016), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2016/november/us-and-chinese-delegations>.

<sup>34</sup> <http://www.wipo.int/edocs/lexdocs/laws/en/cn/cn125en.pdf>.

obligations are placed on domestic licensors. These difficulties are exacerbated by the ability of MOFCOM to require modification of license agreements before allowing payment of royalties. These matters should be negotiated by the contracting parties at arm's length, rather than dictated by regulation in a manner that deprives foreign companies of "national treatment."<sup>35</sup> Additionally, these regulations undermine Article 22 of the recently published Foreign Investment Law of the People's Republic of China (Draft).

The draft 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 draft 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. These include the discriminatory technology transfer regulations discussed above, particularly Articles 24, 25, and 29 of the Regulations on Technology Import and Export Administration of the People's Republic of China. The draft Patent Act, dated 4 January 2019, would increase the power of administrative agencies to investigate patent infringement and seize confidential information including trade secrets (Article 69), which might result in the disclosure of such trade secrets to others, including competitors. Regulatory laws such as environmental, pharmaceutical, and medical device regulatory 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 or affiliated with competitors) or share submitted information with later regulatory applicants (or use it on their behalf).

### ***Patent Enforcement and the Amendment to Chinese Patent Law***

Language in China's current draft revision to its Patent Law<sup>36</sup> raises concerns that in some instances valid patent rights might not be enforced. The draft revision would require those who apply for and exercise patent rights to act in good faith and not misuse patents to "damage public interests or exclude or restrict competition."<sup>37</sup> Little detail has been given to explain this principle or guide the courts and administrative agencies that will ultimately be tasked with enforcing it. Every patent, on some level, is a government-sanctioned restriction on competition. Under the proposed law, there is too much risk and uncertainty that patents might be deemed improper and thus invalidated. Although well-intentioned, such a position would create significant uncertainty and impede the legal exploitation of patents. This also raises questions regarding consistency with TRIPS Article 30, which provides that the exceptions to the exclusive rights conferred by a patent should not unreasonably conflict with a

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<sup>35</sup> See, also, starting at page 7 of the testimony of Mark Cohen to the U.S.-China Economic and Security Review Commission, at the Hearing on the Foreign Investment Climate in China: Present Challenges and Potential for Reform, on January 28, 2015, [https://www.uscc.gov/sites/default/files/Mark%20Cohen\\_testimony.pdf](https://www.uscc.gov/sites/default/files/Mark%20Cohen_testimony.pdf).

<sup>36</sup> The Patent Law of the People's Republic of China Draft Revision dated 4 January 2019.

<sup>37</sup> *Id.* at Art. 20.

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,<sup>38</sup> combined with the lack of examination with respect to patentability, creates substantial uncertainty for U.S. companies in the Chinese market. Although China's National Intellectual Property Administration (CNIPA) has acknowledged the extent of the problem by rejecting some utility model applications that are "obviously unpatentable," more safeguards are needed to ensure these patents are not inappropriately used against innovative American and Chinese companies. One such measure might be to require that the owner of a utility model or design patent in every case obtain a search report from CNIPA supporting the validity of the patent prior to asserting it, and another might be to automatically stay infringement proceedings until timely invalidation requests have been resolved.

The draft revision continues to expand administrative enforcement of patent rights. It would give hundreds of inexperienced local and provincial patent administration and enforcement offices new powers to investigate and inspect, to grant injunctive relief, and to impose compensatory damages, fines, and penalties for patent infringement, and even to enhance damages if the infringement is deemed willful. One of the effects of the draft amendment will be to allow primarily Chinese domestic entities or individuals to assert their rights before local and administrative officials, who might not be technologically and legally qualified, without clear guidance tying any award to the value of the patent. Currently, such proceedings are entrusted only to certain courts selected by the Supreme People's Court due to concerns about the complexity of patent cases. Implementing the proposed draft would fragment enforcement, interpretations, and procedures regarding patent laws and the related rights, making enforcement in China less predictable and extremely difficult to navigate.

To be more effective, China's patent system should allow for appropriate recourse to civil litigation for patent infringement to the exclusion of administrative enforcement remedies, which can be political, unprofessional, and discriminatory. This would help rights-holders demonstrate the value of their patents or other IP, by addressing, among other issues, the problem of insufficiently examined rights by adjudication before more experienced, technical trained, competent, and less political courts.

