January 28, 2026

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 2026 Special 301 Review, Request for Public Comment (Docket No. USTR-2025-0243)

Dear Mr. Lee:

Intellectual Property Owners Association ("IPO") appreciates the opportunity to provide comments regarding the U.S. Trade Representative's ("USTR") 2026 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 an IP system that enables innovation and creativity; 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 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 and digital piracy, (c) compulsory licensing, (d) weak patent enforcement, (e) genetic resources and

traditional knowledge requirements, (f) data legislation, and (g) unpredictability associated with AI-related patent applications and copyrightability of works created using AI.[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.[3] IPO suggests that improving the global environment for the protection of trade secrets be one of the top priorities for the Special 301 Report and future action by USTR, 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, and prohibition of trade secret compulsory licenses.

As part of marketing authorization submissions for medicines, regulatory authorities generally 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

[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 Jan. 26, 2026). 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 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 (EU).

[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.

of new innovative therapies. Unfortunately, several U.S. trading partners do not provide RDP or have inadequate RDP regimes. Examples include Argentina, Brazil, China, Egypt, India, Mexico, and Türkiye.

Counterfeiting and Digital Piracy

Counterfeiting is a global problem that affects more than a brand or brand owner.[5] The sale and manufacture of counterfeit goods pose a significant health and safety threat to consumers throughout the world. The economic damage caused by counterfeiting also 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, Türkiye, 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, Türkiye, United Arab Emirates, and Vietnam.

In a real-world example, last year an executive at the U.S. faucet manufacturer Moen testified before the U.S. Senate Subcommittee on Intellectual Property to a "sharp increase in inexpensive consumer faucets and plumbing supplies . . . , the majority of which are imported from China" and infringed on Moen's intellectual property.[6] These products are often sold through online e-commerce platforms, with an estimated 35 million off-brand faucets sold in the U.S. in the last five years.[7] Independent testing of these faucets revealed the majority leached lead above the allowable threshold; contained chemicals linked to liver and kidney damage, lymphoma, respiratory problems, and birth defects; and exceeded safe temperature thresholds.[8] The executive also noted that Moen expected the threat to the health and safety of American consumers to "become more acute as [i]mposter [b]rands leverage advanced AI technologies capable of creating more deceptive advertising and faster replication of our IP."[9]

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[5] In 2021, the global trade in counterfeit goods was valued at approximately USD 457 billion, accounting for 2.3% of total global imports. Org. for Econ. Coop. & Dev. [OECD], Eur. Union Intell. Prop. Off., Illicit Trade Mapping Global Trade in Fakes 2025: Global Trends and Enforcement Challenges, at 23 (2025).

[6] *Foreign Competitive Threats to American Innovation and Economic Leadership: Hearing Before the Subcomm. on Intell. Prop. of the S. Comm. on the Judiciary*, 119th Cong. 1 (2025) (statement of Aaron Todd Bores, Executive Vice President Product Development, Moen Incorporated).

[7] *Foreign Competitive Threats to American Innovation and Economic Leadership: Hearing Before the Subcomm. on Intell. Prop. of the S. Comm. on the Judiciary*, 119th Cong. 2 (2025) (statement of Aaron Todd Bores, Executive Vice President Product Development, Moen Incorporated).

[8] *Foreign Competitive Threats to American Innovation and Economic Leadership: Hearing Before the Subcomm. on Intell. Prop. of the S. Comm. on the Judiciary*, 119th Cong. 3–4 (2025) (statement of Aaron Todd Bores, Executive Vice President Product Development, Moen Incorporated).

[9] *Foreign Competitive Threats to American Innovation and Economic Leadership: Hearing Before the Subcomm. on Intell. Prop. of the S. Comm. on the Judiciary*, 119th Cong. 2 (2025) (statement of Aaron Todd Bores, Executive Vice President Product Development, Moen Incorporated).

