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January 30, 2024

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 2024 Special 301 Review, Request for Public Comment (Docket No. USTR-2023-0014)

Dear Mr. Lee:

Intellectual Property Owners Association (IPO) appreciates the opportunity to provide comments regarding the U.S. Trade Representative’s (USTR’s) 2024 Special 301 Review. IPO’s comments highlight concerns with key issues surrounding the effective protection of intellectual property (IP) rights globally.

IPO is an international trade association representing a “big tent” of diverse companies, law firms, service providers and individuals in all industries and fields of technology that own, or are interested in, intellectual property (IP) rights. IPO membership includes over 125 companies and spans over 30 countries. IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; supporting and advocating for diversity, equity, and inclusion in IP and innovation; and disseminating information to the public on the importance of IP rights.

IPO’s vision is the global acceleration of innovation, creativity, and investment necessary to improve lives. The Board of Directors has adopted a strategic objective to foster diverse engagement in the innovation ecosystem and to integrate diversity, equity, and inclusion in all its work to complement IPO’s mission of promoting high quality and enforceable IP rights and predictable legal systems for all industries and technologies.

IPO’s comments are organized in four sections: (I) highlighted broad-based concerns, (II) country-specific concerns, in alphabetical order by country; (III) multi-country community concerns, and (IV) concerns about the push to weaken IP rights within multilateral fora. IPO notes that, in addition to highlighting areas of concern, it has also tried to identify areas in which some countries of concern have made improvements to their IP systems. IPO believes that such improvements demonstrate an international recognition that there is a strong tie between high quality IP systems and a successful innovation ecosystem that can best serve society.

I. HIGHLIGHTED BROAD-BASED CONCERNS

IPO will first highlight a few high-level concerns with protection of intellectual property around the world, without intending to minimize problems not featured in this section. Among these concerns are (a) inadequate trade secret protection, (b) counterfeiting, (c) compulsory licensing, (d) weak patent enforcement, (e) genetic resources and traditional knowledge requirements, and (f) data legislation.¹

Trade Secret Protection

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

As part of marketing authorization submissions for medicines, regulatory authorities require pre-clinical and clinical trial information demonstrating the safety and efficacy of a medicine, which includes trade secrets. Regulatory data protection (RDP), which is required by TRIPS⁴, provides a minimum level of protection to innovators, during which time no unauthorized third party can rely on the data submitted by the innovator for regulatory approval. RDP recognizes the extensive time, effort, and cost of clinical studies required to ensure that drugs developed are safe and effective for patients—and it provides critical incentives to engage in continued research and development of new innovative therapies. Unfortunately, several U.S. trading partners do not

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

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

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

⁴ Article 39.3 of TRIPS states that member countries should provide effective protection against unfair competition in the event of “the submission of undisclosed test data or other data, the origination of which involves considerable effort,” and that member states “shall protect such data against disclosures, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”

provide RDP or have inadequate RDP regimes. Examples include Argentina, Brazil, China, Egypt, India, and Turkey.

Counterfeiting

Counterfeiting is a global problem that affects more than a brand or brand owner. The sale and manufacture of counterfeit goods poses a significant health and safety threat to consumers throughout the world. Counterfeiting has well known links to organized crime, terrorism, and money laundering. IPO members have reported counterfeiting issues in countries such as Canada, China, India, Peru, Russia, South Africa, Thailand, Turkey, the United Arab Emirates, the United States, Vietnam, and the United Kingdom.

Ecommerce and social media platforms have made it easier for counterfeiters to sell counterfeit products. These platforms provide counterfeiters with an opportunity to engage with consumers throughout the world anonymously with very little effort. Many ecommerce and social media platforms allow counterfeit products to be displayed next to authentic products and in search results for related products. In many cases, consumers are not even aware they purchased a counterfeit product and only realize this after the product fails. The number of ecommerce platforms increase every year, making it easier for counterfeiters to move from one platform to another to avoid detection.

Many brand owners use vendors to help enforce their brands on ecommerce and social media platforms. Other brand owners cannot afford to do this and must rely on internal resources and the cooperation of the platforms where they find counterfeit products. Some platforms cooperate well with brand owners, while others are more difficult in this regard. More action is needed by ecommerce platforms to prevent the sale of counterfeit goods on their platforms and provide accurate information on the source of counterfeit goods. Governments also need to play a role in protecting consumers from the sale of counterfeit goods on ecommerce platforms. Unless ecommerce platforms are held liable when they sell counterfeit goods, there is no incentive for such platforms to put in place measures to both protect consumers and reduce the damage to brands as a result of the sale of counterfeit goods.

Over the past few years brand owners have seen counterfeiters increase the use of social media to sell counterfeit goods. For example, social media platforms are used often by counterfeiters to promote the sale of counterfeit goods. Once a counterfeiter engages with a customer through social media they switch to the use of, for example, WeChat, Telegram Messenger, or other messaging platforms to continue the conversation and finalize the sale. It is important that governments put in place measures to protect consumers from the use of social media platforms to sell counterfeit goods.

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

One of the issues that continues to be a challenge for brand owners is the use of free trade zones and free ports by counterfeiters to ship counterfeit goods from the location of manufacture to ports all over the world. Counterfeit goods travel through free trade zones and free ports and are transshipped through multiple ports. This allows counterfeiters to hide their true country of manufacture and also take advantage of countries where Customs protection for transshipped or in transit goods is known to be weak or non-existent. It is difficult to get Customs to seize counterfeit goods in a free trade zone or goods in transit. The transshipment of goods needs to be carefully controlled and more scrutiny applied by Customs offices to goods in transit.

Countries in which effective anticounterfeiting mechanisms are lacking in one or more areas (e.g., border control, enforcement mechanisms, government support, etc.), include the following: Brazil, Canada, China, Colombia, Ecuador, India, Indonesia, Kuwait, Malaysia, Mexico, Paraguay, Philippines, Russia, Saudi Arabia, Singapore, Thailand, Turkey, United Arab Emirates, United Kingdom, and Vietnam.

Compulsory Licensing

The patent system drives and enables research and development that is delivering valuable new innovations to society, and it has facilitated an unprecedented amount of collaboration that is advancing solutions to the most pressing issues facing society today. However, several countries, such as Argentina, Brazil, Chile, Colombia, Egypt, Russia, Thailand, and Turkey, have adopted or are considering resolutions, laws, or regulations that promote or provide broad discretion to issue a compulsory license. The European Commission has proposed draft legislation for the grant of EU-wide compulsory licenses. Compulsory licenses have been issued in previous years in several countries, including Hungary, India, Indonesia, Israel, Malaysia, and Russia. Granting compulsory licenses undercuts the importance of a predictable and reliable patent system and undermines investment in innovative solutions that benefit society. IPO believes that licensing of IP rights is best accomplished through voluntary efforts.⁵

Patent Enforcement

Effective, efficient, and fair means for enforcing patents are foundational principles for a legal system to deliver the intended benefits of patent rights. Unreasonable barriers to patent enforcement include excessive evidentiary burdens for the initial complaint, statutory caps or limited damage awards, slow resolution of legal disputes, and the failure of courts to understand technical issues or IP-specific legal concepts. It is also foundational for a legal system to provide all parties with the ability to fully explore and resolve the merits of disputes in a balanced process.

IPO urges legislative and administrative reforms that allow patent holders improved access to legal systems by adopting reasonable complaint pleading and evidentiary requirements,

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

establishing standards of proof that are aligned with the parties' access to the relevant facts, and appointing experienced and competent judges to adjudicate patent matters. IPO further urges reforms to ensure patent proceedings in court are held fairly and equitably and conclude within an appropriate timeline due to the time sensitivity of these claims, as well as adoption of appropriate legal changes to compensate patent holders for their losses in a case of proven infringement.

Additionally, mechanisms for resolution of patent disputes before marketing approval is granted for a generic or biosimilar product are important to support continued investment in the research and development that leads to new medicines. The premature launch of a medicine that is later found to infringe a patent may disrupt patient treatment and cause commercial damage to the innovative company that is impossible to repair later. IPO welcomes efforts by China to implement such a mechanism and hopes that efforts will be made to provide meaningful protection for innovators' patent rights. Additional countries, such as India and Russia, among others, should also seek to implement such a mechanism. Countries such as Saudi Arabia that grant marketing approval to generic drugs during the term of the innovator's patent prevent effective enforcement of patent rights and impair the incentives to invest in the development of drugs.⁶

Genetic Resources and Traditional Knowledge Requirements

Patent laws that impose patent disclosure requirements regarding the source and origin of genetic resources introduce uncertainties into the patent system that inhibit innovation in relevant technologies and undermine the potential of benefit-sharing. In some cases, compliance with such requirements is impossible, particularly where the existence or origin of any genetic resources incorporated into a product may be unknown or untraceable. IPO supports the objectives of the Convention on Biological Diversity ("CBD") and recognizes the national sovereignty of States over biological resources. However, patent disclosure requirements do not adequately address these issues, and instead diminish the potential for developing benefits to be shared. IPO believes patent disclosure requirements, implemented in various countries (e.g., China, India, Indonesia, Malaysia, Thailand, Brazil and the Andean Community), introduce uncertainty for innovators and undermine the sustainable use of technology related to biological resources, and should be eliminated.

Genetic resources are now largely utilized in archived electronic digital sequence information (DSI) form and accessed from publicly available databases composed of voluntary submissions. Given that large and complex comparative genetics analyses are typically required for innovation, determining the correct apportionment of relative contributions is not practical. Further any requirements for *a priori* access and benefits sharing agreements create uncertainty in patent validity and administrative burdens. Because special disclosure requirements for the source of genetic resources in patent applications do not further the goals of promoting innovation and issuing valid patents to create benefits for sharing, IPO opposes such special genetics resources disclosure requirements in patent laws.

⁶ E.g., Saudi SFDA grant of marketing approval for a generic version of the Hepatitis Drug Daclatasvir during the term of the patent granted by the Patent Office of the Gulf Cooperation Council (which includes Saudi Arabia).

Furthermore, unrestricted access to public collections of genetic DSI is essential to encourage innovation and promote scientific progress. Accordingly, IPO is concerned about suggestions to restrict access to public collections of DSI and to impose advanced mandatory benefit sharing mechanisms for the use of such DSI as it relates to patent laws, and opposes these proposals. Nations should consider the improvement and use of databases for the defensive protection of genetic resources and traditional knowledge associated with genetic resources. Erroneous granting of patents can be effectively addressed by improving databases for storing genetic resources and non-secret traditional knowledge associated with genetic resources that are used for prior art or reference material searches, as well as through utilizing certain existing institutional systems in coordination more efficiently.

Examples of concerning developments include proposed amendments to Malaysia's IP laws and procedural barriers in Thailand. The proposed amendments to Malaysia's IP laws include provisions for disclosure of traditional knowledge and genetic resources, as well as compulsory licensing, which raise concerns for genetics research-based industries. Thailand could impose procedural barriers by requiring applicants to disclose information regarding the use of genetic resources as part of their patent application. Such disclosure requirements could present significant barriers to patentability and should be removed.

In India, failure to disclose or wrongly describe the source and geographical origin of biological material that is not publicly available is a ground for opposition, and ultimately for revocation of the patent. In practice, the Indian Patent Office frequently raises these objections, regardless of whether the referenced biological material is publicly available or not. India has created a National Biodiversity Authority (NBA) to regulate use of the genetic resources of India, whereby a non-Indian person or company requires the approval of the NBA to access the genetic resources, or to include the genetic resources in a patent application in India. The NBA also has the right to require benefits sharing or royalties to the Indian government, based on the use of the Indian origin genetic resources employed in the patent application.

In China, the requirement to disclose the direct source and original source of genetic resources for any invention "based on genetic resources" is particularly broad and includes "any material taken from human, animal, plant or microorganism which contains functional units of heredity and is of actual or potential value, and genetic information generated from the use of such material". China's law allows for the rejection of any patent right where the required information for the genetic resources is not disclosed. Moreover, China has a separate law governing the use of certain human genetic resources requiring that a Chinese entity report with the Ministry of Science and Technology when it plans to share human genetic resources with a non-Chinese entity, requiring a security review. Under the Implementing Regulations, the Ministry and provincial science and technology administration department are also tasked with supervising and inspecting the disposal of intellectual property rights arising from the sharing of the human genetic resources.

Data Legislation

While artificial intelligence (AI) seemed pervasive in 2023, improvements in capability also add concerns around uses, regulations, and IP protections including a wide range of copyright, patent, and trade secret issues.

A range of actions and attention around legal rights in data have implications for IP rights. For example, automated decision-making tools have led to demands on sharing algorithms and data sets used for training. Country attention around information technology systems and network security have led to concerns around sharing trade secret data about system setup and security measures. China's quickly evolving landscape of data security laws, cybersecurity laws, personal information protection laws, cross-border data transfer laws, and privacy more generally, has led to some demands to install "sniffers" in networks of private companies operating in China.

Similarly, India's Digital Personal Data Protection Act ("DPDP"), passed in August 2023 after years of deliberation, regulates data transfer very broadly through central controls with mandates around network/data monitoring equipment installation in private companies operating in India. Data can be collected and processed after individual consent, or for a range of "legitimate" uses including medical emergencies, epidemics, and more.

The European Union's Data Act, which became effective in January 2024, regulates part of the data space by mandating that a data holder make content available to users of products or services. The EU General Data Protection Regulations (GDPR), require, *inter alia*, sharing meaningful information about the logic involved in automated decision-making protocols involving personal data, with recent cases involving technology used to match riders to drivers in ride-sharing Apps. The court decisions have gone both ways – requiring disclosure of logic, and protecting such disclosure. The positive intentions behind the efforts in overall data protection and privacy need to be balanced with a fundamental purpose of intellectual property rights - encouraging innovation and progress by allowing intellectual property to be subject to appropriate protections.

The EU AI Act, which has been described as the world's first comprehensive AI law, sets governing rules by risk level: Unacceptable (threat to people, thus banned), High (review & registration before marketing is allowed), General purpose and generative AI (require transparency and potential deeper review), and Limited (users informed to make their own decisions).⁷ China has been active in AI regulation for some time, addressing concerns (e.g., intellectual property rights, preventing discrimination, transparency, social morality, national security, etc.) in successive regulations instead of taking an overall comprehensive approach.⁸

⁷ [EU AI Act: first regulation on artificial intelligence | News | European Parliament \(europa.eu\)](#), EU "Parliament reached a provisional agreement" which proceeds toward formal adoption before becoming EU law. Last visited: Jan. 19, 2024. See also, [Dentons - The New EU AI Act – the 10 key things you need to know now](#). Last visited: Jan. 19, 2024.

⁸ See, e.g., [Interim Measures for the Management of Generative Artificial Intelligence Services at https://www.chinalawtranslate.com/en/generative-ai-interim/ \(unofficial translation\)](#). Last visited: Jan. 19, 2024. See also, the Cyberspace Administration of China content found at http://www.cac.gov.cn/2023-04/11/c_1682854275475410.htm.

II. COUNTRY-SPECIFIC CONCERNS

ARGENTINA

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

The patent examination backlog in Argentina is challenging for innovators to manage. In general, the earliest that patent applications are resolved is five years, and for pharmaceutical and biotech inventions it can take up to ten to twelve years. Such delays in securing patent rights make it difficult for innovators to attract investors or support business plans. We welcome efforts by Argentina's Patent Office to reduce the backlog, including the enactment of Resolution 56/2016⁹, and subsequent entry into a Patent Prosecution Highway (PPH) pilot program with the USPTO that started in 2017 and extended to 2020.¹⁰ Some patents were granted under the pilot program, which was a positive step. Unfortunately, the pilot program was not renewed. Notwithstanding the efforts of Argentina's Patent Office to reduce the backlog, 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 2012.¹¹ This resolution introduced more restrictive patentability criteria for chemical and pharmaceutical inventions.¹² The restrictive guidelines refuse pharmaceutical patents for: compositions and formulations, salts, esters and ethers, polymorphs, analogy processes, active metabolites and pro-drugs, enantiomers, selection patents and certain Markush-type claims. These criteria are inconsistent with Argentina's obligations under the TRIPS agreement. When these criteria are combined with the substantial backlog, significant uncertainty results for innovators in the chemical and pharmaceutical areas.

Furthermore, Regulation No. 283/2015 issued on September 25, 2015, amended the patentability guidelines for the examination of biotechnological inventions. This Regulation imposes additional patentability criteria that go beyond those of fulfilling the novelty, inventive step and industrial application requirements as provided by the TRIPS Agreement, the Patent Law No. 24,481, and its Regulating Decree.

⁹ Resolución 56/2016, Instituto Nacional de la Propiedad Industrial.

¹⁰ See <https://www.uspto.gov/patents-getting-started/international-protection/patent-prosecution-highway/patentprosecution-12>.

¹¹ Joint Resolutions 118/2012, 546/2012 and 107/2012 established by the Industry Ministry, the Health Ministry and the National Institute of Industrial Property of the Argentine Republic, "GUIDELINES FOR THE EXAMINATION OF PATENT APPLICATIONS ON PHARMACEUTICAL INVENTIONS"; *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>. See, <http://servicios.infoleg.gob.ar/infolegInternet/anexos/195000-199999/196991/norma.htm>.

¹² Guidelines for the Patentability Examination of Patent Applications for Chemical and Pharmaceutical Inventions

Regulations P-107/2012 and 283/2015 (which in some biotech/pharma cases are applied together) run contrary to the obligations assumed by Argentina under the TRIPS Agreement and discourage local and foreign direct investment.

Patent Cooperation Treaty

Argentina remains outside of the Patent Cooperation Treaty (PCT), notwithstanding that the PCT has 157 contracting states representing most of the world¹³ and that the PCT simplifies the filing and examination of patents. Argentina adhering to this agreement would be a positive step for inventors such as universities, institutions, individuals or companies (private and public) toward reducing extra expenses and facilitating filing strategies.

Increased Risk of Compulsory Licenses

In December 2019, Argentina passed an Emergency Economic Law that would increase the likelihood of the grant of compulsory licenses being required by the Ministry of Health.¹⁴ The law would allow compulsory licenses as a mechanism to control price increases. Compulsory licensing, however, undermines the economic incentives created by the IP system for innovation and investment in research and development.

Lack of Regulatory Data Protection

Argentina does not provide protection for regulatory test data, which is inconsistent with Argentina's TRIPS obligations (Article 39.3). Specifically, Law 24,766 and Decree 150/92 permit Argentine officials to rely on data submitted by originators to approve requests by competitors to market similar products.

Piracy

Argentina also continues to show deficiencies in copyright and trademark protection. The level of enforcement against piracy of protected goods (copyright and/or trademark) is very weak, both in local courts and in terms of preventive measures taken by security forces (such as local police) and customs officials. Federal courts have made little effort to combat counterfeiters, thus encouraging them to increase illegal activity.