One positive development is that the revisions to the Patent Examination Guidelines, implemented by CNIPA on April 1, 2017,<sup>39</sup> include provisions in section 3.5 requiring patent examiners to consider post-filing data provided by patent applicants in support of their applications. We believe these changes will foster timely filing of applications for new drugs by allowing applicants to later submit additional information consistent with the drug development process. Further amendments would be useful to clarify that such data can be submitted in response to various kinds of rejections. We also note changes in sections 4.2 and 4.3.1 harmonizing Chinese patent practice with U.S. patent practice in allowing invalidity petitioners to submit new evidence of invalidity when patent owners seek to amend their claims during the invalidity proceeding.

We note that the Beijing IP Court has embarked upon an initiative to use guiding cases in deciding new IP cases, including establishing a database of guiding cases and a research organization for identifying

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<sup>38</sup> 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%).

<sup>39</sup> Decision on Amending the Patent Examination Guidelines (Feb. 2017), [http://www.sipo.gov.cn/zwgg/201712/t20171220\\_1322147.html](http://www.sipo.gov.cn/zwgg/201712/t20171220_1322147.html).

guiding cases to add to the database. Such efforts reveal a desire on the part of China's judiciary to bring some transparency and predictability to enforcement of IP rights in China. We believe transparency and predictability in IP enforcement in China will be improved if a system of guiding cases can be adopted by more IP courts.

### ***Potential Negative Impact of Draft Laws and Regulations Regarding Service Inventions***

The current draft revision of the Patent Law proposes amendments to Article 6 to list specific examples of incentive mechanisms for employers to share innovation profit with service inventors. We believe that the list of incentive mechanisms is unnecessary and might cause confusion.<sup>40</sup> Article 16 of the Patent Law already requires an employee entity to give the inventor or designer (of a service invention) a reasonable amount of remuneration (but without specifying exactly how). We are concerned that the proposed amendments to Article 6 could be misinterpreted as requiring share-based awards as the only acceptable type of remuneration, and thereby limiting the employee entity's freedom in remunerating its employees. We would like to see clarification that the obligation under Article 16 of the Patent Law to give inventors remuneration shall be considered satisfied by compliance with an employer's invention remuneration rules, regulations, plan, policy, or compliance with an agreement between employer and inventor regarding inventor remuneration.

CNIPA continues to develop administrative service invention regulations with the intent to promote innovation. IPO commends CNIPA's efforts to promote scientific advancement and technological innovation within China. Although we understand the policy that inventors should be appropriately incentivized, the current form of the draft regulations has the potential to negatively affect the ability of companies to make commercial choices about how to best motivate their employees and use or dispose of IP assets their employees have been compensated to create.

We have previously noted improvements to the service invention regulations in the draft released in April 2015.<sup>41</sup> Specifically, reference to "technical secrets" in Article 4, which could have put trade secrets at risk, has been removed. The entitlement for inventors to know the "economic benefit" of their service inventions, which could have required companies to reveal confidential information to ex-employee inventors hired by competitors, has also been removed. Other references to trade secrets or know-how remain, however, and the requirement for entities to show "economic benefit" in disputes with inventors remains. This requirement could lead to a strategy in which competitors purposely hire inventors and encourage them to dispute their remunerations to learn strategic insights from their competitors.

The draft could be improved in several additional areas. For example, although the draft regulations make it appear possible for companies to create their own agreements or policies regarding inventor remuneration, an entity would do so at great risk. Policies or agreements that revoke an undefined set of inventor rights or attach "unreasonable conditions" are considered invalid. A finding that prior policies or agreements are invalid would result in the draft regulation default rules retroactively applying, which for many commercial entities might be quite onerous. For example, fixed remuneration arrangements, currently in wide use by entities and by far the simplest way to reward inventors, cannot satisfy the requirements in the latest draft of the regulations. Rather than fostering a

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<sup>40</sup> The Patent Law of the People's Republic of China Draft Revision dated 4 January 2019, Art. 6.

<sup>41</sup> Notice of the Office of Legislative Affairs of the State Council on Public Consultation on the Draft of Service Invention Regulation (Draft for review) (Apr. 2015), <http://zqyj.chinalaw.gov.cn/readmore?listType=1&id=143>.

collaborative and harmonious relationship that encourages innovation and development, the regulations could inadvertently create an adversarial relationship between companies and their inventors.

