January 27, 2025

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

Submitted via: https://www.regulations.gov

Re: USTR 2025 Special 301 Review, Request for Public Comment (Docket No. USTR-2024-0023)

Dear Mr. Lee:

Intellectual Property Owners Association ("IPO") appreciates the opportunity to provide comments regarding the U.S. Trade Representative's ("USTR") 2025 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 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.

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 successful innovation ecosystems that can best serve society.

I. HIGHLIGHTED BROAD-BASED CONCERNS

IPO will first highlight a few high-level concerns with protection of IP 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 and Regulatory Data Protection

For years, Article 39 of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement" or "TRIPS") has required World Trade Organization ("WTO") members to ensure the effective protection of trade secrets.[2] In the years since TRIPS Article 39 was agreed upon on December 15, 1993, many WTO member countries have made insufficient efforts 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 future action, which 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 often includes trade secrets. Regulatory data protection ("RDP"), which is required by TRIPS, 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.[4] RDP recognizes the extensive time, effort, and cost of clinical studies required to ensure that drugs developed are safe and effective for patients and provides critical incentives to engage in continued research and development of new

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[1] IPO also highlighted several of these concerns in its comments to the USTR regarding the 2021 National Trade Estimate Report on Foreign Trade Barriers. Intell. Prop. Owners Ass'n, Comment Letter on 2021 National Trade Estimate Report on Foreign Trade Barriers (Oct. 29, 2020), https://ipo.org/wp-content/uploads/2020/11/IPO-Comments-for-NTE-Report-on-Foreign-Trade-Barriers.pdf.

[2] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 39, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 300.

[3] The Uruguay Round negotiations created the WTO and negotiated the TRIPS Agreement, all of which became effective January 1, 1995. *Overview: the TRIPS Agreement*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Nov. 11, 2024). Even in the case of the European Union, 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. Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the Protection of Undisclosed Know-How and Business Information (Trade Secrets) Against Their Unlawful Acquisition, Use and Disclosure, art. 19, 2016 O.J. (L 157) 1.

[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 a 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." Agreement on Trade-Related Aspects of Intellectual Property Rights art. 39.3, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 300.

innovative therapies. Unfortunately, several U.S. trading partners do not provide RDP or have inadequate RDP regimes. Examples include Argentina, Brazil, China, Egypt, India, Mexico, 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. In addition, the economic damage caused by counterfeiting affects businesses, reduces tax revenues, and provides significant funding for other types of illicit activities. Counterfeiting has well known links to organized crime, terrorism, and money laundering. IPO members have reported counterfeiting issues in many, if not most, of the countries in which they operate, including China, India, Peru, Brazil, Mexico, Colombia, Russia, South Africa, Thailand, Indonesia, Philippines, Turkey, the United Arab Emirates, and Vietnam. Countries in which effective anticounterfeiting mechanisms are lacking in one or more areas (e.g., border control, enforcement mechanisms, government support, etc.) include Brazil, China, Colombia, Ecuador, India, Indonesia, Kuwait, Malaysia, Mexico, Paraguay, Philippines, Russia, Saudi Arabia, Thailand, Turkey, United Arab Emirates, and Vietnam.

Ecommerce and social media platforms have made it easier for counterfeiters to sell counterfeit products by providing opportunities to engage with consumers throughout the world anonymously and 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 is the case after the product fails. The number of ecommerce platforms increases every year, making it easier for counterfeiters to move from one platform to another to avoid detection. Online marketplaces that allow listings and sales from third-party sellers are particularly problematic. IPO has separately identified specific platforms of concern in its October 3, 2024, comments to the USTR regarding markets to be considered for inclusion in the 2024 Notorious Markets List.[5] Additional complexities arise when purpose-built websites are used to sell counterfeit products. Unlike ecommerce and social media platforms that may obscure the true seller of goods but have publicly known ownership and legal structures, these websites are created to mask all parties involved and can make it especially difficult for brand owners to enforce their rights.

Many brand owners use vendors to help enforce their brands on ecommerce, social media platforms, and other websites. Others cannot afford to do this and must rely on internal resources and the cooperation of platforms with 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 and provide accurate information on their sources. Unless ecommerce platforms are held

[5] Intell. Prop. Owners Ass'n, Comment Letter on 2024 Review of Notorious Markets for Counterfeiting and Comment Request (Oct. 3, 2024), https://ipo.org/wp-content/uploads/2024/10/2024-IPO-Notorious-Markets-Comments.pdf.

liable for selling counterfeit goods, there is no incentive for such platforms to adopt measures protecting consumers and reducing damage to brands.

While brand owners and marketplaces have a significant role in identifying and preventing the sale of counterfeit products, the responsibility should not lie solely with them. IPO members have identified an urgent need for more robust government action to combat this issue and protect consumers from the dangers and economic impacts of counterfeit goods. Current legislative efforts to address counterfeiting are insufficient in many countries, leaving consumers, governments, and the public-at-large vulnerable.

IPO urges governments to strengthen their legislative frameworks and enforcement mechanisms to effectively combat counterfeiting. This includes increasing penalties for counterfeiters, enhancing cross-border collaboration, requiring marketplaces to cooperate with enforcement efforts, and providing adequate resources for law enforcement agencies to effectively address this issue. By taking decisive action, governments can play a crucial role in protecting consumers, supporting legitimate businesses, preserving government revenue sources, and maintaining market integrity.

As a significant step in driving marketplace accountability, IPO recognizes the European Commission's ("EC") October 2024 initiation of formal proceedings to determine whether the online marketplace Temu acted in violation of the European Union's ("EU") Digital Services Act.[6] Similar legislative and regulatory enforcement efforts in other countries and regions can, and should, play a large role in combatting counterfeits.

Over the past few years, brand owners have seen an increase in the use of social media to sell counterfeit goods. For example, social media platforms are often used to promote counterfeit goods and initially engage with customers. Counterfeiters will then switch to another messaging platform, such as WeChat or Telegram Messenger, to continue the conversation and finalize the sale. It is important that governments put measures in place 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 products from entering a country. However, effective border enforcement is not available in many countries, making it easier for counterfeiters to ship counterfeit products throughout the world and focus their activities on countries with weak border and IP enforcement. Even countries with traditionally strong border enforcement struggle with new ways of commerce, in particular small parcel shipments, where low-volume but high-value products can slip through the cracks.

A continuing challenge for brand owners is the ability of counterfeiters to use free trade zones and free ports to transship counterfeit goods from the location of manufacture through multiple ports all over the world. This allows counterfeiters to hide their true country of manufacture and take advantage of countries where customs protection for

[6] Press Release, European Comm'n, Commission Opens Formal Proceedings Against Temu Under the Digital Services Act (Oct. 31, 2024), https://ec.europa.eu/commission/presscorner/api/files/document/print/en/ip_24_5622/IP_24_5622_EN.pdf.

transshipped or in-transit goods is weak or non-existent. The transshipment of goods needs to be carefully controlled, and customs offices must apply more scrutiny to goods in transit.

Compulsory Licensing

The patent system drives and enables research and development that delivers valuable new innovations to society and has facilitated an unprecedented amount of collaboration, 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 compulsory licenses. The EC has proposed draft legislation for the grant of EU-wide compulsory licenses and compulsory licenses have previously been issued in several countries, including Hungary, India, Indonesia, Israel, Malaysia, and Russia.[7] In 2024, Colombia granted a compulsory license for an antiviral drug which was protected by a granted Colombian patent.[8] 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.[9]

Compulsory licensing outside the U.S. will harm innovators, particularly, at this time, U.S.-based biopharmaceutical companies, as their industry is currently the target of such measures. Compulsory licensing discourages innovators from investing the large amounts of time and money needed to research and develop new medicines. Discouraging innovation will harm U.S. industry and will deprive the public of advances in medicine and health care. Further, as countries consider extending compulsory licensing to other areas of technology, the incentives to invest in research and development for other innovations that would benefit society will also be reduced.

In contrast to compulsory licensing, voluntary licensing allows innovators to select responsible and capable licensing partners with whom they can work to develop technologies and products, relying on IP protection to be able to share their knowledge while protecting the investments that made their innovations possible. Innovators that can rely on IP rights with confidence will have the security to make the investments in research and development and establish voluntary partnerships involving the sharing of information that are necessary to advance public goals. IPO requests that the USTR encourage U.S. trading partners to develop laws and practices that encourage voluntary licensing rather than compulsory licensing.

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[7] *See Commission Proposal for a Regulation of the European Parliament and of the Council on Compulsory Licensing for Crisis Management and Amending Regulation (EC) 816/2006*, COM (2023) 224 final (Apr. 27, 2023) (EU).

[8] Superintendencia de Industria y Comercio, Resolución 20049, Abril 23, 2024 [Superintendence of Industry and Commerce, Resolution 20049, April 23, 2024] (Colom.).

[9] *See, e.g.*, *Resolution on Compulsory Licensing*, INTELL. PROP. OWNERS ASS'N (Dec. 3, 2020), https://ipo.org/index.php/resolution-on-compulsory-licensing/.

Patent Enforcement

Effective, efficient, and fair means for enforcing patents are the 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, limited damage awards, slow resolution of legal disputes, and the failure of courts to understand technical issues or IP-specific legal concepts. It is 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, 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 the 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 further efforts will be made to provide meaningful protection for innovators' patent rights.[10] Additional countries, such as India and Russia, among others, should also seek to implement such a mechanism. Countries, such as Saudi Arabia, which 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.[11]

Genetic Resources and Traditional Knowledge Requirements

Patent laws that impose 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

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[10] Guanyu Jiu "Yaopin Zhuanli Jiufen Zaoqi Jiejue Jizhi Xingzheng Caijue Banfa (Zhengqiu Yijian Gao)" Gongkai Zhengqiu Yijian de Tongzhi (关于就《药品专利纠纷早期解决机制行政裁决办法（征求意见稿）》公开征求意见的通知) [Notice on Soliciting Public Opinions on the Administrative Adjudication Measures for the Early Resolution Mechanism of Pharmaceutical Patent Disputes (Draft for Comments)] (promulgated by the Nat'l Intell. Prop. Admin., Feb. 9, 2021) (China).

[11] *E.g.*, Saudi Food and Drug Authority's 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). Philip Stevens, *Saudi Missteps on Intellectual Property Will Hold Back Its Economy*, HILL (Sept. 17, 2017), https://thehill.com/opinion/international/351074-saudis-missteps-on-intellectual-property-will-hold-back-its-economy/.

origin of any genetic resources incorporated into a product may be unknown or untraceable. IPO supports the objectives of the Convention on Biological Diversity and recognizes the national sovereignty of states over biological resources.[12] 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, undermine the sustainable use of technology related to biological resources, and should be eliminated.

IPO is opposed to Member States' ratification of the Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge adopted by the World Intellectual Property Organization ("WIPO") on May 24, 2024, requiring disclosures of the country of origin of genetic resources and/or traditional knowledge associated with genetic resources in patent filings.[13]

Genetic resources are now largely used in archived electronic digital sequence information ("DSI") form and accessed from publicly available databases composed of voluntary submissions. Given that large and complex comparative genetic 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 genetic resources disclosure requirements in patent laws.

Furthermore, unrestricted access to public collections of genetic DSI is essential to encourage innovation and promote scientific progress. Accordingly, IPO is concerned about and opposes proposals 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. 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 using certain existing institutional systems in coordination more efficiently.

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[12] Convention on Biological Diversity, *opened for signature* June 4, 1992 (entered into force Dec. 29, 1993).

[13] World Intellectual Property Organization [WIPO] Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, *adopted* May 24, 2024, WIPO Lex. No. TRT/GRATK/001; *see also* Intell. Prop. Owners Ass'n, Comment Letter on World Intellectual Property Organization Intergovernmental Committee Negotiations on Genetic Resources and Associated Traditional Knowledge (Jan. 22, 2023), https://ipo.org/wp-content/uploads/2024/01/IPO-Comments-WIPO-IGC-January-22-2024.pdf.

Examples of concerning developments include proposed amendments to Malaysia's IP laws, which include provisions for disclosure of traditional knowledge and genetic resources, as well as compulsory licensing, which raise concerns for genetics research-based industries.[14] Additionally, 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 revocation, of the patent.[15] 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.[16] 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.[17]

In China, the requirement to disclose the direct and original source of genetic resources for any invention based on genetic resources is particularly broad and includes any material taken from a 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.[18] China's law allows for the rejection of any patent right where required information for the genetic resources is not disclosed.[19] 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 and conduct a security review.[20] Under the law's implementing regulations, the Ministry and provincial science and

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[14] Patents (Amendment) Act 2021, ss.14, 40 (Malay.).

[15] OFF. OF THE CONTROLLER GEN. OF PATS., DESIGNS & TRADEMARKS, GUIDELINES FOR PROCESSING OF PATENT APPLICATIONS RELATING TO TRADITIONAL KNOWLEDGE AND BIOLOGICAL MATERIAL 2 (2017) (India).

[16] The Biological Diversity Act, 2002, §§3, 6 (India).

[17] The Biological Diversity Act, 2002, §6(2) (India).

[18] Zhonghua Renmin Gongheguo Zhuanli Fa Shishi Xize (2023 Nian Xiuding) (中华人民共和国专利法实施细则 (2023 年修订)) [Implementing Rules of the Patent Law of the People's Republic of China] (promulgated by the State Council of the People's Republic of China, June 15, 2001, rev'd Dec. 11, 2023), arts. 27, 29 (China).

[19] Zhonghua Renmin Gongheguo Zhuanli Fa Shishi Xize (2023 Nian Xiuding) (中华人民共和国专利法实施细则 (2023 年修订)) [Implementing Rules of the Patent Law of the People's Republic of China] (promulgated by the State Council of the People's Republic of China, June 15, 2001, rev'd Dec. 11, 2023), art. 50 (China).

[20] Zhonghua Renmin Gongheguo Renlei Yichuan Ziyuan Guanla Tiaola (中华人民共和国人类遗传资源管理条) [Regulations of the People's Republic of China on the Administration of Human Genetic Resources] (promulgated by the State Council of the People's Republic of China, May 28, 2019, effective July 1, 2019) (China).

technology administration departments are also tasked with supervising and inspecting the disposal of IP rights arising from the sharing of the human genetic resources.[21]

Data Legislation

While artificial intelligence ("AI") seemed pervasive in 2024, improvements in capability also added concerns around uses, regulations, and IP protections related to data, 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. International attention around information technology systems and network security has led to concerns around sharing trade secret data regarding 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, 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.[22] Data can be collected and processed after individual consent, or for a range of "legitimate" uses including medical emergencies, epidemics, and more.[23]

The EU 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.[24] The Data Act is intended to be an extension of the EU General Data Protection Regulations ("GDPR"), *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.[25] Courts

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[21] Zhonghua Renmin Gongheguo Renlei Yichuan Ziyuan Guanla Tiaola (中华人民共和国人类遗传资源管理条) [Regulations of the People's Republic of China on the Administration of Human Genetic Resources] (promulgated by the State Council of the People's Republic of China, May 28, 2019, effective July 1, 2019), art. 4 (China).

[22] The Digital Personal Data Protection Act, 2023 (India).

[23] The Digital Personal Data Protection Act, 2023, §§4(1), 7 (India).

[24] Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on Harmonised Rules on Fair Access to and Use of Data and Amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act), art. 4.1, O.J. L, 2023/2854, 22.12.2023, ELI: https://eur-lex.europa.eu/eli/reg/2023/2854/oj.

[25] Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on Harmonised Rules on Fair Access to and Use of Data and Amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act), art. 1.5, O.J. L, 2023/2854, 22.12.2023, ELI: https://eur-lex.europa.eu/eli/reg/2023/2854/oj; Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation), art. 13.2(f), 2016 O.J. (L 119) 1.

have interpreted the disclosure requirements of the GDPR in strikingly dissimilar ways—with some requiring disclosure of logic and others protecting against such disclosure.

The positive intentions behind the efforts in overall data protection and privacy must be balanced with a fundamental purpose of IP rights—encouraging innovation and progress by allowing IP to be subject to appropriate protections.

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 patent applications are resolved is five years from the filing date and, for pharmaceutical and biotech inventions, it can take up to 10 to 12 years. Such delays in securing patent rights make it difficult for innovators to attract investors or support business plans. IPO welcomes efforts by Argentina's Patent Office to reduce the backlog, including its enactment of Resolution 56/2016 and subsequent entry into a Patent Prosecution Highway ("PPH") pilot program with the U.S. Patent and Trademark Office ("USPTO") that started in 2017 and extended to 2020.[26] While some patents were granted under the pilot program, it was unfortunately not renewed. Notwithstanding the efforts of Argentina's Patent Office, a significant backlog remains, and 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 Joint Resolution 118/2012, 546/2012, and 107/2012 in May 2012, which introduced more restrictive patentability criteria for chemical and pharmaceutical inventions and refused pharmaceutical patents for: polymorphs; enantiomers; certain Markush-type claims; selection patents; salts, esters, and ethers; active metabolites; compositions and formulations; and analogy processes.[27] These criteria are inconsistent with Argentina's obligations under the TRIPS Agreement, and, when combined with the substantial backlog, result in significant uncertainty for innovators in the chemical and pharmaceutical areas.

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[26] Resolution No. 56/2016, Sept. 12, 2016, [33464] B.O. 19, 19, *translated in Argentina: Resolution No. 56/2016*, WORLD INTELL. PROP. ORG., https://www.wipo.int/export/sites/www/scp/en/meetings/session_25/comments_received/Argentina_1.pdf (last visited Dec. 3, 2024) (allowing the National Patent Administration to accept international prior art searches and examinations conducted by foreign offices with the same patentability requirements as Argentina); *see Patent Prosecution Highway Between USPTO and INPI-Argentina (Pilot)*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/basics/international-protection/patent-prosecution-highway/patent-prosecution-12 (last visited Dec. 3, 2024).

[27] Joint Resolution Nos. 118/2012, 546/2012 & 107/2012, May 2, 2012, [32392] B.O. 17, 18, 19 (approving the Guidelines for the Examination of Patent Applications of Pharmaceutical and Chemical Inventions).

Resolution 283/2015, issued on September 25, 2015, amended the patentability guidelines for the examination of biotechnological inventions and imposed additional patentability criteria that went 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.[28] Additionally, Joint Resolution 118/2012, 546/2012, and 107/2012 and Resolution 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. In particular, IPO believes that the guidelines violate Article 27.1 of TRIPS, which requires member states to provide patent protection for inventions "in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[29] Article 27.1 further provides that "patents shall be available and patent rights enjoyable without discrimination as to the . . . field of technology . . . ."[30]

Patent Cooperation Treaty

Argentina remains outside of the Patent Cooperation Treaty ("PCT"), notwithstanding that the PCT has 158 contracting states representing most of the world and simplifies patent filing and examination.[31] Argentina adhering to this agreement would be a positive step toward reducing extra expenses and facilitating filing strategies for inventors such as universities, institutions, individuals, and companies (private and public).

Lack of Regulatory Data Protection

Argentina does not provide protection for regulatory testing data, which is inconsistent with Argentina's TRIPS obligations under Article 39.3.[32] Specifically, Law 24,766 and Decree 150/92 permit Argentine officials to rely on data submitted by biopharmaceutical originators to approve requests by competitors to market similar products.[33]

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 enforcement officers, such as local police and customs officials. Federal courts have made little effort to combat counterfeiters, thus encouraging an increase in illegal activity.

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[28] Resolution No. 283/2015, Sept. 25, 2015, [33228] B.O. 16, 16–17.
[29] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27.1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 300.
[30] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27.1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 300.
[31] *The PCT Now Has 158 Contracting States*, WORLD INTELL. PROP. ORG., https://www.wipo.int/pct/en/pct_contracting_states.html (last visited Dec. 3, 2024).
[32] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights art. 39.3, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 300.
[33] Law No. 24766, Dec. 20, 1996, [28553] B.O. 3; Decree No. 150/1992, Jan. 20, 1992, [27311] B.O. 2.

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 requires that the patent applicant describe the best method known to the applicant (not the inventors) at the date of filing the complete specification (as opposed to the priority date).[34] 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 of whether the entirety of the patent, or only certain claims, will be invalid if the best method is found to have not been disclosed. There is also ongoing uncertainty and debate about what constitutes the relevant "filing date" of the complete application, whether it is the "date of the patent" (i.e., the filing date of the first complete application in a patent family) or the local filing date of any divisional application. Such a requirement is inconsistent with international practice.

Best method is routinely used as a powerful ground for revocation in Australian patent cases. Several cases have confirmed the continued applicability of the best method requirement. For example, in *Dometic Australia Pty. Ltd. v. Houghton Leisure Products Pty. Ltd.*, the Federal 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 and not the filing date of the earlier parent (PCT) application.[35] This decision 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 after the priority date but prior to the divisional application being filed.

Most recently, in *Zoetis Services LLC v. Boehringer Ingelheim Animal Health USA Inc.*, the Full 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.[36] The Full Court unanimously upheld the first instance decision, finding that even though the requirement for an enabling disclosure had been satisfied, the best method requirement was not satisfied by the disclosure of broad ranges from which the preferred concentrations could be discovered through further research and testing, as such a disclosure did not relieve a skilled addressee from "confronting blind alleys and pitfalls" already overcome by the patentee.[37] The Full Court also confirmed that the assessment of best method inquiry is directed to the invention disclosed in the whole of the specification, including the claims.[38]

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[34] *Les Laboratoires Servier v Apotex Pty Ltd* [2016] FCAFC 27 (8 March 2016) 6.
[35] [2018] FCA 1573 (19 October 2018) 56–57.
[36] [2024] FCAFC 145 (15 November 2024) 2.
[37] *Zoetis Servs* [2024] FCAFC at 6, 17.
[38] *Zoetis Servs* [2024] FCAFC at 11.