AUSTRALIA

Australia's Onerous Best Method Requirements for Patents

An unusual feature of Australian patent law is its "best method" requirement. Failure to disclose the "best method" is an independent ground of invalidity, and the requirement is that the patent applicant must describe the best method known to the applicant (not that which is known to the

¹³ https://www.wipo.int/export/sites/www/pct/en/docs/list_states.pdf

¹⁴ Article 70 of the December 2019 Emergency Economic Law.

inventors) at the date of filing the complete specification (as opposed to the priority date).¹⁵ This requirement complicates matters for applicants because, if the best method is not disclosed in the complete specification, it cannot be introduced after filing via amendment. There is also a serious question whether the entirety of the patent, or only certain claims, will be invalid if the best method is not disclosed. Furthermore, there is ongoing uncertainty and debate about what constitutes the relevant “filing date” of the complete application, *i.e.*, whether it is the “date of the patent” (which is the filing date of the ultimate complete application) or the local filing date of any divisional application. Such a requirement is inconsistent with international practice, and harms U.S. inventors seeking to protect their inventions in Australia.

Best method is routinely used as a ground for revocation in Australian patent cases. Several cases have confirmed the continued applicability of the best method requirement. For example, the Federal Court considered the best method requirement in *Dometic Australia Pty Ltd. v. Houghton Leisure Products Pty Ltd.*¹⁶ In *Dometic*, the Court found that the best method requirement was based on what was known by the Applicant at the date of filing of the divisional application (not the filing date of any earlier parent or priority application). In this case, the date of filing the application was the date on which a divisional was filed, not the date on which the parent PCT application was filed. This also creates other issues as adding new information in the divisional specification could also affect the priority date of any claims that rely on the added matter. It also means that already granted divisional patents could potentially be at risk of an invalidity challenge where evidence can be adduced that the patentee became aware of a better method of performing the invention in the period prior to the divisional application being filed.

More recently, in *Boehringer Ingelheim Animal Health USA Inc v Zoetis Services LLC*,¹⁷ the Federal Court considered the best method requirement in relation to an experimental vaccine that contained specific concentrations of ingredients that were critical to achieving the benefits of the claimed invention. The best method requirement was not satisfied by the disclosure of broad ranges from which these preferable concentrations could be discovered through further research and testing, as such a disclosure did not relieve a skilled addressee “from having to confront the blind alleys and pitfalls... already overcome by the patentee.”

Recent Consideration of the Support Requirement

Australian courts have recently considered the requirement for claims to be supported by matter disclosed in the specification. In *Merck Sharp & Dohme Corp. v. Wyeth LLC (No 3)*¹⁸ the Federal Court construed the requirement of support in a manner that is inconsistent with Article 17.9(12) of the Australia-U.S. Free Trade Agreement (*AUSFTA*). Under the court’s approach, unduly specific disclosures are required in the specification before a claimed invention can be said to be “supported.” This requires the specification to disclose a technical contribution to the

¹⁵ *Les Laboratoires Servier v. Apotex Pty. Ltd.*, FCAFC 27 (2016).

¹⁶ *Dometic Australia Pty Ltd. v. Houghton Leisure Products Pty Ltd.* [2018] FCA 1573 (19 October 2018).

¹⁷ *Boehringer Ingelheim Animal Health USA Inc v Zoetis Services LLC* [2023] FCA 1119 (21 September 2023).

¹⁸ *Merck Sharp & Dohme Corp. v. Wyeth LLC (No 3)* [2020] FCA 1477, affirmed by the Full Federal Court of Australia in *Jusand Nominees Pty Ltd v Rattlejack Innovations Pty Ltd* [2022] FCA 540. See also *Cytec Industries Inc v Nalco Company* [2021] FCA 970, *TCT Group Pty Ltd v Polaris IP Pty Ltd* [2022] FCA 1493.

art that justifies the breadth of the claims. Additionally, a more recent authority has stated that there may be some claims which lack support not because they are too broad, but because they define an invention that is materially different to what is described in the body of the specification.¹⁹

Patentable Subject Matter in Relation to Computer-Implemented Inventions

In Australia, there is uncertainty regarding patentable subject matter in relation to computer-implemented inventions. The uncertainty has resulted in claims that have been found allowable in the U.S. being rejected in Australia, even when examined under the Patent Prosecution Highway. Such unpredictability has been to the detriment of those who innovate in this space.

The High Court of Australia recently grappled with this issue in *Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents*.²⁰ Although the long-awaited High Court decision had been expected to clarify (and potentially change) the current practice adopted by the Australian Patent Office, the bench was split evenly as to what approach should be taken. As a result, under the Judiciary Act 1903 (Cth), the appeal was dismissed and the lower court ruling stands albeit without being binding precedent.²¹

Each Justice of the High Court rejected the Full Court of the Federal Court of Australia's requirement for there to be an advancement in computer technology for the invention to be patentable subject matter.²² However, uncertainty remains as the Justices who dismissed Aristocrat's case did not agree with a two-step approach adopted by the lower court. Instead, they applied a test to determine whether there had been some adaptation or addition to technology beyond common general knowledge in the art in order to accommodate a new idea. It is not clear how the Justices envisage the common general knowledge to be ascertained for this purpose. In current practice, (often voluminous) evidence as to common general knowledge is usually required when assessing novelty and inventive step. The Justices who found in favour of Aristocrat adopted a lower threshold, more in line with other jurisdictions, but due to the split decision, no clear approach has been provided and Australia remains at odds with the U.S and most other trade partners around the world.

The Australian Patent Office has updated its examination manual to take into account the High Court's decision but the practical experience of applicants is that it is more difficult, or potentially not possible, to obtain protection for certain computer implemented inventions in Australia when such protection would be available in the U.S and with other major trade partners.

¹⁹ *Calix Limited v Grenof Pty Ltd* [2023] FCA 378.

²⁰ *Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents* [2022] HCA 29.

²¹ Chief Justice Kiefel, and Justices Gageler and Keane dismissing the appeal by reason of a technical majority under section 23(2)(a) of the *Judiciary Act 1903* (Cth); Justices Gordon, Edelman and Steward allowing the appeal.

²² *Aristocrat Technologies Pty Ltd v Commissioner of Patents* [2022] HCA 29 summarised at <https://cdn.hcourt.gov.au/assets/publications/judgment-summaries/2022/hca-29-2022-08-17.pdf>.

Market-Size Damages

Australia's Department of Health has continued to implement its policy by which it seeks damages from biopharmaceutical innovators that commence proceedings to enforce their patents and obtain a preliminary injunction but are ultimately unsuccessful on the merits.²³ Those damages are designed to compensate Australia's pharmaceutical reimbursement scheme (PBS) for any delay in the reduction in PBS prices during the period of the preliminary injunction, which (given the value of the subsidies under the PBS) could amount to damages in the hundreds of millions.²⁴ The PBS imposes automatic and irreversible price cuts on medicines as soon as a first competing brand enters the market, but there is no corresponding mechanism for automatic compensation for innovators as a result of the PBS price cut if an infringing product is launched prematurely; the innovator must instead seek to recover those losses from the infringing generic as part of its damages claim.

Nevertheless, in a 2020 case that was substantively affirmed on appeal to the Full Court,²⁵ the Department of Health was unsuccessful in seeking compensation as a result of a generic company being restrained from supplying products in Australia and obtaining a PBS listing of such products. This case turned on findings of fact that, but for the interlocutory injunction, the generic company would not have applied for PBS listing. Therefore, this finding does not prevent the Commonwealth from establishing that a relevant party would have sought and obtained PBS listing of its products in future cases – it will necessarily depend on the nature and strength of the evidence.

This “market-size damages” approach has issues. It tips the scales in commercial patent disputes by exposing patentees to significant compensation claims and thus may discourage innovators from enforcing their patents. It means that the same government that examined and granted a patent (albeit through different government entities) can seek damages from the patentee for unsuccessfully trying to enforce it.

Biopharmaceutical innovators must be able to rely on and enforce patents issued by competent government authorities. Laws or policies that allow governments or other non-parties to a patent dispute to collect market-size damages undermine legal certainty, predictability, and the incentives patents provide for investment in new treatments and cures.

IPO believes the Australian Government should take steps to increase the period of notification a patent holder receives regarding entry of a generic competitor, in an effort to reduce the need for emergency injunctive action. Nonetheless, the ongoing existence of the market-sized damages policy remains an obstacle to innovation and investment.

²³ See https://www.health.gov.au/sites/default/files/2023-10/department-of-health-and-aged-care-annual-report-2022-23_0.pdf at p. 228.

²⁴ The claimed damage must have "necessarily and naturally flowed" from the interlocutory injunction for it to be recoverable.

²⁵ *Commonwealth of Australia v Sanofi (formerly Sanofi- Aventis) (No 5) [2020] FCA 543 (28 April 2020) affirmed in Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis) (2023) 411 ALR 315; [2023] FCAFC 97*. Special leave for appeal was granted by the High Court in *Commonwealth of Australia v Sanofi (Formerly Sanofi-Aventis) & Ors [2023] HCATrans 184 (18 December 2023)*. (Note hearing expected 5th February 2024.)

Weak Regulatory Data Protection

Australia provides regulatory data protection (RDP) of 5 years for small molecule and biologic products; however, Australia does not provide RDP relating to the registration of new formulations, combinations, indications, populations, or dosage forms of currently registered therapeutic goods.²⁶ The lack of data protection for product changes supported by new clinical information, and the lack of protection for more than 5 years for biological products, potentially puts pharmaceutical innovators at a disadvantage in Australia in comparison to other developed countries. After expiry of the initial 5-year period, generic competitors can rely on innovators' clinical data to obtain abridged approvals without delay (subject to any patent protection). Thus, the Australian data protection system does not adequately reward innovators for the cost of obtaining the clinical data to support the approval of product changes for the benefit of Australian patients.

Removal of IP Rights Exemption from Australian Competition Law

IPO is concerned about the removal of the exceptions to Australian competition law for agreements relating to IP rights. Specifically, Section 51(3) of the Competition and Consumer Act 2010 (Cth), which exempted certain conditions in intellectual property licenses from some competition law prohibitions, was repealed on 13 September 2019. Licensors and licensees may now be held criminally liable for breaching cartel prohibitions, unless the anti-overlap provisions apply, if the agreement contract includes price, territorial or quota restrictions. Guidelines have been published by the Australian Competition and Consumer Commission on the effect of this repeal.²⁷

When Trademark Applications are Inadvertently Filed in the Incorrect Name, the Defect is Fatal

The Australian Federal Court in *Pham Global Pty Ltd v Insight Clinical Imaging Pty Ltd* [2017] FCAFC 83 made it clear that when trademark applications are filed in the incorrect name in Australia, the defect is fatal and cannot be cured by amendment. It is vital that trademark owners ensure that valid rights have been secured. A remedy is needed for instances of clerical error upon filing.

BRAZIL

Accession to the Hague Agreement for the International Registration of Industrial Designs

IPO notes some positive developments in Brazil that are consistent with efforts at international harmonization. The Hague Agreement on the international registration of industrial designs, which simplifies procedures and reduces costs for users of the system, became effective for

²⁶ *Therapeutic Goods Act 1989* (Cth) s 25A.

²⁷

https://www.accc.gov.au/system/files/1619RPT_Guidelines%20on%20the%20repeal%20of%20subsection%2051_FA1.pdf.

Brazil in August 2023. Accession to the agreement was part of the government's strategic agenda to modernize the Brazilian IP system, which also led to the accession to the Madrid Protocol in 2019. Updated design examination guidelines were published in October 2023 with relevant and long-awaited changes, such as the acceptance of broken lines to disclaim elements or portions of the design.

Compulsory Licensing Laws and Forced Technology Transfer

Brazil's recent modifications to the rules governing compulsory licenses are concerning to IP owners. Of particular concern were forced technology transfer provisions that were proposed during the legislative process (but ultimately vetoed by the President). IPO notes that the new compulsory license provisions have not yet been put into practice.

IPO strongly opposes compulsory licensing of intellectual property rights with respect to all industries and technologies. Although IPO recognizes that compulsory licenses of IP rights may be legally permissible in limited and rare situations, IPO believes that licensing of IP rights is best accomplished through voluntary efforts.

Further, forced technology transfer could jeopardize IP rights and violate international treaties. As explained in the U.S. Trade Representative's 2023 Special 301 Report, such transfers "disadvantage U.S. companies" and "discourage foreign investment in national economies, hurt local manufacturers, distributors, and retailers, and slow the pace of innovation and economic progress."²⁸

Patent and Trademark Application Backlogs

In Brazil, utility patent applications regularly remain pending far longer than in most other patent offices around the world. The lengthy backlog hurts innovators by complicating investment decisions and often impairing access to critical funding, especially for smaller companies. Such delays hurt both would-be patent owners and potential competitors, adding to market uncertainty and increasing the cost of innovation. This situation, however, has seen recent improvement through the implementation of various strategies, such as hiring additional examiners, creating fast-track programs such as PPH agreements, and leveraging examination of foreign counterpart applications. Although these developments are very encouraging, it is important to continue to build on this momentum and reduce patent application pendency times.

The Brazilian National Institute of Industrial Property (INPI) has significantly reduced the patent backlog, which decreased from an average of 11.5 years to approximately 7 years. According to INPI's strategic plan, the goal is to reach an average of 3 years in July 2025 and 2 years in 2026. For 2024, INPI plans to hire 40 new patent examiners and 40 new trademark examiners.

With respect to trademarks, both the backlog and the examination period have decreased substantially. Thanks to Brazil's accession to the Madrid Protocol in July 2019, its National

²⁸ 2023 Special 301 Report, at page 24.

Institute of Industrial Property, INPI, has implemented the changes necessary to comply with international standards. Trademarks are now being granted in 6 months on average.

Proposed Patent Term Adjustment for INPI Delay

Brazil should reinforce the above-described efforts to reduce patent examination backlogs by establishing a mechanism to restore patent term lost due to unreasonable delays during patent examination. Currently, due to the Supreme Court's decision to eliminate the sole paragraph of Article 40, patent applicants have no recourse to address such delays. The time has come for Brazil to establish a patent term adjustment mechanism to restore patent term lost due to unreasonable delays in the patent examination process.

In July 2022, a bill was submitted at the Brazilian House of Representatives to amend the patent statute towards the establishment of a patent term adjustment system (PTA) based on INPI's delays during examination (PL No. 2.056/2022). According to the bill, patentees would be able to request PTA when INPI takes more than 60 days to issue decisions; the adjustment would be limited to an additional 5 years of patent protection.

Lack of Regulatory Data Protection

Brazilian law provides data protection for veterinary, fertilizer, and agrochemical products, but does not provide similar protection for pharmaceutical products for human use,²⁹ 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.

Genetic Resources and Traditional Knowledge

Brazilian patent law requires a declaration of access to a sample of the Brazilian genetic heritage. As discussed above in the Broad-based Concerns, such country specific patent disclosure laws, requiring information of the source of genetic resources used in the invention, inhibit innovation in biotechnology and undermine the potential of benefit-sharing. Compliance with such requirements can be impossible, particularly where the existence or origin of genetic resources incorporated into a product may be unknown or untraceable. These Brazilian disclosure requirements introduce uncertainty for innovators and undermine the sustainable use of technology related to biological resources, and should be eliminated.

Technology Agreements

In a welcome move, INPI now accepts: (i) records of licensing agreements of unpatented technology/know-how; (ii) records of royalty payments for pending trademark applications, and

²⁹ See Law 10.603/02

(iii) digital signatures. Formerly, INPI denied the possibility of licensing unpatented technology/know-how as a matter of law and did not allow for agreements to suspend use of the know-how upon termination.³⁰ Also, formerly, INPI considered trademark applications to be merely an expectation of rights and thus did not allow the applicant the benefit of receiving royalties notwithstanding contrary provisions in an agreement between the parties.³¹

Furthermore, INPI no longer requires: (a) notarization and apostille to legalize foreign signatures made in digital format; (b) the parties to initial the agreement pages and annexes; (c) two witnesses to sign agreements having a Brazilian city as place of execution, and (d) the Brazilian licensee to present company governance documents (articles of association, bylaws, etc.).

CANADA

Lack of Adequate Trade Secret Protection

The USTR Special 301 Report has persistently noted Canada's lack of trade secret legislation as part of a robust intellectual property enforcement regime. In 2020 Canada took an important, but ultimately incomplete step, to correct this deficiency. Pursuant to its obligations under the USMCA trade agreement, Canada enacted new Criminal Code provisions related to trade secrets, which came into force on July 1, 2020. These new provisions are aimed at the intentional theft of trade secrets and require proof of "deceit, falsehood or other fraudulent means" and the knowing obtainment or communication of a trade secret (Article 391(1)). Anyone convicted of these new offences (or related offences of conspiracy or attempt to commit or being an accessory after the fact in relation to the theft of a trade secret) can be punished either by way of an indictable offence (with imprisonment for a term not exceeding 14 years), or a summary conviction (Article 391(3)).

While this development in the protection of intellectual property in Canada is an important step, it appears to ultimately do little to provide an effective enforcement option for trade secret rights holders. First, to the best of IPO's knowledge, no prosecutions have taken place under these new provisions. Second, while the new Criminal Code focuses on intentional acts of fraud, this provides no protection to a trade secret rights holder pursuing an unintentional or mistaken breach of confidence. In these instances, Canada's lack of statutorily-granted civil right of action continues to be problematic. In Canada (except in Quebec), one continues to have to resort to common law causes of action for breach of confidence, which according to a leading commentator "remains a significant challenge for litigants."³² Unlike its largest trading partner, Canada has yet to codify the basic principles of common law trade secret protection in a uniform

³⁰ Ordinances n° 26/2023 and 27/2023. See also <https://www.daniel-ip.com/en/client-alert/implementation-of-innovative-changes-to-the-recordal-of-technology-agreements-in-brazil/>; <https://patentblog.kluweriplaw.com/2023/08/14/brazil-implements-changes-to-facilitate-the-recordal-of-ip-agreements/>; <https://www.montaury.com.br/en/new-guidelines-for-the-recordal-of-technology-transfer-and-licensing-agreements-in-brazil>

³¹ <https://www.daniel-ip.com/en/client-alert/implementation-of-innovative-changes-to-the-recordal-of-technology-agreements-in-brazil/>; <https://www.montaury.com.br/en/new-guidelines-for-the-recordal-of-technology-transfer-and-licensing-agreements-in-brazil>

³² See M. Malone, "A Comparative History of the Law of Confidential Information and Trade Secrets in Canada and the United States: Towards Harmonization?" 34 I.P.J. 81 at p. 5 (November 2021).

manner, like the U.S. federal Defend Trade Secrets Act — and the Uniform Trade Secrets Act adopted by 49 U.S. states and the District of Columbia (DC) as of 2018. This next step is a critical adjunct to the new Criminal Code protections and would address Canada’s continued lack of adequate enforcement while potentially providing harmonization with the U.S. in the protection of these key intellectual property rights in a digital economy.

Slow Examination of Trademark Applications

IPO remains concerned about the slow pace of examination of trademark applications by CIPO. It appears, based on available statistics, that CIPO continues to be the slowest national office in the world when it comes to the examination of trademark applications.³³

CIPO’s primary strategy for dealing with the backlog has been to accelerate the examination of applications that solely use the Approved List of Goods and Services contained in CIPO’s Goods and Services Manual (“Sole Approved List Applications”). We note, however, that CIPO’s preferential treatment of such applications has come at the expense of applications that do not solely use the Approved List of Goods and Services (“Not Sole Approved List Applications”).