Variations among industry sectors, market conditions, and corporate circumstances have led companies to pursue different ways to promote and reward innovation internally. The one-size-fits-all structure of the draft regulations, particularly with respect to calls for minimum financial compensation to inventors, would impair the carefully thought-out policies that many companies have established based on experience and knowledge of their respective industries. No single set of financial incentives works well for everyone or should be applied to all inventors.

Another practical challenge involves the requirement that, to abandon a patent, the inventor must be notified,<sup>42</sup> which makes it difficult, if not impossible, to dispose of private property. Beyond the practical concerns attending compliance with such a regulation, companies would be required to provide this information to former employees. Given that it is not unusual for former employee inventors to be hired by competitors, this could provide unique strategic insight for their new employers.

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

### ***Unique Challenges to Pharmaceutical Protection***

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

With respect to patent examination, China recently changed its patent examination guidelines to allow patent applicants to file additional biological data after filing their applications, and confirmed that its patent examination guidelines would no longer be applied retroactively. This is a welcome step. Concerns remain, however, that CNIPA appears to be imposing new and unfair or inappropriate limitations and interpretations of the new amendment, especially at the PRB (Patent Reexamination Board) level on the use of post-filing data to satisfy inventive step requirements. With respect to enforcement, transparent mechanisms are needed in China to ensure that patent issues can be resolved before potentially infringing pharmaceutical products are launched on the market. Neither China's Drug Administration Law nor the Provisions for Drug Registration provide an effective mechanism for enforcing patent rights vis-à-vis regulatory approval of follow-on products.

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.

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<sup>42</sup> *Id* at Art. 15.

### ***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.<sup>43</sup> Hiring a third party, however, can increase both expense and risk that confidential information is lost in the process. For companies with significant operations in foreign countries, it is not uncommon to have in-house operations that manage the patent application process. Yet, this is not possible under China's current Patent Law.

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

## **ECUADOR**

### ***Advances to Weaken the Global IP Infrastructure***

Ecuador has granted "mandatory licenses" at an alarming rate since the country expanded the ability to pursue compulsory licenses in 2009.<sup>44</sup> A number of applications for such licenses are pending. Although these licenses are limited to "public health" priorities, Ecuador has also sought to weaken patent protection for green technology. Ecuador has also supported discussions in international fora to reduce the patent term and expand flexibilities to weaken the related IP.<sup>45</sup> This preference towards accessing technology outside of market channels damages the incentive to invest. It can also slow down the process of technology dissemination.

## **INDIA**

### ***National IPR Policy***

Overall India's IPR Policy (Policy) unveiled in May 2016 provides a valuable roadmap for realizing the potential of India's creativity and recognizes the central role IP plays in this regard.<sup>46</sup> 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.<sup>47</sup> As discussed below, improving India's trade secret regime is critical to ensuring a level playing field for non-Indian innovators.

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<sup>43</sup> Patent Law of the People's Republic of China, at Art. 19, [http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119\\_566244.html](http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244.html).

<sup>44</sup> Executive Decree No. 118, <http://www.wipo.int/edocs/lexdocs/laws/en/ec/ec035en.pdf>.

<sup>45</sup> TRIPS Council, Contribution of Intellectual Property to Facilitating the Transfer of Environmentally Rational Technology, IP/C/W/585 (Feb. 2013).

<sup>46</sup> National Intellectual Property Rights Policy, Government of India (May 2016) (National IPR Policy), <http://dippnic.in/English/Schemes/IntellectualPropertyRights/NationalIPRPoly08.08.2016.pdf>.

<sup>47</sup> National IPR Policy at ¶ 3.8.4.

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

Taken as a whole, the Policy includes many positive actions for improving India's IP systems but we have not yet seen much in the way of implementation. The U.S. should continue to monitor the implementation of the Policy as it unfolds.

### ***Additional Patentability Criteria***

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

### ***Policies That Mandate or Encourage Compulsory Licensing***

Section 4.4 of India's National Manufacturing Policy discusses the use of compulsory licensing to help domestic companies "access the latest patented green technology."<sup>48</sup> 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.<sup>49</sup> TADF is empowered to request compulsory licensing from the Government of India.<sup>50</sup>

Similarly, India's National Competition Policy requires IP owners to grant access to "essential facilities" on "agreed and nondiscriminatory terms" without reservation.<sup>51</sup> 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."<sup>52</sup> The unconditional application of the essential facilities doctrine to such a broad technology landscape substantially decreases the value of the underlying IP and can undermine incentives for innovation.