Ecommerce and social media platforms have made it easier for counterfeiters to sell 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 until 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. Larger networks are also more sophisticated and able to set up multiple shell companies offering the same fake products, allowing them to close accounts when identified through monitoring and take-down work by brand owners without drastically impacting their sales. The ease with which counterfeiters can create new entities often makes brand owners feel like they are playing a game of Whac-a-Mole®; once a counterfeiter's profile is taken down from one site, the same person and products will reappear under a new business name.[10] One way to combat these issues is by implementing a central repository with known counterfeiters and personal details (such as ID numbers or banking details) linking different entities to the same network. Another is by having ecommerce platforms issue verification numbers to sellers that require the seller to submit personal details.

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. IPO has separately identified specific platforms of concern in its October 1, 2025, comments to the USTR regarding markets to be considered for inclusion in the 2025 Notorious Markets List.[11]

Over the past few years, brand owners have also seen an increase in the use of social media to sell counterfeit goods. For example, social media platforms are often used to promote counterfeits and initially engage with customers. Counterfeiters will then switch to another messaging platform, such as WhatsApp, WeChat, or Telegram Messenger, to continue the conversation and finalize the sale. In some cases, the sale is consummated through an online store where the seller advertises a different product and/or brand, using the platform to process orders with low risks of detection.

Many brand owners use vendors to help enforce their brands on ecommerce markets, social media platforms, and other websites. Others cannot afford to do this and must rely on internal resources and ecommerce platform cooperation, however some platforms work 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. IPO supports encouraging platforms to pursue more proactive measures to combat counterfeits in cooperation with IP owners.

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[10] WHAC-A-MOLE, Registration No. 2,536,814.

[11] Intell. Prop. Owners Ass'n, Comment Letter on 2025 Review of Notorious Markets for Counterfeiting and Piracy (Oct. 1, 2025), https://ipo.org/wp-content/uploads/2025/10/IPO-2025-Notorious-Market-List-Comments.pdf.

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, enacting measures to protect consumers from the use of social media and messaging platforms to sell counterfeit goods, 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.[12]

In particular, governments should increase penalties for pharmaceutical counterfeiting, as fake medicines pose serious health risks to consumers and can lead to treatment failures, harmful reactions, and even death. Current penalties in many countries are far too low compared to the enormous profits counterfeiters make, especially as they use online platforms, small-parcel shipping, and free-trade zones to avoid detection. Stronger penalties, larger fines, and improved enforcement are essential to create real deterrence and ensure that the consequences for producing or selling dangerous fake medicines reflect the serious health risks they pose to patients.

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 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 counterfeiters' ability 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

[12] IPO appreciates the Organisation for Economic Co-operation and Development's (OECD) recent efforts in drafting its "Guidelines for Countering Illicit Trade in Counterfeit Goods on Online Marketplaces." IPO's comments to the U.S. Patent and Trademark Office regarding the OECD Guidelines include further suggestions for how governments and ecommerce sites may protect against the online sale of counterfeits. Intell. Prop. Owners Ass'n, Comment Letter on OECD's Working Party on Countering Illicit Trade (WP-CT) Draft Voluntary Guidelines for Countering Illicit Trade in Counterfeit Goods on Online Marketplaces (Aug. 26, 2025), https://ipo.org/wp-content/uploads/2025/08/IPO-Comments-to-USPTO-on-OECD-Final.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.

As a significant step in driving marketplace accountability, IPO recognizes the European Commission's October 2024 initiation of formal proceedings against the online marketplace Temu, which preliminarily found Temu had breached its obligation under the European Union's ("EU") Digital Services Act to properly assess the risks of illegal products being disseminated on its marketplace.[13] Similar legislative and regulatory enforcement efforts in other countries and regions can, and should, play a large role in combatting counterfeits.

The internet's global reach and the ease of digital content distribution have also made copyright enforcement against digital piracy an international and complex challenge. Copyright protection is territorial and the variation in individual countries' laws makes enforcing rights against a single online infringer operating across multiple borders both costly and time-consuming. Digital pirates can and do hide their identities and locations using virtual private networks ("VPNs"), making it difficult for copyright holders to find and prosecute them. Legal disputes can become entangled in complicated jurisdictional issues, especially when the infringer is in a country with weaker enforcement laws. Despite treaties like the TRIPS Agreement, effective global enforcement mechanisms are still limited. IPO encourages USTR to pursue stricter digital piracy provisions in trade agreements and more cross-border collaboration against such infringements.