CIPO is reporting, as of October 17, 2023, that it is only examining Not Sole Approved List Applications that were filed on May 2, 2019 (a delay of 55 months). Despite this worsening backlog, the CIPO has not introduced a viable path for owners of these applications to accelerate examination.

For example, even if the owner of Not Sole Approved List Application makes a request to CIPO to add particular goods/services to the Manual, CIPO is frequently rejecting such requests, even though it acknowledges that the goods/services are described in specific and ordinary commercial terms, because it has concluded that other trademark owners are unlikely to want to use those descriptions. The end result is that owners of such applications are seeing their applications languish while much more recently-filed Sole Approved List Applications are being examined.

Although CIPO is to be congratulated on its recent announcement that it has hired more than 100 new examiners, it must be noted that previous hiring initiatives have not served to make a significant dent in the backlog of unexamined applications.

Language Requirements

Recent changes made by the province of Québec to its language laws in Bill 96 will, when fully implemented, make it considerably more difficult for trademark owners to use English-only versions of their trademarks in the province.

³³ According to the WIPO Statistics Portal, Canada’s pendency is 860 days measured from the filing of a trademark application to a first trademark office action. WIPO statistics database. Last updated: January 2024, <https://www3.wipo.int/ipstats/index.htm?tab=trademark>.

IPO is concerned in particular about the provisions of Bill 96 which, when they take effect on June 1, 2025, will mandate that a trademark can be displayed on a product solely in a language other than French only if: the trademark is registered with the Canadian Intellectual Property Office (“CIPO”); and no French version of the mark has been registered as a trademark. In addition to its concerns about these restrictions on the right of a trademark owner to display their mark in the language of their choice, IPO is also concerned that CIPO’s slow pace of examination will make it practically impossible for a trademark owner who wishes to take advantage of the above exception to obtain a registration for a non-French version of their mark before the law takes effect on June 1, 2025.

Patented Medicines Price Review Board (PMPRB) Regulations

The PMPRB’s authority and mandate under the *Patent Act* is to ensure that patentees of patented medicines do not abuse their patent rights by selling patented medicines at excessive prices.

IPO has concerns about the *Regulations Amending the Patented Medicines Regulations*³⁴ (the “*Regulations*”) that came into force on July 1, 2022. IPO is particularly concerned about changes to the list of comparator countries under section 4(1)(f)(iii) of the *Regulations* that removed the United States and Switzerland and added Australia, Belgium, Japan, Netherlands, Norway, and Spain to form a new list of 11 countries (“PMPRB11”). The removal of the U.S. and the absence of other countries such as Mexico, another one of Canada’s largest trading partners, is concerning. Also troubling is the selection of countries for the list that in general have lower drug prices than Canada without considering the impact this has on accessibility to new medicines in those jurisdictions. Furthermore, the U.S. and Switzerland are home to many of the world’s pharmaceutical and biotechnology research companies, sending a message that Canada is interested in the benefits of that research, but not in compensating or incentivizing the research necessary to create the benefits.

The PMPRB implements the *Regulations* through its Guidelines. The PMPRB’s Guidelines are intended to provide predictability for innovative manufacturers by giving guidance on when patented drugs are at risk of being excessively priced. The PMPRB has not had final Guidelines in place since July 1, 2022, when the PMPRB11 was brought into force. Instead, the PMPRB has been operating under an Interim Guidance³⁵ that: (1) places an ongoing “price freeze” on existing medicines previously reviewed by the PMPRB, despite the *Patent Act*’s consideration for Consumer Price Index (“CPI”) price increases, and (2) leaves new medicines launched after July 1, 2022 to wait for price guidance until new Guidelines are in place, unless they are priced very low (i.e., “below the median” of the PMPRB11).

With final Guidelines not expected before mid-2024 or 2025, these interim policies have been in place far too long causing unacceptable levels of pricing uncertainty for innovative manufacturers selling and seeking to launch new patented medicines for the benefit of Canadian patients.

³⁴ See <http://www.gazette.gc.ca/rp-pr/p1/2017/2017-12-02/html/reg2-eng.html>.

³⁵ See <http://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-new-medicines/decision-amended-interim-guidance.html>.

IPO is also concerned about the reduction in reporting requirements for patented generic medicines (approved by means of Abbreviated New Drug Submission (“ANDS”)). Generic medicines are exempt from the continual reporting of information unless requested by the PMPRB. At the same time, innovative manufacturers have expansive reporting requirements, triggered by having any patent that “pertains to a medicine” as falling within the jurisdiction of the PMPRB, while the PMPRB continues to support an even more expansive patent reporting scope.³⁶ As an example, there is a matter proceeding through the Federal court where PMPRB asserts that the patent covering an extended-release formulation of drug product gives PMPRB jurisdiction over the original immediate release formulation³⁷.

The *Regulations* unnecessarily discourage innovation and increase reporting requirements for innovative patent holders. When incentives for patent innovation are diminished, particularly in a major market like Canada, the value of intellectual property is negatively impacted for all types of patent owners everywhere. Simply put, Canada’s system is that of a *free rider* with Canada unwilling to pay its share of the research and development costs of pharmaceuticals. These concerns are heightened when reference to Canada’s patent statute is used as the basis for lowering prices for patent-protected technologies as it raises the likelihood that similar regulations could be extended to other consumer goods.

Further, IPO is concerned that referencing a patent statute as a basis for placing patentees at an economic disadvantage compared to non-patent holders sets a troubling and disincentivizing precedent. Indeed, IPO believes that many patentees are likely to consider abandoning patents to avoid coming under the jurisdiction of the PMPRB. Other manufacturers may choose to withdraw from Canada, assuming they elect to enter, which further heightens the weakness of Canada’s pricing mechanism. Given that drug prices/rebates are highly negotiated with public and private drug plans in Canada and drug pricing is also heavily regulated at the provincial level, the additional burden of federal regulation by the PMPRB on patentees is particularly troubling and seemingly unnecessary in order for drug plans to manage their budgets.

Weak Patent Enforcement

The *Patented Medicines (Notice of Compliance) Regulations*³⁸ (the “*PMNOC Regulations*”) include deficiencies that weaken Canadian patent enforcement, including insufficient time for final patent determinations in a single proceeding, increasing liability for damages under section 8 (e.g., granting damages in excess of 100% of the total generic market, as discussed further below), and a separate litigation track for some types of patents due to their ineligibility for listing on the Patent Register (e.g., arbitrary timing requirements).

³⁶ The PMPRB has found that the phrase “pertains to a medicine” in section 79(2) of the *Patent Act* should be given a broad interpretation, whereby an invention that is the subject of a patent may “pertain to a medicine,” and therefore come under PMPRB jurisdiction, even if the invention does not encompass the medicine.

³⁷ See Court file: T-906-20 *Galderma Canada Inc. v. Attorney General of Canada*; <https://www.fct-cf.gc.ca/en/court-files-and-decisions/court-files#cont>

³⁸ <https://www.laws-lois.justice.gc.ca/eng/regulations/SOR-93-133/page-1.html>.

45 Days for Action on Notice of Allegation

The *PMNOC Regulations* provide that if a proceeding is not brought within the 45-day 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.³⁹ This provision has the effect of revoking a statutorily granted patent right due to a missed deadline, and puts on the patentee the onus of showing that there was something justifiably irregular in failing to sue at first instance.

Excessive Damages

IPO is also concerned about the potential expansion of liability for pharmaceutical innovators under section 8 of the *PMNOC Regulations*.

The *PMNOC Regulations* explicitly consider all plaintiffs in the infringement action to be jointly and severally liable for losses suffered by the “second person”⁴⁰ as opposed to only the “first person”⁴¹ 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 *PMNOC 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.⁴² Also, section 8 of the *PMNOC Regulations* do not impose any limits to the period of a first person’s liability. Thus, second persons under the *PMNOC Regulations* may be able to claim losses suffered beyond the date of any dismissal or discontinuance. These section 8 related amendments create a risk of “windfall” damage awards. Furthermore, such awards are contrary to the traditional compensatory function of damages and, in situations of section 8 damages in excess of 100% of the total generic market, constitute a punitive award which is inconsistent with the limited remedy of declaratory relief currently provided for under Section 60(1) of the *Patent Act*, and would be an inequitable result.

³⁹ Patented Medicines (Notice of Compliance) Regulations, sections 6(1) and 6.01.

⁴⁰ A “second person means the person referred to in subsection 5(1) or (2) who files a submission or supplement referred to in those subsections. (seconde personne),” Patented Medicines (Notice of Compliance) Regulations, 2 (1), <https://laws-lois.justice.gc.ca/eng/regulations/SOR-93-133/page-1.html#h-949984>; “5 (1) If a second person files a submission for a notice of compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted . . . ,” <https://laws-lois.justice.gc.ca/eng/regulations/SOR-93-133/page-2.html#docCont>.

⁴¹ A “first person means the person referred to in subsection 4(1); (première personne),” Patented Medicines (Notice of Compliance) Regulations, 2 (1), <https://laws-lois.justice.gc.ca/eng/regulations/SOR-93-133/page-1.html#h-949984>; 4 (1) “A first person who files or who has filed a new drug submission or a supplement to a new drug submission may submit to the Minister a patent list in relation to the submission or supplement for addition to the register,” <https://laws-lois.justice.gc.ca/eng/regulations/SOR-93-133/page-1.html#h-949984>.

⁴² 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.

Certificate of Supplementary Protection (CSP) Restrictions

Although it is positive that Canada has recently provided for restoration of patent terms for pharmaceutical inventions, under certain circumstances, by means of a Certificate of Supplementary Protection (“CSP”), IPO is concerned that there is still a bar to certain types of innovations being CSP eligible, including, for example, the invention of new processes and formulations. Overly restrictive eligibility criteria result in the exclusion of otherwise worthy patents from receiving a CSP and will likely discourage innovation.

In addition, the requirement that the innovator file a complete new drug submission in Canada within a year of filing in the U.S or Europe (or several other smaller markets) is overly restrictive, especially with respect to smaller companies who do not have the resources to file in multiple jurisdictions before they receive an indication of whether their submission is sufficient to receive approval. Both of these restrictive requirements are unlike patent term restoration requirements in other jurisdictions.

Furthermore, Canada’s term for a CSP is capped at two years of the possible five – an unduly restrictive time limit. This is well outside the global norm that applies, for example, in the U.S. and Europe, according to which up to five years of lost patent life can be restored.

Finally, the CSP does not grant the full bundle of patent protections during the CSP period by providing a “manufacture for export” exception, *i.e.*, it is not an act of infringement during the CSP period to make, construct, use or sell the patented medicine for the purpose of export from Canada.

Multiple and Conflicting Certificate of Supplementary Protection Applications

IPO is concerned that there remains a significant risk under the current CSP regime for unnecessary conflicts between patent owners. Under the current CSP regime, one or more third parties are allowed to seek a CSP based upon the Notice of Compliance (“NOC”) obtained by the pharmaceutical innovator. 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 face a significant risk of losing the CSP to a third party thereby denying pharmaceutical innovators the incentive and reward for undertaking the costly and risky journey of drug development. IPO believes that third parties not be allowed to seek CSPs using a pharmaceutical innovator’s NOC without the permission of the innovator.

Patent Term Adjustment Restrictions

On June 22, 2023, Canada passed legislation on its first ever patent term adjustment (PTA) regime.⁴³ PTA is intended to compensate patentees for “unreasonable delays” by the patent office in issuing a patent. The regime is scheduled to come into force by no later than January 1,

⁴³ Bill C-47, [An Act to implement certain provisions of the budget tabled in Parliament on March 28, 2023](#) (assented to June 22, 2023)

2025, in order to comply with Canada's treaty obligations under the United States-Mexico-Canada Agreement ("USMCA"), Article 20.44. Although this should be an encouraging development for Canadian patentees, IPO is concerned about several aspects of the proposed PTA framework.

Canada is taking a very strict and minimal approach in adopting PTA to meet the basic requirements of the USMCA only. The Canadian Intellectual Property Office ("CIPO") has published a proposed framework for PTA regulations.⁴⁴ If implemented, this proposed framework would render most patents ineligible for PTA because of the extensive time periods that would be deducted from any potential eligible term. For example, unlike the U.S. system, Canada proposes that all days will be deducted from potential term once a notice requiring applicant action is issued, leaving applicants with no reasonable response time. It is also being proposed that all days relating to an appeal to the courts of the CIPO's refusal of an application will also be deducted, even where the applicant's appeal is successful.

Further, PTA will not be granted automatically as it is in the United States, but instead, applicants will be required to apply for PTA and, moreover, must do so within three months from the issuance of the patent or lose this benefit. A proposal to allow third party observations as part of the initial PTA determination would transform what should be an administrative application into an adversarial process for applicants.

Finally, IPO is concerned about the narrow scope of Canada's proposed implementation of PTA. Notably, unlike the equivalent U.S. regimes, the PTA term in Canada will run concurrently, not consecutively, with any CSP term granted to pharmaceutical patentees. Running these terms concurrently is inconsistent with their different remedial objectives, as CSPs are intended to compensate for patent term lost over time spent in research and development and regulatory approval.

IPO believes that Canada should reconsider its PTA framework to ensure that its implementation is compliant with the remedial objectives of Canada's USMCA treaty obligations on PTA.

Limitation of Listing of Valid Patents and Circumventing the Patent Register

Patent owners continue to be prevented from listing their patents on the Patent Register per *PNOC Regulations* when the patents do not meet certain, seemingly arbitrary, timing requirements.⁴⁵ These timing restrictions are not present in the U.S. under the Hatch-Waxman Act.

Even when patents are eligible for listing on the Patent Register, subsequent entrants are being provided with expanded opportunities to circumvent the Patent Register by selectively relying on unmarketed strengths/dosage forms of otherwise marketed innovative drug products.⁴⁶

⁴⁴ See, CIPO, [Consultation Scene Setter – Additional Term and Miscellaneous Amendments to the Patent Rules](#).

⁴⁵ Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, as amended, <https://laws-lois.justice.gc.ca/eng/regulations/sor-93-133/FullText.html>.

⁴⁶ See *AbbVie Corporation v. Canada (Health)*, 2022 FC 1209 (currently under appeal to Federal Court of Appeal).

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 or whose listing is improperly evaded by subsequent entrants.

Introduction of the Promise Doctrine into Allegations of Overbreadth

The promise doctrine involved the Court identifying the utility that is alleged to be “promised” in the patent specification, and then measuring the utility of the invention against those promises.⁴⁷ In 2017, the Supreme Court of Canada (“SCC”) rejected this approach in *AstraZeneca*, calling the doctrine “unsound.”⁴⁸ The SCC held that the promise doctrine was “excessively onerous” on patentees,⁴⁹ as it improperly imported disclosure requirements into the utility analysis, requiring that any disclosed use be demonstrated or soundly predicted at the filing date, regardless of what was included in the claims or the nature of the invention.⁵⁰

Despite rejecting the promise doctrine as part of the utility requirement, the SCC held that the “scheme of the Act treats the mischief of overpromising in multiple ways.”⁵¹ The Court, in paragraph 46 of its opinion, specifically stated a number of potential groundings for this potential mischief, including, *inter alia*, overbreadth. These statements in paragraph 46 have become the foundation of a number of allegations of invalidity from patent challengers. In particular, IPO is concerned that Canadian courts are introducing a version of the promise doctrine into determinations of overbreadth, thereby reintroducing the uncertainty of the promise doctrine into the law, and lowering the threshold for findings of overbreadth without any statutory basis for doing so.

In Canadian patent law, a claim is overbroad if it is broader than the invention disclosed in the patent’s specification, or broader than the invention made by the inventor.⁵² Alleged infringers are gaining traction by arguing that a claim is overbroad when certain elements of embodiments described in the specification are not included in the claims.

The Federal Court of Appeal (“FCA”) in a recent decision, *Seedlings Life Science Ventures*,⁵³ stated that

“[i]t is apparent that determining that a feature of an invention is essential is a distinct exercise for the purpose of overbreadth than for the purpose of claim construction. For overbreadth, the focus is not whether omitting or changing the feature avoids the claim (as it is for claim construction), but rather whether that feature is so key to the invention described in the disclosure that a claim that omits it encompasses embodiments that were not contemplated in the disclosure... The challenge in the present appeal is in

⁴⁷ *AstraZeneca Canada Inc v Apotex Inc*, 2017 SCC 36 at paras 29-30.

⁴⁸ *Id.* at para 36.

⁴⁹ *Id.* at para 37.

⁵⁰ *Id.* at para 44.

⁵¹ *Id.* at para 46.

⁵² *Western Oilfield Equipment Rentals Ltd et al v M-I LLC*, 2021 FCA 24 at para 128.

⁵³ *Seedlings Life Science Ventures, LLC v Pfizer Canada ULC*, 2021 FCA 154 at paras 54, 60.

determining which elements go to the core of the invention such that their absence from the claims results in invalidity for overbreadth.”

Therefore, the FCA could be interpreted as inviting zealous lawyers to read a patent specification in such a way as to persuade a Court as to the nature of the “core of the invention.”⁵⁴ This introduces a similar approach to, and therefore similar uncertainties and onerousness on patentees as, the rejected promise doctrine.

Elevating the Disclosure Requirement for Patents

IPO is concerned that the FCA has elevated the disclosure requirement for patents. In *Seedlings*,⁵⁵ the FCA stated that: “the disclosure must teach the skilled person to put into practice all embodiments of the invention, and without exercising inventive ingenuity or undue experimentation.”⁵⁶ It then found that the patent at issue for an apparatus for auto-injection of medication was invalid on that basis. The FCA found that the patent omitted from the claims certain preferred elements from embodiments that were described in the disclosure. The disclosure did not describe how to make embodiments other than the preferred embodiment.⁵⁷ This increased disclosure requirement adopted by the FCA appears to place an unmanageable burden on inventors to disclose all embodiments of an invention.

Further, this could mean that any inventive improvement on a first patent that falls within that first patent’s claims would make that first patent invalid. The improvement would fall within the scope of the first patent’s claims but, if inventive, the embodiment would not have been disclosed in the first patent by definition.⁵⁸ This elevated disclosure requirement is novel, and would place undue burden on innovators to meet the requirements for a valid patent.

Other Concerns

IPO believes that the Government of Canada should be more progressive in its approach by amending its laws to better define their boundaries in order to create greater business certainty. For example, Canada’s policy of allowing transfer of prior user rights to third parties establishes an unstable foundation for reliable patent protection.⁵⁹ Another example is Canada’s file wrapper estoppel rules,⁶⁰ which have been unfairly applied retroactively and created a significant

⁵⁴ *Pfizer Canada Inc v Mylan Pharmaceuticals ULC*, 2012 FCA 103 at para 57. See also *Aux Sable Liquid Products LP v. JL Energy Transportation Inc.*, where the FC invalidated a patent due to overbreadth. In that decision, the Court disregarded that an embodiment that was disclosed in the patent was encompassed by the claims, instead finding that the claims did not cover other embodiments which it found amounted to the “invention disclosed in the patent,” as described in the specification (paras 58-60, 65-66).

⁵⁵ *Seedlings Life Science Ventures, LLC v Pfizer Canada ULC*, 2021 FCA 154.