Australia's Support Requirement

IPO continues to monitor the Australian requirement for claims to be "supported" by matter disclosed in the specification. Courts have recently considered this requirement. In *Merck Sharp & Dohme Corp. v. Wyeth LLC (No. 3)* the Federal Court held that the specification must disclose a "technical contribution to the art" in addition to providing an enabling disclosure that justifies the breadth of the claims.[39]

In *Jusand Nominees Pty. Ltd. v. Rattlejack Innovations Pty. Ltd.*, the Full Federal Court applied the concept of a "relevant range" from recent case law in the United Kingdom ("UK").[40] In doing so, the Full Court held that a range would be relevant if it was expressed in "reference to a variable which significantly affects the value or utility of the product in achieving the purpose for which it is to be made."[41] The Full Court expanded on the determination of the "relevant purpose" as starting from the claim itself, but taking into consideration the "essence or core of the invention" (referring to another recent UK decision).[42] The Full Court articulated a number of factors to be taken into consideration for this test, but in essence found that, if there was a relevant range in a claim, the specification must disclose how to perform the invention across the whole width of this range without there being undue burden on the person skilled in the art.[43] The High Court (Australia's ultimate appellate court) refused an application for special leave to appeal the *Jusand* decision.

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."[44]

Support and Enablement Considerations for Claiming Antibodies

Similar to the U.S., it is becoming increasingly more difficult to obtain broad antibody claims in Australia, predominantly because of the strict implementation of Australia's support and enablement requirements by the Australian Patent Office. To date, there has been little judicial consideration of the support and enablement requirements in relation to therapeutic antibodies.

In a typical scenario where antibodies are raised against known targets, an antibody must usually be claimed by reference to all six complementarity-determining region sequences ("CDR"). In some instances, it might be possible to avoid reciting all six CDRs.

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[39] [2020] FCA 1477 (14 October 2020) 144; *see also Cytec Indus Inc v Nalco Co* [2021] FCA 970 (19 August 2021) 40; *TCT Grp Pty Ltd v Polaris IP Pty Ltd* [2022] FCA 1493 (14 December 2022) 59.
[40] [2023] FCAFC 178 (13 November 2023) 54–55; Regeneron Pharms. Inc. v. Kymab Ltd. [2020] UKSC 27, [56] (appeal taken from Eng.) (UK).
[41] *Jusand Nominees* [2023] FCAFC at 55.
[42] *Jusand Nominees* [2023] FCAFC at 56; Illumina Cambridge Ltd. v. Latvia MGI Tech SIA [2021] EWHC 57 (Pat), [279(iv)] (Eng. & Wales).
[43] *Jusand Nominees* [2023] FCAFC.
[44] *Calix Ltd v Grenof Pty Ltd* [2023] FCA 378 (28 April 2023) 36.

However, this is only possible if the data shows one or more of the CDRs are not involved with antigen binding, or a particular antibody format allows epitope recognition by fewer CDRs (e.g., heavy chain only antibodies).

Patentable Subject Matter in Relation to Computer-Implemented Inventions

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

The High Court of Australia grappled with this issue in *Aristocrat Technologies Australia Pty. Ltd. v. Commissioner of Patents*.[45] Although the long-awaited High Court decision was 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 stood, albeit without being binding precedent.[46]

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.[47] However, uncertainty remains as the Justices who dismissed Aristocrat's case did not agree with a two-step approach adopted by the lower court.[48] Instead, they applied a test to determine whether there had been some adaptation or addition to the technology beyond common general knowledge in the art in order to accommodate a new idea.[49] It is not clear how the Justices envisage the common general knowledge to be ascertained for this purpose. Under the current practice, evidence as to common general knowledge is usually required when assessing novelty and inventive step. The Justices who found in favor 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 consider the High Court's decision, but the practical experience of applicants is that it is difficult, or potentially not possible, to obtain protection for certain computer implemented inventions in Australia.[50]

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[45] [2022] HCA 29 (17 August 2022) 1.
[46] *Aristocrat Techs* [2022] HCA at 37, 63 (C.J. Kiefel, J. Gageler, and J. Keane dismissing the appeal by reason of a technical majority under Section 23(2)(a) of the *Judiciary Act 1903* (Cth); J. Gordon, J. Edelman, and J. Steward allowing the appeal).
[47] *Aristocrat Techs* [2022] HCA at 32, 61–62.
[48] *Aristocrat Techs* [2022] HCA at 32.
[49] *Aristocrat Techs* [2022] HCA at 34.
[50] 2 IP AUSTL., PATENT MANUAL OF PRACTICE AND PROCEDURE § 5.6.8.6 (2024).

The Federal Court has recently granted special leave for Aristocrat to appeal the decision, and this appeal is expected to be heard in 2025.[51]

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.[52] Those damages are designed to compensate Australia's pharmaceutical benefits 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.[53] 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, the practical operation of this policy is currently under review by the High Court of Australia.[54] In a long running case, the Department of Health was initially 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.[55] This case turned on findings of fact that, but for the interlocutory injunction, the generic company would not have applied for a PBS listing.[56] Therefore, this finding does not prevent the Commonwealth from establishing that a relevant party would have sought and obtained a PBS listing of its products in future cases—it will necessarily depend on the nature and strength of the evidence. Whilst this decision was affirmed by the Full Court, special leave was granted, and Australia now eagerly awaits the decision of the High Court.

This "market-size damages" approach 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

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[51] *Aristocrat Techs Austl Pty Ltd v Comm'r of Pats* [2024] FCA 987 (30 August 2024) 2.

[52] DEP'T OF HEALTH & AGED CARE, ANNUAL REPORT 2023-24 296 (2024).

[53] The claimed damage must "have 'necessarily and naturally flowed' from the interlocutory injunction for it to be recoverable." *Commonwealth v Sanofi (formerly Sanofi-Aventis) [No. 5]* [2020] FCA 543 (28 April 2020) 106, *aff'd*, [2023] FCAFC 97 (26 June 2023) (quoting *Air Express Ltd v Ansett Transport Indus Operations Pty Ltd* [1981] HCA 75 (10 February 1981)).

[54] *See generally Sanofi* [2020] FCA 543. Special leave for appeal was granted by the High Court in 2023. Transcript of Record at 21–22, *Commonwealth v Sanofi (formerly Sanofi-Aventis)* [2023] HCATrans 184 (18 December 2023); *see also* Transcript of Record, *Commonwealth v Sanofi (formerly Sanofi-Aventis)* [2024] HCATrans 058 (4 September 2024); Transcript of Record, *Commonwealth v Sanofi (formerly Sanofi-Aventis)* [2024] HCATrans 059 (5 September 2024).

[55] *Sanofi* [2020] FCA at 4, 162.

[56] *Sanofi* [2020] FCA at 108.

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 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.

Regulatory Data Protection

Australia provides RDP of five 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.[57] The lack of data protection for product changes supported by new clinical information and the lack of protection for more than five years for biological products potentially puts pharmaceutical innovators at a disadvantage in Australia in comparison to other developed countries. After expiry of the initial five-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.

Australia to Implement Changes to Strengthen Design Protection

IP Australia is expected to circulate draft legislation in 2025 that will provide better protection for designs, particularly virtual and partial designs.[58] Implementing such legislation will further align Australia with its major trading partners, including the U.S. However, there is no current proposal for Australia to join the Hague System for the International Registration of Industrial Designs (the "Hague System"), which simplifies procedures and reduces costs for users of the system.[59] Australia should be encouraged to make the changes needed to join the Hague System.

The amendments to allow virtual designs is a welcome shift. Notably, IP Australia currently takes the position that Australia's design registration system is geared towards protecting "the overall appearance of physical products."[60] This can create difficulties when seeking design protection in Australia in relation to products that do not have physical forms, or which comprise elements that are only visible when the products are in use, such as graphical user interfaces, which transcend the technologies of more

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[57] *Therapeutic Goods Act 1989* (Cth) s 25A.

[58] *See Enhancing Australian Design Protection*, IP AUSTL., https://consultation.ipaustralia.gov.au/policy/enhancing-australian-design-protection/ (last visited Nov. 25, 2024).

[59] *See* Geneva Act, July 2, 1999, WIPO Lex. No. TRT/HAGUE/006.

[60] *Virtual Designs*, IP AUSTL. (June 13, 2023), https://consultation.ipaustralia.gov.au/policy/enhancing-australian-design-protection/user_uploads/factsheet---virtual-designs.pdf.

traditional display screens.[61] In the absence of Australian judicial authority on this issue, the availability and scope of protection for virtual designs is currently uncertain and it is unclear whether virtual designs are enforceable in Australia.

The proposed amendments to partial designs will allow protection for designs in relation to things that are not typically manufactured separately from an entire product (e.g., component parts of physical products).[62] This differs from the current position which requires design registrations to exist in relation to "products" and does not expressly include partial products.[63]

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 IP licenses from some competition law prohibitions, was repealed on September 13, 2019.[64] With the repeal of the exemptions, licensors and licensees may be held criminally liable for breaching cartel prohibitions, unless the anti-overlap provisions apply, if the contract includes price, territorial, or quota restrictions. Guidelines have been published by the Australian Competition and Consumer Commission on the effect of this repeal.[65]

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.* 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.[66] It is vital that trademark owners ensure that valid rights have been secured. A remedy is needed for instances of clerical error upon filing.

Nice Classification Not Relevant to the Scope of Registered Goods and Services

The Australian Full Court recently cast doubt on the longstanding principle in Australian trademark law that the Nice Classification of goods can be considered when interpreting the scope of goods and services. In that decision, the Full Court found that "non-alcoholic

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[61] For example, Apple, Inc. failed to obtain a design registration in respect of a "display screen." *Apple, Inc* [2017] ADO 6 (14 June 2017); *see also DRiV IP, LLC* [2024] ADO 3 (3 October 2024) (where the delegate of the Registrar of Designs revoked DRiV IP's designs for an "electronic device including a display screen" and "display screen.").

[62] *Partial Designs*, IP AUSTL. (June 13, 2023), https://consultation.ipaustralia.gov.au/policy/enhancing-australian-design-protection/user_uploads/factsheet---partial-designs.pdf.

[63] *Partial Designs*, IP AUSTL. (June 13, 2023), https://consultation.ipaustralia.gov.au/policy/enhancing-australian-design-protection/user_uploads/factsheet---partial-designs.pdf.

[64] *Competition and Consumer Act 2010* (Cth) compilation no. 119 s 51(3); *see Treasury Laws Amendment (2018 Measures No. 5) Act 2019* (Cth) sched. 4 (repealing Section 51(3)).

[65] AUSTL. COMPETITION & CONSUMER COMM'N, GUIDELINES ON THE REPEAL OF SUBSECTION 51(3) OF THE COMPETITION AND CONSUMER ACT 2010 (CTH) (2019).

[66] [2017] FCAFC 83 (26 May 2017).

beverages" in class 32 includes coffee beverages, notwithstanding that coffee beverages are classified separately under class 30.[67] According to the Full Court, it is important to focus primarily on the description of goods and services in a trademark registration, without regard to class numbers.[68]

Reputation Not Relevant to an Assessment of Deceptive Similarity

The Australian High Court recently delivered a unanimous judgment which clarified that the reputation of a trademark should not be taken into account when assessing deceptive similarity under the trademark infringement provision of Section 120(1) of the Trade Marks Act 1995 (Cth) (or the trademark prosecution section of 44(1)).[69]

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 System became effective for Brazil in August 2023.[70] Accession to the System was part of the government's strategic agenda to modernize the Brazilian IP system, which also led to Brazil's accession to the Madrid Protocol in 2019.[71] 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.[72]

Compulsory Licensing Laws and Forced or Pressured Technology Transfer

Brazil's 2021 modifications to the rules governing compulsory licenses were concerning to IP owners. Forced technology transfer provisions were even proposed during the legislative process, but ultimately vetoed by the President.[73]

IPO strongly opposes compulsory licensing of IP 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

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[67] *Energy Beverages LLC v Cantarella Bros Pty Ltd* [2023] FCAFC 44 (22 March 2023) 33.
[68] *Energy Beverages LLC* [2023] FCAFC at 29–30.
[69] *Self Care IP Holdings Pty Ltd v Allergan Austl Pty Ltd* [2023] HCA 8 (15 March 2023) 22.
[70] *IP Treaties Collection*, WORLD INTELL. PROP. ORG., https://www.wipo.int/wipolex/en/treaties/parties/remarks/BR/9 (last visited Jan. 2, 2025); *see also* Geneva Act, July 2, 1999, WIPO Lex. No. TRT/HAGUE/006.
[71] *See* Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks, Nov. 12, 2007, WIPO Lex. No. TRT/MADRIDP-GP/001.
[72] Portaria No. 36, de 06 de Setembro de 2023 [Ordinance No. 36, of September 6, 2023]; *Manual de Desenhos Industriais*, INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL [Industrial Design Manual, National Institute of Industrial Property], https://manualdedi.inpi.gov.br/projects/manual-de-desenho-industrial/wiki (July 12, 2024).
[73] *See* Veto No. 48/2021, de 02 de Setembro de 2021 [Veto No. 48/2021, of September 2, 2021]; Mensagem No. 432/2021, de 03 de Setembro de 2021 [Message No. 432/2021, of September 3, 2021].

is best accomplished through voluntary efforts. Voluntary licensing allows for companies to choose responsible and capable licensing partners with whom to share IP, and to work with partners to develop technologies and products. Innovators will not be able to make investments in research and development if they cannot rely on their IP rights with confidence.

Further, forced technology transfer could jeopardize IP rights and violate international treaties. As explained in the USTR's 2024 Special 301 Report, such transfers "disadvantage U.S. companies, conditioning market entry on surrendering their intellectual property," and "discourage foreign investment in national economies, hurt local manufacturers, distributors, and retailers, and slow the pace of innovation and economic progress."[74]

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 under PPH agreements, and leveraging examination of foreign counterpart applications.[75] Although these developments are very encouraging, it is important to continue to build on this momentum and reduce patent application pendency times.

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, the National Institute of Industrial Property ("INPI") has implemented the changes necessary to comply with international standards, and trademarks are now being granted in 14 months on average.

Changes in Patent Examination Queue

On December 17, 2023, INPI published Technical Note No. 27, which proposes that the order of the queue of examination of patent applications be changed from their filing date to their examination request date.[76] INPI states that the current order does not allow for a precise definition of when a patent application will be examined, as other patent applications can join the queue in an earlier position at any time.[77] INPI believes that the

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[74] OFF. OF THE U.S. TRADE REPRESENTATIVE, 2024 SPECIAL 301 REPORT (2024).

[75] 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 4.6 years. According to INPI's strategic plan, the goal is to reach an average of two years in 2026. In 2024, INPI hired 40 new patent examiners and 40 new trademark examiners. INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, STRATEGIC PLAN: 2023-2026 22 (version 2.0, 2023).

[76] Nota Técnica No. 27, de 17 de Dezembro de 2023 § 1 [Technical Note No. 27, of December 17, 2023].

[77] Nota Técnica No. 27, de 17 de Dezembro de 2023 § 8 [Technical Note No. 27, of December 17, 2023].

proposed new order would be advantageous for the following reasons: (a) an applicant would be encouraged to request the examination earlier in the administrative procedure; (b) an applicant could anticipate or delay the examination request in accordance with its needs; (c) an interested third-party could better decide whether or not to request the examination of an application; and (d) the Brazilian practice would be in line with the international practice.[78] In addition, the change would be within INPI's goal to issue a final decision on patent applications within two years.

Nonetheless, Note No. 27 did not provide any information regarding the queue of applications for which the examination has already been requested, although INPI has informally stated that this new rule will apply for all patent applications waiting to be examined.

New INPI Rules for the Appellate Stage

In 2024, INPI introduced new rules for the appellate stage, with the goal of reducing the backlog of pending appeals.[79] Under these new rules, claim amendments and auxiliary claim sets are only accepted if they result from combinations of claims from the claim set that was rejected by the first instance examination.[80] In other words, adding new matter to the rejected claim set from the specification is no longer possible at the appellate stage. INPI's intention to apply this rule retroactively to pending appeals has raised concerns, as those appeals were filed under the previous, more reasonable rules.

Proposed Patent Term Adjustment for INPI Delay

Brazil should reinforce the above-described efforts to reduce the patent examination backlog by establishing a mechanism to restore patent term lost due to unreasonable delays during patent examination. Currently, due to the Brazilian Supreme Court's decision to eliminate the sole paragraph of Article 40 of the Brazilian Patent Law, patent applicants have no recourse to address such delays.[81] The time has come for Brazil to establish a patent term adjustment ("PTA") 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 in the direction of establishing a PTA system based on INPI's delays during

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[78] Nota Técnica No. 27, de 17 de Dezembro de 2023 § 24 [Technical Note No. 27, of December 17, 2023].

[79] Parecer No. 00016/2023/CGPI/PFE-INPI/PGF/AGU, de 12 de Dezembro de 2023, Revista da Propriedade Industrial de 12.12.2023 [Opinion No. 0016/2023/CGPI/PFE-INPI/PGF/AGU, of December 12, 2023, Industrial Property Magazine of 12.12.2023]; Parecer No. 00019/2023/CGPI/PFE-INPI/PGF/AGU, de 12 de Dezembro de 2023, Revista da Propriedade Industrial de 12.12.2023 [Opinion No. 0019/2023/CGPI/PFE-INPI/PGF/AGU, of December 12, 2023, Industrial Property Magazine of 12.12.2023].

[80] Parecer No. 00019/2023/CGPI/PFE-INPI/PGF/AGU, de 12 de Dezembro de 2023, Revista da Propriedade Industrial de 12.12.2023 [Opinion No. 0019/2023/CGPI/PFE-INPI/PGF/AGU, of December 12, 2023, Industrial Property Magazine of 12.12.2023].

[81] *See* S.T.F., Ação Direta de Inconstitucionalidade No. 5.529 [Direct Action of Unconstitutionality No. 5,529], Relator: Min. Dias Toffoli, 12.05.2021.

examination.[82] According to the bill, patentees would be able to request PTA when INPI took more than 60 days to issue decisions; the adjustment would be limited to an additional five years of patent protection.[83]

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, resulting in discriminatory treatment.[84] 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 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.[85] As discussed above, Brazil's disclosure requirements introduce uncertainty for innovators, inhibit innovation in biotechnology, undermine the potential of benefit-sharing, and should be eliminated.

Technology Agreements

In a welcome move, INPI now accepts: (a) records of licensing agreements of unpatented technology/know-how; (b) records of royalty payments for pending trademark applications; and (c) 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.[86] 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.

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[82] Projeto de Lei No. 2056/2022, de Julho de 2022 [Bill No. 2056/2022, July 2022].
[83] Projeto de Lei No. 2056/2022, de Julho de 2022 [Bill No. 2056/2022, July 2022].
[84] *See* Lei No. 10.603, de 17 de Dezembro de 2022 [Law No. 10,603, of December 17, 2023].
[85] *See* Decreto No. 8.772, de 11 de Maio de 2016 [Decree No. 8,772 of May 11, 2016].
[86] Portaria No. 26/2023, de 07 de Julho de 2023 [Ordinance No. 26/2023, of July 7, 2023]; Portaria No. 27/2023, de 7 de Julho de 2023 [Ordinance No. 27/2023, of July 7, 2023]; *see also Implementation of Innovative Changes to the Recordal of Technology Agreements in Brazil*, DANIEL L. (July 8, 2023), https://www.daniel-ip.com/en/client-alert/implementation-of-innovative-changes-to-the-recordal-of-technology-agreements-in-brazil/; Karlo Tinoco & Roberto Rodrigues Pinho, *Brazil Implements Changes to Facilitate the Recordal of IP Agreements*, WOLTERS KLUWER: KLUWER PAT. BLOG (Aug. 14, 2023), https://patentblog.kluweriplaw.com/2023/08/14/brazil-implements-changes-to-facilitate-the-recordal-of-ip-agreements/; Pablo Torquato, *New Guidelines for the Recordal of Technology Transfer and Licensing Agreements in Brazil*, MONTAURY PIMENTA MACHADO & VIEIRA DE MELLO (July 12, 2023), https://www.montaury.com.br/en/new-guidelines-for-the-recordal-of-technology-transfer-and-licensing-agreements-in-brazil.

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.

CANADA

Lack of Adequate Trade Secret Protection

In 2020, Canada took an important, but ultimately incomplete, step to combat its lack of adequate trade secret legislation. Pursuant to its obligations under the United States-Mexico-Canada Trade Agreement ("USMCA"), Canada enacted new Criminal Code provisions related to trade secrets, which came into force on July 1, 2020.[87] These provisions were aimed at the intentional theft of trade secrets and required proof of "deceit, falsehood or other fraudulent means" and the knowing obtainment or communication of a trade secret.[88] Anyone convicted of these new offenses (or related offenses of conspiracy, attempt to commit, or accessory after the fact in relation to the theft of a trade secret) can be punished either by way of an indictable offense, with imprisonment for a term not exceeding 14 years, or a summary conviction.[89]

While this development 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 (excluding Québec) lack of a statutorily granted civil right of action continues to be problematic, as rights holders continue 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."[90] Unlike its largest trading partner, Canada has yet to codify the basic principles of common law trade secret protection in a uniform manner and should adopt legislation similar to the U.S. Federal Defend Trade Secrets Act and the state Uniform Trade Secrets Act (which was adopted by the vast majority of U.S. states and the District of Columbia as of 2024).[91] 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 IP rights.