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 Türkiye, have adopted or are considering resolutions, laws, or regulations that promote or provide broad discretion to issue compulsory licenses. In particular, in 2025 the European Union agreed on the adoption of an EU-wide compulsory licensing scheme.[14] The new regulation may lead to broader use of compulsory licensing, posing a threat to the investment in research that is necessary to develop new medicines and improve human health.

Compulsory licenses have previously been issued in several countries, including Hungary, India, Indonesia, Israel, Malaysia, Colombia, and Russia. Granting compulsory licenses undercuts the importance of a predictable and reliable patent system and

[13] Press Release, European Comm'n, Commission Preliminarily Finds Temu in Breach of the Digital Services Act in Relation to Illegal Products on its Platform (July 27, 2025).

[14] Regulation 2025/2645 of the European Parliament and of the Council of 16 December 2025 on Compulsory Licensing for Crisis Management and Amending Council Regulation No 816/2006, O.J. L, 2025/2645, 30.12.2025, ELI: http://data.europa.eu/eli/reg/2025/2645/oj.

undermines investment in innovative solutions that benefit society. IPO believes that licensing of IP rights is best accomplished through voluntary efforts.[15]

Compulsory licensing outside the U.S. harms innovators, particularly 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, which 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 benefit society also will 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. Innovators that can rely on IP rights with confidence will have the security to make investments in research and development and establish voluntary partnerships 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.

Patent Enforcement

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

IPO urges governments to adopt legislative and administrative reforms instituting 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 court patent proceedings are held fairly and equitably, conclude within an appropriate timeline due to the time sensitivity of these claims, and include mechanisms to compensate patent holders for their losses in cases 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 later repair. IPO welcomes efforts by China to implement such a mechanism and hopes that further efforts

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

will be made to provide meaningful protection for innovators' patent rights.[16] In contrast, countries, such as India and Saudi Arabia, grant marketing approval to generic drugs during the term of the innovator's patent, preventing effective enforcement of patent rights and impairing the incentives to invest in the development of drugs.

Saudi Arabia is in violation of its requirements under Article 39 of TRIPS to provide regulatory data exclusivity for newly approved pharmaceuticals. In fact, Saudi Arabia has provisions in its domestic law to ensure the confidentiality of test data used to obtain marketing approval for a pharmaceutical having a new chemical entity.[17] Nevertheless, in practice the Saudi government continues to rely on innovator's data to approve generic versions of an innovator's drugs.

Saudi Arabia has also failed to adopt a mechanism for determining patent infringement before approval of a generic drug. The Saudi government instituted a plan in 2022 to consider patent rights before granting approval of generic drugs, however, the provisions have proven to be ineffective, in that they lack notice to the innovator of the generic application.[18] The provisions also do not provide for a stay of generic approval during the patent dispute, as required for an equitable procedure. IPO urges USTR to encourage the Saudi government to institute a fair system for resolving patent disputes before generic approval and to respect the innovator's confidential regulatory data.

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 origin of any genetic resources incorporated into a product is unknown or untraceable. IPO supports the objectives of the Convention on Biological Diversity and recognizes the national sovereignty of states over biological resources.[19] 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

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[16] Yaopin Zhuanli Jiufen Zaoqi Jiejue Jizhi Xingzheng Caijue Banfa (药品专利纠纷早期解决机制行政裁决办法) [Administrative Adjudication Procedures for Early Resolution of Pharmaceutical Patent Disputes] (promulgated by the St. Intell. Prop. Off., July 5, 2021, effective July 5, 2021).

[17] Regulations for the Protection of Confidential Commercial Information, Umm al-Qura Minister of Commerce and Industry Decision No. 3218, 25/03/1426H (2005) art. 5.