⁵⁶ *Id.* at para 68.

⁵⁷ *Id.* at para 71.

⁵⁸ See Norman Siebrasse’s article: “Enabling After-Arising Technology”, Sept 7, 2021, online at: <<http://www.sufficientdescription.com/2021/09/enabling-after-arising-technology.html>>.

⁵⁹ Section 56(2) of the Canadian Patent Act, last amended on 2021-06-30, <https://laws-lois.justice.gc.ca/eng/acts/P-4/section-56.html>.

⁶⁰ Section 53.1 of the Canadian Patent Act (R.S.C., 1985, c. P-4), last amended on 2021-06-30, <https://laws-lois.justice.gc.ca/eng/acts/P-4/section-56.html>.

disruption in existing patent proceedings. Canada's data protection practices are also a concern due to court challenges calling into question the scope of protection provided for test data. Notably, when the Government of Canada has sought public comments on new proposals, the deadlines for comment are sometimes extremely short and, in IPO's view, do not allow sufficient time for a thoughtful perspective to be provided. This was an issue in the recent consultations relating to Patent Term Adjustment. Innovators would like Canada to take steps to provide stronger protections for innovation.

CHILE

Pending Fármacos-II Bill

Chile, which has developed a leading health and innovation ecosystem, is at risk of reversing progress, developing anti-intellectual property laws, and suggesting unhelpful modifications to its regulatory affairs process. Amendments proposed by the Health Committee of the Chamber of Deputies under the Fármacos II bill remain pending and would expand compulsory licenses, restrict use of brand names for medicines, and suggest modifications to regulatory affairs for bioequivalent drugs and in the process for regulatory registration of drugs. These developments risk Chile's leading position and threaten continued innovation in Chile.

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

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

CHINA

Lack of Transparency into IP Enforcement⁶¹

After the Supreme People's Court in 2013 issued the "Regulation Concerning the Publication of People's Courts' Judgements and Rulings on the Internet," which required that all judicial

⁶¹ IPO Board Resolution dated July 14, 2022: "*RESOLVED that IPO generally supports transparency including publishing of judicial and administrative decisions shortly after being rendered that pertain to the subject matter of*

decisions should be published,⁶² publication of judicial decisions rose dramatically, peaked in 2020, and the rate of publication has declined dramatically since.⁶³

In a separate initiative, at the direction of the Supreme People's Court, the Beijing IP Court used guiding cases in deciding new IP cases, including establishing a database of “Guiding Cases” and a research organization for identifying guiding cases to add to the database. A centralized tribunal for hearing appeals in IP cases – the Supreme Peoples’ Court Intellectual Property Court – began operating on January 1, 2019. By the end of 2019 the Court reported that it had closed 1433 cases, but only about 20-30 had been published. By the end of 2020 the Court closed an additional 2787 cases, of which 55 Guiding Cases had been published, but the number of any additional published cases was not readily available.⁶⁴ The establishment of the IP Court of the Supreme Peoples’ Court, and the publication of guiding cases, was a positive step towards bringing predictability to enforcement of IP rights in China, but the relatively few decisions published and/or the lack of disclosure of the number of published cases, raised concerns about the transparency of such enforcement.

More recently, transparency in IP enforcement in China appears to have declined severely, and commentary in the Chinese legal community suggests that publication of judicial decisions of all kinds will come to a halt in 2024. The reasons for the decline in transparency were previously unknown, but recent announcements about the reorganization of databases for judicial decisions have been widely regarded as putting a stop to the routine publication of judicial decisions altogether.⁶⁵ [Caixin.com](https://www.caixin.com) reported that the “Notice on Building a National Court Judgment Document Database” posted online on December 11 was issued by the General Office of the Supreme People’s Court on November 21, 2023. ... Judgment documents can only be retrieved by court personnel on an internal private network and cannot be accessed by lawyers, legal researchers and the wider public.” The South China Morning Post reported that “[t]he right to view judgments is written into the Law of Civil Procedure and was a promise the country made when it joined the World Trade Organization in 2001.⁶⁶ It noted that China had promised to amend laws to abide by the WTO agreement and judicial review procedures for administrative actions.

the TRIPS Agreement (except for decisions on unpublished applications for intellectual property rights)."

<https://ipo.org/index.php/resolution-relating-to-transparency-of-decisions/>

⁶² with narrow exceptions (e.g. for national security)

⁶³ See [Donald Clarke, “The end of China Judgments Online?”, Chinese Law Notes, December 13, 2023](#) (citing [Zichen Wang, Peiyu Li, and Yuxuan Jia, “Tsinghua Law Professors Call for Renewing Open Access to China’s Court Judgments,” Pekingology, December 12, 2023](#)). See also [Herbert Smith Freehills, “Chinese Supreme People’s Court Announces Mandatory Publication of Court Decisions”, January 8, 2014](#) (“Under the 2013 Regulation, people’s courts at all levels throughout China must submit their judgments and rulings for publication on a central website, established and maintained by the SPC.”); [Mu Qi, “If court rulings are not made public, what are people worried about?”, December 15, 2023](#) (“In 2020, the number of documents reached more than 23 million. In 2023 there are currently only more than 3 million, and old judgments are constantly being removed and cannot be searched.”).

⁶⁴ See <http://ipc.court.gov.cn/en-us/news/view-1392.html>; see also <http://ipc.court.gov.cn/en-us/news/view-1225.html>.

⁶⁵ See [Zeyi Yang, “China’s judicial system is becoming even more secretive”, MIT Technology Review, December 20, 2023](#).

⁶⁶ [“Back to ‘black box’? As China tightens access to court records, legal experts fear for future of judicial transparency”, South China Morning Post, December 31, 2023](#).

Transparency in IP enforcement is crucial to the fair and effective operation of an IP system. Among other things, it is critical for entities to understand their risk of undertaking activities in China; will a particular product or service result in infringement of another's IP rights? A judicial decision on infringement of a given patent arising from a given product or service will help a potential manufacturer or service provider of a similar product or service determine whether to offer their products or services in China or to redesign them, if possible, so they do not give rise to infringement.

More specifically, Article X, paragraph 1, of the World Trade Agreement and Article 69(1) of TRIPS, Uruguay Round Agreement,⁶⁷ each require transparency in IP enforcement, which is critical to fair trade.⁶⁸ A patent is a legal instrument of general application - more than one party can be found to infringe it - so judicial decisions construing patent claims and applying them to the activities of a given party are also of general application.⁶⁹ The reasoning in a decision that a product of one party gave rise to infringement may also apply to products of other parties. Ignorance of judicial decisions finding that a similar product results in infringement of another's patents may lead a party to invest to its detriment in the offering of a product in China. This decline in IP enforcement transparency appears to be potential breach of Article X of the World Trade Agreement and Article 69(1) of TRIPS.

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

Phase I Economic and Trade Agreement

The United States and China entered into Phase I of the Economic and Trade Agreement on January 15, 2020 ("2020 Phase I Trade Agreement"), which promised improvements in intellectual property and tech transfer in China. IPO notes, in particular, that provisions in Chapter 1 called for needed improvements in trade secret protection, measures against bad faith

⁶⁷ https://www.wto.org/english/docs_e/legal_e/27-trips_07_e.htm.

⁶⁸ Article X paragraph 1 of the World Trade Agreement provides (emphasis added): "Laws, regulations, ***judicial decisions and administrative rulings of general application***, made effective by any contracting party, pertaining to the classification or the valuation of products for customs purposes, or to rates of duty, taxes or other charges, or to requirements, restrictions or prohibitions on imports or exports or on the transfer of payments therefor, or ***affecting their sale***, distribution, transportation, insurance, warehousing, inspection, exhibition, processing, mixing or other use, shall be ***published promptly*** in such a manner as to enable governments and traders to become acquainted with them. Agreements affecting international trade policy which are in force between the government or a governmental agency of any contracting party and the government or governmental agency of any other contracting party shall also be published. The provisions of this paragraph shall not require any contracting party to disclose confidential information which would impede law enforcement or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of particular enterprises, public or private."

⁶⁹ Note that in WTO proceedings "the term 'general application' is given a generous interpretation so as not to limit the scope of measures covered under Article X". [Padideh Ala'i, "From the Periphery to the Center? The Evolving WTO Jurisprudence on Transparency and Good Governance", *Journal of International Economic Law*, 1, 14, 2008.](#)

trademarks, and the protection of patents relating to pharmaceuticals. IPO has monitored the implementation of the agreement and continues to do so.

New Examination Guidelines and Implementing Regulations

In December 2023, the China National Intellectual Property Administration (CNIPA) published final versions of the revised Patent Examination Guidelines and Implementing Regulations for the last amendment to the Patent Law of China.⁷⁰

The Guidelines 2023 have many significant changes bringing the Chinese patent system closer to the international norm. IPO applauds CNIPA for including in the Patent Examination Guidelines: (1) default incorporation by reference using the CNIPA application forms, (2) allowing for both whole and partial designs to be included in one application, and (3) clarifying that only genetic information derived from organisms belongs to non-patentable subject matter. IPO also applauds CNIPA for including in the Implementing Regulations: (1) clarity on the inventor information that must be provided in an application, (2) limiting the types of parties who may request an evaluation report, (3) improving fairness to patentees of reexamination procedures, (4) improving the recordation procedures for open licensing contracts, and (5) providing that alternative inventor remuneration may be provided not only by agreement, but also by policy.

One concern with the revised examination guidelines is that the changes to the guidelines may allow the CNIPA to deem an application to be not filed by an unclear bad faith accusation. Some filings initially determined not to be in good faith may have actually been in good faith, and therefore should not be treated as if they have not been filed without giving the applicant a chance to explain.

Serial Patent Challenges

In China, a petitioner can file as many patent challenges as it wishes regardless of whether the China Patent Reexamination Board (PRB) has already adjudicated the same patent between the same parties. China's current "finality" rule is limited to the same evidence – namely, China PRB only denies a subsequent petition if that subsequent petition presents the same evidence as in the previous proceeding. It is easy, however, to put new evidence in a subsequent petition to get around that narrow "finality" rule.⁷¹

⁷⁰ See also IPO letter dated December 14, 2022, to CNIPA re Draft Revised Patent Examination Guidelines, <https://ipo.org/wp-content/uploads/2022/12/IPO-Comments-to-CNIPA-on-Draft-Revised-Patent-Examination-Guidelines-14-Dec.-2022.pdf>; IPO letter dated September 22, 2021, to CNIPA re Draft Revised Examination Guidelines (Draft for Solicitation of Comments), <https://ipo.org/wp-content/uploads/2021/09/IPO-Comments-on-CNIPAs-Draft-Revised-Patent-Examination-Guidelines-22-Sept.-2021.pdf>; and <https://ipo.org/wp-content/uploads/2021/01/IPO-Comment-Letter-Implementing-Regulations-Patent-Law.pdf>

⁷¹ In the U.S., if PTAB has reached a final decision in a post-grant proceeding (e.g., IPR or PGR), the petitioner could not challenge the same patent in a subsequent proceeding based on a ground or evidence that reasonably could have been raised in the prior proceeding.

IPO is concerned about the weakness of the finality rule in China, and suggests the adoption of a broader “finality” rule to prevent subsequent patent challenges by the same party based on evidence that it could have reasonably been in the previous proceeding.

Acceptance of Supplemental Data to Support Patentability

Before the 2020 Phase I Trade Agreement, China had a stringent requirement for the acceptance of supplemental data to support patentability. Specifically, China required that in order for additional data to be considered by patent examiners, the technical effect supported by the additional data must be “obtainable from the original patent disclosure”. This practice was a great departure from other major countries or regions, such as the U.S., EU, and Japan. Furthermore, Article 1.10 of the 2020 Phase I Trade Agreement specifically requires China to accept additional data for the purpose of patentability without any condition. But China so far has not changed its prior-2020 requirement and its examination guideline still uses the same language for that stringent standard (i.e., “obtainable from the original patent disclosure”).

IPO is concerned that China’s restriction on supplemental data does not appear to comply with Article 1.10 of the 2020 Phase I Trade Agreement.

Regulatory Data Protection

China provides Swiss companies with 6 years of regulatory data exclusivity for pharmaceuticals and biologics pursuant to Article 11.11(2) of the 2013 China-Switzerland bilateral trade agreement.⁷² Under the most-favored nation clause of the TRIPS agreement, China is required to provide U.S. innovators with same benefit as Swiss nationals “immediately and unconditionally” as they were provided to Swiss nationals.⁷³ But China does not extend such protection to U.S. companies.

IPO believes that China should provide U.S. companies with at least the same regulatory data protection in China as Swiss companies receive.

⁷² Article 11.11(2) of the Switzerland-China Free Trade Agreement (entered into force 1 July 2014): “The Parties shall prevent applicants for marketing approval for pharmaceuticals, including chemical entities and biologics, and agricultural chemical products from relying on, or referring to, undisclosed test data or other data submitted to the competent authority by the first applicant for a period, counted from the date of marketing approval, of at least six years for pharmaceuticals and for agrochemical products.” See,

<https://www.seco.admin.ch/dam/seco/en/dokumente/Aussenwirtschaft/Wirtschaftsbeziehungen/Freihandelsabkommen/Partner%20weltweit/China/Abkommenstexte/Texts%20in%20English/Switzerland-China%20FTA%20-%20Main%20Agreement.pdf.download.pdf/Switzerland-China%20FTA%20-%20Main%20Agreement.pdf>

⁷³ Article 4, Sentence 1, of TRIPS: “With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members.”

Trade Secrets: Positive Developments and the Need to Upgrade

Trade secret law in China is fragmented, with protection provided under several different legal and administrative provisions, including those involving anti-unfair competition, contract, and labor laws, among others. In these differing regimes, there have been a few developments.

For example, China amended its Anti-Unfair Competition Law in 2019.⁷⁴ The State Administration for Market Regulation then published Draft Rules on Trade Secret Protection for public comments in 2020 and published a revised draft of the Anti-Unfair Competition Law in November 2022, but to our knowledge no final rules have been put in place.⁷⁵ The Supreme People's Court and Supreme People's Procurate also jointly published Interpretations on Several Issues Concerning the Application of Law in the Trial of Civil Cases of Trade Secret Infringement Disputes.⁷⁶ These amendments, new rules, and judicial interpretations appear to indicate that China desires stronger enforcement against trade secret misappropriation. IPO hopes that this continues a trend of expanded enforcement of trade secret rights in China.

Although recent developments are promising, trade secret owners still face significant challenges protecting their confidential information. High evidentiary burdens, limited discovery, and multiple 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 significant⁷⁷ and possibly irreversible injury has taken place.

Positive developments regarding this issue have occurred in the civil law, but it is still not likely that a criminal investigation in China will begin until there is proof that significant damage has occurred (at which time the damage may be irreversible). More specifically, under recent amendments to China's Anti-Unfair Competition Law, a civil plaintiff may make a showing of certain elements that allow for burden shifting to the defendant, which is an improvement in this area. Recent amendments to the criminal law have also been made, but showing damage of

⁷⁴ See Anti-Unfair Competition Law (as amended April 2019),

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

⁷⁵ See Rules on Trade Secret Protection (Draft for Solicitation of Comments), published on September 4, 2020, Link to this content at China Ministry of Justice no longer functional. See, also, <https://chinaipr.com/2020/09/12/samr-releases-draft-trade-secret-rules-for-public-comment/>, and IPO's comments to China's State Administration of Market Supervision on its Draft Rules on Trade Secret Protection, <https://ipo.org/wp-content/uploads/2020/10/IPO-Comment-Letter-on-Trade-Secrets.pdf>; Announcement of the State Administration for Market Regulation on Publicly Soliciting Opinions on the Anti-Unfair Competition Law of the People's Republic of China (Revised Draft for Comments), November 2, 2022, https://www.samr.gov.cn/hd/zjdc/202211/t20221121_351812.html

⁷⁶ See the Interpretations on Several Issues Concerning the Application of Law in the Trial of Civil Cases of Trade Secret Infringement Disputes, jointly released by the Supreme People's Court and Supreme People's Procurate on August 24, 2020 and implemented on September 12, 2020, <http://www.court.gov.cn/zixun-xiangqing-254751.html>. See also https://www.spp.gov.cn/spp/xwfbh/wsfbt/202009/t20200918_480430.shtml#1 and <https://www.slwip.com/resources/chinas-threshold-for-criminal-trade-secret-misappropriation-to-drop-to-300000-rmb/>.

⁷⁷ A threshold of 300,000 RMB must be met. See the Interpretation on Several Issues Concerning the Specific Application of Law in Handling Criminal Cases of Infringement of Intellectual Property Rights, released jointly by the Supreme People's Court and Supreme People's Procuratorate on September 13, 2020.

300,000 RMB for criminal cases is currently an element to be proven.⁷⁸ Although proving “use” is not required, the test to meet the damage requirement, in the absence of proof of damages based on use, is, in IPO’s opinion, subjective. Absent clarification of the test, in practice, proof of significant damage remains the test in criminal cases.⁷⁹

The way a misappropriator uses a trade secret can also affect the ability to obtain relief under civil law. For example, where the misappropriator benefits from a trade secret by virtue of accelerated development rather than actual profits or other unjust gains, such a concept is not formally recognized in the determination of damages to the trade secret owner.

The requirements for many businesses to submit technical and functional features of their products, as well as confidential test data, as a condition for access to the Chinese market present further challenges for protecting confidential business information. Further, China’s Patent Law gives 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.⁸⁰ Our members are concerned with the significant risk of trade secret disclosure that could result from administrative investigations. Absent proper safeguards, such administrative enforcement of patents could result in disclosure of confidential information.

The consequences of such disclosures to government agencies can be particularly harmful because receiving agencies might be willing to provide such confidential information to the public on request. In some cases, the information provided is reviewed by expert panels that include employees of local businesses and institutions that might benefit financially from having access to another company’s trade secrets. Although, at the 2014 Joint Commission on Commerce and Trade, 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.⁸¹ China’s Ministry of Justice published draft “Guiding Opinions on Strengthening the Protection of Trade Secrets and Confidential Business Information in Administrative Licensing (Draft Solicitation for Comments)” on August 14, 2020, but IPO is not aware of any related developments since that time.⁸²

In summary, in China, our members face high burdens of proof, limited discovery, and damages issues when seeking to enforce their trade secrets. While preliminary injunctions in the form of

⁷⁸ See the Interpretation on Several Issues Concerning the Specific Application of Law in Handling Criminal Cases of Infringement of Intellectual Property Rights, released jointly by the Supreme People’s Court and Supreme People’s Procuratorate on September 13, 2020, at Article 4. (IPO notes that a subsequent revised draft of Several Issues Concerning the Specific Application of Law in Handling Criminal Cases of Infringement of Intellectual Property Rights was published for comment on January 28, 2023.)

⁷⁹ IPO Response to Questions, March 7, 2023, USTR 2023 Special 301 Review (Docket No. USTR– 2022-0016), <https://ipo.org/wp-content/uploads/2023/03/Responses-to-Questions-Intellectual-Property-Owners-Association.pdf>

⁸⁰ The Patent Law of the People’s Republic of China effective 1 June 2021, Article 69.