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[87] Canada-United States-Mexico Agreement Implementation Act, S.C. 2020, c 1, art 36–37; *see* Agreement Between the United States of America, the United Mexican States, and Canada, art 20.71, July 1, 2020.
[88] Criminal Code, R.S.C. 1985, c C-46, art 391(1).
[89] Criminal Code, R.S.C. 1985, c C-46, art 391(3).
[90] Matt Malone, *A Comparative History of the Law of Confidential Information and Trade Secrets in Canada and the United States: Towards Harmonization?*, 34 INTELL. PROP. J. 81, 92 (2021).
[91] Defend Trade Secrets Act of 2016, Pub. L. No. 114-153, 130 Stat. 376 (2016); UNIF. TRADE SECRETS ACT WITH 1985 AMENDS. (NAT'L CONF. OF COMM'RS ON UNIF. STATE LS. 1985).

Slow Examination of Trademark Applications

IPO remains concerned about the slow pace of trademark application examination by the Canadian Intellectual Property Office ("CIPO"). Based on available statistics, it appears that CIPO continues to be the slowest national office in the world when it comes to the examination of trademark applications.[92]

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").[93] CIPO's preferential treatment of such applications, however, 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 to be applauded for the recent efforts it has made to reduce the backlog for the Not Sole Approved List Applications. As of December 2024, CIPO reported that it is examining Not Sole Approved List Applications that were filed on July 28, 2021 (a delay of 41 months), and, from October 2023 to November 2024, CIPO decreased the backlog for Not Sole Approved List Applications by 13 months.[94] CIPO advised it anticipates that by the end of January 2025 it will be examining Not Sole Approved List Applications filed as of March 25, 2022, further reducing the backlog by an additional eight months to a delay of 34 months. This decrease in backlog can be attributed to the 143 new examiners hired by CIPO in 2023 and 2024. CIPO has indicated that it expects the backlog of Not Sole Approved List Applications to continue to decrease until it is on par with the Sole Approved List Applications.

The owner of a Not Sole Approved List Application may request CIPO add particular goods/services to the Manual in an attempt to convert the application to a Sole Approved List Application. However, CIPO often rejects such requests, even though it acknowledges that the goods/services are described in specific and ordinary commercial terms, because other trademark owners are unlikely to want to use those descriptions. CIPO will sometimes suggest alternative wording, which may assist in future applications, but will not help expediate the current pending applications.

Applicants may also request expedited examination under certain circumstances, namely, when a court action is expected or underway in Canada with respect to the applicant's trademark in association with the goods or services listed in the application; the applicant

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[92] According to the WIPO Statistics Database, Canada's pendency from filing a trademark application to a first office action was 854 in 2023. The 2024 data is not yet available. *WIPO IP Statistics Data Center*, WORLD INTELL. PROP. ORG., https://www3.wipo.int/ipstats/ips-search/search-result?type=IPS&selectedTab=trademark&indicator=114&reportType=11&fromYear=1980&toYear=2023&ipsOffSelValues=CA&ipsOriSelValues=&ipsTechSelValues=161 (Dec., 2024).

[93] *See Goods and Services Manual*, CAN. INTELL. PROP. OFF., https://ised-isde.canada.ca/site/canadian-intellectual-property-office/en/trademarks/goods-and-services-manual (Sept. 18, 2024).

[94] *Trademarks: Dates of Trademark Applications Being Distributed for Examination*, CAN. INTELL. PROP. OFF., https://ised-isde.canada.ca/site/canadian-intellectual-property-office/en/trademarks (last visited Dec. 18, 2024).

is in the process of combating counterfeit products at the Canadian border with respect to the applicant's trademark in association with the goods or services listed in the application; when the applicant requires registration of its trademark in order to protect its IP rights from being severely disadvantaged on online marketplaces; or the applicant requires registration of its trademark in order to preserve its claim to priority within a defined deadline and following a request by a foreign IP office.[95] Upon approval, the application is examined as soon as possible, often within two to three weeks.

French Language Requirements

Recent changes made by the province of Québec to its language laws and regulations will lead to uncertainty and increased costs for brand owners, particularly when it comes to the use of non-French trademarks. For example, the final version of Québec's regulation made under the Charter of the French Language, published on June 26, 2024, requires trademark owners to translate into French a non-French trademark that appears on a product or its packaging.[96] The final version of the regulation states that a "recognized trademark," within the meaning of the Trademarks Act, may appear on a product without the need for translation if no corresponding French version of the mark is registered.[97] It will be difficult for the owner of a non-French trademark to determine whether their mark qualifies as a "recognized trademark," particularly if it has not yet been registered.

IPO is also concerned about provisions of the regulation to the effect that if a generic term or a description of a product (other than words constituting the name of the enterprise or the name of the product as sold) is included in a trademark, "it must appear in French on the product or on a medium permanently attached to the product."[98] IPO's concern relates to the possibility that different standards regarding what is generic or descriptive may be applied under the Québec requirement as compared to the interpretations given to each of these terms in court decisions regarding the Federal Trademarks Act.

Patented Medicine Prices Review Board Regulations

The Patented Medicine Prices Review Board's ("PMPRB") authority and mandate under the Canadian Patent Act is to ensure that patentees do not abuse their patent rights by selling patented medicines at excessive prices.[99]

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[95] *Requests for Expedited Examination*, CAN. INTELL. PROP. OFF., https://ised-isde.canada.ca/site/canadian-intellectual-property-office/en/trademarks/practice-notices/requests-expedited-examination (May 11, 2021).

[96] *Regulation to Amend Mainly the Regulation Respecting the Language of Commerce and Business*, (2024) 156 G.O.Q. II, nº 26, 2683, p. 2684.

[97] *Regulation to Amend Mainly the Regulation Respecting the Language of Commerce and Business*, (2024) 156 G.O.Q. II, nº 26, 2683, p. 2684.

[98] *Regulation to Amend Mainly the Regulation Respecting the Language of Commerce and Business*, (2024) 156 G.O.Q. II, nº 26, 2683, p. 2684.

[99] Patent Act, R.S.C. 1985, c P-4, art 83(1)–(3).

IPO has expressed concerns in the past about the Regulations Amending the Patented Medicines Regulations (the "Amended Regulations") that came into force on July 1, 2022.[100] In particular, the Amended Regulations changed the list of comparator countries under Section 4(1)(f)(iii) to remove the U.S. and Switzerland and add Australia, Belgium, Japan, Netherlands, Norway, and Spain, forming a new list of 11 countries ("PMPRB11").[101] 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 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 researchers behind it.

The PMPRB implements the Amended Regulations through the PMPRB Guidelines (the "Guidelines"), which are intended to provide predictability for innovative manufacturers by giving guidance on when patented drugs are at risk of being excessively priced.[102] 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 Guidance 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).[103]

Draft guidelines were published on December 19, 2024, and are open for public consultation until March 19, 2025.[104] The interim policies have caused unacceptable levels of pricing uncertainty for innovative manufacturers selling and seeking to launch new patented medicines for the benefit of Canadian patients, and such concerns remain with respect to the draft guidelines. In addition to an initial price review, the PMPRB has proposed continuous (annual) reassessment of prices throughout the lifetime of the patent, wherein the prices are determined based on the highest international price of the

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[100] Intell. Prop. Owners Ass'n, Comment Letter on Regulations Amending the Patented Medicines Regulations (Feb. 14, 2018), https://ipo.org/wp-content/uploads/2018/02/IPO-Comments-on-Proposed-PM-Regs.pdf; *see also* Regulations Amending the Patented Medicines Regulations, 151 C. Gaz. 4497 (2017); *see also* Regulations Amending the Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), No. 5, SOR/2022-162 (stating the Regulations would go into effect July 1, 2022).

[101] Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), SOR/2019-298 at 5945–46, 5957–58.

[102] *See* PATENTED MED. PRICES REV. BD., PMPRB GUIDELINES (2021) (no longer in force).

[103] *See Decision on the Amended Interim Guidance Consultation*, PATENTED MED. PRICES REV. BD. (Sept. 27, 2023), http://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-new-medicines/decision-amended-interim-guidance.html; *Interim Guidance*, PATENTED MED. PRICES REV. BD., https://www.canada.ca/en/patented-medicine-prices-review/services/legislation/interim-guidance.html (Sept. 27, 2023).

[104] *Draft Guidelines for PMPRB Staff*, GOV'T OF CAN. (Dec. 19, 2024), https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines-pmprb-staff.html.

PMPRB11. However, if the PMPRB recommends a hearing to review a given price, other factors may be considered. This could mean that even if an initial price review concludes that a price is non-excessive, a future review could reverse that determination and find that a price is excessive, even if a patentee restricts its list price increases to CPI. This continued price erosion of patented medicines is very concerning.

IPO is also concerned about the reduction in reporting requirements for patented generic medicines (approved by means of an Abbreviated New Drug Submission) introduced through the Amended Regulations.[105] Generic medicines are exempt from the continual reporting of information unless requested by the PMPRB.[106] 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.[107]

The Amended 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 IP 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 for 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 for drug plans to manage their budgets.

Weak Patent Enforcement

The Patented Medicines (Notice of Compliance) Regulations (the "PMNOC Regulations") include deficiencies that weaken Canadian patent enforcement, including

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[105] Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), SOR/2019-298 at 5958.

[106] Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), SOR/2019-298 at 5958.

[107] The PMPRB has found that the phrase "pertain 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. *See* PATENTED MED. PRICES REV. BD., PMPRB GUIDELINES 6 (2021) (no longer in force).

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).[108]

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 served, then an innovator cannot bring a proceeding under the Patent Act, unless it had a reasonable basis for not bringing the action in response to the NOA.[109] This provision has the effect of revoking a statutorily granted patent right due to a missed deadline and puts the onus of showing a justifiably irregular failing to sue at first instance on the patentee.

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," as opposed to only the "first person" under the previous regulations.[110] However, there is no requirement for all second persons in Notice of Compliance ("NOC") proceedings related to the same patented medicine to bring their Section 8 claims together. Furthermore, there have been no proposals allowing courts 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 regarding the same patent, there is a risk that they will be subject to a cumulative damage award.[111] Additionally, Section 8 does not impose any statutory limits to the period of a first person's liability. Thus, second persons under the

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[108] Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, ss. 6(1), 8(1).

[109] Patented Medicines (Notice of Compliance) Regulations, SOR/93-133 ss. 6(1), 6.01.

[110] 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." Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 2(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 . . . ." Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 5(1). A "first person means the person referred to in subsection 4(1)." Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 2(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." Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 4(1).

[111] *See, e.g.,* Apotex, Inc. v. Sanofi-Aventis, 2014 FCA 68; Teva Can. Ltd. v. Sanofi-Aventis Can. Inc., 2014 FCA 67.

PMNOC Regulations may be able to claim losses suffered beyond the date of any dismissal or discontinuance.

These Section 8 amendments create a risk of "windfall" damage awards which are contrary to the traditional compensatory function of damages and, in situations where Section 8 damages are 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.[112]

Certificate of Supplementary Protection Restrictions

Although it is positive that Canada has recently provided for restoration of certain patent terms for pharmaceutical inventions 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.[113] 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., 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.[114] Both of these restrictive requirements are inconsistent with 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.[115] 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. Currently, one or more third parties are allowed to seek a CSP based upon the NOC obtained by the pharmaceutical innovator.[116]

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[112] *See* Patent Act, R.S.C. 1985, c P-4, s. 60(1).
[113] *See* Certificate of Supplementary Protection Requirements, SOR/2017-165, ss. 2–3.
[114] Certificate of Supplementary Protection Requirements, SOR/2017-165, s. 6(1).
[115] Certificate of Supplementary Protection Requirements, SOR/2017-165, s. 6(1)(b)(i).
[116] Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 5(1).

As Canadian law mandates only one CSP per drug, proceedings to resolve any "conflict" between one or more CSP applications citing the same NOC are unnecessary and costly. Pharmaceutical innovators face a significant risk of losing their CSPs to third parties, thereby denying innovators the incentive and reward for undertaking the costly and risky journey of drug development. IPO believes third parties should 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 PTA regime, which came into force on January 1, 2025, in order to comply with Canada's treaty obligations under the USMCA, Article 20.44.[117] Although this should be an encouraging development for Canadian patentees, IPO is concerned about several aspects of the PTA framework.

CIPO's framework for PTA regulations takes a very strict and minimal approach in adopting PTA, only meeting basic requirements in the Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act.[118] For example, unlike the U.S. system, Canada states that all days will be deducted from the potential term once a notice requiring applicant action is issued, leaving applicants with no reasonable response time.[119] Additionally, all days relating to a judicial appeal of CIPO's refusal of an application will be deducted, even where the applicant's appeal is successful.[120]

The framework also renders most patents ineligible for PTA because of 38 proposed categories of excluded periods that would be subtracted in the PTA term calculation to account for delays attributed to the applicant rather than CIPO.[121] Examples of such excluded periods include: (a) the period when an applicant makes a request for continued examination and ending on the day the final fee is paid; (b) the period when an applicant agrees to amend an application on the day of an examiner interview and ending on the day that the applicant submits the amendments; and (c) the days taken to pay certain fees, including maintenance and late fees.[122]

PTA will not be granted automatically as it is in the U.S.; applicants will instead be required to apply for PTA within three months from the issuance of the patent or lose the

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[117] An Act to Implement Certain Provisions of the Budget Tabled in Parliament on March 28, 2023, S.C. 2023, c 26, s. 493; *see* Agreement Between the United States of America, the United Mexican States, and Canada, art. 20.44, July 1, 2020.

[118] Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act, SOR/2024-241.

[119] Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act, SOR/2024-241, s. 15(117.03)(1).

[120] Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act, SOR/2024-241, ss. 15(117.03)(1)(w), (z.1).

[121] Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act, SOR/2024-241, s. 15(117.03)(1).

[122] Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act, SOR/2024-241, ss. 15(117.03)(1)(d), (m), (p).

benefit.[123] The regulations permit any third party to request shortening the PTA potentially available to a patentee, but do not allow a patentee to request a longer PTA in circumstances when they believe the CIPO's PTA calculation is erroneous.[124] The 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 implementation of PTA. Notably, unlike the equivalent U.S. regime, the PTA term in Canada would run concurrently, not consecutively, with any CSP term granted to pharmaceutical patentees.[125] This is inconsistent with the different remedial objectives of PTA and CSPs, 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 and make significant changes to the regulations to ensure that its implementation is compliant with the remedial objectives of Canada's USMCA treaty obligations.

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 PMNOC Regulations when the patents do not meet certain, seemingly arbitrary, timing requirements, which are not present in the U.S. under the Hatch-Waxman Act.[126]

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.[127] The effect is to deny pharmaceutical innovators access to enforcement procedures in the context of early work 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

Under the promise doctrine, a court identifies the utility alleged to be "promised" in the patent specification and then measures the utility of the invention against those promises.[128] In 2017, the Supreme Court of Canada ("SCC") rejected this approach in

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[123] Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act, SOR/2024-241, ss. 15(117.01)(1), (117.03)(u), (z), (z.01).
[124] Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act, SOR/2024-241, s. 15(117.1).
[125] Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act, SOR/2024-241, ss. 27–28.
[126] Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 4(6).
[127] *See* AbbVie Corp. v. Minister of Health, 2022 FC 1209 (currently under appeal to Federal Court of Appeal).
[128] AstraZeneca Can. Inc. v. Apotex Inc., 2017 SCC 36, paras. 29–31.

AstraZeneca Canada Inc. v. Apotex Inc., calling the doctrine "unsound."[129] The SCC held that the promise doctrine was "excessively onerous" on patentees, 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.[130]

Despite this rejection, the SCC held that "[t]he scheme of the Act treats the mischief of overpromising in multiple ways" and specifically stated a number of potential groundings for this potential mischief, including, *inter alia*, overbreadth.[131] The Court's statements 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."[132] 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") stated in a recent decision that:

> It 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 determining which elements go to the core of the invention such that their absence from the claims results in invalidity for overbreadth.[133]

Therefore, the FCA decision could be interpreted as inviting "zealous lawyer[s] to read a patent specification in such a way as to persuade a Court" as to the nature of the "core of the invention."[134] This introduces a similar approach to, and therefore similar uncertainties and onerousness on patentees as, the rejected promise doctrine.

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[129] *AstraZeneca*, 2017 SCC at para. 36.
[130] *AstraZeneca*, 2017 SCC at paras. 37, 44.
[131] *AstraZeneca*, 2017 SCC at para. 46.
[132] W. Oilfield Equip. Rentals Ltd. v. M-I L.L.C., 2021 FCA 24, para. 128.
[133] Seedlings Life Sci. Ventures, LLC v. Pfizer Can. ULC, 2021 FCA 154, paras. 54, 60.
[134] Mylan Pharms. ULC v. Pfizer Can. Inc., 2012 FCA 103, para. 57; *see also* Aux Sable Liquid Prods. LP v. JL Energy Transp. Inc., 2019 FC 581 (invalidating 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,

Elevating the Disclosure Requirement for Patents

IPO is concerned that the FCA has elevated the disclosure requirement for patents. In *Seedlings Life Science Ventures, LLC v. Pfizer Canada ULC*, the FCA stated "[t]he disclosure must teach the skilled person to put into practice all embodiments of the invention, and without exercising inventive ingenuity or undue experimentation" and found a patent for an apparatus for auto-injection of medication was invalid for omitting certain preferred elements from embodiments that were described in the disclosure from the claims.[135] 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.[136] This elevated disclosure requirement would place undue burden on innovators to meet the requirements for a valid patent.

Other Concerns

IPO believes that Canada should be more progressive in amending its laws to better define their boundaries and 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.[137] Canada's file wrapper estoppel rules have also been unfairly applied retroactively and created a significant disruption in existing patent proceedings.[138] 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 Canada has sought public comment on new proposals, the comment periods are sometimes too short, in IPO's view, to allow sufficient time for a thoughtful perspective to be provided. 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 its progress by developing anti-IP laws and proposing unhelpful modifications

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. *Aux Sable*, 2019 FC at paras. 58–60, 65–66.

[135] *Seedlings*, 2021 FCA at para. 68.

[136] *See* Norman Siebrasse, *Enabling After-Arising Technology*, SUFFICIENT DESCRIPTION (Sept. 7, 2021), http://www.sufficientdescription.com/2021/09/enabling-after-arising-technology.html.

[137] Patent Act, R.S.C. 1985, c P-4, s. 56(2).

[138] Patent Act, R.S.C. 1985, c P-4, s. 53.1.

to its regulatory affairs process. Amendments proposed by the Health Committee of the Chamber of Deputies under the Fármacos II bill have been pending since 2015 and would expand compulsory licenses, restrict use of brand names for medications, modify regulatory affairs for bioequivalent drugs, and change the process for regulatory registration of drugs.[139] These developments risk Chile's leading position and threaten continued innovation.

More specifically, IPO is concerned about the doctor's obligation to prescribe medications exclusively by their international common name, not their registered trademark, and the requirement that pharmaceutical packaging must include the international common name of the medicine in letters of a size that, as a whole, use at least one third of one of its main faces.[140] Medicines may only have a "fantasy" name on the container, in a size that, as a whole, does not exceed 50% of the size used for the international common name.[141] Requiring qualified professionals to prescribe drugs using the international common name of the drug will lead the pharmacy to dispense any version of the drug, including bioequivalent drugs, without any input from 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.[142] They are not consistent with internal legislation or with the international treaties Chile has signed.

CHINA

Phase I Economic and Trade Agreement

The U.S. and China entered into Phase I of the Economic and Trade Agreement on January 15, 2020, which promised improvements in IP and tech transfer in China.[143] IPO

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[139] Bulletin No. 9.914-11, Modifica el Código Sanitario Para Regular Los Medicamentos Bioequivalentes Genéricos y Evitar la Integración Vertical de Laboratorios y Farmacias, Marzo 10, 2015 [Modifies the Health Code to Regulate Generic Bioequivalent Drugs and Prevent Vertical Integration of Laboratories and Pharmacies, March 10, 2015].

[140] Indication 040-367, Formula Indicación Al Proyecto de Ley Que Modifica el Código Sanitario Para Regular Los Medicamentos Bioequivalentes Genéricos y Evitar la Integración Vertical de Laboratorios y Farmacias (Boletín N° 9.914-11) s. 1(a), Abril 23, 2019 [Formal Indication to the Bill Amending the Health Code to Regulate Generic Bioequivalent Medicines and Prevent the Vertical Integration of Laboratories and Pharmacies (Bulletin No. 9,914-11) s. 1(a), April 23, 2019].

[141] Indication 040-367, Formula Indicación Al Proyecto de Ley Que Modifica el Código Sanitario Para Regular Los Medicamentos Bioequivalentes Genéricos y Evitar la Integración Vertical de Laboratorios y Farmacias (Boletín N° 9.914-11) s. 1(a), Abril 23, 2019 [Formal Indication to the Bill Amending the Health Code to Regulate Generic Bioequivalent Medicines and Prevent the Vertical Integration of Laboratories and Pharmacies (Bulletin No. 9,914-11) s. 1(a), April 23, 2019].

[142] Bulletin No. 9.914-11, Modifica el Código Sanitario Para Regular Los Medicamentos Bioequivalentes Genéricos y Evitar la Integración Vertical de Laboratorios y Farmacias, Marzo 10, 2015 [Modifies the Health Code to Regulate Generic Bioequivalent Drugs and Prevent Vertical Integration of Laboratories and Pharmacies, March 10, 2015].

[143] Economic and Trade Agreement Between the Government of the United States of America and the Government of the People's Republic of China, China-U.S., Jan. 15, 2020.

notes, in particular, that provisions in Chapter 1 promise needed improvements in trade secret protection, measures to counter bad faith trademarks, and the protection of patents relating to pharmaceuticals.[144] IPO has monitored the implementation of the agreement and continues to do so.

Trade Secrets: Positive Developments and the Need to Upgrade

Trade secret law in China is fragmented, with protection provided under several different legal and administrative provisions, including, among others, those involving anti-unfair competition, contract, and labor laws. However, there have been several promising developments in these differing regimes in recent years. For example, in 2020, China amended its Anti-Unfair Competition Law, the State Administration for Market Regulation published Draft Rules on Trade Secret Protection for public comment, and the Supreme People's Court published Interpretations on Several Issues Concerning the Application of Law in the Trial of Civil Cases of Trade Secret Infringement Disputes.[145] These amendments, rules, and judicial interpretations indicate China's desire for stronger enforcement against trade secret misappropriation and continue a trend of expanded enforcement of trade secret rights in China.