Although other motives might be at play, the impetus to use compulsory licensing appears directly tied to industrial policy. Even though not adopted, a 2011 discussion paper produced by the Ministry of Commerce provides some insights. It explains that "compulsory licensing has a strong and persistent

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<sup>48</sup> 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](http://dipp.nic.in/English/policies/National_Manufacturing_Policy_25October2011.pdf).

<sup>49</sup> *Id.* at ¶ 4.4.1.

<sup>50</sup> *Id.* at ¶¶ 4.2, 4.4.3.

<sup>51</sup> National Competition Policy, § 5.1(vi) (2011), [http://www.mca.gov.in/Ministry/pdf/Revised\\_DraftNationalCompetition\\_Policy201117nov2011.pdf](http://www.mca.gov.in/Ministry/pdf/Revised_DraftNationalCompetition_Policy201117nov2011.pdf).

<sup>52</sup> *Id.*

positive effect on domestic invention.”<sup>53</sup> The objective of the paper was “to develop a predictable environment” for compulsory licensing to be used.<sup>54</sup>

### ***Lack of Regulatory Data Protection***

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

### ***Local Working Requirements***

In addition to the policies discussed above, patent holders risk compulsory licensing if they fail to “work” their inventions in India within three years of the respective patent grant.<sup>55</sup> This appears to include situations when patent holders import the related technology into the country, but do not locally manufacture it. It is difficult to understand how this complies with TRIPS, which requires patents and their associated rights to be available “without discrimination as to the place of invention, the field of technology and whether products are *imported or locally produced*.”<sup>56</sup> Among those rights is the ability to exclude others from making, using, or selling their invention.<sup>57</sup>

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.<sup>58</sup> Statements of Working (Form 27)<sup>59</sup> must be provided annually.<sup>60</sup> Failure to provide the requested information is punishable by fine or imprisonment.<sup>61</sup>

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. Not only might this be impossible to provide on a per patent basis, but it also forces patent holders and their licensees to potentially provide confidential business information to the government and public.

In addition, Patent Rules, as amended in 2016, require all Forms, including Form 27, to be submitted electronically by the agents or representatives of the patentees.<sup>62</sup> Although this is a welcome move, the

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<sup>53</sup> Discussion Paper on Compulsory Licensing, ¶70, DIPP (2011), <http://dipp.nic.in/English/Discusspaper/CLDraftDiscussion02September2011.doc>.

<sup>54</sup> *Id.* at ¶ 2.

<sup>55</sup> The Patents Act, § 84(1)(c), Intellectual Property India (1970), <http://ipindia.nic.in/ipr/patent/eVersionActRules/sections/ps84.html>.

<sup>56</sup> TRIPS, Art. 27.1 (emphasis added).

<sup>57</sup> TRIPS, Art. 28(1).

<sup>58</sup> The Patents Act, § 146, <http://ipindia.nic.in/ipr/patent/eVersionActRules/sections/ps146.html>.

<sup>59</sup> 72 Statement Regarding the Working of the Patented Invention on Commercial Scale in India, <http://patinfo.nic.in/pdf/form27.pdf>.

<sup>60</sup> The Patents Rules, § 131, Intellectual Property India (2003), <http://ipindia.nic.in/ipr/patent/eVersionActRules/rules/pr131.html>.

<sup>61</sup> 74 The Patents Act at n.57.

<sup>62</sup> Public Notice No.CG/F/Public Notice/2016, published in Pt. II, Section 3, Sub-Section (i) of the Gazette of India (May

electronic version of Form 27 requires mandatory submission of information which otherwise is not required to be submitted in the manual version of Form 27. This inconsistency causes a great deal of hardship to patentees.

The emphasis on Form 27 suggests that India intends to impose working requirements on users of its patent system. India issued its first compulsory license in 2012, which survived several legal challenges including at the Supreme Court of India. Most troubling about the decision was the interpretation that, at least in some circumstances, the working requirement might not be fully satisfied through importation.<sup>63</sup> In many cases it would be impractical, if not impossible, for patent holders or licensees to manufacture in every country around the world. The ability to make commercial choices with respect to manufacturing is imperative, both in terms of preserving competitiveness and reducing the cost of critical technologies.