[18] الهيئة السعودية للغذاء والدواء, آلية التعامل مع براءات الاختراع عند تسجيل المستحضرات الصيدلانية الجنيسة في الهيئة العامة للغذاء والدواء [SAUDI FOOD & DRUG AUTH., THE MECHANISM FOR HANDLING PATENTS WHEN REGISTERING GENERIC PHARMACEUTICAL PRODUCTS AT THE GENERAL FOOD AND DRUG AUTHORITY] (2002).

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

Intellectual Property Organization ("WIPO") on May 24, 2024, requiring disclosure of the country of origin of genetic resources and/or traditional knowledge identified in patent filings.[20] As of July 9, 2025, the treaty has been signed by 44 countries, five of which (Bolivia, Ecuador, Iran, Switzerland, and Zambia) signed in 2025.[21] The treaty has been ratified by two countries, Malawi (in 2024) and Uganda (in 2025), and will come into force three months after there have been 15 total ratifications and accessions.

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 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.

Examples of concerning developments include amendments to Malaysia's IP laws, which passed in 2021 and include genetic resources disclosure requirements and compulsory licensing provisions that raise concerns for genetics research-based industries.[22] Additionally, Thailand could impose procedural barriers by requiring applicants to disclose information regarding the use of genetic resources as part of their patent

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[20] 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* 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; Intell. Prop. Owners Ass'n, Comment Letter on World Intellectual Property Organization Treaty on Intellectual Property, Genetic Resources, and Associated Traditional Knowledge (Mar. 18, 2025), https://ipo.org/wp-content/uploads/2025/03/IPO-Comments-to-USPTO-on-WIPO-GRATK-Treaty.pdf.

[21] *WIPO-Administered Treaties*, WORLD INTELL. PROP. ORG. https://www.wipo.int/wipolex/en/treaties/ShowResults?search_what=C&treaty_id=19830 (last visited Jan. 26, 2026).

[22] Patents Act 1983 (Act 291), §§ 48–54, 80(4) (Malay.).

application.[23] Such disclosure requirements could present significant barriers to patentability and should be removed.

In India, failure to disclose or correctly 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.[24] 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 the use of genetic resources originating from India, whereby a non-Indian person or company requires NBA approval to access or include such genetic resources in an Indian patent application.[25] The NBA also has the right to require benefits sharing or royalties to the Indian government, based on the use of the India-originating genetic resources employed in the patent application.[26]

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 and the genetic information generated from the use of any material taken from a human, animal, plant, or microorganism which contains functional units of heredity and is of actual or potential value.[27] China's law allows the government to reject any patent right where the required information for genetic resources is not disclosed.[28] Moreover, China has a separate law governing the use of certain human genetic resources, requiring that a Chinese entity report to the Ministry of Science and Technology when it plans to share human genetic resources with a non-Chinese entity and conduct a security review.[29] Under the law's implementing regulations, the Ministry and provincial science and technology administration departments are also tasked with supervising and inspecting the disposal of IP rights arising from the sharing of human genetic resources.[30] By its terms, China's human genetic resources law disadvantages U.S. and other non-Chinese entities, restricting their IP rights, while it does not apply to Chinese entities.

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[23] DRAFT PATENT ACT (No. …), art. 10 B.E. … (2020) (Thai.).

[24] The Patents Act, 1970, § 64(p) (India).

[25] The Biological Diversity (Amendment) Act, 2023, § 4 (India).

[26] The Biological Diversity (Amendment) Act, 2023, § 18 (India).

[27] 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 St. Council of the People's Republic of China, June 15, 2001, rev'd Dec. 11, 2023), arts. 27, 29 (China).

[28] 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 St. Council of the People's Republic of China, June 15, 2001, rev'd Dec. 11, 2023), art. 50 (China).

[29] 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 St. Council of the People's Republic of China, May 28, 2019, effective July 1, 2019) ch. 3 (China).

[30] Renlei Yichuan Ziyuan Guanli Tiaoli Shishi Xize (人类遗传资源管理条例实施细则) [Implementing Regulations for the Management of Human Genetic Resources] (promulgated by the Ministry of Sci. & Tech., May 26, 2023, effective July 1, 2023) art. 56(iii).