Although these developments are promising, trade secret owners still face significant challenges against protecting their confidential information. High evidentiary burdens, limited discovery, and damages issues are considerable obstacles. Not only is the act of seeking relief difficult, but it can require waiting until additional damage transpires. Under China's criminal law, trade secret theft is determined by the consequences of the loss, as opposed to the act of misappropriation.[146] Even if a trade secret owner knows a theft has taken place, a criminal investigation cannot begin until there is a significant and

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[144] Economic and Trade Agreement Between the Government of the United States of America and the Government of the People's Republic of China, China-U.S., ch. 1, §§ B–C, H, Jan. 15, 2020.

[145] Zhonghua Renmin Gongheguo Fan Bu Zhengdang Jingzheng Fa (中华人民共和国反不正当竞争法) [Anti-Unfair Competition Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., Apr. 23, 2019, effective Apr. 23, 2019), *translated in Law of the People's Republic of China Against Unfair Competition*, WORLD INTELL. PROP. ORG., https://www.wipo.int/wipolex/en/legislation/details/19557 (last visited Dec. 6, 2024); Shangye Mimi Baohu Guiding (Zhengqiu Yijian Gao) (商业秘密保护规定 (征求意见稿)) [Draft Provisions on the Protection of Trade Secrets (Draft for Solicitation of Comments)] (promulgated by the State Admin. for Mkt. Regul., Sept. 4, 2020); Shenli Qinfan Shangye Mimi Minshi Anjian Shiyong Falu Ruogan Wenti De Guiding (审理侵犯商业秘密民事案件适用法律若干问题的规定) [Interpretations on Several Issues Concerning the Application of Law in the Trial of Civil Cases of Trade Secret Infringement] (promulgated by the Sup. People's Ct., Aug. 24, 2020, effective Sept. 12, 2020), *translated in* U.S. Pat. and Trademark Off., *English Translation of Interpretation of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Civil Disputes Over Infringements on Trade Secrets*, CHINA IPR, https://chinaipr.com/wp-content/uploads/2020/06/spc-ji-application-of-law-in-the-trial-of-civil-cases-involving-trade-secrets-embassy-translation.pdf (last visited Dec. 6, 2024).

[146] Zhonghua Renmin Gongheguo Xingfa (1997 Nian Xiudìng) (中华人民共和国刑法 (1997 年修订)) [Criminal Law of the People's Republic of China (Revised in 1997)] (promulgated by the President of the People's Republic of China, Mar. 14, 1997, effective Oct. 1, 1997) art. 219.

possibly irreversible injury.[147] The way a misappropriator uses a trade secret can also affect the ability to obtain relief under civil law. For example, situations where the misappropriator benefits from a trade secret by virtue of accelerated development, rather than actual profits or other unjust gains, are not formally recognized in the determination of damages to be awarded to the trade secret owner. Like its criminal counterpart, the current civil law prevents early intervention to minimize damages.

The requirement for many businesses to submit technical and functional features of their products, as well as confidential test data, for access to the Chinese market present further challenges for protecting confidential business information. Further, China's Patent Law would give local and provincial patent administration and enforcement offices new powers to investigate patent infringement cases, including broad authority to inspect sites where the alleged infringement took place and to review and copy relevant documents.[148] Our members are concerned with the significant risk of trade secret disclosure that could result from administrative investigations and enforcement absent proper safeguards.

The consequences of such disclosures can be particularly harmful because receiving agencies may 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 ("JCCT"), China promised to hold government officials with access to confidential business information accountable and otherwise shield the details from public disclosure, the impact of any changes has yet to be felt.[149]

In summary, our members face high burdens of proof, limited discovery, damages issues, and requirements to submit confidential details to government agencies when seeking to enforce their trade secrets in China. While more preliminary injunctions in the form of conduct preservations have recently been granted in trade secret actions, such relief remains uncommon and unpredictable, particularly in view of the high burden of proof, causing a trade secret owner to not seek relief until a significant and possibly irreversible injury has taken place. Although IPO is encouraged by recent updates, more needs to be done. IPO is encouraged by Section B of the Phase I Economic and Trade Agreement

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[147] A threshold of 500,000 RMB needs to be met. *See* Guanyu Yinfa "Zuigao Renmin Jianchayuan Gong'an Bu Guanyu Gong'an Jiguan Guanxia de Xingshi Anjian Li'an Zhuisu Biaozhun Di Guiding (Er)" de Tongzhi (2022 Xiuding) (关于印发《最高人民检察院 公安部关于公安机关管辖的刑事案件立案追诉标准的 规定（二）》的通知 (2022 修订)) [Notice on Issuing the "Regulations of the Supreme People's Procuratorate and Ministry of Public Security on the Standards for Filing and Prosecuting Criminal Cases under the Jurisdiction of Public Security Organs (II) (Revised in 2022)] (promulgated by the Sup. People's Procuratorate & Ministry of Pub. Sec., Apr. 6, 2022, effective Apr. 29, 2022).

[148] Zhonghua Renmin Gongheguo Zhuanli Fa Xiuzheng An (Cao'an) (中华人民共和国专利法修正案（草案）) [Amendment to the Patent Law of the People's Republic of China (Draft)] (promulgated by the Nat'l People's Cong., Jan. 4, 2019) art. 15.

[149] *U.S.-China Joint Fact Sheet on the 25th U.S.-China Joint Commission on Commerce and Trade*, OFF. OF THE U.S. TRADE REP., https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2014/december/us-china-joint-fact-sheet-25th-us (last visited Jan. 14, 2025).

between the U.S. and China, which if fully implemented, will substantially improve trade secret protection in China.[150]

China Lacks a Meaningful Grace Period for Design Applications

China is one of the few modern countries without a meaningful grace period during which a design owner can file a design application after disclosing the design publicly anywhere in the world. Unsophisticated designers may not appreciate the need to file a design application before disclosing their design, at which point protection will be unavailable in China. Further, grace periods—like those adopted in the U.S., Europe, Japan, South Korea, and Canada, and under consideration in Australia—provide applicants the time and flexibility to consider the need for protection and prepare quality applications. China should be encouraged to adopt a generally applicable grace period of at least six months, and preferably one year.

***Anti-Suit Injunctions*[151]**

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 issues. This topic is particularly difficult to analyze or keep updated in any systematic way due to very limited transparency into anti-suit injunctions in China.[152] In the face of a specific request by the EU, 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.[153] Japan, Canada, and the U.S. joined in the Art. 63.3 Consultation process. IPO remains optimistic that these efforts will yield substantial improvements in due process

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[150] Economic and Trade Agreement Between the Government of the United States of America and the Government of the People's Republic of China, China-U.S., ch. 1, § B, Jan. 15, 2020.

[151] On July 20, 2023, the IPO Board adopted a resolution related to Anti-Suit Injunctions and stating: "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: 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)." *Resolution Related to Anti-Suit Injunctions*, INTELL. PROP. OWNERS ASS'N (July 20, 2023), https://ipo.org/index.php/resolution-related-to-anti-suit-injuntions/.

[152] *See* Letter from Intell. Prop. Owners Ass'n to Daniel Lee, Assistant U.S. Trade Rep. for Innovation and Intell. Prop. 4 (Mar. 7, 2023), https://ipo.org/wp-content/uploads/2023/03/Responses-to-Questions-Intellectual-Property-Owners-Association.pdf.

[153] Request for Information Pursuant to Article 63.3 of the TRIPS Agreement, *European Union—Communication to China*, WTO Doc. IP/C/W/682 (July 6, 2021); Response to Request for Information Pursuant to Article 63.3 of the TRIPS Agreement, *China—Communication to European Union*, WTO Doc. IP/C/W/683 (Sept. 7, 2021).

and transparency. The EU has requested that a panel be set up by the Dispute Settlement Body to examine the matter. The panel has been composed and a report is expected.

Challenges Created by Chinese Trademark Law

Several amendments to China's trademark law became effective on November 1, 2019, and, together with those made in 2013, improved the law by adding a good-faith requirement when applying for new marks and the rejection of bad faith trademark registrations without an intent to use.[154] Yet, brand owners still face substantial challenges in China. 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 China Trademark Law eliminated opposition review, depriving both parties of their rights of action and negatively impacting the already low success rate of opposition in China.[155] Once bad faith registrants receive registration certificates, brand owners bear a heavy burden to invalidate them and risk infringement actions for continuing to use their unregistered mark. Even if the invalidation action goes well, the process takes about one year and the bad faith registrant may continue to appeal to the courts, 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.[156] Although this represents needed progress, China should be encouraged to continue to rein in trademark abuse.

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[154] Zhonghua Renmin Gongheguo Shangbiao Fa (2019 Nian 4 Yue 23 Ri Xiuzheng) (中华人民共和国商标法 (2019 年 4 月 23 日修正)) [Trademark Law of the People's Republic of China (Revised on April 23, 2019)] (promulgated by the Standing Comm. of the Fifth Nat'l People's Cong., Aug 23, 1982, rev'd Apr. 23, 2019) arts. 4, 7, *translated in Trademark Law of the People's Republic of China (Amended up to April 23, 2019), China*, WORLD INTELL. PROP. ORG., https://www.wipo.int/wipolex/en/legislation/details/19559 (last visited Jan. 14, 2025).

[155] Quanguo Renmin Daibiao Dahui Changwu Weiyuanhui Guanyu Xiugai "Zhonghua Renmin Gongheguo Shangbiao Fa" de Jueding (全国人民代表大会常务委员会关于修改《中华人民共和国商标法》的决定) [Decision of the Standing Committee of the National People's Congress on Amending the Trademark Law of the People's Republic of China] (promulgated by the Standing Comm. of the Twelfth Nat'l People's Cong., Aug. 30, 2013).

[156] *See* Zhonghua Renmin Gongheguo Shangbiao Fa (2019 Nian 4 Yue 23 Ri Xiuzheng) (中华人民共和国商标法 (2019 年 4 月 23 日修正)) [Trademark Law of the People's Republic of China (Revised on April 23, 2019)] (promulgated by the Standing Comm. of the Fifth Nat'l People's Cong., Aug 23, 1982, rev'd Apr. 23, 2019) art. 7.

Bad faith trademark filings include those by "trademark squatters," who file applications and obtain registrations on the internationally established trademarks of brand owners, either to sell them back to the brand owner or to confuse consumers. Establishing bad faith in these circumstances is extremely difficult, as 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 authorities should look outside China for evidence of whether a trademark is famous or well known, rather than limiting such inquiry to fame within China. IPO looks forward to seeing more rejections of bad faith trademark applications under the newly amended Article 4 and to implementation of the Phase I Economic and Trade Agreement between the U.S. and China.[157]

Notwithstanding the above, there has been improvement in examinations of trademark applications with concurrent cancellations of conflicting earlier registrations. In the past, this could lead to refusal of the application based on an earlier right that might have been cancelled a few months later, causing both the applicant and the earlier rights holder to file multiple back-up applications with an element of luck in deciding who obtained protection. In June 2023, a new Work System for the Examination and Trial of Trademark Review and Adjudication Cases was issued, allowing examination of such trademark applications to be suspended, such as if a cited earlier registration was subject to cancellation proceedings or was in a renewal grace period.[158] Overall, this has been positive for rights holders by reducing the need to file back-up applications and lowering the cost and complexity of obtaining rights in China.

Incomplete Delinking of Indigenous Innovation from Government Procurement

Since 2011, China has committed to delinking 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.[159] It is clear, however, that a relationship between indigenous innovation and government procurement has continued. Examples have included the catalogue of indigenous innovation products established by the Economic and Information Technology Bureau of Yingzou District and the budget notice from Nanxian County, Hunan, stipulating the same preferences. Therefore, although IPO is

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[157] Zhonghua Renmin Gongheguo Shangbiao Fa (2019 Nian 4 Yue 23 Ri Xiuzheng) (中华人民共和国商标法 (2019 年 4 月 23 日修正)) [Trademark Law of the People's Republic of China (Revised on April 23, 2019)] (promulgated by the Standing Comm. of the Fifth Nat'l People's Cong., Aug 23, 1982, rev'd Apr. 23, 2019) art. 4; Economic and Trade Agreement Between the Government of the United States of America and the Government of the People's Republic of China, China-U.S., art. 1.24, Jan. 15, 2020.

[158] "Pingshen Anjian Zhongzhi Qingxing Guifan" Jiedu (《评审案件中止情形规范》解读) [Interpretation of the Regulations on Suspension of Review Cases] (promulgated by the Trademark Off. of China Nat'l Intell. Prop. Admin., June 13, 2023).

[159] *Status Report: China's Innovation and Government Procurement Policies*, U.S.-CHINA BUS. COUNCIL (May 1, 2013), https://www.uschina.org/wp-content/uploads/2013/06/innovation-status-report.pdf.

encouraged by China's renewed commitment at the 27th JCCT to build on its 2011 commitment, the U.S. should encourage implementation at a more rapid pace.[160]

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

Forced or Pressured 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.[161] Article 22 of the law provides, among other things, that "[n]o administrative department or its staff member shall force any transfer of technology by administrative means."[162] The concern is that this language might prove open to loopholes that would prevent it from 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, as a practical matter, joint venture and data localization requirements for internet, cloud, and biopharmaceutical companies conducting research in China force foreign companies to hand over their IP to local companies in order to participate in the Chinese market. Moreover, the Fourth Amendment to the Patent Act, effective June 1, 2020, increased the power of administrative agencies to investigate patent infringement and seize confidential information, including trade secrets, which could result in disclosure to others, including competitors.[163] 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; where the regulatory agencies share submitted information with competitors (such as technical experts employed by or affiliated with competitors); or where agencies share submitted information with later regulatory applicants (or use it on their behalf). IPO looks forward to 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

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[160] Press Release, U.S. Off. of the Trade Rep., U.S. and Chinese Delegations Conclude the 27th Session of the U.S.-China Joint Commission on Commerce and Trade (Nov. 23, 2016), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2016/november/us-and-chinese-delegations.

[161] Zhonghua Renmin Gongheguo Waishang Touzi Fa (中华人民共和国外商投资法) [Foreign Investment Law of the People's Republic of China] (promulgated by the President of the People's Republic of China, Mar. 15, 2019, effective Jan. 1, 2020).

[162] Zhonghua Renmin Gongheguo Waishang Touzi Fa (中华人民共和国外商投资法) [Foreign Investment Law of the People's Republic of China] (promulgated by the President of the People's Republic of China, Mar. 15, 2019, effective Jan. 1, 2020), art. 22.

[163] Zhonghua Renmin Gongheguo Zhuanli Fa Xiuzheng An (Cao'an) (中华人民共和国专利法修正案（草案）) [Amendment to the Patent Law of the People's Republic of China (Draft)] (promulgated by the Nat'l People's Cong., Jan. 4, 2019) art. 15.

secrets and confidential business information from unauthorized disclosure by government authorities and prohibit forced technology transfer through administrative and licensing requirements.[164]

Patent Enforcement and the Amendment to Chinese Patent Law

Language in China's Fourth Amendment to its Patent Law raises concerns that, in some instances, valid patent rights might not be enforced.[165] Article 20 of the Patent Law requires those who apply for and exercise patent rights to act in good faith and not misuse patents to "damage public interests or other's legal rights."[166] Little detail has been given to explain this principle or guide the courts and administrative agencies that will ultimately be tasked with enforcing it.

There is too much risk and uncertainty that patents might be deemed abnormal and thus invalidated. Although well-intentioned, this would create significant uncertainty and impede the legal exploitation of patents. This also raises questions regarding consistency with TRIPS Article 30, which provides that the exceptions to the exclusive rights conferred by a patent should not "unreasonably conflict with a normal exploitation of the patent" and "unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties."[167]

Moreover, the high and growing volume of utility models in China, combined with the lack of examination with respect to patentability, creates substantial uncertainty for U.S. companies in the Chinese market.[168] Although the China National Intellectual Property Administration ("CNIPA") has acknowledged the extent of the problem by rejecting some utility model applications that are "obviously unpatentable," more safeguards are needed to ensure these patents are not inappropriately used against innovative companies. One such measure would be to automatically stay infringement proceedings until timely invalidation requests have been resolved.

The Fourth Amendment to the Patent Law continues to expand administrative enforcement of patent rights by giving hundreds of inexperienced local and provincial patent administration and enforcement offices new powers to investigate, inspect, grant injunctive relief, impose compensatory damages, fines, and penalties for patent

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[164] Economic and Trade Agreement Between the Government of the United States of America and the Government of the People's Republic of China, China-U.S., arts. 1.9, 2.3, Jan. 15, 2020.

[165] Zhonghua Renmin Gongheguo Zhuanli Fa Xiuzheng An (Cao'an) (中华人民共和国专利法修正案（草案）) [Amendment to the Patent Law of the People's Republic of China (Draft)] (promulgated by the Nat'l People's Cong., Jan. 4, 2019).

[166] Zhonghua Renmin Gongheguo Zhuanli Fa Xiuzheng An (Cao'an) (中华人民共和国专利法修正案（草案）) [Amendment to the Patent Law of the People's Republic of China (Draft)] (promulgated by the Nat'l People's Cong., Jan. 4, 2019) art. 2.

[167] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights art. 30, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 300.

[168] *See* STATE INTELL. PROP. OFF. OF CHINA, 2017 SIPO ANNUAL REPORT 45 (2018) (stating that in 2017, utility model applications grew by over 22%).

infringement, and even to enhance damages if the infringement is deemed willful.[169] One of the effects of the Fourth Amendment is to allow primarily Chinese domestic entities or individuals to assert their rights before local and administrative officials, who might not be technologically and legally qualified, without clear guidance tying any award to the value of the patent. Currently, such proceedings are entrusted only to certain courts selected by the Supreme People's Court due to concerns about the complexity of patent cases. This change would fragment enforcement, interpretations, and procedures regarding patent laws and related rights, making enforcement in China less predictable and extremely difficult to navigate.

To be more effective, China's patent system should allow for appropriate recourse through 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 revisions to the Patent Examination Guidelines, implemented by CNIPA on January 15, 2021, whereby supplementary data can be conditionally accepted to prove both sufficient disclosure and inventive step, even if the applications as filed do not provide any data.[170] IPO believes these changes foster timely filing of applications for new drugs by allowing applicants to later submit additional information consistent with the drug development process. 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.[171]

IPO is encouraged by CNIPA's effort to improve patent quality and examination process of invention patent applications containing algorithm or business rule and method features, as indicated by the Draft of the Amendment to the Examination Guidelines (Second Batch of Draft for Solicitation published on November 10, 2020).[172] However,

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[169] Zhonghua Renmin Gongheguo Zhuanli Fa Xiuzheng An (Cao'an) (中华人民共和国专利法修正案(草案)) [Amendment to the Patent Law of the People's Republic of China (Draft)] (promulgated by the Nat'l People's Cong., Jan. 4, 2019).

[170] Guojia Zhishi Chanquan Ju Guanyu Xiugai "Zhuanli Shencha Zhinan" De Gonggao (Di 391 Hao) (国家知识产权局关于修改《专利审查指南》的公告（第 391 号）) [Announcement of the State Intellectual Property Office on the Revision of the Patent Examination Guidelines (No. 391)] (promulgated by the State Intell. Prop. Off., Dec. 11, 2020, effective Jan. 15, 2021) art. I.

[171] Guojia Zhishi Chanquan Ju Guanyu Xiugai "Zhuanli Shencha Zhinan" De Gonggao (Di 391 Hao) (国家知识产权局关于修改《专利审查指南》的公告（第 391 号）) [Announcement of the State Intellectual Property Office on the Revision of the Patent Examination Guidelines (No. 391)] (promulgated by the State Intell. Prop. Off., Dec. 11, 2020, effective Jan. 15, 2021).

[172] Guanyu Jiu "Zhuanli Shencha Zhinan Xiugai Cao'an (Di Er Pi Zhengqiu Yijian Gao)" Gongkai Zhengqiu Yijian De Tongzhi (关于就《专利审查指南修改草案（第二批征求意见稿）》公开征求意见的通知) [Notice on Soliciting Public Opinions on the Draft Amendments to the Patent

this amendment introduces confusion as to patentable subject matter for computer programs and further clarity is needed on whether an invention includes a "technical means."[173] IPO is concerned about these changes, which are being made at a relatively low level (via examination guidelines), substantively impacting the patentability standards for computer programs and causing broader confusion on how to apply patentability standards, without being coherently addressed in higher-order changes to the laws or regulations.

IPO notes that the Beijing IP Court embarked upon an initiative to use guiding cases in deciding IP cases, including establishing a database of guiding cases and a research organization for identifying guiding cases to add to the database. Such efforts reveal a desire on the part of China's judiciary to help bring transparency and predictability to enforcement of IP rights in China, which will be further improved if a system of guiding cases can be adopted by more IP courts.

The Supreme People's Court Intellectual Property Court, a centralized tribunal for hearing appeals in IP cases, began operating on January 1, 2019. By the end of 2019 the Court reported that it had closed 1,433 cases, but only about 20-30 had been published. The establishment of this court may bring predictability to enforcement of IP rights in China, but the relatively few decisions published to date raises concerns about the transparency of such enforcement.

Judicial transparency is critical to ensuring fairness to parties and consistent case law development and lack of transparency continues to pose challenges for parties using the Chinese court system. In 2014, China mandated public access to all judicial decisions via a database called China Judgments Online.[174] Although this mandate increased the availability of judicial decisions, courts in China have still not been consistently publishing decisions. Indeed, observers have concluded that Chinese courts appear to publish only around half of their patent judgments.[175] Even in the face of a specific request by the EU, which filed an Article 63.3 request at the WTO on July 6, 2021 requesting further information on four SEP cases in China, China failed to make those

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Examination Guidelines (Second Draft for Comments)] (promulgated by the China Nat'l Intell. Prop. Admin., Nov. 10, 2020).