⁸¹ 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>.

⁸² See IPO letter to the Ministry of Justice for China dated September 30, 2020, on Guiding Opinions on Strengthening the Protection of Commercial Secrets and Confidential Business Information in the Process of Administrative Licensing (Draft for Solicitation of Comments), <https://ipo.org/wp-content/uploads/2020/10/IPO-Comments-Admin.-Licensing.pdf>.

conduct preservations are more recently being granted in trade secret actions, such relief remains uncommon and unpredictable particularly in view of the high threshold of proof, and thus a trade secret owner usually must wait until a significant and possibly irreversible injury has taken place before seeking relief. Our members also face requirements to submit confidential details to government agencies. Although IPO is encouraged with recent upgrades, such as the expanded availability of injunctive relief in China's amended civil procedure framework, more needs to be done to protect trade secrets. IPO is encouraged by Section B (Articles 1.3-1.9) of the Phase I Economic and Trade Agreement between the U.S. and China, which when fully implemented, will substantially improve trade secret protection in China.

China Lacks a Meaningful Grace Period for Design Applications

While the recently updated Patent Law of China makes a number of improvements to design patent law, including provision for partial designs and a longer term of protection, China is one of the few modern countries not to have a meaningful grace period during which a design owner can file a design application after disclosing the design publicly anywhere in the world.⁸³ This is one of the reasons deterring foreign applicants from obtaining design patents in China, as reflected by the numbers of grant of design patents.⁸⁴ Unsophisticated designers may not appreciate the need to file a design application before disclosing their design, at which point protection will be unavailable in China. Further, grace periods — like those adopted in the U.S., Europe, Japan, South Korea, Canada, and Australia — provide applicants the time and flexibility to consider the need for protection and to prepare quality applications. China should be encouraged to adopt a generally applicable grace period of at least 6 months, and preferably 1 year.

Implementation Guidelines are Needed to Give Effect to the Improvements in the Amendments Regarding Industrial Designs

We commend China on recent improvements in the patent law amendments with respect to the protection of industrial designs. However, without implementation details in effect, no guidance or standards exist for how these changes should be carried out. As such, there is uncertainty about how these changes will be implemented. We encourage China to swiftly move forward with finalizing its implementation guidelines to create more certainty and consistent practices.

Anti-Suit Injunctions⁸⁵

Beginning in August 2020, Chinese courts have issued anti-suit injunctions that have arguably tipped the scales in favor of domestic businesses, while raising due process and transparency

⁸³ There are grace periods for disclosures for the benefit of the public interest. See the Patent Law of China, effective June 1, 2021, Article 24.

⁸⁴ In 2021, design patent grants from the CNIPA were: 17,061 to foreigners, 768,460 to domestic entities. See <https://english.cnipa.gov.cn/col/col3050/index.html>.

⁸⁵ See also IPO Board Resolution dated July 20, 2023 related to Anti-Suit Injunctions: *RESOLVED, that IPO believes that an anti-suit injunction (ASI) should not be granted in SEP cases involving F/RAND-encumbered intellectual property rights matters where:*

issues. This topic is particularly difficult to analyze or keep updated in any systematic way due very limited transparency into anti-suit injunctions in China.⁸⁶ In the face of a specific request by the European Union, which filed an Article 63.3 request at the WTO on July 6, 2021 requesting further information on four standard essential patent (SEP) cases in China, China rebuffed the EU's request and failed to make those decisions public.⁸⁷ Since then, Japan, Canada, and the U.S. have joined in the Art. 63.3 Consultation process. IPO remains optimistic that these efforts will yield substantial improvements in due process and transparency. The EU has requested that a panel be set up by the Dispute Settlement Body to examine the matter.

Challenges Created by Chinese Trademark Law

Several amendments to China's trademark law became effective on November 1, 2019. These amendments, together with those made in 2013, improved the law, such as with the addition of a good-faith requirement when applying for new marks and the rejection of bad faith trademark registrations without an intent to use. Yet, brand owners still face substantial challenges. For example, failed oppositions result in immediate registration of challenged marks in the absence of a right to appeal, forcing brand owners to initiate separate invalidation proceedings before the Trademark Review and Adjudication Board. As the brand owner waits, a bad faith registrant can build up years of use, improving its chances to use the mark permanently under Chinese jurisprudence. Bad faith registrants might even be able to take enforcement action against a brand owner's use of its own trademark.

The 2014 PRC Trademark Law dropped the Opposition Review, depriving both parties of their rights of action. As the success rate of opposition in China is very low, the removal of Opposition Review from the PRC trademark framework can only make things worse. Once bad

*due process, including proper notice, is lacking;
transparency is lacking; or
disproportionate penalties are included.*

FURTHER RESOLVED, IPO further believes that courts should carefully consider the following factors before granting or denying an ASI in SEP cases whether:

*under generally accepted legal principles and/or by consent of the parties, the domestic court has jurisdiction over the parties and the subject matter of the foreign proceedings;
the foreign proceedings threaten the domestic court's jurisdiction;
generally accepted principles of equity and comity counsel in favor of or against an injunction;
the parties and issues overlap in the domestic and foreign proceedings;
the foreign proceedings would frustrate a domestic public policy;
the outcome of the domestic action would be dispositive of the foreign proceedings;
the foreign proceedings are vexatious or oppressive; and
both parties have expressly consented to the domestic court setting binding F/RAND license terms for the F/RAND encumbered IPRs issued by foreign jurisdiction(s).*

<https://ipo.org/index.php/resolution-related-to-anti-suit-injunctions/>

⁸⁶ IPO Response to Questions, March 7, 2023, Question 6, USTR 2023 Special 301 Review (Docket No. USTR-2022-0016), <https://ipo.org/wp-content/uploads/2023/03/Responses-to-Questions-Intellectual-Property-Owners-Association.pdf>.

⁸⁷ See European Union, Request for Information Pursuant to Article 63.3 of the TRIPS Agreement (July 6, 2021), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=t:/IP/C/W682.docx&Open=True>; see also, P.R. China, Response to the European Union's Request for Information Pursuant to Article 63.3 of the TRIPS Agreement (Sep. 7, 2021), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W683.pdf&Open=True>.

faith registrants get their registration certificates, the brand owners will bear a heavy burden to invalidate them, not to mention the infringement risks caused by the registration if the non-registrant brand owner continues using their unregistered mark. Even if the invalidation action goes well, the process takes about one year, and the bad faith registrant might continue to appeal to the courts at three levels, which takes at least an additional three years, delaying resolution of the dispute, to the detriment of the brand owner.

IPO also notes that, in late 2015, the Chinese Trademark Office began invoking the Article 7 good faith requirement to invalidate abusive trademark registrations. On November 22, 2021, the CNIPA revised its trademark examination guidelines,⁸⁸ defining 10 actions of bad faith trademark application behavior with no purpose of use. Factors to consider include the number of trademarks filed by the applicant and transaction situation (targeting professional squatters), the business nature of applicant, and similarity to famous trademarks.

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

Draft Amendment to the Trademark Law

The China National Intellectual Property Administration (CNIPA) published “Draft Amendment to the Trademark Law of the People’s Republic of China” on January 13, 2023.⁸⁹ IPO supports efforts for international harmonization of trademark laws and procedures, and appreciates the aim of CNIPA to try to improve the trademark system through this amendment. An important part of such harmonization is having consistent grounds for rejections of trademarks, such as those recognized in international treaties.⁹⁰

The draft amendments, in many instances, introduce prohibitions on the use or registration of trademarks that would be unobjectionable in many other countries. Such prohibitions include where such use or registration would be contrary to what is described generally as “national

⁸⁸ See https://www.cnipa.gov.cn/art/2021/11/22/art_74_171575.html.

⁸⁹ https://www.cnipa.gov.cn/art/2023/1/13/art_75_181410.html

⁹⁰ See also IPO Letter dated February 27, 2023, to CNIPA re “Draft Amendment to the Trademark Law of the People’s Republic of China (Draft for Comment), <https://ipo.org/wp-content/uploads/2023/02/IPO-Comment-Letter-on-Chinas-Trademark-Law.pdf>

interests,” “public interest,” “public order,” and “good customs.”⁹¹ IPO notes that these prohibitions in the draft law will lead to trademarks that would be unobjectionable in many other countries being rejected in China. Removing these prohibitions would give trademark owners clearer guidance as to when their trademarks or their exercise of their trademark rights might be seen to be objectionable. Should the prohibitions not be removed before China enacts the Amendment to the Trademark Law, however, IPO would suggest that trademark owners be given an opportunity to respond to any such objections and that the circumstances in which trademark rights are prohibited for the above reasons be limited, specified, and clear.

The draft amendment removes language that currently permits an opposed party who is dissatisfied with the decision of disapproval made by CNIPA during an opposition proceeding to request that CNIPA review the decision before appeal to the people’s court. Permitting the opposed party to first request review by CNIPA can reduce burdens on the opposed party, especially a foreign party, to meet the procedural requirements that would be required in a suit at the people’s court. This could also help reduce the already high workload of the court.

IPO applauds China’s expressed commitment to, among other things, publish trademark information in a complete, accurate and timely manner. It would be preferable if Article 96 contained more details regarding the data and documentation that will be made publicly available.

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 have been several examples, such as the catalog of indigenous innovation products established by the Economic and Information Technology Bureau of Yinzhou District or the budget notice from Nanxian County, Hunan stipulating the same preferences. Therefore, although IPO is encouraged by China’s renewed commitment at the 27th JCCT to build on the country’s 2011 commitment, the U.S. should encourage implementation to move at a more rapid pace.⁹²

⁹¹ The following summarizes some of the prohibitions included in the draft amendment: Article 7 (Trademark owners shall not abuse their trademark rights to damage the national interests, the public interest...); Article 14 (A trademark which is applied for shall not violate public order and good customs); Article 15 (The following signs shall not be used as trademarks: ... those...having other unhealthy influences); Article 22 (An applicant shall not apply for registration of a trademark which is detrimental to the interests of the State or the public interest or has other significant unhealthy effects); Article 27 (Where the intellectual property administrative department of the State Council finds that a trademark applied for registration obviously has significant unhealthy effects, it shall not accept the application); Article 49 (A registered trademark may be revoked if the use of the mark has seriously impaired public interests and cause significant unhealthy effects).

⁹² *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>.

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

Forced Technology Transfer

The 2020 Foreign Investment Law has provisions that, if effective, could constitute substantial progress in dismantling policies, laws, regulations, and practices that force technology transfer. Article 22 of the law provides, among other things, that “administrative organs and their employees must not force the transfer of technology through administrative measures.” The concern is that this language might prove open to loopholes that would prevent it being fully effective. For example, if a transfer is mandated other than “through administrative measures” it might not be considered a violation of the law.

In addition, there are many other laws, regulations, and practices outside the Foreign Investment Law that would serve to undermine the restriction against forced technology transfer. For example, joint venture requirements and data localization requirements for internet and cloud companies, as well as biopharmaceutical companies conducting research in China, mean that foreign companies are, as a practical matter, forced to hand over their IP to local PRC companies in order to participate in the Chinese market. Moreover, the Fourth Amendment to the Patent Act, which was effective June 1, 2021, increases the power of administrative agencies to investigate patent infringement which may involve seizing confidential information including trade secrets, which might result in the disclosure of such trade secrets to others, including competitors. Regulatory laws such as environmental, pharmaceutical, and medical device approval requirements can also result in concerning disclosures of confidential information, particularly where information is sought more broadly than reasonably necessary to accomplish regulatory review or where the regulatory agencies share submitted information with competitors (such as technical experts employed by or affiliated with competitors) or share submitted information with later regulatory applicants (or use it on their behalf). IPO looks forward to further developments in the implementation of Articles 1.9, 2.2 and 2.3 of the Phase I Economic and Trade Agreement, which require improvements in the protection of trade secrets and confidential business information from unauthorized disclosure by government authorities and prohibit forced technology transfer through administrative and licensing requirements, or through requirements for acquisitions, joint ventures, and other transactions.

Patent Enforcement and the Amendment to Chinese Patent Law

Language in China’s 4th Amendment to its Patent Law⁹³ raises concerns that, in some instances, valid patent rights might not be enforced. Article 20 of the Patent Law creates uncertainty by its ambiguity. It requires those who apply for and exercise patent rights to act in good faith and not misuse patents to “damage public interests or others’ legal rights.”⁹⁴ In this context, “bad faith patenting practices” refers to those practices that CNIPA has defined as “abnormal patent application behaviors” in its “Methods regarding governing of patent application behavior.” The

⁹³ The Patent Law of the People’s Republic of China, effective June 1, 2021, <http://www.npc.gov.cn/npc/c30834/202011/82354d98e70947c09dbc5e4eeb78bdf3.shtml>.

⁹⁴ *Id.* at Art. 20.

lack of clarity that this definition creates regarding which practices will be considered patent misuse creates uncertainty in the IP system.⁹⁵ While the Amendments to the Implementation Rules of the Patent Law gives a little more detail, there continues to be a lack of detail to fully explain this principle or guide the courts and administrative agencies that are tasked with enforcing it.⁹⁶

Under the law, there is some risk and uncertainty that certain aggressive and bad-faith patenting practices may be deemed patent misuse. Without a clear definition of what practices may amount to patent misuses that damage the public interest or others' legal rights, this article may create some uncertainty for patent owners who seek to legally exploit and enforce their patents. This also raises questions regarding consistency with TRIPS Article 30, which provides that the exceptions to the exclusive rights conferred by a patent should not unreasonably conflict with a normal exploitation of the patent and unreasonably prejudice the legitimate interests of the patent owner, considering the legitimate interests of third parties. China's National Intellectual Property Administration (CNIPA) has extensively addressed what it has determined to be misuse since 2021, and the current targets are all Chinese entities.⁹⁷ It remains a concern whether such efforts would extend to foreign entities.

Moreover, the high and growing volume of utility models in China,⁹⁸ combined with the lack of examination with respect to patentability, creates substantial uncertainty for U.S. companies in the Chinese market. Although CNIPA has acknowledged the extent of the problem by rejecting some utility model applications that are "obviously unpatentable," more safeguards are needed to ensure these patents are not inappropriately used against innovative companies. One such measure would be to automatically stay infringement proceedings until timely invalidation requests have been resolved. Another measure would be to require that utility models only be granted after obtaining a patentability evaluation report, which would be published with the utility model at grant.

The 4th Amendment to the Patent Law continues to expand administrative enforcement of patent rights. It gives hundreds of inexperienced local and provincial patent administration and enforcement offices new powers to investigate and inspect, to grant injunctive relief, and to impose fines and penalties for patent infringement. One of the effects of the 4th Amendment to the Patent Law is to allow 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. This change fragments enforcement, interpretations, and procedures regarding patent laws and the related rights, making enforcement

⁹⁵ IPO Response to Questions, USTR 2023 Special 301 Review (Docket No. USTR–2022-0016), Question 1, <https://ipo.org/wp-content/uploads/2023/03/Responses-to-Questions-Intellectual-Property-Owners-Association.pdf>

⁹⁶ See, e.g., Implementing Rules 69 and 11, Section 4.1, Chapter 3, Part IV of the Patent Examination Guidelines.

⁹⁷ See "2022 National Intellectual Property Administrative Protection Work Plan", https://www.cnipa.gov.cn/art/2022/1/24/art_75_172901.html; and https://www.cnipa.gov.cn/art/2022/1/25/art_75_172922.html.

⁹⁸ See 2020 SIPO Annual Report at p. 35 of English version (April 27, 2021) (utility model applications grew by 29% in 2020 over 2019). See also <https://bit.ly/30ZizJm> (in 2021, utility models were 72.7% of all Chinese patent filings).

in China less predictable and extremely difficult to navigate. In addition, the 4th Amendment to the Patent Law specifies that certain patent infringement cases with nationwide influence may be handled by CNIPA, and two such cases had already been accepted by the CNIPA in November 2021.⁹⁹ The first decision has been issued on July 27, 2022, in a case with a foreign pharmaceutical company patentee suing a Chinese company, in favor of the foreign patentee.¹⁰⁰ It appears from this case that once the infringement occurred in multiple provinces/municipal cities, CNIPA had the jurisdiction. However, there is still unclear guidance on the criteria for classifying cases as significant cases. While some classes of cases are specified as possibly significant cases, whether a particular case falls within one of those classes is uncertain because of the lack of detail.

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, technically trained, competent, and less political courts.

One positive development is the revision to the previous set of Patent Examination Guidelines, implemented by CNIPA on January 15, 2021,¹⁰¹ whereby supplementary data could be conditionally accepted to prove both sufficient disclosure and inventive step for technical effects already cited in the specification, even if the applications as filed do not provide any data. IPO is encouraged that these changes may foster timely filing of applications for new drugs by allowing applicants to later submit additional information consistent with the drug development process. Whether the amendments will make a substantial impact in the long term, however, is uncertain because in practice the admission of supplementary data is currently examiner dependent, and appears to be generally not welcomed. IPO also notes 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.

Unique Challenges to Pharmaceutical Protection

Our members welcome the patent term extension for pharmaceutical products in Article 42 of the 4th Amendment to the Patent Law. The National Medical Products Administration (NMPA) and CNIPA published Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes ("Measures") on July 4, 2021. The Supreme People's Court also published the Provisions on Several Issues Concerning the Application of Law in the Trial of Patent Civil Cases Involving Drug Marketing Review and Approval ("Provisions") on July 5, 2021. As of

⁹⁹ See https://www.cnipa.gov.cn/art/2021/11/15/art_53_171429.html.

¹⁰⁰ See <https://www.linkedin.com/pulse/1st-cnipa-important-patent-infringement-decision-toby-mak/?trackingId=WmpzpTAPS5S8b9lZro8JvA%3D%3D>, with the decision published briefly on the internet and the removed by the CNIPA.

¹⁰¹ Amendment to the Guidelines of Patent Examination According to CNIPA Announcement No. 391 (effective January 15, 2021).

October 2021, twelve drug patent linkage complaints had been accepted by the CNIPA, while the Beijing IP Court had accepted one.¹⁰²

The patent linkage provisions are new for China. A fair and effective linkage system for China will not only need to balance the interests of generics and innovators, but also will need consistency between the courts and the range of concerned administrative agencies.

Synchronous reforms to the relevant laws and regulations are necessary to enable stakeholders to consider the proposed scheme fully and holistically. Furthermore, rules and judicial interpretations should be harmonized with higher level laws and regulations. On December 21, 2023, the revised Patent Law Implementing Rules (PLIR) and the revised Patent Examination Guidelines were released by CNIPA, following a delay of over two years. However, it is concerning that these revisions seem to restrict important intellectual property incentives to products that are new to the world, thereby denying PTE and PTA to innovative medicines that have been previously approved outside of China. These incentives should be available to all drugs or improved drugs that are new to China.

Article 76 of the Patent Law is directed to drug marketing applications. IPO would like to see a broad definition of “drug” (e.g., to include both chemicals and biologics) to reflect the current state of the art in the field. Similarly, the applicable patents should broadly include those directed to chemical compounds, chemical compositions, pharmaceutical composition or formulation, method of manufacturing of the active ingredient, specific medical use, etc. The current version of the Measures and Provisions needs to be revised to reflect the broad definition of “drug” and the wide range of patents. For example, the Measures limit only sequence structure and medical use patents that can be registered for biologics. For chemicals, patents covering intermediates, metabolites, crystal forms, methods of manufacturing and testing methods are not considered as relevant patents under the patent linkage system.