Data Legislation

While artificial intelligence ("AI") has become pervasive in the last couple of years, improvements in its capability also added concerns around uses, regulations, and IP protections related to data, raising 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, cybersecurity, personal information protection, cross-border data transfer, AI-related, and privacy laws 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.[31] Data can be collected and processed after individual consent, or for a range of "legitimate" uses including medical emergencies, epidemics, and more.[32]

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.[33] 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.[34] Courts 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 EU Artificial Intelligence Act ("AI Act"), which entered into force August 1, 2024, with staggered application dates through 2026 and 2027, regulates AI by risk tier and, among other things, compels extensive transparency for high-risk systems and general-purpose AI models—raising acute concerns among model developers and data

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[31] The Digital Personal Data Protection Act, 2023; Digital Personal Data Protection Rules 2025.

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

[33] Regulation 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 2017/2394 and Directive 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.

[34] Regulation 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 2017/2394 and Directive 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 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.

owners about erosion of trade secret and copyright protections.[35] Required measures, such as maintaining detailed technical documentation and updating it over the model lifecycle, can pressure providers to reveal sensitive design choices, training processes, and evaluation methods.[36] Even where confidentiality carve-outs exist, the breadth of documentation expected for conformity assessment may increase reverse-engineering risk in practice. Similarly, obligations to publish a training-data summary using the EU Commission's template puts a premium on disclosing data sources and characteristics.[37] While intended for accountability, granular source descriptions could expose copyrighted datasets, licensing strategies, and/or proprietary data pipelines. In addition, a copyright-compliance policy across models—including safeguards aligned with the EU Copyright Directive and record-keeping to demonstrate lawful training—may necessitate disclosures to users and regulators that telegraph vendor-specific filtering, de-duplication, or "opt-out" handling, potentially narrowing competitive moats.[38] Finally, information-sharing duties with downstream providers and authorities (e.g., supplying instructions for use, incident reporting, and cooperation with market-surveillance bodies and the EU AI Office) heighten the risk that confidential architecture, tuning methods, and more are indirectly revealed across the supply chain. Together, these obligations may serve the AI Act's transparency goals but, as with the GDPR experience, are likely to be interpreted unevenly by national authorities and courts—leaving developers to risk disclosure of protected trade secrets and loss of copyrighted content.

The positive intentions behind the efforts in overall data protection, AI regulation, 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.

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[35] Regulation 2024/1689 of the European Parliament and of the Council of 13 June 2024 on Laying Down Harmonised Rules on Artificial Intelligence and Amending Regulations No 300/2008, No 167/2013, No 168/2013, 2018/858, 2018/1139 and 2019/2144 and Directives 2014/90/EU, 2016/797 and 2020/1828 (Artificial Intelligence Act), O.J. L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj. For a high level summary of the Act, its disclosure requirements, and implementation timeline, see *High-Level Summary of the AI Act*, FUTURE OF LIFE INST., https://artificialintelligenceact.eu/high-level-summary/ (May 30, 2024); *The European Union Artificial Intelligence Act*, EY GLOBAL (July 12, 2024), https://www.ey.com/content/dam/ey-unified-site/ey-com/en-gl/insights/public-policy/documents/ey-gl-eu-ai-act-07-2024.pdf; Thorsten Ammann et al., *Latest Wave of Obligations Under EU AI Act Take Effect: Key Considerations*, DLA PIPER (Aug. 7, 2025), https://www.dlapiper.com/en-us/insights/publications/2025/08/latest-wave-of-obligations-under-the-eu-ai-act-take-effect.

[36] Regulation 2024/1689 of the European Parliament and of the Council of 13 June 2024 on Laying Down Harmonised Rules on Artificial Intelligence and Amending Regulations No 300/2008, No 167/2013, No 168/2013, 2018/858, 2018/1139 and 2019/2144 and Directives 2014/90/EU, 2016/797 and 2020/1828 (Artificial Intelligence Act), art. 11, apps IV, XI, XII, O.J. L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj.