[173] Guanyu Jiu "Zhuanli Shencha Zhinan Xiugai Cao'an (Di Er Pi Zhengqiu Yijian Gao)" Gongkai Zhengqiu Yijian De Tongzhi (关于就《专利审查指南修改草案（第二批征求意见稿）》公开征求意见的通知) [Notice on Soliciting Public Opinions on the Draft Amendments to the Patent Examination Guidelines (Second Draft for Comments] (promulgated by the China Nat'l Intell. Prop. Admin., Nov. 10, 2020) attach. 2.

[174] *China Judgements Online*, SUP. PEOPLE'S CT. OF CHINA, http://wenshu.court.gov.cn/ (last visited Jan. 14, 2025); *see also* Jeffery Langer, *Rapid Changes in the Chinese Legal System, an Increasingly Attractive Venue for IP Litigation*, IPWATCHDOG (May 7, 2018, 9:15 AM), https://www.ipwatchdog.com/2018/05/07/rapid-changes-chinese-legal-system-attractive-venue-iplitigation/id=96099/.

[175] Chris Bailey, Douglas Clark, Mark Cohen & Aria Tian, *Chinese Patent Litigation Data: What It Tells Us and What It Doesn't*, IAM (Nov. 17, 2021), https://www.iam-media.com/article/chinese-patent-litigation-data-what-it-tells-us-and-what-it-doesnt.

decisions public.[176] Additionally, some parties have observed delays of one year or more from the decision to publication. IPO recommends that China implement measures to ensure that all courts comply with the mandate to publish decisions in a timely manner.

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

Potential Negative Impact of Laws and Regulations Regarding Service Inventions

Article 15 of the Patent Law lists specific examples of incentive mechanisms for employers to share innovation profit with service inventors, which IPO believes is unnecessary and might cause confusion.[177] Article 15 already requires an employer entity give the inventor or designer of a service invention a reasonable amount of remuneration, but without specifying exactly how.[178] IPO is concerned that the listed examples of incentive mechanisms in Article 15 could be misinterpreted as requiring share-based awards as the only acceptable type of remuneration and, thereby, as limiting the employer's freedom in remunerating its employees. IPO would like to see clarification that the obligation under Article 15 of the Patent Law to give inventors remuneration shall be considered satisfied by compliance with an employer's invention remuneration rules, regulations, plan, policy, or compliance with an agreement between employer and inventor regarding inventor remuneration, preferably in the final Implementing Regulations of the Patent Law. IPO notes that the current Implementing Regulations (finalized in December 2023) acknowledge that employers and employees may agree to reward and remuneration as required under Article 15.[179]

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[176] Request for Information Pursuant to Article 63.3 of the TRIPS Agreement, *European Union—Communication to China*, WTO Doc. IP/C/W/682 (July 6, 2021); Response to Request for Information Pursuant to Article 63.3 of the TRIPS Agreement, *China—Communication to European Union*, WTO Doc. IP/C/W/683 (Sept. 7, 2021).

[177] Zhonghua Renmin Gongheguo Zhuanli Fa (2020 Nian Xiuzheng) (中华人民共和国专利法(2020 年修正)) [Patent Law of the People's Republic of China (Revised in 2020)] (promulgated by the Standing Comm. of the Sixth Nat'l People's Cong., Mar. 12, 1984, rev'd Oct. 17, 2020) art. 15, *translated in Patent Law of the People's Republic of China (Translation for Reference Only)*, CHINA NAT'L INTELL. PROP. ADMIN. (Oct. 13, 2022), https://english.cnipa.gov.cn/col/col3068/index.html.

[178] Zhonghua Renmin Gongheguo Zhuanli Fa (2020 Nian Xiuzheng) (中华人民共和国专利法(2020 年修正)) [Patent Law of the People's Republic of China (Revised in 2020)] (promulgated by the Standing Comm. of the Sixth Nat'l People's Cong., Mar. 12, 1984, rev'd Oct. 17, 2020) art. 15.

[179] Guowuyuan Guanyu Xiugai "Zhonghua Renmin Gongheguo Zhuanli Fa Shishi Xize" De Jueding (国务院关于修改《中华人民共和国 专利法实施细则》的决定) [Decision of the State Council on Amending the Implementing Rules of the Patent Law of the People's Republic of China] (promulgated by the Prime Minister of China, Dec. 11, 2023, effective Jan. 20, 2023) para. 42.

Unique Challenges to Pharmaceutical Protection

Our members welcome the patent term extension for pharmaceutical products in Article 42 of the Fourth Amendment to the Patent Law.[180] The National Medical Products Administration ("NMPA") and CNIPA published Draft Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes ("Draft Measures") on September 11, 2020.[181] The Supreme People's Court also published the Provisions on Several Issues Concerning the Application of Law in the Trial of Patent Civil Cases Involving Drug Marketing Review and Approval (Draft for Solicitation of Comments) ("Draft Provisions") on October 29, 2020.

The patent linkage provisions are new for China. A fair and effective linkage system for China will need both to balance the interests of generics and innovators, and provide consistency between the courts and the range of concerned administrative agencies.

Synchronous reforms to the relevant laws and regulations are necessary to enable stakeholders to consider the proposed scheme fully and holistically. Furthermore, rules and judicial interpretations should be harmonized with higher level laws and regulations. Article 76 of the Patent Law is directed to drug marketing applications.[182] 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.

IPO is concerned about the absence of a time limit for the court to issue a decision in the Draft Measures. The current version of the NMPA/CNIPA's Draft Measures has a nine-month time limit for litigation to conclude, which the Draft Provisions do not.[183] Failure to conclude the litigation within nine 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 nine-month time limit applies only to small molecules and not biologics.

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[180] Zhonghua Renmin Gongheguo Zhuanli Fa Xiuzheng An (Cao'an) (中华人民共和国专利法修正案（草案)) [Amendment to the Patent Law of the People's Republic of China (Draft)] (promulgated by the Nat'l People's Cong., Jan. 4, 2019) art. 7.

[181] Yaopin Zhuanli Jiufen Zaoq Jiejue Jizhi Shishi Banfa (Shixing) (药品专利纠纷早期解决机制实施办法（试行)) [Trial Implementing Measures of Early Resolution Mechanism for Drug Patent Disputes (Draft for Comment)] (promulgated by the China Nat'l Med. Prods. Admin. & Nat'l Intell. Prop. Admin, July 4, 2021, effective July 4, 2021), *translated in English Translation of Trial Implementing Measures of Early Mechanism for Drug Patent Disputes (Draft for Comment)*, U.S. PAT. & TRADEMARK OFF., https://chinaipr.com/wp-content/uploads/2021/05/nmpa-cnipa-draft-measures-of-early-resolution-mechanism-for-drug-patent-disputes-eng-embtranslation-1.docx (last visited Jan. 14, 2025).

[182] Zhonghua Renmin Gongheguo Zhuanli Fa (2020 Nian Xiuzheng) (中华人民共和国专利法 (2020 年修正)) [Patent Law of the People's Republic of China (Revised in 2020)] (promulgated by the Standing Comm. of the Sixth Nat'l People's Cong., Mar. 12, 1984, rev'd Oct. 17, 2020) art. 76.

[183] Yaopin Zhuanli Jiufen Zaoq Jiejue Jizhi Shishi Banfa (Shixing) (药品专利纠纷早期解决机制实施办法（试行)) [Trial Implementing Measures of Early Resolution Mechanism for Drug Patent Disputes (Draft for Comment)] (promulgated by the China Nat'l Med. Prods. Admin. & Nat'l Intell. Prop. Admin, July 4, 2021, effective July 4, 2021) art. 8.

Article 1.11(a) of the Phase One Agreement sets out that China shall provide "a system to provide notice to a patent holder, licensee, or holder of marketing approval, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use."[184] IPO is concerned about the lack of a requirement in the NMPA/CNIPA's Draft Measures for a generic drug applicant to notify the marketing authorization holder when it makes a patent statement in its generic drug application. The patentee or interested party opposing such a patent statement is given a 45-day window from the date when NMPA makes the generic drug application public to bring an action.[185] Without notification, the patentee or interested party may have very limited time to prepare for a litigation by the end of the 45-day window.

In addition, the requirement of simultaneous market approval applications in China and abroad is burdensome to innovative pharmaceutical companies.

With respect to patent examination, China 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.[186] This is a welcome step, however, concerns remain that CNIPA appears to be imposing new and unfair or inappropriate limitations and interpretations of the new amendment, especially at the Patent Reexamination and Invalidation Department level, on the use of post-filing data to satisfy inventive step requirements.

The situation has improved somewhat with respect to counterfeit medicines, as China has implemented plans to improve drug safety and severely crack down on the production and sale of counterfeits. 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.[187] Hiring a third party, however, can increase both the expense and the risk that confidential information is lost in the application process. For

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[184] Economic and Trade Agreement Between the Government of the United States of America and the Government of the People's Republic of China, China-U.S., art. 1.11, Jan. 15, 2020.

[185] Yaopin Zhuanli Jiufen Zaoq Jiejue Jizhi Shishi Banfa (Shixing) (药品专利纠纷早期解决机制实施办法（试行)) [Trial Implementing Measures of Early Resolution Mechanism for Drug Patent Disputes (Draft for Comment)] (promulgated by the China Nat'l Med. Prods. Admin. & Nat'l Intell. Prop. Admin, July 4, 2021, effective July 4, 2021) art. 7.

[186] CHINA STATE INTELL. PROP. OFF., ZHUANLI SHENCHA ZHINAN (专利审查指南) [Patent Examination Guidelines] (2023).

[187] Zhonghua Renmin Gongheguo Zhuanli Fa (2020 Nian Xiuzheng) (中华人民共和国专利法(2020 年修正)) [Patent Law of the People's Republic of China (Revised in 2020)] (promulgated by the Standing Comm. of the Sixth Nat'l People's Cong., Mar. 12, 1984, rev'd Oct. 17, 2020) art. 18.

companies with significant operations in foreign countries, it is not uncommon to have in-house operations that manage the patent application process, including application filing. 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 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.

COLOMBIA

Compulsory Licenses

Until recently, no compulsory licenses had been granted in Colombia over the past ten years, despite initiation of some investigations. However, on April 24, 2024, Colombia's Patent Office, the Superintendence of Industry and Commerce ("SIC"), issued its first-ever compulsory license to the Ministry of Health ("MoH") for Patent 1887, owned by VIIV Healthcare Company and Shionogi & Co. Ltd., which covers Dolutegravir, a drug used in the treatment and prevention of HIV/AIDS, for public interest reasons.[188] The compulsory license is restricted to government use, allowing the MoH to manufacture and import Dolutegravir formulations. It will remain in effect until the patent expires on April 28, 2026 or until the public interest conditions no longer apply.[189] Under the terms of the license, the MoH must compensate the patent holders at a rate of 0.11 Colombian pesos/mg (approximately USD 0.000025/mg) of Dolutegravir produced or imported.[190] The SIC has also permitted the MoH to use centralized purchasing mechanisms to secure the drug's availability.

This compulsory license followed a Declaration of Public Interest ("DPI") initiated by the MoH in June 2023, a necessary step before issuing a compulsory license.[191] Despite opposition from the patent holders, the MoH upheld its DPI decision in December 2023, citing several factors, including: the rising number of HIV cases in Colombia; Dolutegravir's proven pharmacological benefits; and the need to provide treatment to vulnerable populations, including migrants.[192]

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[188] Superintendencia de Industria y Comercio, Resolución 20049, Abril 23, 2024 [Superintendence of Industry and Commerce, Resolution 20049, April 23, 2024].

[189] Superintendencia de Industria y Comercio, Resolución 20049, Abril 23, 2024 [Superintendence of Industry and Commerce, Resolution 20049, April 23, 2024], art. 2.2.

[190] Superintendencia de Industria y Comercio, Resolución 20049, Abril, 23, 2024 [Superintendence of Industry and Commerce, Resolution 20049, April 23, 2024].

[191] Ministerio de Salud y Protección Social, Resolución 881, Junio 2, 2023 [Ministry of Health and Social Protection, Resolution 881, June 2, 2023].

[192] Ministerio de Salud y Protección Social, Resolución 2024, Diciembre 1, 2023 [Ministry of Health and Social Protection, Resolution 2024, December 1, 2023].

It is a matter of concern that the MoH reported 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. However, to date there is no knowledge of any new declarations initiated against any other medicine, nor have any additional compulsory licenses been granted for Dolutegravir to the other two laboratories that filed license requests before the SIC. IPO is also concerned about suggestions that the New National Development Plan, which is currently under development, should encourage compulsory licensing.[193]

Industrial Designs

In 2022, SIC issued new guidelines for filing and prosecuting industrial designs.[194] Given that, in 2024, the Andean Community issued the Andean Industrial Design Manual ("AIDM"), it is possible that the guidelines issued by SIC will not be applied.[195] For example, the AIDM allows the use of colors in 3D designs, while the Colombian Guidelines do not, and the use of dotted lines in design applications, as allowed by SIC, is also confirmed in the AIDM.[196] Clarity on which guidelines will be applied would be helpful.

Patent Prosecution

In February 2024, Colombia's President appointed a new Superintendent of Industry and Commerce. Since her appointment, the Superintendent has established new procedures to schedule interviews with examiners and other officials within SIC. It is of great concern that IP users have not been able to schedule meetings with either the Superintendent or her delegates to discuss pressing issues such as renewed objections in office actions, the impact of changing examiners during prosecution of an application, or the lack of training for new examiners. Similarly, applicants have been receiving objections containing elemental misinterpretations of the law or science, particularly in cases related to pharma and biotech inventions.

The landscape today is very different from what was reported for 2023, wherein SIC experienced a record year for issuing final decisions. SIC now has a backlog going back to 2022 in cases where administrative remedies were filed against a first non-final decision.

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[193] Proyecto de Ley 274, Mayo 5, 2023 [Bill 274, May 5, 2023], art. 170.

[194] Superintendencia de Industria y Comercio, Resolución 60452, Septiembre 5, 2022 [Superintendence of Industry and Commerce, Resolution 60452, September 5, 2022].

[195] COMUNIDAD ANDINA, MANUAL PARA EL EXAMEN DE DISEÑOS INDUSTRIALES EN PAÍSE DE LA COMUNIDAD ANDINA [Andean Community, Manual for the Examination of Industrial Designs in Countries of the Andean Community] (2024).

[196] COMUNIDAD ANDINA, MANUAL PARA EL EXAMEN DE DISEÑOS INDUSTRIALES EN PAÍSE DE LA COMUNIDAD ANDINA (2024) [Andean Community, Manual for the Examination of Industrial Designs in Countries of the Andean Community]; Superintendencia de Industria y Comercio, Resolución 60452, Septiembre 5, 2022 [Superintendence of Industry and Commerce, Resolution 60452, September 5, 2022].

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

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 Report No. 161 entitled Review of the Intellectual Property Rights Regime in India before both houses of the Parliament ("Report No. 161").[197] Report No. 161 made 82 recommendations towards strengthening India's IP rights regime, which included: (a) the need for an immediate review of the National Intellectual Property Rights Policy 2016 by the Department for Promotion of Industry and Internal Trade; (b) enacting separate legislation or framework for protection of trade secrets; (c) re-establishing, instead of abolishing, the Intellectual Property Appellate Board ("IPAB") with greater autonomy and reforms; (d) establishment of dedicated IP benches at High Courts; (e) exploring and enabling PPH programs with other countries; (f) including a mechanism to safeguard against the arbitrary exercise of power by the CGPDTM in declining patents; and (g) enacting specific legislation to curb counterfeiting and piracy.[198] On April 6, 2022, the Parliamentary Standing Committee presented before both houses of the Parliament Report No. 169 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 ("Report No. 169").[199] As per Report No. 169, it was recorded that out of 82 recommendations: (a) 48 were accepted by the government; (b) 21 were not pursued in light of government response; (c) 12 responses received from government were not accepted by Committee; and (d) one response was not received from the government.[200]

The government's positive response to recommendations for separate legislation protecting trade secrets, as detailed in Report No. 169, including its report on a draft text of a trade secrets bill and formation of a working group for a new PPH program with

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[197] PARLIAMENT OF INDIA RAJYA SABHA DEP'T RELATED PARLIAMENTARY STANDING COMM. ON COM., ONE HUNDRED AND SIXTY FIRST REPORT: REVIEW OF THE INTELLECTUAL PROPERTY RIGHTS REGIME IN INDIA (2021) [hereinafter STANDING COMM. ON COM., 161ST REPORT].

[198] STANDING COMM. ON COM., 161ST REPORT at 96, 100, 101, 102, 103–104, 111, 114. "CGPDTM" refers to the Controller General of Patents, Designs, and Trademarks, whose office is responsible for administering intellectual property laws in India.

[199] PARLIAMENT OF INDIA RAJYA SABHA DEP'T RELATED PARLIAMENTARY STANDING COMM. ON COM., ONE HUNDRED AND SIXTY NINTH REPORT: ACTION TAKEN BY GOVERNMENT ON THE RECOMMENDATIONS/OBSERVATIONS OF THE COMMITTEE CONTAINED IN ITS ONE HUNDRED AND SIXTY FIRST REPORT ON 'REVIEW OF THE INTELLECTUAL PROPERTY RIGHTS REGIME IN INDIA' (2022) [hereinafter STANDING COMM. ON COM., 169TH REPORT].

[200] STANDING COMM. ON COM., 169TH REPORT at 1.

Denmark, was encouraging.[201] However, IPO notes that the government's response was vague and generic in respect to many key issues, such as arbitrary exercise of power by the controller in refusing patents, resolution of the patentability criteria, and disqualification of incremental inventions under Section 3(d), as flagged by the USTR in its 2023 Special 301 Report.[202] Report No. 169 made further recommendations, including amending legislation and regulations to enable protection of AI-related inventions and establishing IP divisions in all High Courts.[203] A summary of these proposals can be found in the official press release.[204]

National Intellectual Property Rights Policy

Overall, India's National Intellectual Property Rights Policy (the "IPR Policy"), as 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.[205] Among other positive proposals, IPO is encouraged by the IPR Policy's recommendation to further study the protection of trade secrets.[206] As discussed below, improving India's trade secret regime is critical to ensuring a level playing field for non-Indian innovators.

Although much of the IPR Policy is still being implemented, some recommendations should be closely monitored. For example, item 2.16 in the IPR Policy proposes statutory incentives (such as tax benefits linked to IP creation) for the entire value chain from IP creation to commercialization.[207] Although incentivizing IP protection and its use is a laudable objective, caution should be exercised to prevent frivolous filings made solely to benefit from this initiative. Regarding the tax benefits, clarity is needed on how IP creation is to be valued. 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 the 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.[208]

Taken as a whole, the IPR Policy includes many positive actions for improving India's IP system, but, while there have been some efforts made, IPO has yet to see a sustained and organized implementation of several key objectives. In its Report No. 161, the Parliamentary Committee recommended a review of the IPR Policy after five years,

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[201] STANDING COMM. ON COM., 169TH REPORT at 12, 32.
[202] STANDING COMM. ON COM., 169TH REPORT at 12, 13–14.
[203] STANDING COMM. ON COM., 169TH REPORT at 76, 77–78.
[204] Press Release, Dep't Related Parliamentary Standing Comm. on Com., Recommendations/Observations – At a Glance (Apr. 15, 2022).
[205] MINISTRY OF COM. & INDUS. DEP'T OF INDUS. POL'Y & PROMOTION, NATIONAL INTELLECTUAL PROPERTY RIGHTS POLICY (2016).
[206] MINISTRY OF COM. & INDUS. DEP'T OF INDUS. POL'Y & PROMOTION, NATIONAL INTELLECTUAL PROPERTY RIGHTS POLICY 10 (2016).
[207] MINISTRY OF COM. & INDUS. DEP'T OF INDUS. POL'Y & PROMOTION, NATIONAL INTELLECTUAL PROPERTY RIGHTS POLICY 8 (2016).
[208] MINISTRY OF COM. & INDUS. DEP'T OF INDUS. POL'Y & PROMOTION, NATIONAL INTELLECTUAL PROPERTY RIGHTS POLICY 10, 12, 17 (2016).

however, Report No. 169 indicates a further review is not being pursued.[209] In July 2023, the Indian government identified and summarized impacts of the IPR Policy in its "Compendium of Intellectual Property Rights" Report.[210] On July 21, 2023, the Union Minister of State for Commerce and Industry also released an update under the Intellectual Property Rights Policy Management Framework of the IPR Policy, which provided updates on 11 objectives, including the Patent Facilitation Program and creation of Technology Innovation Support Centers.[211] The U.S. should continue to monitor the implementation of the IPR Policy as it unfolds.