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

IPO is also concerned about the lack of moratorium on approval when a generic drug applicant challenges that an in-force patent should be declared invalid under the so-called type 4.1 declaration. This effectively allows the NMPA to process the approval of the generic drug immediately even if the generic drug applicant does not file any invalidation challenge after filing the type 4.1 declaration.

¹⁰² See https://www.cnipa.gov.cn/art/2021/10/29/art_53_171065.html and <https://mp.weixin.qq.com/s/0PNtsFOXBuwxULgYqnV-Uw>.

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, including at the appeal (Patent Reexamination and Invalidation Department) level on the use of post-filing data to satisfy inventive step requirements.

In a positive development, China has implemented plans to improve drug safety and severely crack down on the production and sale of counterfeit medicines. The production, distribution, and sale of counterfeit medicines and unregulated active pharmaceutical ingredients, however, remain rampant in China and continue to pose a threat to China and its trading partners.

Requirements for Foreigners to Hire Local Patent Agencies

In China, domestic applicants may file their patent applications directly with CNIPA. Foreign applicants who want to own their patent assets must appoint a patent agency to represent them before CNIPA.¹⁰³ Hiring a third party, however, can increase both expense and risk that confidential information is lost in the process. For companies with significant operations in foreign countries, it is not uncommon to have in-house operations that manage the patent application process including filing applications. This is not possible under China's current Patent Law.

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

Genetic Resources and Traditional Knowledge

Article 26 of the Patent Law requires patent applicants to indicate the "direct source" and the "original source" of genetic resources if the completion of the claimed invention relies on access to genetic resources. China's definition of genetic resources is particularly broad and includes "any material taken from human, animal, plant or microorganism which contains functional units of heredity and is of actual or potential value, and genetic information generated from the use of such material". China's law allows for the rejection of any patent right where the required information for the genetic resources is not disclosed. These special disclosure requirements are ambiguous and, as a result, impose unreasonable burdens on patent applicants, subjecting

¹⁰³ The Patent Law of the People's Republic of China, published on November 19, 2020, effective June 1, 2021, Article 18, <http://www.npc.gov.cn/npc/c30834/202011/82354d98e70947c09dbc5e4eeb78bdf3.shtml>.

valuable patent rights to great uncertainty. Thus, IPO believes that these requirements should be deleted.

China's human genetic resource (HGR) regulations, which came into effect on July 1, 2019, prohibit human sample collection by foreign parties and restrict the use, analysis and transfer of such samples and related data except in the context of an approved collaboration with Chinese parties, such as medical institutions or enterprises with no foreign investment. The regulations also contain provisions regarding mandatory IP sharing that are inconsistent with Chapter 2 of the Trade Agreement, which provides that any transfer of technology as part of securing marketing approval for innovative medicines occurs on voluntary, market-based terms.

COLOMBIA

Compulsory Licenses

Even though some Compulsory License (CL) investigations have started in Colombia in the past 10 years, no CL has ever been granted. However, in October 2023, the Ministry of Health issued Resolution 1579, declaring the existence of reasons of public interest (DPI) for the purpose of issuing a Compulsory License on a patent for Dolutegravir by VIIV Healthcare Company and Shionogi & Co. A DPI is a prerequisite for issuing a Compulsory License. Resolution 1579 resulted from the procedure initiated by the Ministry of Health in June 2023, recommending the issuance of a compulsory license for Dolutegravir, used for the treatment and prevention of HIV. In this new case, the reasons argued for the DPI relate to the allegedly insufficient supply of HIV treatments in Colombia and their high prices, considering the increase in HIV cases and the need to protect specific populations. Currently, the public interest declaration is being evaluated by the Superintendence of Commerce and Industry to decide whether to proceed with the compulsory license. It is a matter of concern that the Ministry of Health has reported that this will be the first of many declarations of public interest that the government expects to implement in the coming years to reduce the cost of medicines in Colombia. IPO is also concerned about suggestions that the New National Development plan, which is currently under development, should encourage compulsory licensing.

Industrial Designs

In 2022, the Patent Office - Superintendence of Industry and Commerce (SIC) issued new guidelines for filing and prosecuting Industrial Designs. The new guidelines clarify that dotted lines are now allowable in Design applications when used for illustrative purposes to represent context for which no protection is sought. IPO applauds this development.

Patent Prosecution

IPO is also happy to see that provisional statistics show improvement of several patent prosecution metrics. The Examination rate has improved, and the average time for a non-final decision time is 30.8 months. Less than 100 applications are pending that were filed on or before 2019, and less

than 700 applications are pending that were filed on or before 2021. 2023 has been a record year for issuing final decisions, with more than 2011 cases resolved.

Genetic Resources and Traditional Knowledge

Comments relating to Colombia's laws and regulations relating to innovation with respect to genetic resources and traditional knowledge are provided in the section of this letter addressed to Andean Community Concerns.

INDIA

Annual Capacity Building Plan (ACBP) for the office of the Controller General of Patents Designs and Trade Marks (CGPDTM)

In early 2023, a first-ever Annual Capacity Building Plan (ACBP) for the office of the Controller General of Patents Designs and Trade Marks (CGPDTM)¹⁰⁴ was published with a supporting Report. Notably, the Report and ACPB identifies and adopts multiple interventions for capacity building of CGPDTM, which includes numerous short-term, mid-term, and long-term interventions at individual and organizational level, such as training of Examiners & Controllers, creation of subject-matter expert pool, streamlining process for examination, etc. It also envisions capacity building for law enforcement and judicial officials. This generally appears to be a positive development and IPO plans to monitor related developments.

Parliamentary Committee's Report No. 169 on Actions Taken by Government as per the Recommendations in Report No. 161 on "Review of the Intellectual Property Rights Regime in India"

In July 2021, the Parliamentary Standing Committee on Commerce presented a Report (No. 161) entitled "*Review of the Intellectual Property Rights Regime in India*,"¹⁰⁵ before both houses of the Parliament. The Report made 82 recommendations towards strengthening the IPR regime of India. Observations and recommendation include (i) the need for an immediate review of the IPR Policy 2016 by the Department for Promotion of Industry and Internal Trade;¹⁰⁶ (ii) enacting separate legislation or framework for protection of trade secrets;¹⁰⁷ (iii) re-establishing, instead of abolishing, the Intellectual Property Appellate Board (IPAB) with greater autonomy and reforms;¹⁰⁸ (iv) establishment of dedicated IP benches at High Courts;¹⁰⁹ (v) exploring and enabling PPH programs with other countries;¹¹⁰ (vi) including a mechanism to safeguard against

¹⁰⁴ Annual Capacity Building Plan (ACBP) for the office of the CGPDTM, https://cbc.gov.in/sites/default/files/completed-acbps/94_ACBP_IP.pdf

¹⁰⁵ *Review of the Intellectual Property Rights Regime in India*, Department Related Parliamentary Standing Committee on Commerce [161st Report] https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/13/141/161_2021_7_15.pdf.

¹⁰⁶ *Id.*, at page 96.

¹⁰⁷ *Id.*, at page 111.

¹⁰⁸ *Id.*, at page 101.

¹⁰⁹ *Id.*, at page 114.

¹¹⁰ *Id.*, at page 102.

the arbitrary exercise of power by the Controller in declining patents;¹¹¹ and (vii) enacting specific legislation to curb counterfeiting and piracy.¹¹²

On April 6, 2022, the Parliamentary Standing Committee presented a Report (No. 169) before both houses of the Parliament on “*Action Taken by Government on the Recommendations/ Observations of the Committee contained in its 161st Report on 'Review of the Intellectual Property Rights Regime in India.'*”¹¹³ As per the Report, it is recorded that out of 82 recommendations: (a) 48 have been accepted by the government; (b) 21 will not be pursued in light of government response; (c) 12 responses received from government are not accepted by Committee; and (d) one response not received from government. IPO is encouraged by the positive response from the government on the recommendations of separate legislation or framework for protection of trade secrets¹¹⁴ and that a working group has been formed for a new PPH program with Denmark.¹¹⁵ IPO, however, notes that the government’s response is vague and generic in respect of most of the key issues, such as setting up of specialised IP Benches and IP Divisions in the High Courts,¹¹⁶ resolution of the patentability criteria and disqualification of incremental inventions under Section 3(d) as flagged by the USTR Report,¹¹⁷ arbitrary exercise of power by Controller in declining patents,¹¹⁸ etc. The Report made some further recommendations, including making amendments to legislations and regulations to enable protection of AI related inventions and for establishment of IP Divisions in all High Courts.¹¹⁹ These are also summarised the official Press Release.¹²⁰

National IPR Policy

Overall, India’s IPR Policy (Policy) unveiled in May 2016 still provides a valuable roadmap for realizing the potential of India’s creativity and recognizes the central role IP plays in this regard.¹²¹ 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, IPO is encouraged by the Policy’s recommendation to further study the protection of trade secrets.¹²² As discussed below, improving India’s trade secret regime is critical to ensuring a level playing field for non-Indian innovators.

¹¹¹ *Id.*, at page 104.

¹¹² *Id.*, at page 100.

¹¹³ *Action Taken by Government on the Recommendations/ Observations of the Committee contained in its 161st Report on 'Review of the Intellectual Property Rights Regime in India'*, Department Related Parliamentary Standing Committee on Commerce [169th Report],

https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/13/159/169_2022_4_16.pdf

¹¹⁴ *Id.*, at page 32.

¹¹⁵ *Id.*, at page 12.

¹¹⁶ *Id.*, at page 39.

¹¹⁷ *Id.*, at page 14.

¹¹⁸ *Id.*, at page 13.

¹¹⁹ *Id.*, at page 76-78.

¹²⁰ Press Release, Department Related Parliamentary Standing Committee on Commerce,

https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/Press_ReleaseFile/13/159/514P_2022_4_15.pdf

¹²¹ National Intellectual Property Rights Policy, Government of India (May 2016) (National IPR Policy),

https://dipp.gov.in/sites/default/files/National_IPR_Policy_English.pdf.

¹²² *Id.* 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. Further items whose implementation will be interesting to observe include: 3.9 for guidelines on technology transfer, know-how and licensing of SEPs; 4.15 for India's accession to Hague System; 4.16.1 on timelines for grant of registrations and disposal of opposition matters; 6.8 for strengthening protection mechanisms for protection of IP rights; and 6.10 for effective adjudication of IP disputes.

Some of the Policy objectives are implemented through different vehicles. Item 4.13 of the Policy has been implemented, wherein a Cell for IPR Promotion and Management (CIPAM) has been set up with the guidance of the Department for Promotion of Industry and Internal Trade (DPIIT). CIPAM facilitates programs and initiatives for IPR awareness, promotion, creation and commercialization of IP assets as per the Policy. CIPAM prepared and released "*Draft Model Guidelines on Implementation of IPR Policy for Academic Institutions*"¹²³ with the objective to frame a uniform IP Policy for licensing and commercialization of IP rights for academic institutions at the national level. The provisions were primarily based on the *Guidelines on Developing Intellectual Property Policy for Universities and R&D Organizations, WIPO*, and introduce, for the first time, an 'incentive model' for allocation of royalties to inventors. This is related to implementation of at least two objectives under the Policy – Generation of IPRs and Commercialization of IPRs. Also, item 4.14 has been implemented by enabling expedited examination of patent applications for at least selected applicants (such as start-ups and small entities.).

Taken as a whole, the Policy includes many positive actions for improving India's IP systems, and while there have been efforts towards implementation of several objectives to varying degrees, IPO has yet to see a sustained and organized implementation of several key objectives.

In its 2021 Report,¹²⁴ the Parliamentary Committee had recommended a review of the IPR policy upon completion of 5 years. Pursuant to the government's response towards actions undertaken, as recorded in the 2022 Report,¹²⁵ a further review of the Policy is not being pursued. Recently, in July 2023, Impacts of the Policy are recently identified and summarized in the "Compendium of Intellectual Property Rights" Report¹²⁶ issued by the government. On July 21, 2023, Union Minister of State for Commerce and Industry also released an update under IPR Policy Management (IPRPM) framework of National IPR Policy 2016, which provide updates on 11

¹²³ See

https://dpiit.gov.in/sites/default/files/Draft_Model_Guidelines_on_Implementation_of_IPR_Policy_for_Academic_Institutions_09092019.pdf.

¹²⁴ 161st Report, supra at 87, ¶ 1.12

¹²⁵ 169th Report, supra at 95, ¶ 2.2 – 2.6

¹²⁶ https://www.dsir.gov.in/sites/default/files/2023-09/Compendium_IPR_FI_2023.pdf

objectives including Patent Facilitation Program, and setting up of Technology Innovation Support Centers. The U.S. should continue to monitor the implementation of the Policy as it unfolds.

Delays in Patent Examination and Pre-grant Oppositions

Delays owing to Pre-grant oppositions: According to a study by Hidaytullah National Law University (HNLU) Raipur, a leading law school, in which it analysed over 320 cases over a 5 year period (2016-21), serial opposition, benami opposition (filed by vested interests on behalf of others) and delay in issuing notices of opposition by Controller contribute the most towards delay in grant of patents with the average time-frame of 120, 114 and 42 months respectively. In addition, there is no timeline within which such oppositions can be filed thus resulting in inordinate delay in grant of patents. The study also states that there is an average delay of 9 years in the grant of patents which significantly undermines the effort put in by innovators.

IPO suggests there should be a time limit for filing a pre-grant opposition which could be 6-12 months from the date of publication of the patent application. In fact, the Economic Advisory Council to the PM (EAC-PM), in its August 2022 Report, recommended a pre-grant window within six months from the date of issuance of First Examination Report (FER).

The Department for Promotion of Industry and Internal Trade (DPIIT) in August 2023 came out with a draft amendment of the Patent Rules, which is expected to partially address the existing IPR challenges specific to the delay on account of pre-grant opposition (among other things), thereby expediting the grant of patents. The Government subsequently asked for comments/inputs from industry and other stakeholders. The Government is still in the process of carrying out inter-ministry consultations. Additionally, and importantly, these changes on making time-bound disposal of pre-grant oppositions require an amendment to the Act to be institutionalized in policy.

Delays and poor quality of examination owing to insufficient workforce and proper training: Further, the Report identifies, that while the number of Examiners (responsible for issuing first office action) at the Indian Patent Office appears to be adequate, there is an acute shortage of Controllers (responsible for further examination, hearings, and disposal of patent applications). The Report mentions that there are only 247 Controllers in India. The Report relied upon recommendations of Parliamentary Committee's on "*Review of the Intellectual Property Rights Regime in India*" to suggest urgent increase in manpower, particularly Controllers.¹²⁷

The Annual Capacity Building Plan (ACBP) for CGPDTM¹²⁸, under its National Priority objectives, records the CGPDTM's primary vision of "achieving near-zero" pendency by the year 2025. The ACBP relied upon the EAC-PM Report to further emphasize "*the shortage of workforce and procedural issues are major contributing factors to increased pendencies and*

¹²⁷ *Id.*, at pages 9, 10, and 12.

¹²⁸ Supra Note 1, Annual Capacity Building Plan (ACBP) for the office of the CGPDTM, https://cbc.gov.in/sites/default/files/completed-acbps/94_ACBP_IP.pdf

delays”.¹²⁹ The Plan proposed rationalization of the roles of the existing workforce to address the delays in processing patent applications. The Plan also adopted short-term, mid-term and long-term visions, and the training of existing Examiners and Controllers is identified as short-term objective. In July 2023, the Patent Office issued notice of 553 Examiner posts, which is likely to increase the manpower in terms of Examiners. It is noted that the government is fast-tracking the hiring process and promotions of some existing officers (340 Examiners were promoted as Controllers in April 2023). The stated target is to have 963 Examiners and 998 Controllers by 2026.

Thus, it is suggested that the Indian Patent Office should continue to implement measures to improve the speed of the review process for patent applications while also improving the quality of patent examination through induction and training of Examiners and Controllers to bridge the gap.

In a positive development, India entered into its first ever PPH (Patent Prosecution Highway) Program with the Japan Patent Office in 2019. In its April 2022 Report, the Parliamentary Committee also noted that a working group has been formed for a new PPH program with Denmark. IPO hopes that India enters into PPH arrangements with other IP Offices.

Allowability of Divisional Patent Applications

The law and practice with respect to allowability of divisional applications in India has been restrictive. In a divisional application, Applicants are usually not permitted to claim the subject matter disclosed but not claimed in the parent application. A recent decision of the Division Bench of Delhi High Court, however, adopted an interpretation of the law which now enables the applicants to file divisional applications to claim the subject matter which was earlier disclosed but not claimed in the specification of the parent application. Division Bench also clarified that a Divisional Application can be filed by an applicant not only to remedy an objection raised by the Controller on the unity of invention but can also be filed *suo moto*. The Court observed that this position is consistent with the Article 4G of the Paris Convention. While this is a welcome development, IPO would suggest that necessary changes be made in law to avoid the scope of adoption of a different interpretation in future.

Higher Threshold of Patentability for Pharmaceutical Inventions

India's Patent Act provides a threshold for patentability for pharmaceutical composition inventions that appears to be higher than the one allowed under TRIPS. Section 3(d) requires enhanced efficacy for new forms of known substances in order for an invention to be eligible for patent protection. It appears that Section 3(d) is discriminatory against pharmaceutical inventions and the law makes it difficult to secure patent protection for certain types of pharmaceutical inventions and chemical compounds. In its Report,¹³⁰ the Parliamentary Committee, while supporting and upholding the validity and utility of Section 3(d) under the Indian Patents Act,

¹²⁹ Id., at page 53

¹³⁰ 161st Report, supra at 87, ¶ 12.8

observed concerns raised by USTR and recommended resolution of the issue through a bilateral dialogue with the U.S. The Indian Government has not provided a specific response to the recommendation, other than that a stakeholders meeting has been conducted.¹³¹

Further, India law does not afford the availability of post-patent filing data that could be used as evidence to support novelty and inventiveness of such new compound forms.

Compulsory Licensing

It is appreciated that the Government of India took a positive and firm stand (on an Affidavit) against the plea for grant of compulsory license before the Supreme Court of India reciting that it will be “presumptuous to assume that the patent holder will not agree to more voluntary licenses.”¹³² However, the Parliamentary Committee in its Report, had recommended that “the Government should delve into the prospect of temporarily waiving patents rights and issuing Compulsory Licensing to tackle the inadequacy in availability and accessibility of Covid-19 vaccines and drugs during an emergency like situation induced by the pandemic.”¹³³ Also, there have been multiple directions by High courts in the public interest litigations where they have suggested the government invoke the compulsory licensing provisions. In its Response (recorded in the 169th Parliamentary Report of April 2022), while the government supported the legitimacy and validity of the compulsory licensing provisions, it turned down the recommendation of any waiver, citing the voluntary licenses granted by the patent owners. While such provisions have not yet been invoked, developments should be monitored.