### ***The Need to Upgrade Trade Secret Protection***

India lacks civil and criminal statutory protection for trade secrets. Contractual obligations provide the primary vehicle for protecting trade secrets. Although other means of protection might exist, such as suing under the tort of “breach of confidence,”<sup>64</sup> each has a common shortcoming: requiring a close relationship between the trade secret owner and the would-be misappropriator. Bad actors who choose to steal information rather than innovate are often not in privity with trade secret owners.

There are significant benefits to collaborating with Indian firms, especially in light of the country’s highly skilled services sector. Yet, the industries with which it makes the most sense to join forces rely on trade secrets to protect competitiveness. The U.S. and India would mutually benefit from stronger and more transparent trade secret protection, covering a broader range of actors.

Moves by the Indian government indicate that the country might value such an approach. We are encouraged by the commitment at the 2015 U.S. and India Trade Policy Forum to deepen cooperation on trade secrets.<sup>65</sup> There is also a recommendation included in India’s National IPR Policy to study trade secret protection, with an aim for further policy development.<sup>66</sup> Earlier recognition of the need to improve trade secret protection can be found in the 2014 draft National Innovation Act<sup>67</sup> and 2012 draft National IPR Strategy.<sup>68</sup> There is also a growing body of academic literature originating within India that agrees such initiative is critical.<sup>69</sup> The 2012 draft National IPR Strategy made the point

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2016), [http://www.ipindia.nic.in/writereaddata/Portal/IPORule/1\\_42\\_1\\_Patent\\_Amendment\\_Rules\\_2016\\_16May2016.pdf](http://www.ipindia.nic.in/writereaddata/Portal/IPORule/1_42_1_Patent_Amendment_Rules_2016_16May2016.pdf).

<sup>63</sup> 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.

<sup>64</sup> 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>.

<sup>65</sup> *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>.

<sup>66</sup> National IPR Policy, at ¶3.8.4.

<sup>67</sup> The National Innovation Act of 2008 (Draft), Ch. VI, [http://www.prsindia.org/uploads/media/vikas\\_doc/docs/1241500117~~Draftinnovationlaw.pdf](http://www.prsindia.org/uploads/media/vikas_doc/docs/1241500117~~Draftinnovationlaw.pdf).

<sup>68</sup> Invitation of Views on the Draft National IPR Strategy, ¶¶ 50-52, [http://dipp.nic.in/English/Discuss\\_paper/draftNationalIPRStrategy26Sep2012.pdf](http://dipp.nic.in/English/Discuss_paper/draftNationalIPRStrategy26Sep2012.pdf).

<sup>69</sup> 82 See e.g., Hariani, *The Draft National Innovation Act*, India L.J. (2007), <http://indialawjournal.com/volume3/issue1/articlebyanirudh.html>; Kumar et al., *Legal Protection of Trade Secrets*. 11 J. Intell. Prop. Rpts. 379 (Nov. 2006),

when it explained that a “predictable and recognizable trade secret regime will improve investor confidence,”<sup>70</sup> although this was not included in the approved version of the National IPR Strategy. We agree that a national trade secret law that provides sufficient protection against all potential misappropriators, injunctive relief, preservation of evidence, the ability to secure damages, and effective deterrence to prevent acts of theft in the first place, is an important step.

### ***Disclosure of Foreign Filings***

Section 8 of India’s Patent Act requires disclosure and regular updates on foreign applications that are substantially “the same or substantially the same invention.”<sup>71</sup> 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.<sup>72</sup> 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.<sup>73</sup>

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

### ***Computer Related Invention (CRI) Guidelines***

The Indian Patent Office issued guidelines for examination of patent applications involving Computer Related Inventions (CRI) on 21 August 2015 which were acceptable to many stakeholders and were the product of extensive discussions since 2013.<sup>75</sup> Over two years, the Indian Patent Office solicited written comments from all interested stakeholders and held numerous public meetings to discuss all aspects of the proposed CRI Guidelines. Indian Patent Office officials carefully reviewed the relevant statutory language of the 1970 Patent Act, the legislative history and intent behind the statute, and all relevant precedents before publishing the CRI Guidelines.