Delays in Patent Examination and Pre-Grant Oppositions

Delays owing to pre-grant oppositions: In 2023, Hidayatullah National Law University, a leading law school, published a study in which it analyzed 250 patent applications with ongoing opposition proceedings in India over a five-year period between 2016 and 2021.[212] According to its results, serial oppositions, benami oppositions (filed by vested interests on behalf of others), and delays in issuing notices of opposition by the controller contributed most towards delays in the grant of patents, with an average timeframe of 120, 114, and 42 months, respectively.[213] In addition, there was no timeline within which such oppositions could be filed or the controller must issue notice, thus resulting in inordinate delay in the grant of patents.[214] The study also stated that there was an average delay of nine years in the grant of patents, which significantly undermines the effort put in by innovators.[215]

IPO suggests there should be a time limit of six to 12 months from the date of publication of a patent application for filing a pre-grant opposition. In fact, in its August 2022 Report ("EAC-PM Report"), the Economic Advisory Council to the Prime Minister ("EAC-PM") recommended a pre-grant window within six months from the date of issuance of the First Examination Report ("FER").[216]

In a positive move, some of these issues were addressed in the Patents (Amendment) Rules, 2024 which came into force on March 15, 2024.[217] An official fee was instituted

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[209] STANDING COMM. ON COM., 161ST REPORT at 4; STANDING COMM. ON COM., 169TH REPORT at 41–42.
[210] MINISTRY OF SCI. & TECH. DEP'T OF SCI. & INDUS. RSCH., COMPENDIUM OF INTELLECTUAL PROPERTY RIGHTS 10 (2023).
[211] Press Release, Ministry of Com. & Indus., Intellectual Property Rights Policy Management Framework Covers 8 Types of Intellectual Property Rights (July 21, 2023).
[212] V.C. VIVEKANANDAN, UDAY SHANKAR & GARIMA PANWAR, HIDAYATULLAH NAT'L L. UNIV., A STUDY OF PATENT OPPOSITION SYSTEM 10 (2023).
[213] V.C. VIVEKANANDAN, UDAY SHANKAR & GARIMA PANWAR, HIDAYATULLAH NAT'L L. UNIV., A STUDY OF PATENT OPPOSITION SYSTEM 20, 22 (2023).
[214] V.C. VIVEKANANDAN, UDAY SHANKAR & GARIMA PANWAR, HIDAYATULLAH NAT'L L. UNIV., A STUDY OF PATENT OPPOSITION SYSTEM 22, 23 (2023).
[215] V.C. VIVEKANANDAN, UDAY SHANKAR & GARIMA PANWAR, HIDAYATULLAH NAT'L L. UNIV., A STUDY OF PATENT OPPOSITION SYSTEM 18 (2023).
[216] SANJEEV SANYAL & AAKANKSHA ARORA, ECON. ADVISORY COUNCIL TO THE PM, WHY INDIA NEEDS TO URGENTLY INVEST IN ITS PATENT ECOSYSTEM? 10 (2022).
[217] Ministry of Commerce and Industry, Patents (Amendment) Rules, 2024, G.S.R. 211(E) (Notified on Mar. 15, 2024).

for filing a pre-grant opposition, which may help curb frivolous oppositions. Upon being served with a notice of representation, the applicant is required to file its statement and evidence with two months from notice (instead of the earlier timeframe of three months). Awarding of costs, notice to attend the hearing, etc. (currently applicable to post-grant oppositions) are now applicable to pre-grant proceedings. The controller is now required to first decide (with a reasoned order) on *prima facie* maintainability of the pre-grant opposition within one month of the representation. The Applicant is to be notified only once a *prima facie* case is made out. If no *prima facie* case is made out, the Opponent is to be provided an opportunity of hearing, if requested, and a reasoned order of refusal is to be recorded. If a *prima facie* case of pre-grant opposition is made out, the application is to be examined on an expedited basis (FER to be issued within two to four months).

Delays and poor quality of examination owing to insufficient workforce and proper training: Further, the EAC-PM Report identifies that while the number of examiners (those responsible for issuing first office actions) at the Indian Patent Office appears to be adequate, there is an acute shortage of controllers (those responsible for further examination, hearings, and disposal of patent applications).[218] The EAC-PM Report mentions that from 2019–2022 there were only 247 controllers in India and it relies upon recommendations of Report No. 161 to suggest an urgent increase in manpower, particularly controllers.[219]

The August 2023 Annual Capacity Building Plan ("ACBP") for the CGPDTM, under its National Priority Objectives, records the CGPDTM's primary vision of "achieving near-zero" pendency by the year 2025.[220] The ACBP relies upon the EAC-PM Report to further emphasize "*the shortage of workforce and procedural issues are major contributing factors to increased pendencies and delays*."[221] The ACBP proposes rationalization of the roles of the existing workforce to address the delays in processing patent applications and adopts short-term, mid-term, and long-term visions, including the training of existing examiners and controllers as short-term objective.[222] In December 2023, the Patent Office, through the National Testing Agency, issued notice of 553 examiner posts, which is likely to increase the manpower in terms of examiners.[223] 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) and the stated target is to have 963 examiners and 998 controllers by 2026.

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[218] SANJEEV SANYAL & AAKANKSHA ARORA, ECON. ADVISORY COUNCIL TO THE PM, WHY INDIA NEEDS TO URGENTLY INVEST IN ITS PATENT ECOSYSTEM? 4 (2022).

[219] SANJEEV SANYAL & AAKANKSHA ARORA, ECON. ADVISORY COUNCIL TO THE PM, WHY INDIA NEEDS TO URGENTLY INVEST IN ITS PATENT ECOSYSTEM? 5 (2022).

[220] OFF. OF THE CONTROLLER GEN. OF PATS., DESIGNS & TRADE MARKS, ANNUAL CAPACITY BUILDING PLAN REPORT 13 (2023).

[221] OFF. OF THE CONTROLLER GEN. OF PATS., DESIGNS & TRADE MARKS, ANNUAL CAPACITY BUILDING PLAN REPORT 53 (2023) (emphasis added).

[222] OFF. OF THE CONTROLLER GEN. OF PATS., DESIGNS & TRADE MARKS, ANNUAL CAPACITY BUILDING PLAN REPORT 23 (2023).

[223] National Testing Agency, Conduct of the Recruitment for the Post of Examiner of Patents and Designs Against 553 Vacancies (Notified on December 11, 2023).

According to the EAC-PM Report, whereas the global best practice for patent disposal lies within two to three years, in India, the average time taken is just under five years.[224] While this is being addressed through recruitment and training drives, the Patent Office also appointed nearly treble the number of hearings between November 2023 and April 2024 as it did previously to clear backlogs and reduce the time taken for an application to proceed to grant. Consequently, more than 1,000,000 patents have been granted in the last two fiscal years and the time from first office action to disposal has been reduced.[225] Meanwhile, a "Quality Cell" has been established to ensure consistent and quality driven decision making.

Thus, it is suggested that the Indian Patent Office 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.

Additionally, India entered into its first ever PPH program with the Japan Patent Office in 2019 and the Parliamentary Committee noted in Report No. 169 that a working group has been formed for a new PPH program with Denmark.[226] IPO hopes that India enters into PPH arrangements with other IP Offices.

Higher Threshold of Patentability for Pharmaceutical Inventions

India's Patents 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.[227] 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 Report No. 161, the Parliamentary Committee, while supporting and upholding the validity and utility of Section 3(d) under the Indian Patents Act, observed concerns raised by USTR and recommended resolution of the issue through a bilateral dialogue with the U.S.[228] The Indian Government has not provided a specific response to the recommendation, other than that a stakeholders meeting has been conducted.[229]

Further, India's 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.

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[224] SANJEEV SANYAL & AAKANKSHA ARORA, ECON. ADVISORY COUNCIL TO THE PM, WHY INDIA NEEDS TO URGENTLY INVEST IN ITS PATENT ECOSYSTEM? 3 (2022).

[225] Press Release, Ministry of Com. & Indus., Patent Office Grants One Lakh Patents in One Year (Mar. 16, 2024); Press Release, Ministry of Com. & Indus., Indian Patent Office Has Granted 1,03,057 Patents in FY 2023-24 (July 30, 2024).

[226] STANDING COMM. ON COM., 169TH REPORT at 12.

[227] The Patent Acts, 1970, §3(d).

[228] STANDING COMM. ON COM., 161ST REPORT at 30.

[229] STANDING COMM. ON COM., 169TH REPORT at 14.

Compulsory Licensing

It is appreciated that the Government of India took a positive and firm stand via an affidavit against a plea for grant of a compulsory license before the Supreme Court of India, reciting that it would be "presumptuous to assume that the patent holder will not agree to more voluntary licenses."[230] However, in Report No. 161, the Parliamentary Committee recommended that "the Government should delve into the prospect of temporarily waving 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."[231] Also, there have been multiple directions by high courts in public interest litigations suggesting the government invoke compulsory licensing provisions. In response, the government stated that while it 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.[232] 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."[233] 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.[234] TADF is empowered to request compulsory licensing from the Government of India.[235]

Similarly, India's National Competition Policy requires IP owners to grant access to "essential facilities" on "agreed reasonable and nondiscriminatory terms" without reservation.[236] The concept of essential facilities appears to cover a broad range of technologies, including, at least "electricity, communications, gas pipe lines, railway tracks, ports, [and] IT equipment."[237] 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 under the India Patents Act 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

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[230] Affidavit on Behalf of the Union of India, *In re* Distribution of Essential Supplies and Services During Pandemic, Suo Moto Writ Petition (C) No. 3 of 2021, dated Sept. 5, 2021 (SC), 64.
[231] STANDING COMM. ON COM., 161ST REPORT at 62.
[232] STANDING COMM. ON COM., 169TH REPORT at 82–83.
[233] Ministry of Commerce and Industry, National Manufacturing Policy, §4.4.1 (Issued on November 4, 2011).
[234] Ministry of Commerce and Industry, National Manufacturing Policy, §4.4.2 (Issued on November 4, 2011).
[235] Ministry of Commerce and Industry, National Manufacturing Policy, §4.4.3 (Issued on November 4, 2011).
[236] Ministry of Corporate Affairs, National Competition Policy, §5.1(vi) (Issued on July 28, 2011).
[237] Ministry of Corporate Affairs, National Competition Policy, §5.1(vi) (Issued on July 28, 2011).

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 infringement. According to current processes, the Federal and 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. There is also no mechanism for a patent holder to receive information and take preemptive action on any such filings by generic companies. 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 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 new drugs will be respected for the duration of the patent period.

Local Working Requirements

Statutorily, patent holders risk compulsory licensing if they fail to "work" their inventions in India within three years of the respective patent grant.[238]

In a positive move, the Patents (Amendment) Rules, 2024, clarified that importing a patented invention into India amounts to working said invention in India, which has not always been the case.[239] The Rules also relaxed its practice with respect to filing a Statement of Working, which was previously required to be filed every fiscal year along with details on revenue and value accrued from the patent.[240] The change reflects an

[238] The Patent Acts, 1970, §84(1)(c).
[239] Ministry of Commerce and Industry, Patents (Amendment) Rules, 2024, G.S.R. 211(E), §7(v)(2) (Notified on March 15, 2024).
[240] Ministry of Commerce and Industry, Patents (Amendment) Rules, 2024, G.S.R. 211(E), §12 (Notified on March 15, 2024).

effort to streamline reporting requirements and reduce the burden on applicants while ensuring that patent holders and applicants continue to fulfill their legal obligations.[241]

Additionally, a delay in filing the Statement can be condoned or an extension can be sought by filing a request under Form 4.[242] Further, under the Jan Vishwas Act, 2023, the penalty for failure or refusal to file Form 27 has been significantly reduced.[243]

The Need to Upgrade Trade Secret Protection

India lacks civil and criminal statutory protection for trade secrets, with contractual obligations providing the primary vehicle for protection. Although other means of protection might exist, such as suing under the tort of "breach of confidence," each requires a close relationship between the trade secret owner and the would-be misappropriator.[244] 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. In response to the Parliamentary Committee recommendation regarding "enacting a separate legislation or a framework for protection of trade secrets," the government confirmed that the "Department is consulting stakeholders on the same for implementation."[245] IPO is also encouraged by India's commitment at the 2015 U.S. and India Trade Policy Forum to deepen cooperation on trade secrets and a recommendation included in India's IP Rights Policy to study trade secret protection, with an aim for

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[241] Changes in the Rules with respect to the Statement of Working include: (1) The frequency for filing the Statement is reduced from every fiscal year to every three fiscal years. The obligation commences from the fiscal year immediately following the year in which the patent was granted. Licensees may now also jointly file Form 27; (2) The earlier version of the requisite Form 27 required patent holders/licensees to provide specific details pertaining to the revenue/value accrued from patented products manufactured/imported into India, a brief description of the worked patents, reasons for not working, and steps taken to work the patented invention in India. The updated version of Form 27 no longer requires disclosure of the aforesaid details; (3) If a patent is not worked, reasons for not-working can be selected from provided options. If the patentee is exploring licensing of the patent, it may indicate the same in a Statement of Working with contact details; (4) The amended provision will have a prospective effect. Ministry of Commerce and Industry, Patents (Amendment) Rules, 2024, G.S.R. 211(E), §12 (Notified on March 15, 2024).

[242] Ministry of Commerce and Industry, Patents (Amendment) Rules, 2024, G.S.R. 211(E), §12 (Notified on March 15, 2024).

[243] The Jan Vishwas (Amendment of Provisions) Act, 2023, sched. 1(18).

[244] Md Zafar Mahfooz Normani & Faizanur Rahman, *Intellection of Trade Secret and Innovation Laws in India*, 16 J. OF INTELL. PROP. RTS. 341, 345–46 (2011).

[245] STANDING COMM. ON COM., 161ST REPORT at 41; STANDING COMM. ON COM., 169TH REPORT at 32.

further policy development.[246] Earlier recognition of the need to improve trade secret protection can be found in the 2008 Draft National Innovation Act and 2012 Draft National IP Rights Strategy, the latter of which pointed out a "predictable and recognizable trade secret regime will improve investor confidence," although this was not included in the approved version of the National IP Rights Strategy.[247] IPO agrees that adopting 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. There is also a growing body of academic literature originating within India that agrees that improving trade secret protection is critical.[248]

In a positive move, the 22nd Law Commission of India issued a report titled Trade Secrets and Economic Espionage (along with a draft bill) on March 5, 2024, to recommend a *sui generis* legal framework to adjudicate claims related to trade secret disclosure.[249]

First, the Commission noted that trade secrets conceptually cannot be property-like, which is the case with other forms of IP, since there are no definite monopoly rights attached to them.[250] Particularly, unlike patents, there is no disclosure of information in the public domain in the case of trade secrets.[251] Second, since trade secrets are expansive in nature, they should be defined as per the approach in Article 39 of the TRIPS Agreement, wherein secrecy, commercial value, and reasonable steps are the qualifying criteria for protection of trade secrets.[252] Third, when defining misappropriation, an over-protective framework should be avoided, ensuring only bad faith acts attract liability.[253] Finally, negative covenants on post-employment restraints shall not be permitted as they violate the spirit of Section 27 of the Contracts Act, which prohibits agreements in restraint of trade.[254] Additionally, information that is already in the public

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[246] Press Release, Off. of the U.S. Trade Rep., United States and India Joint Statement on the Trade Policy Forum (Oct. 29 2015), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/october/united-states-and-india-joint; MINISTRY OF COM. & INDUS. DEP'T OF INDUS. POL'Y & PROMOTION, NATIONAL INTELLECTUAL PROPERTY RIGHTS POLICY 10 (2016).

[247] The National Innovation Act (Draft), 2008, §§8–14; Sectoral Innovation Council on Intellectual Property Rights, Invitation of Views on the Draft National IPR Strategy, §§50–52 (Issued on September 26, 2012).

[248] *See, e.g.*, Anirudh Hariani, *The Draft National Innovation Act, 2008: Breaking the Shackles of Indian Innovation*, INDIA L. J., https://www.indialawjournal.org/archives/volume3/issue_1/article_by_anirudh.html (last visited Jan. 15, 2025); Abhinav Kumar, Pramit Mohanty & Rashmi Nandakumar, *Legal Protection of Trade Secrets: Towards a Codified Regime*, 11 J. OF INTELL. PROP. RTS. 379 (2006); Md Zafar Mahfooz Normani & Faizanur Rahman, *Intellection of Trade Secret and Innovation Laws in India*, 16 J. OF INTELL. PROP. RTS. 341 (2011); Abik Gua Roy, *Protection of Intellectual Property in the Form of Trade Secrets*, 11 J. OF INTELL. PROP. RTS. 192 (2006).

[249] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE (2024).

[250] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 29 (2024).

[251] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 4–5 (2024).

[252] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 180–81 (2024).

[253] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 181 (2024).

[254] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 181 (2024).

domain cannot be protected by way of confidentiality or secrecy provisions in non-disclosure agreements.[255]

The Commission has contemplated exceptions that should be carved out in such legislation. To start with, it recommended incorporating provisions to protect whistleblowers, as illegal activities under the guise of trade secrets cannot be exempted by law, any non-disclosure agreements to that end would be void under Section 23 of the Contracts Act.[256]

On remedies, it proposed that reliefs for misappropriation of trade secrets include injunctive relief in the form of orders granting interim injunctions, *ex parte* injunctions, and permanent injunctions, as well as other ancillary reliefs ordinarily available under other IP statutes in case of groundless threats of legal proceedings.[257] However, as per the Commission, criminal action may only be taken under the applicable criminal law provisions under various existing statutes.[258]

For procedural issues, among other things, the Commission observed that as trade secrets are commercial assets, the procedure under the Commercial Courts Act, 2015, shall be applicable to suits for misappropriation of trade secrets.[259] In relation to the limitation period, Article 113 of the Limitation Act, 1963, shall be applicable wherein limitation starts three years from when the right to sue accrues.[260] The Commission is silent on whether, like with other forms of IP, a violation by virtue of misappropriation of trade secrets would give rise to a continuing cause of action. It has also proposed built-in confidentiality provisions for proceedings pertaining to misappropriation of trade secrets, such that disclosures to the Court can be given without any apprehension.[261] The Commission has specifically recommended not including a trade secret board or registry as such registry will be counter-intuitive, the task of protecting sensitive information is onerous, and has practical difficulties, coupled with the apprehension that information holders may have in sharing protected information.[262]

Overall, the Commission contemplates the broad framework of the proposed legislation, including provisions on exceptions, limitations, remedies, and a draft bill titled The Protection of Trade Secrets Bill, 2024, annexed to the Commission's Report in an attempt to codify acquisition, use, and disclosure of trade secrets and legal proceedings thereof.[263]

Commentators observe that such a law would offer companies clarity on protection of confidential information; increase industry confidence; enable technology transfer to

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[255] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 181 (2024).
[256] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 182–83 (2024).
[257] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 190 (2024).
[258] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 190 (2024) (such as damages, rendition of accounts or profits, delivery up, surrender, and destruction).
[259] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 191 (2024).
[260] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 191 (2024).
[261] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 192–93 (2024).
[262] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 142 (2024).
[263] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 198–204 (2024).

India; and facilitate negotiation of free trade agreements, where the absence of a clear law on trade secrets is often a point of concern.

Industry body Federation of Indian Chambers of Commerce & Industry ("FICCI") is currently preparing a white paper to help firm up the contours of a trade secret law. The FICCI-USPTO Roundtable on Trade Secret Protection Challenges and Solutions, held on March 12, 2024, provided a useful platform for in-depth discussions on a trade secrets law in India.[264] The International Judicial Conclave on Intellectual Property Rights, hosted by the Delhi High Court on March 16-17, 2024, in conjunction with the Delhi Judicial Academy, USPTO, and the U.S. Department of Justice, was another forum where there was consensus on the need for a statutory framework for the protection of trade secrets.[265]

Disclosure of Foreign Filings

Prior to the Patents (Amendment) Rules, 2024, patent applicants were required to regularly disclose updates on foreign applications that were "the same or substantially the same invention."[266] Non-compliance provided an independent ground for pre- and post-grant opposition, as well as revocation.[267] Furthermore, in the absence of clarity regarding the meaning of "substantially the same invention," it was often difficult to be certain about full compliance with this requirement.

These requirements were antiquated and created unnecessary uncertainty and expense for patent applicants. It was rightly pointed out in the EAC-PM Report 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.[268]

In a positive move, the Patents (Amendment) Rules, 2024, addressed some of these issues by relaxing the frequency of such filings and directing examiners to use an accessible database.[269]

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[264] Fed'n of Indian Chambers of Com. & Indus., *FICCI – USPTO Roundtable on Trade Secret Protection Challenges and Solution*, 13 IP UPDATE 5 (2024).

[265] DELHI HIGH CT. INTELL. PROP. DIV., SECOND ANNUAL REPORT 2023-24 41 (2024).

[266] The Patents Act, 1970, §8(1).

[267] The Patents Act, 1970, §§25(1)(h), 25(2)(h), 64(1)(m).

[268] SANJEEV SANYAL & AAKANKSHA ARORA, ECON. ADVISORY COUNCIL TO THE PM, WHY INDIA NEEDS TO URGENTLY INVEST IN ITS PATENT ECOSYSTEM? 11 (2022).

[269] Some of the salient features of the amendments with respect to filing of Form-3 are: (1) Requirement to periodically file Form-3 within six months of foreign applications is now done away with. Now the Applicants have only two mandatory Form-3 filings: (i) first mandatory Form-3 to be filed within six months of filing patent application in India; and (ii) second mandatory Form-3 to be filed within three months of the FER, even without objection in the FER; (2) examiners are expected to use accessible database for Form-3 information; (3) For an objection/demand of Form-3, Controller needs to give reason; (4) Extension of up to three months available for filing Form-3. Ministry of Commerce and Industry, Patents (Amendment) Rules, 2024, G.S.R. 211(E), §2 (Notified on March 15, 2024).

Foreign Filing Permissions and the Ministry of Defense

India's Patents 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.[270] Non-compliance with this requirement results in a monetary fine, jail term, or both.[271] While the routine FFPs are granted very expeditiously by the Indian Patent Office, which is appreciated, if the Indian Patent Office concludes that the subject matter of an invention is relevant for defense purposes or atomic energy, it is referred to the Ministry of Defense for its prior consent. In some cases, the Ministry may take up to two years to grant consent. This delay is extremely detrimental to obtaining FFP because applicants may lose their application priority date and have no ability to contest the Patent Office's decision.