Further, 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.”¹³⁴ 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.¹³⁵ TADF is empowered to request compulsory licensing from the Government of India.¹³⁶

Similarly, India’s National Competition Policy requires IP owners to grant access to “essential facilities” on “agreed and nondiscriminatory terms” without reservation.¹³⁷ The concept of essential facilities appears to cover a broad range of technologies including at least “electricity,

¹³¹ 169th Report, supra at 95, ¶ 1.35

¹³² In Re: Distribution of Essential Supplies and Services During Pandemic, https://www.livelaw.in/pdf_upload/uo-affidavit-9052021-final-with-annexures-1-91-393168.pdf.

¹³³ Dept. Related Parliamentary Standing Committee on Commerce, 161st Report: Review of Intellectual Property Rights Regime in India, Sections 12-14, p. 58, https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/13/141/161_2021_7_15.pdf.

¹³⁴ National Manufacturing Policy, Government of India Ministry of Commerce & Industry Department of Industrial Policy & Promotion (2011), Section 4.4, p. 15, https://dpiit.gov.in/sites/default/files/National_Manufacturing_Policy_25October2011.pdf.

¹³⁵ *Id.* at ¶ 4.4.1.

¹³⁶ *Id.* at ¶¶ 4.2, 4.4.3.

¹³⁷ National Competition Policy, § 5.1(vi) (2011),

http://www.mcrhrdi.gov.in/87fc/policies/Revised_Draft_National_Competition_Policy.pdf

communications, gas pipelines, railway tracks, ports, [and] IT equipment.”¹³⁸ 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.

Within the life sciences arena, the grounds for issuing a compulsory license in India under the Patents Act, 1970 are broad, vague and appear to include criteria that are not clearly related to legitimate health emergencies. Internationally, in various multilateral fora, India has advocated for the broad adoption and implementation of legislation that facilitates the use of compulsory licenses, contrary to the spirit of the TRIPS Agreement. A market with ongoing threats of compulsory licenses perpetuates an unreliable environment for patent protection and investment.

Lack of Regulatory Data Protection and Patent Linkage

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

The lack of linkages between patent status and drug approval leads to a significant gap that creates room for patent infringements. According to current processes, the Federal and the State Drug Regulators provide approvals for the manufacturing and marketing of new drugs. However, at the time of such approvals, there is no requirement for the approving authority to ascertain the patent status of any such new drug. As such, on numerous occasions, approval to launch is granted for new drugs for which the Government of India may have already granted a valid patent (hence exclusivity for a defined period of time), thereby causing infringement of existing patents. There is also no mechanism for a patent holder to get information on any such filings for approvals by generic companies, a basis which innovators may take pre-emptive action. As such, these infringements are only noticed once the products are already in the marketplace. In the absence of patent linkage, a solution wherein an “information system” is put in place where any new drug approval application is publicly available would help innovators take pre-emptive action to protect duly granted 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.

Local Working Requirements

Patent holders risk compulsory licensing if they fail to “work” their inventions in India within three years of the respective patent grant.¹³⁹ This appears to include situations when patent holders import the related technology into the country, but do not locally manufacture it. India’s interpretation does not appear to be in compliance with TRIPS, which requires patents and their associated rights to be available “without discrimination as to the place of invention, the field of

¹³⁸ *Id.*

¹³⁹ *The Patents Act, 1970*, Section 84(1)(c).

technology and whether products are imported or locally produced.”¹⁴⁰ Among those rights is the ability to exclude others from making, using, or selling their invention.¹⁴¹

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.¹⁴² Towards this, a Statement of Working (Form 27) is required to be filed annually (each financial year).¹⁴³ Failure to provide the requested information is punishable by fine.¹⁴⁴ Although the Form-27 was amended to relax certain details required to be furnished, the Statement is still very much required to be filed on an annual basis and is still onerous to complete.¹⁴⁵ IPO believes that the Statement requirement should be ended.

The push to enforce the submission of Statements of Working is likely to increase the availability of compulsory licensing. The subsequent publication of the statements in a standalone database is further evidence of that intention. Form 27 is also extremely burdensome, including requests concerning the value of the products worked and the licenses or sub-licenses that are granted for a given patent. Not only might it be difficult to calculate and provide such information, but this also forces patent holders and their licensees to potentially provide confidential business information to the government and public. Currently, there is no mechanism to submit the information with a request for confidentiality and to avoid the information from becoming public after filing.

The emphasis on Form 27 suggests that India could impose compulsory licenses on users of its patent system even if the relevant product is available in India, if it is not manufactured there. India issued its first compulsory license for a pharmaceutical drug 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.¹⁴⁶ 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. While the revised Form-27 does seek separate data about the revenues generated from the import and manufacturing in India, a clarification must be provided that availability only through import does satisfy the requirement of working in India.

In a welcome move, the Parliamentary Committee in its July 2021 Report had recommended the “Department to consider relaxing the requirement to furnish information under the form on a yearly basis to ease the compliance burden on universities, R&D institutions, start-ups and small

¹⁴⁰ *TRIPS*, Art. 27.1 (*emphasis added*).

¹⁴¹ *TRIPS*, Art. 28(1).

¹⁴² *The Patents Act, 1970*, Section 146.

¹⁴³ *The Patents Rules*, § 131, Intellectual Property India (2003).

¹⁴⁴ *The Patents Act, 1970*, Section 122 (1).

¹⁴⁵ See *Patents (Amendment) Rules, 2020*,

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

¹⁴⁶ Intellectual Property Appellate Board, *Bayer Corporation v. Union of India through the Secretary & Ors.*, Order No. 45, ¶ 52 (Mar. 2013); see also *Bayer v. Union of India*, Writ Petition No. 1323 of 2013, at 48.

enterprises.” Relief from this requirement, however, should be given to all IP owners, from independent inventors to innovators with large research and development programs, without discrimination. In its Response (recorded in the April 2022 Report), however, it appears that the government has been able to satisfy this recommendation by showing the recent changes in Form-27.

Recently, in August 2023, Draft Patents (Amendment) Rules, 2023¹⁴⁷ were published for public comments. They propose that the Statement of Working of patents be filed for periods of three financial years starting from the financial year commencing immediately after the financial year in which the patent was granted. This reduced frequency in filing of the Statement will lessen the burdens on innovators and IPO hopes that this practice will be adopted and implemented soon.

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,”¹⁴⁸ 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. Stakeholders in 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. Recently, in response to the Parliamentary Committee recommendation (in its 161st Report of 2021) regarding “enacting a separate legislation or a framework for protection of trade secrets,”¹⁴⁹ the government confirmed that “Department is consulting stakeholders on the same for implementation.”¹⁵⁰ IPO is also encouraged by the commitment at the 2015 U.S. and India Trade Policy Forum to deepen cooperation on trade secrets.¹⁵¹ There is also a recommendation included in India’s National IPR Policy to study trade secret protection, with an aim for further

¹⁴⁷ Supra Note 31, Section 11

¹⁴⁸ Zafar Mahfooz Normani & Faizanur Rahman, *Intellection of Trade Secrets and Innovation Laws in India*, Journal of Intellectual Property Rights., Vol. 16 346 (July 2011).

¹⁴⁹ *Review of the Intellectual Property Rights Regime in India*, Department Related Parliamentary Standing Committee on Commerce [161st Report], https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/13/141/161_2021_7_15.pdf, at page 111.

¹⁵⁰ *Action Taken by Government on the Recommendations/ Observations of the Committee contained in its 161st Report on 'Review of the Intellectual Property Rights Regime in India'*, Department Related Parliamentary Standing Committee on Commerce [169th Report],

https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/13/159/169_2022_4_16.pdf, at page 32.

¹⁵¹ United States and India Joint Statement on the Trade Policy Forum (Oct. 2015), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/october/united-states-and-india-joint>.

policy development.¹⁵² Earlier recognition of the need to improve trade secret protection can be found in the 2008 draft National Innovation Act¹⁵³ and 2012 draft National IPR Strategy.¹⁵⁴ There is also a growing body of academic literature originating within India that agrees that improving trade secret protection is critical.¹⁵⁵ The 2012 draft National IPR Strategy made the point when it explained that a “predictable and recognizable trade secret regime will improve investor confidence,”¹⁵⁶ although this was not included in the approved version of the National IPR Strategy. IPO agrees 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 (under form 3) on foreign applications that are “the same or substantially the same invention.”¹⁵⁷ 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.¹⁵⁸ However, failure to provide the required information can be prejudicial to the patent applicant. Non-compliance provides an independent ground for pre- and post-grant opposition, as well as revocation.¹⁵⁹ Furthermore, in the absence of clarity regarding the meaning of “substantially the same invention,” in many cases, it is difficult to be certain about full compliance with this requirement.

Failure to comply with section 8 is now a commonly cited ground in the pre-grant and post-grant opposition and revocation proceedings. Patentees must worry about co-pending family members

¹⁵² National IPR Policy, at ¶3.8.4.

¹⁵³ The National Innovation Act of 2008 (Draft), Ch. VI.

¹⁵⁴ Invitation of Views on the Draft National IPR Strategy, ¶¶ 50-52,

https://dpiit.gov.in/sites/default/files/draftNational_IPR_Strategy_26Sep2012%20%2010.pdf.

¹⁵⁵ See e.g., Hariani, *The Draft National Innovation Act*, India L.J. (2007),

https://www.indialawjournal.org/archives/volume3/issue_1/article_by_anirudh.html; Kumar et al., *Legal Protection of Trade Secrets*, 11 J. Intell. Prop. Rpts. 379 (Nov. 2006),

<http://nopr.niscair.res.in/bitstream/123456789/3604/1/JIPR%2011%286%29%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>).

¹⁵⁶ Draft National IPR Strategy, ¶ 52 (2012).

¹⁵⁷ *The Patents Act*, (1970), Section 8(1),

https://www.indiacode.nic.in/bitstream/123456789/1392/1/AA1970_39.pdf.

¹⁵⁸ Patent Cooperation Treaty, Art. 42, <https://www.wipo.int/pct/en/texts/articles/a42.html>.

¹⁵⁹ *The Patents Act*, (1970), Sections 25(1)(h), 25(2)(h), and 64(1)(m) respectively.

as well as other similar patents.¹⁶⁰ The requirements set forth by section 8 are antiquated and create unnecessary uncertainty and expense for patent applicants, particularly when the Indian Patent Office, which is also an ISA, is equipped to search and find all the patent applications in the concerned patent family. This is rightly pointed out in the Report of Economic Advisory Council to the Prime Minister that since India is a member of WIPO CASE (Centralized Access to Search and Examination), this cumbersome compliance requirement should be done away with, at least for the PCT national phase applications.¹⁶¹

In a positive move, as per the Draft Patents (Amendment) Rules 2023¹⁶², this requirement for mandatory filing of the disclosure and updates (under Form-3) is proposed to be done away with, and the Examiners are directed to refer to the public databases for the relevant information. As per the proposed Rules, the Examiner may ask for the information from the Applicant only in an objection with reasons to be recorded in writing. IPO is looking forward to an early implementation of these provisions.

Foreign Filing Permissions and the Ministry of Defense

India's Patent Act requires that an invention having a resident Indian inventor should not make or cause to make any patent application outside India unless a Foreign Filing Permission (FFP) is obtained from the Indian Patent Office.¹⁶³ Non-compliance with this requirement results in monetary fine or a jail term or both.¹⁶⁴ While the routine FFPs are granted very expeditiously by the Indian Patent Office, which is appreciated, in case the Indian Patent Office concludes that the subject matter of an invention is relevant for defense purposes or atomic energy, the matter is referred to Ministry of Defense (MoD) for its prior consent. In some cases, it has been learned that the MoD may take up to two years to grant consent. This delay is extremely detrimental to obtaining FFP. Applicants might lose their application priority date and have no ability to contest the Patent Office's decision.

Genetic Resources and Traditional Knowledge

Section 10(4)(ii)(D) of India's Patents Act requires applicants to disclose the source and geographical origin of biological materials that are not publicly available and are not used to make an invention that is the subject of a patent application. Failure to correctly identify the geographical source of a biological material is a ground for pre-grant and post-grant oppositions as well as revocation proceedings. Further, even when the origin of the source of biological material is not India, the Applicants are required to identify the specific location / city of origin, which is onerous and unwarranted. In practice, the Indian Patent Office frequently raises

¹⁶⁰ See *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.* FAO (OS) 188/2008, (Apr. 2009).

¹⁶¹ *Why India Needs to Urgently Invest in its Patent Ecosystem?*, Economic Advisory Council to the PM of India, <https://www.ies.gov.in/pdfs/why-India-needs-to-urgently-invest-in-its-IPR-ecosystem-16th-Aug-2022.pdf>, at page 15.

¹⁶² Draft Patents (Amendment) Rules, 2023, Section 7.

<https://ipindia.gov.in/writereaddata/Portal/Images/pdf/248296.pdf>, Rule 2

¹⁶³ *The Patents Act*, (1970), Section 39.

¹⁶⁴ *Id.* at § 118.

objections under Section 10(4), regardless of whether the referenced biological material is publicly available or not. India has created a National Biodiversity Authority (NBA), to regulate use of the genetic resources of India. A non-Indian person or company requires the approval of the NBA to access the genetic resources, or to include the genetic resources in a patent application in India. The NBA also has the right to require benefits sharing or royalties to the Indian government, based on the use of the Indian origin genetic resources employed in the patent application. These special disclosure requirements and the scope of what constitutes a genetic resource are at best ambiguous, subjecting the validity of valuable patent rights to damaging uncertainty. Thus, IPO believes that these requirements should be deleted.

IP Divisions and New Rules

In April 2023, the Madras High Court adopted “*Madras High Court Intellectual Property Rights Division Rules, 2022*” for its IP Division. There is urgent need to have corresponding Rules in other High Courts and district courts in India which are handling IP disputes.

In a progressive move, on February 24, 2022, after few rounds of comments and inputs from stakeholders, the Delhi High Court published “*The High Court of Delhi Rules Governing Patent Suits, 2022*” (Patent Suit Rules)¹⁶⁵ and “*The Delhi High Court Intellectual Property Rights Division Rules, 2022*” (IPD Rules).¹⁶⁶ These Rules streamline the procedure for conducting the proceedings for Patents (infringement and cancellation) as well as other IP matters in a time-bound manner before the newly constituted IP Division of Delhi High Court. Procedures for summary adjudication, litigation hold notice, hot-tubbing,¹⁶⁷ constitution of confidentiality clubs, early neutral evaluation, etc. have been introduced. Matters from the IPAB (now abolished) are now being listed before the IP Divisions, and IPO will be following how the large backlogs will be tackled.

Trademark Oppositions and Enforcement

While the timeframes for prosecution and grant of trademarks have reduced, disposal of contentious proceedings, such as opposition and cancellation proceedings, as well as litigation matters addressing the merits, is still very lengthy.

Stakeholder Consultation to discuss key issues related to Designs and GIs in India

On August 28, 2023, the Controller General conducted a stakeholders meeting to invite views regarding the desirability of India acceding to: (i) Strasbourg Agreement Concerning the International Patent Classification; (ii) Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs, and (iii) Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications.

¹⁶⁵ *The High Court of Delhi Rules Governing Patent Suits, 2022*, [Patent Suit Rules, 2022]
<https://egazette.nic.in/WriteReadData/2022/233727.pdf>

¹⁶⁶ *The Delhi High Court Intellectual Property Rights Division Rules, 2022* [DHC-IPD Rules, 2022]
<https://egazette.nic.in/WriteReadData/2022/233739.pdf>

¹⁶⁷ Two or more fact or expert witnesses being questioned together. Practice originated in arbitration proceedings.

Towards streamlining the practice and procedure, the Controller General also invited public comments for amending the Designs Manual in September 2023.

Earlier, in June 2022, the Government of India conducted a stakeholder consultation meeting to discuss some of the key issues related to registration of industrial designs in India, including: (i) extension of term of protection for designs from 15 to 25 years; (ii) protection of unregistered designs in India; (iii) adequacy of grace period under the designs law; (iv) India's accession to Hague Convention for international registration of designs; (v) removal of restrictions for protection of designs under copyright law; (vi) protection of activities of exporting, stocking, and using under the designs law; and (vii) protection of graphic symbols, logos, and graphical user interfaces (GUIs) under designs law; and (viii) restrictive requirement of filing design embodiments in the applications. It will be interesting to monitor how the design law in India is amended to address these issues, and particularly the progress on India's accession to the Hague System for protection of Designs.

India Lacks a Meaningful Grace Period for Design Applications

India is one of the few countries not to have a meaningful grace period during which a design owner can file a design application after disclosing the design publicly anywhere in the world. Unsophisticated designers may not appreciate the need to file a design application before disclosing their design, at which point protection will be unavailable in India. Further, grace periods — like those adopted in the U.S., Europe, Japan, South Korea, Canada, and Australia — provide applicants the time and flexibility to consider the need for protection and to prepare quality applications. India should be encouraged to adopt a generally applicable grace period of at least 6 months, and preferably 1 year.

INDONESIA

Genetic Resources and Traditional Knowledge

Indonesia's 2016 Patent Law imposes patent disclosure requirements regarding the source and origin of genetic resources or traditional knowledge related to inventions. Such requirements introduce uncertainties into the patent system that inhibit innovation in relevant technologies and undermine the potential of benefit-sharing.

Compulsory Licensing

In 2021, Indonesia issued CLs for antiviral COVID-19 therapeutics. Moreover, Indonesia issued a CL for one of these antiviral therapeutics despite the rights holder entering into a voluntary licensing agreement with generic manufacturers to supply the Indonesian market. Also, in 2020, Indonesia issued Presidential Regulation No. 77/2020 on government use of CLs. The regulation broadly enables government agencies to request CLs for pharmaceutical products to address emergency needs in the public interest. If a CL is granted and the government is unable to implement the patent, it may appoint a third party to do so. Despite efforts in 2019 to address and

revise existing CL regulations to align more appropriately with global norms and best practices, this new regulation and the process by which it was developed and issued, along with the CLs for the antiviral COVID-19 therapeutics, send a troubling signal to innovators. Additionally, in August 2023, the Government enacted the Health Omnibus Law (Law No. 17). Articles 314 and 326 of the Law reiterate the Government's responsibility, and right, to override patent protection through the use of compulsory licenses to "ensure the sustainability of the supply chain." The new Health Omnibus Law also strengthens the long-standing drive to localize biopharmaceutical production.

Forced Localization Requirements

The newly issued 2023 Omnibus Health Law emphasizes prioritization for use of locally-made products. In addition, while the revisions to Article 20 of the 2016 Patent Law in the 2020 Omnibus Job Creation Law are a positive step forward, other forced localization requirements still remain in Decree 1010. IPO looks forward to additional measures to address outstanding concerns regarding Decree 1010 and other ministerial regulations to ensure that Indonesian patients have access to new medicines.

MEXICO

Divisional Applications under the New IP Law

Provisions for divisional applications changed in the new Federal Law for the Protection of Industrial Property (FLPIP), which entered in force on November 5, 2020. Now voluntary divisional applications can only derive from a parent case and cannot derive from another divisional application. Thus, voluntary divisional applications deriving from divisional applications are not allowed, unless that the Mexican PTO (IMPI) determines that said divisional is allowable. In the case that the Examiner issues a unity of invention objection in a divisional application, the applicant can still file a divisional from said previous divisional in which unity of invention was objected.