However, in December 2015, the Indian Patent Office abruptly suspended the August 2015 CRI Guidelines. As a sharp turn in policy, the Indian Patent Office issued revised CRI Guidelines on 19

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

<sup>70</sup> Draft National IPR Strategy, ¶ 52 (2012).

<sup>71</sup> Indian Patents Act, § 8(1) (1970), [http://www.wipo.int/wipolex/en/text.jsp?file\\_id=128091](http://www.wipo.int/wipolex/en/text.jsp?file_id=128091).

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

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

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

<sup>75</sup> Guidelines for Examination of Computer Related Inventions (CRIs), Government of India (Aug. 2015).

February 2016 (currently in force) without taking the same deliberative, multi-stakeholder engagement approach.<sup>76</sup> The revised CRI Guidelines, which require a novel hardware element rather than a further technical effect, will prevent most software enabled inventions from receiving patent protection in India.<sup>77</sup> This result would be contrary to the 1970 Patent Act, and inconsistent with international practice. The speed with which such contradiction has emerged and lack of any legal basis in issuing revised CRI guidelines is extremely worrisome and goes against the very objective of National IPR Policy of providing a stable IP Policy regime.

### ***Foreign Filing Permissions and Ministry of Defense***

India's Patent Act requires that an invention having a resident Indian inventor should not make or cause to make any patent application outside India unless a Foreign Filing Permission (FFP) is obtained from the Indian Patent Office.<sup>78</sup> Non-compliance with this requirement results in monetary fine or a jail term or both.<sup>79</sup> If the Indian Patent Office concludes that the subject matter of an invention is relevant for defense purposes or atomic energy, it refers the FFP application to Ministry of Defense (MoD) for their prior consent. We understand that the MoD can take up to two years to grant consent. This delay is extremely detrimental to FFP. Applicants might lose their application priority date and have no ability to contest the Patent Office's decision.

### ***IP Enforcement***

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

## **MEXICO**

### ***Challenges to Enforcement of Patent and Trademark Rights***

Although preliminary injunctions that result in the seizure of infringing goods are possible in patent and trademark infringement proceedings, as a practical matter this tool is often ineffective. After seizure, defendants can post a bond that causes the Mexican Institute of Industrial Property (IMPI) to release the goods in question without any additional requirements or obligations, except for posting a counterbond which tends to cost between \$15,000 and \$20,000. This makes it easy to lift injunctions and continue the infringing behavior. Another challenge in patent proceedings is that IMPI uses its examiners to act as expert witnesses, in effect serving as both judge and party.

Recovery of damages for trademark and patent infringement is also challenging in Mexico. Although damages can be claimed, this can only be done after proceedings are final. In patent cases, it can take

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<sup>76</sup> Guidelines for Examination of Computer Related Inventions (CRIs), Government of India (Feb. 2016), [http://tematelecom.in/pdf/GuidelinesExamination\\_CRI\\_19February2016.pdf](http://tematelecom.in/pdf/GuidelinesExamination_CRI_19February2016.pdf).

<sup>77</sup> *Id.* at § 5(3).

<sup>78</sup> Indian Patents Act, § 39.

<sup>79</sup> *Id.* at § 118.

more than ten years to exhaust the four potential stages of litigation in the administrative arena, and remands from higher to lower courts are common.

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

Mexico's health regulatory agency (COFEPRIS) and IMPI have committed to improve the application of Mexico's 2003 linkage decree which mandates coordination between COFEPRIS and IMPI and to provide protection for data generated to obtain marketing approval for pharmaceutical products. Despite these commitments, innovative biopharmaceutical companies are unable to obtain accurate and timely information from COFEPRIS prior to marketing authorization being granted on a generic or biosimilar drug where the innovator product is used as a reference. As a result, companies have little to no notice that a potentially patent infringing product is entering the market. Further, obtaining effective preliminary injunctions or final decisions on cases regarding infringement within a reasonable time (as well as collecting adequate damages when appropriate) remains challenging.

## **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.<sup>80</sup> 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, an up-to-date record of those with access to the information, and 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 would cause many businesses to grind to a halt instead of offering any meaningful protection.