Genetic Resources and Traditional Knowledge

Section 10(4)(d)(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.[272] 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.[273] Further, even when the origin of the source of biological material is not Indian, the applicants are required to identify the specific location or city of origin, which is onerous and unwarranted.[274] In practice, the Indian Patent Office frequently raises objections under Section 10(4), regardless of whether the referenced biological material is publicly available or not. India has created an NBA to regulate use of the genetic resources of India.[275] 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.[276] 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.[277] 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 a progressive move on February 24, 2022, after a few rounds of comments and input from stakeholders, the Delhi High Court published The High Court of Delhi Rules Governing Patent Suits, 2022 ("Patent Suit Rules") and The Delhi High Court Intellectual

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[270] The Patents Act, 1970, §39.
[271] The Patents Act, 1970, §118.
[272] The Patents Act, 1970, §10(4)(d)(ii)(D).
[273] OFF. OF THE CONTROLLER GEN. OF PATS., DESIGNS & TRADEMARKS, GUIDELINES FOR PROCESSING OF PATENT APPLICATIONS RELATING TO TRADITIONAL KNOWLEDGE AND BIOLOGICAL MATERIAL 2 (2017).
[274] The Biological Diversity Act, 2002, §6(1).
[275] The Biological Diversity Act, 2002, §§3, 6.
[276] The Biological Diversity Act, 2002, §6.
[277] The Biological Diversity Act, 2002, §6(2).

Property Rights Division Rules, 2022 ("IPD Rules").[278] These rules streamline the procedure for conducting patent infringement and cancellation proceedings, as well as other IP matters in a time-bound manner before the newly constituted IP Division of Delhi High Court, and introduce procedures for summary adjudication, litigation hold notice, hot-tubbing, constitution of confidentiality clubs, early neutral evaluation, and more.[279] Matters from the now-abolished IPAB are listed before the IP divisions. Further, under the IPD Rules, if a trademark or patent is involved in multiple suits, the court can consolidate the proceedings towards a common trial.[280] Consolidation, when it is not to the prejudice to the rights of either party, saves judicial time and costs for litigants. The court can also seek the assistance of independent experts, whose persuasive and technically competent opinions enable well-reasoned judgments while addressing nuanced questions in IP rights disputes.[281]

The supervisory jurisdiction granted to intellectual property division ("IPD") benches over IP offices has enabled it to pass orders enhancing the overall function of the Indian IP offices while hearing appeals emanating from decisions issued by the IP offices. For instance, in *Saurav Chaudhary v. Union of India & Anr*, the Delhi High Court, for the first time in Indian IP jurisprudence, directed the CGPDTM to come up with a draft Code of Conduct regulating patent and trademark agents by December 31, 2024.[282]

As per the recently released Delhi High Court Intellectual Property Division Second Annual Report 2023-24, in its second year, the IP Division disposed of 1,217 cases

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[278] High Court of Delhi: New Delhi, High Court of Delhi Rules Governing Patent Suits, 2022, No. 14/Rules/DHC (Notified on February 24, 2022); High Court of Delhi: New Delhi, Delhi High Court Intellectual Property Rights Division Rules, 2022, No. 13/Rules/DHC (Notified on February 24, 2022).

[279] High Court of Delhi: New Delhi, High Court of Delhi Rules Governing Patent Suits, 2022, No. 14/Rules/DHC, §§16, 8(1), 9(iii), 11, 12 (Notified on February 24, 2022); High Court of Delhi: New Delhi, Delhi High Court Intellectual Property Rights Division Rules, 2022, No. 13/Rules/DHC, §§16, 18(ii), 19, 27, 37 (Notified on February 24, 2022).

[280] High Court of Delhi: New Delhi, High Court of Delhi Rules Governing Patent Suits, 2022, No. 14/Rules/DHC (Notified on February 24, 2022); High Court of Delhi: New Delhi, Delhi High Court Intellectual Property Rights Division Rules, 2022, No. 13/Rules/DHC, §40 (Notified on February 24, 2022).

[281] High Court of Delhi: New Delhi, High Court of Delhi Rules Governing Patent Suits, 2022, No. 14/Rules/DHC, §5(iii) (Notified on February 24, 2022); High Court of Delhi: New Delhi, Delhi High Court Intellectual Property Rights Division Rules, 2022, No. 13/Rules/DHC, §31 (Notified on February 24, 2022).

[282] W.P.(C)-IPD 9 of 2023, Decided on July 4, 2024 (Delhi H.C.), 59. The Office of the CGPDTM published two public notices on September 13, 2024 regarding formation of two committees to draft a code of conduct and address complaints against Patent or Trademark agents. As of January 16, 2025, we have not seen a public draft of or finalized Code of Conduct. Office of the Controller General Patents, Designs, & Trade Marks, Compliance with WP(C)-IPD 9/2023 Order Dated 4th July 2024 – Constitution of a Special Committee to Draft 'Code of Conduct' to Regulate the Conduct of Patent and Trademark Agents, CGPDTM-18020(16)/34/2023-POD/LLC-008 (Notified on September 13, 2024); Office of the Controller General Patents, Designs, & Trade Marks, Compliance with Para. 68 of WP(C)-IPD 9/2023 Order dated 4th July 2024 – Constitution of an Ad-Hoc Committee to Deal With the Complaints, If Any, Filed Against Patent or Trademark Agents Until a 'Code of Conduct' to Regulate the Conduct of Patents and Trademarks Agents is Notified, CGPDTM-18020(16)/34/2023-POD/LLC-009 (Notified on September 13, 2024).

transferred from the IPAB.[283] Thus, as of June 2024, more than 60% (1,977 cases) of the cases received from the IPAB have been disposed of.

In addition, from January 2023 to June 2024, the Delhi High Court IP Division disposed of 2,026 fresh cases, surpassing the 1,917 new cases instituted during the same period and reducing overall pendency of IP cases from 3,799 in 2023 to 3,742.

In April 2023, the Madras High Court adopted the Madras High Court Intellectual Property Rights Division Rules, 2022 for its IP Division.[284] On September 20, 2024, the notification for the Calcutta High Court's IP Division Rules was published in the Kolkata Gazette, making it the newest high court, after Delhi and Madras, to have its own dedicated IP Division and relevant rules.[285] The Calcutta rules have a lot in common with their Delhi and Madras counterparts, especially in terms of institutional set up and procedural formalities. Though the Himachal Pradesh High Court published its Intellectual Property Rights Division Rules, 2022 on July 8, 2024, the latest roster dated September 25, 2024, does not mention an IPD bench.[286] This leaves Bombay as the only high court with original civil jurisdiction that does not yet have IPD Rules. Further, the Karnataka High Court formed a sub-committee for drafting their IPD Rules on June 20, 2024.[287]

Decriminalization of IP Offenses

Through Jan Vishwas (Amendment of Provisions) Act, 2023, India decriminalized minor IP offenses by imposing only a monetary penalty.[288] For instance, the offence of falsely representing a trademark as registered has been decriminalized and now, the penalty is a sum equal to 0.5% of the total sales or turnover in the business or of the gross receipts as computed in the audited accounts or a sum equal to INR 5 lakh, whichever is less. Likewise, if a person falsely represents that any article sold by him is patented in India or is the subject of an application for a patent in India, he will be liable for a penalty that may extend to INR 10 lakh, and in case of a continuing claim, a further penalty of INR 1,000 for every subsequent day during which such claim continues. Decriminalized IP

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[283] DELHI HIGH CT. INTELL. PROP. DIV., SECOND ANNUAL REPORT 2023-24 9 (2024).

[284] High Court of Judicature at Madras, Madras High Court Intellectual Property Rights Division Rules, 2022, SRO C-6/2023 (Notified April 5, 2023).

[285] High Court at Calcutta, Intellectual Property Rights Division Rules of the High Court at Calcutta, 2023, WB/SC-247 (Notified July 2, 2024).

[286] High Court of Himachal Pradesh, Shimla, The Himachal Pradesh High Court Intellectual Property Rights Division Rules, 2022, HHC/Rules/IPD/2022 (Notified August 7, 2024); *see* High Court of Himachal Pradesh, Shimla, All Courts Shall Give Top Most Priority to Old Pending Matters, Particularly Prior to the Year 2014, HHC/Judl/ROSTER/96-17090 (Issued on September 25, 2024).

[287] High Court of Karnataka, HCLC 59/2022 (Notified June 20, 2024); Praharsh Gour, *Karnataka High Court Forms a Sub-Committee to Draft IPD Rules*, SPICY IP (June 25, 2024), https://spicyip.com/2024/06/karnataka-high-court-forms-a-sub-committee-to-draft-ipd-rules.html.

[288] The Jan Vishwas (Amendment of Provisions) Act, 2023. The provisions related to patents, trademarks, geographical indications, and copyright laws came into effect on August 1, 2024, through notification published by the Ministry of Commerce and Industry on July 26. Ministry of Commerce and Industry, S.O. 2972(E) (Notified on July 26, 2024).

offenses should be counter-balanced by stricter laws, policies, and standards for enforcement, to deter infringers and counterfeiters.

In a positive move, the penalty for failure to file or refusal to file Form 27 (Statement of Working) has been reduced by ten-fold.[289]

Trademark Oppositions, Pendency, Grievance Redressal and Enforcement

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

The Trademark Office has taken steps to resolve the backlog and strengthen its manpower. A progress report submitted by the Trademark Office to the High Court of Delhi in August 2023 revealed that the Office had revised its associate managers to 200, out of which 111 joined, and were entrusted with hearing and adjudicating opposition cases, amongst other duties.[290] The Delhi High Court's direction to the Office of the CGPDTM to resolve the trademark opposition backlog and continuous monitoring of the same has been a positive step, though progress is slow.

However, in continuing their commitment to address stakeholder concerns and resolve IP related issues in a timely manner, the IP Office launched an Open House Helpdesk Portal in February 2024.[291] Once registered, users can log in, submit queries, and manage responses through the portal. The types of questions that can be submitted depend on the particular IP category involved. This is a welcome development and a valuable complement to the daily online Open House Sessions that enable direct interaction with the IP Office officials. Also, in September 2024, an AI and machine learning-based trademark search technology tool was launched by the IP Office to enable clearance of trademark applications in a more efficient and accurate manner.[292] Also released was the 'IP Saarthi' Chatbot—a digital assistant designed to provide instant support and guidance to users navigating the IP registration process.

It may be noted that, until 2017, a mark could only be declared as well-known in India through contested proceedings. However, the 2017 Trademarks Rules specifically included a provision whereby one could file an application at the Trademark Office to have their mark determined as well-known and included in the official list of such

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[289] The Jan Vishwas (Amendment of Provisions) Act, 2023, sched. 1(18).

[290] Praharsh Gour, *Trademark Registry Files Latest Data on Oppositions Before the Delhi High Court*, SPICY IP (Aug. 9, 2023), https://spicyip.com/2023/08/trademark-registry-files-latest-data-on-oppositions-before-the-delhi-high-court.html.

[291] *Office of the Controller General of Patents, Designs and Trademarks (CGPDTM) Launches Open House Portal – Submit your Grievance on Any IP and Raise a Ticket for Resolution*, OFF. OF THE CONTROLLER GEN. OF PATS., DESIGNS & TRADEMARKS (Feb. 14, 2024), https://www.ipindia.gov.in/newsdetail.htm?951.

[292] Press Release, Ministry of Com. & Indus., Shri Piyush Goyal Unveils AI and ML-Based Trademark Search Technology, IP Saarthi Chatbot (Sept. 18, 2024).

marks.[293] In May 2023, the Delhi High Court clarified that both a court and the Registrar can determine if a trademark is worthy of well-known status, and if a court has already bestowed such a status on a trademark, the Registrar is consequently obligated to include said mark on the list and cannot initiate a re-determination process.[294] However, the proprietor has to separately file an application before the Registrar of Trademarks to have its mark included in the list of well-known trademarks, even if a court has declared it to be so.

Stakeholder Consultation to Discuss Key Issues Related to Designs and GIs in India

On August 1, 2024, the CGPDTM conducted a stakeholders' meeting to discuss issues and provisions related to protection of industrial designs. The Indian Government, through its meeting agenda, invited comments from stakeholders on key topics such as: (a) grace period; (b) deferred publication; (c) time limit relaxations; (d) restoration of priority rights; (e) renewal; (f) exceptions for publicly accessible design databases; (g) single application for multiple designs; and (h) international filing mechanisms under the Hague System.

Similar stakeholder meetings were conducted on August 28, 2023, when the CGPDTM invited views regarding the desirability of India acceding to: (a) Strasbourg Agreement Concerning the International Patent Classification; (b) Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs; and (c) Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications.[295] India's IP Rights Policy still provides a valuable roadmap for possible future accession to the Hague System and India should be encouraged to do so.[296]

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.[297]

India Lacks a Meaningful Grace Period for Design Applications

India is one of the few countries without 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, and Canada, and being considered in Australia—provide applicants the time and

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[293] Ministry of Commerce and Industry, G.S.R. 199(E), §124 (Notified on March 6, 2017).
[294] Tata Sia Airlines Ltd. v. Union of India, W.P.(C)-IPD 64 of 2021, Decided on May 25, 2024 (Delhi H.C.), 21.
[295] Controller General Patents, Designs & Trademarks, Stakeholder Meeting Regarding the Desirability of Acceding to Hauge Agreement, Lisbon Agreement and Strasbourg Agreement Administered by WIPO, (Notified on August, 25, 2023).
[296] MINISTRY OF COM. & INDUS. DEP'T OF INDUS. POL'Y & PROMOTION, NATIONAL INTELLECTUAL PROPERTY RIGHTS POLICY 12 (2016).
[297] Geneva Act, July 2, 1999, WIPO Lex. No. TRT/HAGUE/006.

flexibility to consider the need for protection and prepare quality applications. India should be encouraged to adopt a generally applicable grace period of at least six months, and preferably one year.

Inconsistent Trademark Examination

There appears to be an increase in inconsistent examination in India. The standards for examination seem to vary by controller, objections can be terse and unsupported by reference to laws or rules, and when an applicant requests clarification, they are similarly met with terse responses. India should be encouraged to offer more training to controllers to help with examination quality and consistency, and to require that controllers apply the same examination standards, supported by references to a universal set of examination guidelines.

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.[298] 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 compulsory licenses for antiviral COVID-19 therapeutics.[299] Moreover, Indonesia issued a compulsory license 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 compulsory licenses, which broadly enables government agencies to request compulsory licenses for pharmaceutical products to address emergency needs in the public interest.[300] If a compulsory license 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 compulsory license regulations to align more appropriately with global norms and best practices, this new regulation, the process by which it was developed and issued, and the compulsory licenses for the antiviral COVID-19 therapeutics, send a troubling signal to innovators. Additionally, in August 2023, the Government enacted the Health Omnibus Law,

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[298] Undang-Undang Republik Indonesia Tentang Paten [Law of the Republic of Indonesia on Patents], Nomor 13, art. 26 (2016).

[299] Peraturan Presiden Nomor 100, Pelaksanaan Paten Oleh Pemerintah Terhadap Obat Remdesivir [Presidential Regulation Number 100, Implementation of Patents by the Government Regarding Remdesivir Drug] (Nov. 10, 2021); Peraturan Presiden Nomor 101, Pelaksanaan Paten Oleh Pemerintah Terhadap Obat Favipiravir [Presidential Regulation Number 101, Implementation of Patents by the Government Regarding Favipiravir Drug] (Nov 10, 2021).

[300] Peraturan Presiden Nomor 77, Tata Cara Pelaksanaan Patent Oleh Permerintah [Presidential Regulation Number 77, Procedures for Implementing Patents by the Government] (July 7, 2020).

Articles 314 and 326 of which 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."[301]

Forced Localization Requirements

The 2023 Omnibus Health Law emphasizes prioritization for use of locally made products. 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.[302] 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 ("LFPPI"), which entered into force on November 5, 2020.[303] Under the law, voluntary divisional applications can only derive from a parent case and cannot derive from another divisional application.[304] Thus, voluntary divisional applications deriving from divisional applications are not allowed, unless the Mexican Patent Office, the Institute of Industrial Property ("IMPI"), determines otherwise. If an 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 to.

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 under Mexico's law and Constitution that laws (statutes), and provisions within them, cannot be applied retroactively.[305] However, shortly after implementation of LFPPI, IMPI started denying all voluntary cascade divisional applications regardless of whether the parent case was filed before or after November 5, 2020, despite the fact that LFPPI contains transitional articles that specifically state that patent applications filed

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[301] Undang-Undang Republik Indonesia Tentang Kesehatan [Law of the Republic of Indonesia on Health], Nomor 17, arts. 314, 326 (2023).

[302] Peraturan Menteri Kesehatan Nomor 1010/Menkes/Per/XI/208, Registrasi Obat [Regulation of the Minister of Health Number 1010/Menkes/Per/XI/208, Drug Registration] (Nov. 3, 2008).

[303] Ley Federal de Protección a la Propiedad Industrial [Federal Law for the Protection of Industrial Property] [LFPPI] art. 100, Diario Oficial de la Federación [DOF] 01-07-2020.

[304] Ley Federal de Protección a la Propiedad Industrial [Federal Law for the Protection of Industrial Property] [LFPPI] art. 100, Diario Oficial de la Federación [DOF] 01-07-2020.

[305] Constitución Política de los Estados Unidos Mexicanos [Political Constitution of the United Mexican States], CP, art. 14, Diario Oficial de la Federación [DOF] 05-02-1917, últimas reformas DOF 10-02-2014.

under the former law should be prosecuted under the former law (in which cascade divisional applications had no restrictions whatsoever).[306]

This criterion was eventually 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 2023, it is not accepting any voluntary cascade divisionals if the first parent case was allowed and issued as a patent or if it was abandoned. In the last weeks of August and first weeks of September 2023, IMPI began to issue substantive office actions rejecting cascade divisionals that were previously accepted and complied with all formal requirements.

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 has then rejected the application for being a divisional filed after the first parent case had been allowed.

IMPI is basing this criterion on Federal Court jurisprudence that provides it is not possible to file divisional applications once the prosecution of the parent case has been finalized.[307] However, this court decision does not mention cascade divisionals and, thus, IPO believes that this jurisprudence is being misapplied to voluntary cascade divisional applications.

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 have been already accepted and thus, 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 1991, the year in which the former law entered into force.

In April 2024, the Mexican Supreme Court of Justice considered the issue of legal standing to file invalidity actions against patents.[308] The Court held being a commercial

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[306] Ley Federal de Protección a la Propiedad Industrial [Federal Law for the Protection of Industrial Property] [LFPPI] transitorios noveno, décimo, Diario Oficial de la Federación [DOF] 01-07-2020; *c.f.* Ley de la Propidad Industrial [Industrial Property Law] [LPI], Diario Oficial de la Federación [DOF] 27-06-1991, últimas reformas DOF 25-01-2006 (no longer in force).

[307] División de Patente. La Solicitud, a Petición de Parte, Debe Presentarse Hasta Antes de Que el Instituti Mexicano de la Propiedad Industrial (IMPI) Concluya el Examen de Fondo, a la Luz del Principio de Unidad Inventiva (Ley de la Propiedad Industrial Abrogada) [Patent Division. The Application, at the Request of a Party, Must Be Submitted Before the Mexican Institute of Industrial Property (IMPI) Concludes the Substantive Examination, in Light of the Principle of Inventive Unity (Repealed Industrial Property Law)], Plenos de Circuito, Semanario Judicial de la Federación y su Gaceta, Undécima Época, Julio de 2022, Tesis PC.I.A. J/11 A (11a).

[308] Patentes. El Artículo 188 de la Ley de la Propiedad Industrial, al Establecer Como Requisto Contar Con Interés Jurídico Para Iniciar el Procedimiento de Declaración Administrativa a Petición de Parte, Respeta el Derecho a la Tutela Judicial Efectiva (Legislación Vigente Hasta 2020) [Patents. Article 188 of the Industrial Property Law, By Establishing the Requirement of Having Legal Interest to Initiate the

competitor did not generate a legal interest in initiating administrative declaration procedures before IMPI, an outcome that has the possibility of affecting cascade divisional patents.[309]

Article 100 of LFPPI is the main article regulating the filing of divisional applications in Mexico and contemplates the possibility of filing divisional applications either voluntarily or through a requirement issued by IMPI, such as a lack of unity objection.[310] It also defines the timeframe for filing divisional applications and specifically states that a voluntary divisional application will only be possible if it derives from its parent case.[311] In other words, voluntary divisionals deriving from divisionals will no longer be allowed. The only possible scenario for filing cascade divisionals (divisionals from divisionals) is if IMPI requests the further division through a lack of unity objection. Article 100 also mentions that when unity of invention is objected, any invention or group of inventions that are not included in the initial application or in the application that originated the division, cannot be included again in any of said applications.[312]

On the other hand, Article 113 of LFPPI states that when an application lacks unity of invention, the examiner will only consider as the main invention that which is mentioned first in the claims and will evaluate the compliance of the remaining patentability requirements (novelty, inventive step, etc.) only for this main invention.[313] In this case, IMPI will require the applicant to limit the claims to the main invention and, if needed, to file the corresponding divisional(s) applications. Article 113 has caused several problems in Mexican patent practice because of the numerous 113 objections raised by examiners, which complicate the strategy for filing divisional applications.

There have been cases in which applicants receive a lack of unity objection in a first office action and, instead of limiting the claims of the parent case to those of the first invention identified by the examiner, they limit the claims of the parent case to one of the other inventions identified by the examiner. However, in the second office action, the

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Procedure for Administrative Declaration at the request of a Party, Respects the Right to Effective Judicial Protection (Legislation in Force Until 2020)], Pleno de la Supreme Corte de Justicia de la Nación [SCJN], Semanario Judicial de la Federación y su Gaceta, Undécima Época, Tomo II, Abril de 2024, página 2108, Pfos. 56–58.