These changes ought not be a problem for divisional applications filed after November 5, 2020, that derive from a divisional that was filed before November 5, 2020, since it is clear in Mexican law and Constitution that laws (statutes), and provisions within them, cannot be applied retroactively. The Mexican Patent Office (IMPI), however, started denying all voluntary cascade divisional applications regardless of whether the parent case was filed before or after November 5, 2020. IMPI did so despite the fact that the FLPIP contains transitional articles that specifically state that patent applications filed under the former law should be prosecuted still under the former law (in which cascade divisional applications had no restrictions whatsoever).

After several months, this criterion was modified and in the first months of 2022 IMPI started accepting voluntary cascade divisionals which derived from a parent case filed before November 5, 2020. However, IMPI has abruptly changed their criteria and, since May of this year, it is not accepting any voluntary cascade divisionals if the first parent case has been allowed and has issued as a patent or if it was abandoned. In the last weeks of August and first weeks of September, IMPI began to issue substantive office actions rejecting cascade divisionals that were

previously accepted, and which had complied with all formal requirements. It is overturning its decision to accept voluntary cascade divisionals deriving from a parent case filed before the new law entered in force on November 5, 2020, even though these cascade divisionals were filed long before the change of criteria that occurred in May of this year.

IPO has been informed that there are recent cases in which IMPI has issued one or two office actions objecting to substantive issues such as lack of inventive step, lack of clarity, etc., and in the last office action it has then rejected the application for being a divisional that was filed after the first parent case had been allowed.

IMPI is basing this criterion on a Federal Court jurisprudence that provides that it is not possible to file divisional applications once the prosecution of the parent case has finalized. However, this court decision does not mention the specific case of cascade divisionals and thus, IPO believes that this jurisprudence is being misapplied to all voluntary cascade divisional applications, regardless of the applicable law.

The current situation is very concerning not only because of the lack of legal support, but because IMPI is applying this new criterion to cases that had been already accepted and thus, are applying contradictory criterions in a single application. This new criterion also potentially opens the door for a landslide of patent invalidity actions against the huge number of cascade divisional applications that were filed and granted since the year in which former law entered into force in 1991.

Currently, the Mexican Supreme Court of Justice (MSCJ) has to rule on a case regarding legal standing to file invalidity actions against patents. The MSCJ needs to decide whether general standing, such as being a company doing business with the same or related technology as to the one protected by the patent, is enough, or if an infringement action is needed, to have legal standing. The outcome of this decision will impact the possibility of attacking cascade divisional patents.

Supplementary Certificate of Life Term Correction Due to Delays in Prosecution.

On a positive note, the IP Law (LFPI) that entered in force in Mexico on November 5, 2020, includes a mechanism to adjust patent terms (for patents filed on or after that date) to recover up to five years of term lost due to unreasonable delays by IMPI in prosecuting and granting patents by way of a “supplementary certificate.” The supplementary certificate is only available if the time between filing and grant exceeds five years. This change was included in the IP law which entered into force on November 5, 2020. Thus, it applies only to patents filed in Mexico beginning on this date and no patent has yet been subject to it. IPO expects the first petitions to be filed around the end of the year 2026.

The mechanism, however, does not provide an automatic patent term adjustment, but rather requires that the applicant file a request, fees, and a supporting brief, which is unduly burdensome given that IMPI has in its possession all information necessary to compute the unreasonable delay. More specifically, it is currently expected that the burden for the applicant will primarily be because the adjustment will have to be requested through a brief submitted

independently when replying to the notice of allowance. Since calculating the patent term adjustment is a purely mathematical exercise based on information available within IMPI, IMPI should be able to calculate the patent term adjustment without expense to the applicant in preparing and submitting a brief.

Enforcement of Pharmaceutical or Biologics Patents

The temporality of 8 years for biologics patents and 3 years for chemical patents in the Roche-Bolar exception were removed in the new law. However, the health law regulations have not yet been amended accordingly. The regulations should be amended to be consistent with the law.

Post Grant Amendments

The new IP law establishes that no post grant amendments can be made to granted patents that are subject to review, if the validity of the patents is previously questioned. This limitation was not present in previous law.

RUSSIA

The 2023 Special 301 Report placed Russia on the Priority Watch List. It also noted that “the ability of the Office of the U.S. Trade Representative to raise and resolve intellectual property (IP) protection and enforcement issues in Russia is severely limited.”¹⁶⁸ IPO offers the following comments regarding Russia, expecting that this limitation on the ability to raise and resolve IP issues likely remains, and understanding that U.S.-Russia trade has significantly decreased,¹⁶⁹ but also recognizing that USTR may again want to identify Russia in its Report.

Russian Law Fails to Provide Adequate Trade Secret Protection

Russia offers nominal and weak protection for trade secrets, leaving little protection for American 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.¹⁷⁰ 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 providing a specific inventory of the information to be protected and an up-to-date record of those with access to the information. The trade secret must be marked as both confidential and with the full name and address of the owner. Such prerequisites for protection often fail to correspond with the commercial realities of most businesses. 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

¹⁶⁸ 2023 Special 301 Report, at page 62, U.S. Trade Representative, April 26, 2023.

¹⁶⁹ See Ken Roberts, “Russia’s Rank As U.S. Trade Partner At 30-Year Low, New Data Shows,” *Forbes*, <https://www.forbes.com/sites/kenroberts/2022/10/11/russias-rank-as-us-trade-partner-at-30-year-low-new-data-shows/?sh=47bc65086614> (October 2022).

¹⁷⁰ Federal Law on Commercial Secrecy No. 98-FZ, 32 SZ RF item 3283 2004 (July 2004) (as amended).

practice, these formalities could cause businesses to grind to a halt instead of offering any meaningful protection.

Enforcement tends to be inadequate as well. Although preliminary remedies such as injunctions and seizures are available for some types of intellectual property, such as injunctions and seizures in domain and parallel import disputes, Russian courts rarely issue injunctions in patent cases and never in trade secret misappropriation cases. Criminal penalties are lacking, often limited to community service — despite significant losses for the trade secret owner. Considering these shortcomings, the APEC Best Practices for Trade Secret Protection and Enforcement, which Russia endorsed as part of a 2016 APEC declaration, should be implemented.¹⁷¹

Challenges to Patent Protection

On December 31, 2020, the Russian Government adopted Decree No. 3718-p, which in accordance with the current provisions of Article 1360 of the Russian Civil Code, granted a compulsory license to a local generic company, Pharmasyn tez, to produce a patent protected product,¹⁷² – antiviral medicine Remdesivir. The patent holder challenged the Decree in the Supreme Court arguing that it breaches the IP rights and contradicts applicable national legislation and international conventions. In May 2021, the Supreme Court ruled against the patent holder, confirming the validity of the Decree. In parallel there is an ongoing trend of local generic companies applying for compulsory licenses on innovative drugs pursuant to the Article 1362 of the Russian Civil Code.

In April 2021, the Russian Government adopted new legislation amending Article 1360 of the Russian Civil Code and introducing new rules on patent usage in the interest of national security. New rules expand the government’s discretion to issue a permit to use the invention, utility model, or industrial design “to ensure national security or protect human lives or health, in case of emergency” without the consent of the patent holder, but with a notice and compensation approved by the Government. Current wording mentioning healthcare as one of the grounds for issuing the permit opens the door to applying these rules to patents on innovative medicines and healthcare products.

In March 2022, in response to the sanctions taken against Russia following the invasion of Ukraine, Russia introduced measures to substantially lessen IP protections for foreign companies from “unfriendly countries.” “Unfriendly countries” included any country that supports sanctions. One decree set a 0% compensation for the “government compulsory licensing” of inventions if the patent holder has the citizenship of or place of registration/primary business/primary profit in an “unfriendly state.” Another measure allows parallel import, i.e. importation without the consent of the IP rights holders, of certain goods according to a list adopted by the

¹⁷¹ AMM Joint Statement, APEC Peru (2016), https://www.apec.org/meeting-papers/annual-ministerial-meetings/2016/2016_amm; *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>.

¹⁷² See <https://www.cms-lawnow.com/ealerts/2021/01/russian-government-issues-first-compulsory-pharmaceutical-licence>.

Ministry of Industry & Trade (MoIT). In combination with the possibility of importing medicines in foreign packaging (with a self-adhesive label in Russian), the basic conditions have thus been created for allowing parallel importing of individual (or all) medicines. In addition, trademark rights are not exempt from the danger of being used without permission or compensation, and it has been reported that Russian applicants have filed Russian trademark applications copying well-known U.S. marks.

III. MULTI-COUNTRY COMMUNITY CONCERNS

ANDEAN COMMUNITY

Genetic Resources

Access to genetic resources is regulated in the Andean Community (Bolivia, Colombia, Ecuador and Peru) by Decision 391, which among others, defines what is considered such access. In practice, if the resource is considered endogenous or native to any of these countries, and it has been accessed or is going to be accessed, a contract should be requested before the corresponding Agency in each country (regardless of the status of the research and possible patent applications). As for its relation with patent protection, Decision 486 establishes that a copy of the contract should be provided upon filing, but it could be later requested either in formal or substantive examination. Each patent office in the Andean Region handles this issue differently, and in the recently issued Andean Patent Manual (APM), a chapter was included explaining the general procedure and provides examples of cases in Colombia and Peru wherein a contract was required during prosecution and the rationale for that requirement. Many applicants, so far mostly local, have been impacted with applications being declared abandoned for not being able to formally comply with the requirements. As a result, innovation can be inhibited, and innovators will be reluctant to invest in related research.

IPO also believes that, in addition to unnecessarily linking the risk of patent invalidity to the genetic resource disclosure, the “or developed from” language implicates the use of genetic digital sequence information (DSI) which is currently maintained in publicly accessible databases. The concerns are that such legislation is very likely to deter investment in research on these genetic resources because the validity of any patents based thereon could be determined by the accuracy of voluntarily uploaded research information. Moreover, limiting free access to such DNA sequence databases would impede commonly performed large scale sequence comparisons, and likely result in more privatization of DSI databases.

EUROPEAN UNION

Compulsory Licensing

The European Commission has put forward a proposed Regulation for an EU-wide compulsory licensing framework in case of a crisis or emergency; this proposal implicitly also covers trade secrets and includes a maximum royalty of 4%. There is no clear evidence to support the need for an EU-wide compulsory license. Continuing efforts to weaken IP protections, without clear

and compelling evidence, will set a dangerous precedent for the innovative community. The resulting unpredictability can be expected to adversely impact the innovation system globally, at a time when we need to encourage innovation to address our global challenges.¹⁷³

In addition to the overall broad concern regarding the proposal for EU wide compulsory licensing, there are many concerns with specific aspects of the proposal. There is no clear definition of a crisis or how it is triggered. Leaving such a vital aspect of the Regulation vague and unclear would prevent a rights-holder (or potential rights-holder) from understanding the scope of their rights. There is ambiguity as to when a rights-holder will be notified of a compulsory license (CL) or the potential thereof.

The proposed Regulation covers not just granted patents, but patent applications as well, bringing into question its compliance with the TRIPS Agreement. This will also create complexity around appropriate notification of rights holders and adequate compensation; for example, how can it be predetermined if a license will be required or what the appropriate level of compensation would be before the final claim scope has been determined?

The role and constitution of the Advisory Board is unclear. Although Article 6 indicates that the “opinion of the advisory board shall not be binding on the Commission,” more clarity is needed in relation to the specific role, responsibilities, and constitution of this Board. In terms of its constitution, members from the innovative industry should be represented and advisers should have appropriate expertise.

The proposal overall is opaque on process and lacks independent judicial oversight. The processes described throughout the proposal do not seem to be subject to any independent scrutiny, and although Recital 31 addresses the judicial review of the Commission's decision to grant a Union CL, the Articles of the draft regulation do not address it.

The “adequate” remuneration is capped at a level that may be materially insufficient for all situations.

The Commission is provided with the power to impose severe and disproportionate financial penalties for the breach of vague obligations such as the principle of “good faith and cooperation” or failing to comply with “any obligation” that results from “additional measures complementing” the Union CL. Such additional measures potentially include the transfer of trade secrets and/or know-how to help effectuate the success of the CL. A requirement that would demand the disclosure of highly valuable, sensitive and confidential business information – without appropriate compensation, and with the threat of significant penalties – sets a dangerous precedent towards quelling innovation and would run contrary to the TRIPS Agreement. By penalizing rights-holders, it would place the rights-holders in an arguably worse position than had they not sought patents in the first place. In addition, under the TRIPS Agreement, a CL restricts a government granted right (i.e., the patent), but it does not compel the

¹⁷³ See also IPO Comments dated July 31, 2003, to the European Commission on EU Compulsory Licensing Proposal. https://ipo.org/wp-content/uploads/2023/08/IPO-Comments_EUCompulsoryLicensing.pdf

rights-holder to affirmatively act. A CL does not come with a duty to transfer trade secrets or technical know-how to others. In other words, there is no duty to provide technical information to others, other than that which must be disclosed in the patent itself. A system that includes the risk of imposing such far reaching, indefinite duties has the potential for discouraging investment in those markets, as innovators have reasonable concerns about being forced to transfer their technologies and confidential information.

Geographical Indications

On November 16, 2023, the EU regulation on geographical indication protection for craft and industrial products entered into force with the goal of protecting the traditional know-how and expertise of European artisans and producers. The regulation will allow products linked to a specific geographical area of production to enjoy similar protection to regionally produced foods or beverages. This protection will extend beyond the European Union to 59 countries under the 2015 Geneva Act of the Lisbon Agreement. While the IPO supports the use of trademarks, broad protections for geographic indications have the potential to limit trade and place non-EU members at a disadvantage on the European market.

Pharmaceutical Legislation

In April 2023, the European Commission (EC) tabled a number of proposals to revise long-standing EU rules on medicinal products for human use. As part of these proposals, IPO is concerned to see a reduction of the baseline duration of IP incentives which enable investment in innovation, such as regulatory data protection (RDP) for all innovative products, as well as of orphan market exclusivity (OME) for orphan drugs. Coupled with more stringent requirements and conditionalities in several areas, a weaker IP framework for pharmaceutical R&D in the EU will be detrimental for the sector and ultimately for the development of future treatments for patients.

European Commission's Packaging and Packaging Waste Regulation (PPWR) proposal

The European Union, through the European Commission's Packaging and Packaging Waste Regulation (PPWR) proposal is pursuing the admirable goal of identifying opportunities to reduce the use of excess plastic in packaging materials. This regulation seeks to require manufacturers to reduce the weight and volume of their packaging to that minimum necessary for the packaging to perform the function of delivering its content to the end user.

This reduction, however, should not be so prescriptive as to undermine distinctive, unique, and consumer-identifiable packaging designs that allow manufacturers to distinguish themselves from each other, and provide visual cues to consumers as to their source identifiers. In other words, a packaging design can serve as a trademark or the overall trade dress of a package design can serve as a source identifier to allow manufactures to distinguish themselves from one another on the shelf, help prevent counterfeiting, encourage innovation, and ensure that consumers can clearly identify the products which they desire to purchase. Therefore, while reducing plastic and other elements of packaging, it is critical to allow manufacturers to

distinguish themselves and their product offerings, and not to allow this legislation to undermine important source identifiers that consumers leverage to make purchasing decisions.

Ensuring this legislation protects existing and future intellectual property rights is critical. For example, an initial draft limited a manufacturer's rights to "design rights" – a technical term relating to a European Union Design Registration which (a) is only for a limited period of time; and (b) must be sought prior to or shortly after the launch of a product. The first problem with this is the time limitation – a truly iconic bottle design, for example, should not have a time limitation, so long as it is in use. Trademarks, unlike European Design Rights, do not expire so long as the trademarks remain in use. Thus, tying this legislation to European Design Rights is the wrong "IP" to be referencing. Secondly, sometimes a product is launched in a region outside of Europe, and then gains iconic fame, before it is introduced into the European Union but, by that point, European Design Rights are unable to be sought. Therefore, tying the PPWR proposal to "design rights" is potentially problematic.

IPO would recommend that any exceptions to the PPWR proposal focus more broadly on "intellectual property" rights that a manufacturer may have in packaging design. Protecting "intellectual property" rights will help enhance innovation, provide manufactures with the ability to distinguish their goods on the shelf, help prevent counterfeiting, and will ultimately serve as a consumer protection mechanism to ensure consumers get the products that they desire.

IV. PUSH TO WEAKEN IP RIGHTS WITHIN MULTILATERAL FORA

IP protection continues to come under fire in multilateral fora. Such efforts are largely based on misinformation about the impact of IP rights on innovation and technology diffusion. The principal argument is that IP systems are a barrier that needs to be dismantled if countries with developing economies 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.¹⁷⁴

Multilateral organizations, notably WIPO, but also the World Trade Organization ("WTO") and World Health Organization ("WHO"), play an important role in ensuring the existence of robust evidence about the contribution of IP systems to innovation and technology diffusion. They also have the responsibility to push back on erroneous and misleading statements about how IP works in practice. However, this has become extremely difficult due to intense political engagement by several countries in these "member-driven" organizations. Many countries aggressively orient work programs and discussions towards IP weakening. They seek technical assistance, analysis, and recommendations in favor of compulsory licensing, unduly restrictive patentability criteria, and lack of enforcement. Such efforts align with their industrial strategies, aimed at obtaining proprietary technologies at reduced cost.

¹⁷⁴ K. Lybecker & S. Lohse, *Innovation and Diffusion of Green Technologies: The Role of Intellectual Property and Other Enabling Factors*, WIPO Global Challenges Report (2015).

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, a lessening of the incentives necessary to support innovative efforts, 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 innovations, a robust U.S. interagency process is necessary to effectively monitor U.S. interests in this regard. And, more importantly, sustained U.S. leadership is critical to encourage these bodies to recognize that IP turns ideas into innovative products, exports, and jobs.

IPO strongly supports equitable, widespread, and successful distribution of vaccines and other measures necessary to meet the challenges of COVID-19. As a world, we asked our innovative industries to find solutions to help us battle COVID-19. They did so and continue to do so, in many cases building on innovations that have been developed over the years for other purposes based on extensive research and development.

IPO was disappointed in the June 2022 WTO Ministerial Decision on the Agreement on Trade-Related Aspects of Intellectual Property Rights that applied to COVID-19 vaccines, and we urge against extending this Decision to cover COVID therapeutics and diagnostics. IPO expresses additional disappointment as the debate regarding the weakening of intellectual property rights has permeated the negotiations on a pandemic treaty led by the WHO. As evidence has demonstrated, a stable and predictable IP framework is crucial to investors, inventors, and others who take the necessary risks to bring needed technology innovations to the marketplace.

In summary, IPO believes that discussions regarding the IP system in multi-lateral bodies, such as the WTO, the WHO, and WIPO, should always be evidence-based. IPO believes that, when this is the case, the evidence will show that IP facilitates innovation, as well as voluntary and successful partnerships, that help, not hinder, society's efforts to meet global challenges.

IPO thanks 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 2024 Special 301 Report.

Sincerely,



Krish Gupta
President