Enforcement tends to be inadequate as well. Although preliminary remedies such as injunctions and seizures are theoretically available, there is little available evidence that indicates they are ever used. Criminal penalties are similarly lacking, often limited to community service — despite significant losses for the trade secret owner. Considering these shortcomings, the U.S. should encourage the implementation of the APEC Best Practices for Trade Secret Protection and Enforcement, which Russia endorsed as part of a 2016 APEC declaration.<sup>81</sup>

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<sup>80</sup> Federal Law on Commercial Secrecy No. 98-FZ, 32 SZ RF item 3283 2004 (July 2004) (as amended).

<sup>81</sup> *AMM Joint Statement*, APEC Peru (2016), [http://www.apec.org/Meeting-Papers/Annual-Ministerial-Meetings/Annual/2016/2016\\_amm.aspx](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>.

### ***Challenges to Patent Protection***

In addition, the Russian Government is pursuing draft legislation and other measures that would prevent inventors from securing patents on many types of innovative medicines and that would facilitate the compulsory licensing of patents. In June 2018, 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. That decision is currently on appeal.

### **SAUDI ARABIA**

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

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

### **SOUTH AFRICA**

#### ***Proposed National IPR Policy***

South Africa's Department of Trade and Industry released in July 2018 the first phase of the long-awaited Intellectual Property Policy.<sup>82</sup>

The policy could result in a number of concerning amendments to the Patents Act including permitting parallel importation of pharmaceuticals, so that pharmaceuticals bought in a foreign country can be imported into South Africa without approval of the patent holder in some circumstances; introducing a research exemption to patent infringement; 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; and enabling the government to exercise its march-in rights without negotiation with the patent holder under certain circumstances, subject to procedural fairness. These policies would require an amendment of the current Patents Act, which is expected to take a few years.

### **UNITED ARAB EMIRATES**

The UAE Ministry of Health has registered generic pharmaceutical products for sale in the UAE that appear to infringe the patents of innovative medicines. At that time, the patents in the countries of origin remained in force and, thus, should have been honored in the UAE as required by Decree 404.<sup>83</sup> This is a troubling development.

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<sup>82</sup> [http://www.thedti.gov.za/news2018/IP\\_Policy2018-Phase\\_I.pdf](http://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf)

<sup>83</sup> Ministry of Health Decree No. 404, issued on 30 April 2000 (MOH Decree).

## II. PUSH TO WEAKEN IP RIGHTS WITHIN MULTILATERAL FORA

Within the UN system, IP protection continues to come under fire. Such efforts are largely based on misinformation about the impact of IP rights on innovation and technology diffusion. The principal argument is that IP systems are a barrier that needs to be dismantled if developing countries are to advance. Yet this argument does not accurately reflect the contribution of IP to innovation, socio-economic growth, and technology diffusion in the real world. It ignores that the IP system has supported life-changing innovations across all sectors for decades and that there is no empirical evidence that IP rights are a barrier to advancement.<sup>84</sup>

A variety of proposals aimed at weakening the global IP framework are regularly raised including: compulsory or concessional licensing; the elimination of IP rights for certain technologies; technology buyouts, or other international IP mechanisms; and non-assertion pledges for patents on technology used by developing countries. There have also been efforts to implement these types of measures at the national level.

For example, at WIPO, within the Standing Committee on Patents, several countries continue to pursue a work program that would promote exceptions and limitations to patents. The continued effort is based, at least in part, on a 2010 proposal.<sup>85</sup> Designed in three phases, this proposal involves a detailed exchange of experiences on exceptions and limitations, a determination of the most effective exceptions and limitations, and the development of an “exceptions and limitations manual.” Similar discussions are ongoing as part of WIPO’s Committee on Development as well.

UN bodies, notably WIPO, but also WTO and WHO, play an important role in ensuring the existence of robust evidence about the contribution of IP systems to innovation and technology diffusion. They also have the responsibility to push back on erroneous and misleading statements about how IP works in practice. However, this has become extremely difficult due to intense political engagement by several countries in these “member-driven” organizations. Many 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 take the leap that turn ideas into the products and services that will generate innovative products, exports, and jobs.

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<sup>84</sup> 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>.

<sup>85</sup> Standing Committee on the Law of Patents at n. 24.

7 February 2019

We again thank the USTR for permitting IPO to provide comments and would welcome any further dialogue or opportunity to provide additional information to assist your efforts in developing the 2019 Special 301 Report.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark W. Lauroesch". The signature is fluid and cursive, with a long horizontal stroke at the end.

Mark W. Lauroesch  
Executive Director