[309] Patentes. El Artículo 188 de la Ley de la Propiedad Industrial, al Establecer Como Requisto Contar Con Interés Jurídico Para Iniciar el Procedimiento de Declaración Administrativa a Petición de Parte, Respeta el Derecho a la Tutela Judicial Efectiva (Legislación Vigente Hasta 2020)) [Patents. Article 188 of the Industrial Property Law, By Establishing the Requirement of Having Legal Interest to Initiate the Procedure for Administrative Declaration at the request of a Party, Respects the Right to Effective Judicial Protection (Legislation in Force Until 2020)], Pleno de la Supreme Corte de Justicia de la Nación [SCJN], Semanario Judicial de la Federación y su Gaceta, Undécima Época, Tomo II, Abril de 2024, página 2108, Pfo. 61.

[310] Ley Federal de Protección a la Propiedad Industrial [Federal Law for the Protection of Industrial Property] [LFPPI] art. 100, Diario Oficial de la Federación [DOF] 01-07-2020.

[311] Ley Federal de Protección a la Propiedad Industrial [Federal Law for the Protection of Industrial Property] [LFPPI] art. 100, Diario Oficial de la Federación [DOF] 01-07-2020.

[312] Ley Federal de Protección a la Propiedad Industrial [Federal Law for the Protection of Industrial Property] [LFPPI] art. 100, Diario Oficial de la Federación [DOF] 01-07-2020.

[313] Ley Federal de Protección a la Propiedad Industrial [Federal Law for the Protection of Industrial Property] [LFPPI] art. 113, Diario Oficial de la Federación [DOF] 01-07-2020.

examiner will state that according to Article 113, the applicant is obligated to limit the claims of the parent case to those of the invention which is mentioned in first place in the set of claims and cannot claim any other invention in the parent case. In some cases, the examiner has even gone to the extent of requesting the applicant abandon the parent case and file a divisional application directed to the invention of interest in order to comply with Article 113.

IPO believes that this interpretation of Article 113 is erroneous and does not benefit the applicant. Article 113 does not specifically say that the applicant is obligated to limit the scope of the parent case to the invention that is mentioned in the first place of the set of claims and that none of the other identified inventions can be claimed in the parent case. With this interpretation, IMPI is making an arbitrary decision and forcing the applicant to claim in the parent case an invention which at that time may no longer be of commercial interest to him.

Supplementary Certificate of Life Term Correction Due to Delays in Prosecution

On a positive note, LFPPI 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."[314] The supplementary certificate is only available if the time between filing and grant exceeds five years. IPO expects the first petitions under this law to be filed around the end of 2026.

The mechanism, however, does not provide an automatic PTA, 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 requesting the adjustment through a brief submitted independently in reply to the notice of allowance. Since calculating the PTA is a purely mathematical exercise based on information available within IMPI, IMPI should be able to calculate the PTA without expense to the applicant in preparing and submitting a brief.

Enforcement of Pharmaceutical or Biologics Patents

The temporality of eight years for biologics patents and three years for chemical patents in the Roche-Bolar exception were removed in the new law.[315] However, the health law regulations have not yet been amended accordingly and should be so amended to be consistent with the law.[316]

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[314] Ley Federal de Protección a la Propiedad Industrial [Federal Law for the Protection of Industrial Property] [LFPPI] art. 131, Diario Oficial de la Federación [DOF] 01-07-2020.

[315] *See* Ley Federal de Protección a la Propiedad Industrial [Federal Law for the Protection of Industrial Property] [LFPPI], Diario Oficial de la Federación [DOF] 01-07-2020.

[316] Reglamento de Insumos Para la Salud [Health Supplies Regulation] art. 167-bis, Diario Oficial de la Federación [DOF] 04-02-1998, últimas reformas DOF 31-05-21.

Post Grant Amendments

The LFPPI establishes that no post-grant amendments can be made to granted patents that are subject to review if the validity of the patents was previously questioned.[317] This limitation was not present in previous law and is concerning.

Constitutional Judicial Reforms in Mexico

In a very short period, a constitutional judicial reform act was approved by the Mexican Congress, by most of the state legislatures, signed by the President, and published in the Official Gazette of the Federation, taking effect on September 16, 2024.[318]

This reform entails the following substantial modifications to the country's judicial system including:

(a) *Election of Justices, Magistrates, and Judges by popular vote*: This will be implemented gradually, beginning in 2025 and concluding in 2027;
(b) *Qualifications changed:* Candidates only need to be Mexican citizens, hold a professional law degree, and have a minimum GPA of 8 of 10, in the subjects related to the position for which they are applying, in their bachelors, specialty, masters, or doctorate degrees. This change opens the door to new profiles within the judiciary, with the potential risk of a lack of specialization;
(c) *Supervision under a new body*: The Federal Judiciary Council will be replaced by the Judicial Discipline Tribunal, which will lead a transition and restructuring of judicial oversight and control; and
(d) *New electoral organization*: The National Electoral Institute will be responsible for organizing the elections for judicial positions, which will begin as early as the first half of 2025.[319]

The impacts that this reform will have in the IP field will be clearer in the next few years.

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[317] Ley Federal de Protección a la Propiedad Industrial [Federal Law for the Protection of Industrial Property] [LFPPI] art. 116, Diario Oficial de la Federación [DOF] 01-07-2020.

[318] Decreto Por el Que se Reforman, Adicionan y Derogan Diversas Disposiciones de la Constitución Política de los Estados Unidos Mexicanos, en Materia de Reforma del Poder Judicial [Decree By Which Various Provisions of the Political Constitution of the United Mexican States are Amended, Added and Repealed, in Relation to the Reform of the Judicial Branch], Diario Oficial de la Federación [DOF] 15-09-2024.

[319] Decreto Por el Que se Reforman, Adicionan y Derogan Diversas Disposiciones de la Constitución Política de los Estados Unidos Mexicanos, en Materia de Reforma del Poder Judicial [Decree By Which Various Provisions of the Political Constitution of the United Mexican States are Amended, Added and Repealed, in Relation to the Reform of the Judicial Branch] art. 96(IV), Diario Oficial de la Federación [DOF] 15-09-2024.

Translation of Priority Document

When a design application is filed under the Hague System and designates Mexico, Mexico requires a translation of the priority document. This requirement is onerous and unusual for Hague-originated applications. Further, it is not well known among applicants and failure to provide the translation can be fatal to the application. Mexico should be encouraged to eliminate this requirement for at least Hague System filings, or to provide applicants with more time or a chance to cure the failure to file the translation in the required timeframe.

Lack of Regulatory Data Protection for Biologics

As part of obtaining marketing authorization, innovative drug companies need to submit pre-clinical and clinical trial data to support the safety and efficacy of a drug candidate. RDP, which is required by TRIPS, protects innovators by providing a period of time during which third parties can rely on the innovator's data.[320]

RDP is particularly important for biologics submissions, but Mexico does not provide RDP for biologics. This is contrary to the requirements of Article 39 of TRIPS, and also contrary to Mexico's obligations under the USMCA.

RUSSIA

The 2023 Special 301 Report placed Russia on the Priority Watch List and noted that "the ability of the Office of the USTR to raise and resolve IP protection and enforcement issues in Russia is limited."[321] 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, but also recognizing that USTR may again want to identify Russia in its Report.[322]

Russian Law Fails to Provide Adequate Trade Secret Protection

Russia offers nominal and weak protection for trade secrets, leaving little protection for 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.[323] Although this

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[320] 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." Agreement on Trade-Related Aspects of Intellectual Property Rights art. 39.3, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 300.

[321] OFF. OF THE U.S. TRADE REPRESENTATIVE, 2023 SPECIAL 301 REPORT 62 (2023).

[322] *See* Ken Roberts, *Russia's Rank As U.S. Trade Partner At 30-Year Low, New Data Shows*, FORBES (Oct. 11, 2022, 6:28 AM), https://www.forbes.com/sites/kenroberts/2022/10/11/russias-rank-as-us-trade-partner-at-30-year-low-new-data-shows/?sh=47bc65086614.

[323] Federal'nyĭ Zakon Rossiyskoy Federatsii Kommercheskoy Tayne art. 10 [Federal Law of the Russian Federation on Commercial Secrecy] 2007, No. 98-FZ.

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 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 IP, such as 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 Asia-Pacific Economic Cooperation ("APEC") Best Practices for Trade Secret Protection and Enforcement, which Russia endorsed as part of a 2016 APEC declaration, should be implemented.[324]

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, Pharmasyntez, to produce a patent protected product, the antiviral medicine Remdesivir.[325] The patent holder challenged the Decree in the Supreme Court, arguing that it breached the owner's IP rights and contradicted applicable national legislation and international conventions. In May 2021, the Supreme Court ruled against the patent holder, confirming the validity of the Decree.[326] 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 1,360 of the Russian Civil Code and introducing new rules on patent usage in the interest of

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[324] *2016 APEC Ministerial Meeting: AMM Joint Statement*, ASIA-PAC. ECON. COOP. (Nov. 17, 2016), https://www.apec.org/meeting-papers/annual-ministerial-meetings/2016/2016_amm; ASIA-PAC. ECON. COOP., BEST PRACTICES IN TRADE SECRET PROTECTION AND ENFORCEMENT AGAINST MISAPPROPRIATION (2016).

[325] Rasporiazheniia [Resolution], 2020, No. 3718-p.

[326] Postanovlenie Plenuma Verkhovnogo Suda Rossiĭskoĭ Federatsii "Remdesivir" ot 27 May 2021 [Plenary Ruling of the Supreme Court of the Russian Federation, "Remdesivir"] 2021, No. АКПИ21-303.

national security.[327] The 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.[328] Current language 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 reduce IP protections for foreign companies from "unfriendly countries" supporting sanctions. One decree set a 0% compensation for the "government compulsory licensing" of inventions if the patent holder is a citizen of, registered in, primarily conducts business in, or primarily profits from an "unfriendly state."[329] 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 Ministry of Industry & Trade.[330] 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 importation 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.

TURKEY

Requirement for birthdates

In Turkey, an applicant is required to submit the birthdate for all inventors. This new requirement is inconsistent with other jurisdictions that do not require birthdates to be submitted. Turkey is encouraged to eliminate this requirement.

Translation of Priority Document

When a design application is filed under the Hague System and designates Turkey, Turkey requires a translation of the priority document. This requirement is onerous and unusual for Hague-originated applications. Further, it is not well known among

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[327] Federal'nyĭ Zakon O Vnesenii Izmeneniya v Stat'yu 1360 Chasti Chetvertoy Grazhdanskogo Kodeksa Rossiyskoy Federatsii [Federal Law on Amendments to Article 1360 of Part Four of the Civil Code of the Russian Federation], 2021, No. 107-FZ.

[328] Federal'nyĭ Zakon O Vnesenii Izmeneniya v Stat'yu 1360 Chasti Chetvertoy Grazhdanskogo Kodeksa Rossiyskoy Federatsii § 1 [Federal Law on Amendments to Article 1360 of Part Four of the Civil Code of the Russian Federation], 2021, No. 107-FZ.

[329] Postanovlenie [Resolution], 2022, No. 299.

[330] Postanovlenie o Tovarakh (Gruppakh Tovarov), v Otnoshenii Kotorykh Ne Mogut Primenyat'syaotdel'nyye Polozheniya Grazhdanskogo Kodeksa Rossiyskoy Federatsii Ozashchite Isklyuchitel'nykh Prav Na Rezul'taty Intellektual'noy Deyatel'nosti, Vyrazhennyye v Takikh Tovarakh, I Sredstva Individualizatsii, Kotorymi Takiye Tovary Markirovany [Resolution About Products (Groups Goods) to Which Certain Provisions May Not Apply Provisions of the Civil Code of the Russian Federation on Protection Exclusive Rights to the Results of Intellectual Activities Expressed in Such Goods and Means Individualizations With Which Such Goods Are Marked], 2022, No. 506.

applicants and failure to provide the translation can be fatal to the application. Turkey is encouraged to eliminate this requirement for at least Hague System filings or to provide Applicant with more time or a chance to cure the failure to file the translation in the required timeframe.

III. MULTI-COUNTRY COMMUNITY CONCERNS

ANDEAN COMMUNITY

Genetic Resources

As noted above, 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.

Current laws in the Andean countries (Bolivia, Colombia, Ecuador, and Peru) regarding genetic resources and traditional knowledge, and particularly regarding inventions based on such genetic resources or derivatives thereof, are Andean Decisions 391 and 486.[331] To date, the only requirement established in said decisions for patent applications claiming subject matter that comes from accessing genetic resources is the subscription of an access contract between the applicant and the corresponding National Authority, namely the Environmental Ministry in each country.[332]

Even though the applicant is required to obtain said contract when investigation starts, or it can be required during prosecution of a later filed application (typically during the formal examination stage), neither Decision 391 nor Decision 486 oblige the applicant in any way to disclose that the invention is based on genetic resources or the country/source of said resources. Therefore, it is currently possible that an invention based on genetic resources is properly granted a patent if the access contract is timely filed, even though there is no disclosure of said resources' origin in the application as filed.

As an exception, Peru's patent office, the National Institute for the Defense of Free Competition and the Protection of Intellectual Property ("INDECOPI"), has recently started requiring a disclosure, similar to the one established in the recently issued WIPO Treaty.[333] If the application form does not provide the requested information, INDECOPI will issue a requirement, and the applicant must submit a brief either confirming the type and origin of the resources or indicating that the invention does not relate to genetic resources or traditional knowledge.

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[331] *See generally* Comm'n of the Andean Cmty. Dec. 391, Establishing Common Regime on Access to Genetic Resources (July 2, 1996); Comm'n of the Andean Cmty. Dec. 486, Common Provisions on Industrial Property (Sept. 14, 2000).

[332] Comm'n of the Andean Cmty. Dec. 391, tit. V; Comm'n of the Andean Cmty. Dec. 486, para. 275.

[333] *See* World Intellectual Property Organization [WIPO] Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, paras. 3.1–3.2, *opened for signature* May 24, 2024.

IPO will be following whether, and how, the new WIPO Treaty on Genetic Resources and Traditional Knowledge will be applied in the Andean countries, how the Treaty's disclosure requirement will affect PCT patent applications that may be based on native genetic resources and would then require an access contract when entering the National Phase, and how the Treaty will be harmonized with Decision 486, which would be in breach of the Treaty by not offering a post-grant procedure that provides the opportunity to rectify an omission before going to court to have a patent annulled or invalidated for lack of an access contract.[334]

EUROPEAN UNION

Compulsory Licensing

On April 27, 2023, the EC put forward a proposed Regulation on Compulsory Licensing for Crisis Management and Amending Regulation (EC) 816/2006 (the "Compulsory Licensing Regulation"), which also calls for forced technology transfer of confidential business information.[335] 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.[336]

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 or the potential thereof.

The proposed Compulsory License Regulation covers not just granted patents. Some of the language in the proposal calls for the compulsory licensing provisions to cover "measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence."[337] Thus, the regulations potentially call for the forced transfer of technology, including patent applications, confidential business information, and clinical trial data. The proposed expansion beyond patent rights exceeds

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[334] *See* World Intellectual Property Organization [WIPO] Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, para. 5.2, *opened for signature* May 24, 2024.

[335] *Commission Proposal for a Regulation of the European Parliament and of the Council on Compulsory Licensing for Crisis Management and Amending Regulation (EC) 816/2006*, COM (2023) 224 final (Apr. 27, 2023).

[336] Intell. Prop. Owners Ass'n, Comment Letter on Proposal for a Regulation of the European Parliament and of the Council on Compulsory Licensing for Crisis Management and Amending Regulation (EC) 816/2006 (July 31, 2023) at 2, https://ipo.org/wp-content/uploads/2023/08/IPO-Comments_EUCompulsoryLicensing.pdf.

[337] *Commission Proposal for a Regulation of the European Parliament and of the Council on Compulsory Licensing for Crisis Management and Amending Regulation (EC) 816/2006*, at 25, COM (2023) 224 final (Apr. 27, 2023).

the compulsory licensing provisions of TRIPS.[338] The proposed regulation 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 7 indicates that "[t]he opinion of the advisory body shall not be binding on the Commission," more clarity is needed in relation to the specific role, responsibilities, and constitution of this Board.[339] In terms of its constitution, members from the innovative industry should be represented and advisers should have appropriate expertise.

The Compulsory Licensing Regulation 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 compulsory license, the Articles of the draft regulation do not address it.[340]

The "adequate" remuneration is capped at a level that may be materially insufficient for some situations.[341]

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 compulsory licence."[342] Such additional measures potentially include the transfer of trade secrets and/or know-how to help effectuate the success of the compulsory license. 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 compulsory license restricts a government granted right (i.e., the patent), but it does not compel the rights-holder to affirmatively act. A compulsory license does

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[338] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 300.

[339] *Commission Proposal for a Regulation of the European Parliament and of the Council on Compulsory Licensing for Crisis Management and Amending Regulation (EC) 816/2006*, at 24, COM (2023) 224 final (Apr. 27, 2023).

[340] *Commission Proposal for a Regulation of the European Parliament and of the Council on Compulsory Licensing for Crisis Management and Amending Regulation (EC) 816/2006*, at 18, COM (2023) 224 final (Apr. 27, 2023).

[341] *Commission Proposal for a Regulation of the European Parliament and of the Council on Compulsory Licensing for Crisis Management and Amending Regulation (EC) 816/2006*, at 26, COM (2023) 224 final (Apr. 27, 2023).

[342] *Commission Proposal for a Regulation of the European Parliament and of the Council on Compulsory Licensing for Crisis Management and Amending Regulation (EC) 816/2006*, at 30, COM (2023) 224 final (Apr. 27, 2023).

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.[343] The regulation allows products linked to a specific geographical area of production to enjoy similar protection to regionally produced foods or beverages.[344] This protection will extend beyond the EU to 59 countries under the 2015 Geneva Act of the Lisbon Agreement.[345] While 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 EC tabled a number of proposals to revise long-standing EU rules on medicinal products for human use.[346] 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 RDP for all innovative products, as well as orphan market exclusivity for orphan

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[343] Regulation (EU) 2023/2411 of the European Parliament and of the Council of 18 October 2023 on the Protection of Geographical Indications for Craft and Industrial Products and Amending Regulations (EU) 2017/1001 and (EU) 2019/1753, art. 2, O.J. L., 2023/2411, 27.10.2023, ELI: http://data.europa.eu/eli/reg/2023/2411/oj.

[344] Regulation (EU) 2023/2411 of the European Parliament and of the Council of 18 October 2023 on the Protection of Geographical Indications for Craft and Industrial Products and Amending Regulations (EU) 2017/1001 and (EU) 2019/1753, recital 5, O.J. L., 2023/2411, 27.10.2023, ELI: http://data.europa.eu/eli/reg/2023/2411/oj.

[345] Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications and Regulations Under the Geneva Act of the Lisbon Agreement, May 20, 2015.

[346] *Commission Proposal for a Regulation of the European Parliament and of the Council Laying Down Union Procedures for the Authorisation and Supervision of Medicinal Products for Human Use and Establishing Rules Governing the European Medicines Agency, Amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and Repealing (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006*, COM (2023) 193 final (Apr. 26, 2023); *Commission Proposal for a Directive of the European Parliament and of the Council on the Union Code Relating to Medicinal Products for Human Use, and Repealing Directive 2001/83/EC and Directive 2009/35/EC*, COM (2023) 192 final (Apr. 26, 2023); *Commission Proposal for a Council Recommendation on Stepping Up EU Actions to Combat Antimicrobial Resistance in a One Health Approach*, COM (2023) 191 final (Apr. 26, 2023); *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Reform of the Pharmaceutical Legislation and Measures Addressing Antimicrobial Resistance*, COM (2023) 190 final (Apr. 26, 2023).

drugs.[347] Coupled with more stringent requirements and conditionalities in several areas, a weaker IP framework for pharmaceutical research and development 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

The EU, through the EC's Packaging and Packaging Waste Regulation ("PPWR"), is pursuing the admirable goal of identifying opportunities to reduce the use of excess plastic in packaging materials.[348] This regulation seeks to require manufacturers to reduce the weight and volume of their packaging to that minimally necessary for the packaging to perform the function of delivering its content to the end user.[349]

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 can serve as a source identifier to allow manufacturers 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 to not 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. It currently provides only limited protection to a manufacturer's IP rights. IPO would recommend that any exceptions to the PPWR focus more broadly on any IP rights that a manufacturer may have in packaging design. Protecting IP rights will help enhance innovation, provide manufacturers 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.

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[347] *Commission Proposal for a Regulation of the European Parliament and of the Council Laying Down Union Procedures for the Authorisation and Supervision of Medicinal Products for Human Use and Establishing Rules Governing the European Medicines Agency, Amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and Repealing (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006*, at 68, 70, 87–88, COM (2023) 193 final (Apr. 26, 2023); *Commission Proposal for a Directive of the European Parliament and of the Council on the Union Code Relating to Medicinal Products for Human Use, and Repealing Directive 2001/83/EC and Directive 2009/35/EC*, 97–100, COM (2023) 192 final (Apr. 26, 2023).

[348] Regulation of the European Parliament and of the Council on Packaging and Packaging Waste, Amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904 and Repealing Directive 94/62/EC, 19.12.2024.

[349] Regulation of the European Parliament and of the Council on Packaging and Packaging Waste, Amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904 and Repealing Directive 94/62/EC, 142–45 19.12.2024.

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.[350]

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

Activities in these bodies can influence legislation. Unfortunately, misguided modifications of IP systems, like those discussed in many of these bodies, can lead to significant uncertainty, reducing 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.

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.

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[350] KRISTINA M. LYBECKER & SEBASTIAN LOHSE, WORLD INTELL. PROP. ORG., GLOBAL CHALLENGES REPORT: INNOVATION AND DIFFUSION OF GREEN TECHNOLOGIES: THE ROLE OF INTELLECTUAL PROPERTY AND OTHER ENABLING FACTORS (2015).

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 2025 Special 301 Report.

Sincerely,

Krish Gupta

Krish Gupta
President