[37] *Explanatory Notice and Template for the Public Summary of Training Content for General-Purpose AI Models*, EUR. COMM'N (July 24, 2025), https://digital-strategy.ec.europa.eu/en/library/explanatory-notice-and-template-public-summary-training-content-general-purpose-ai-models.

[38] Regulation 2024/1689 of the European Parliament and of the Council of 13 June 2024 on Laying Down Harmonised Rules on Artificial Intelligence and Amending Regulations No 300/2008, No 167/2013, No 168/2013, 2018/858, 2018/1139 and 2019/2144 and Directives 2014/90/EU, 2016/797 and 2020/1828 (Artificial Intelligence Act), art. 53(c), O.J. L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj.

Unpredictability Associated with AI-Related Patent Applications and Copyrightability of Works Created Using AI

As AI technologies mature, patent offices around the world are updating their procedures to address the new challenges that come with protecting these innovations. Multiple countries have recently released new guidance for handling AI-related patent applications, touching issues of subject matter eligibility, disclosure sufficiency, and inventorship.

In the latter half of 2025 alone, India released new guidelines for computer-related inventions, China finalized its updated patent examination guidelines with significant revisions related to AI, and Brazil released its draft guidelines for patent examination of AI inventions.[39] The various approaches within these regulations are likely to have an impact on international filings as applicants attempt to accommodate the different regimes.

Sufficiency of disclosure poses a particular risk for inventors of AI-related technology because, under the current rules, an application that is sufficiently detailed for a patent in the U.S. may fail to meet the relatively strict requirements in countries such as India or those proposed in Brazil. Unfortunately, patent applicants will have to predict the proper level of disclosure and risk disclosing application contents with uncertain protection, likely for years, as this space becomes more defined.

Similar to the question of sufficiency, jurisdictional differences in subject matter eligibility of AI-related inventions can render a new, non-obvious, and enabled invention eligible for patent protection in one country and not in the other. This risks creating jurisdictions where patent rights for AI technologies are impossible to acquire and enforce, resulting in a loss of rights. Inventorship is also becoming an issue, with differing approaches arising between offices to how much human involvement is needed to earn a patent when involving AI tools.

There is a global divergence concerning copyrightability of AI-assisted and AI-generated works. Most jurisdictions maintain that copyright protection requires original human authorship, while creative works generated *solely* by AI are often not copyrightable. However, these countries generally allow copyright protection of works created using AI as a tool, but only where the human still maintains significant creative control in the selection, arrangement, or modification of the output.

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[39] Office of the Controller General of Patents, Designs & Trade Marks, Guidelines for Examination of Computer Related Inventions (CRIs) (issued on July 29, 2025); Guojia Zhishi Chanquan Ju Guanyu Xiugai "Zhuanli Shencha Zhinan" de Jueding (Ju Ling di 84 Hao) (国家知识产权局关于修改《专利审查指南》的决定(局令第 84 号) [Decision of the State Intellectual Property Office on Revising the Guidelines for Patent Examination (Order No. 84)] (promulgated by the St. Intell. Prop. Off., Nov. 10, 2025, effective Jan. 1, 2026); Consulta Pública No. 3, de 16 de Agosto de 2025, Diário Oficial da União [D.O.U.] de 18.8.2025.

The U.S. Copyright Office firmly requires human authorship and has denied registration for purely AI-generated works, even when a human uses hundreds of prompt iterations.[40] Similarly, the EU's stance emphasizes that copyrightable subject matter must be the "author's own intellectual creation" and reflect their personal contribution.[41] In China, the Beijing Internet Court has recognized copyright protection for AI-generated images, provided they reflect a human's intellectual effort and originality.[42] Additionally, a UK law grants "computer-generated works" without a traditional human author a shorter 50-year copyright term, though its current status is subject to review and potential legislative changes.[43] IPO encourages the USTR to promote global harmonization on this issue, as diverging laws in major world markets greatly complicate protection for stakeholders.

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IPO encourages USTR to prioritize global predictability and legal coherence in its engagement with trading partners. Consistency in the administration of IP rights advances the rule of law and strengthens the international innovation ecosystem. Inconsistent or discretionary application of IP standards undermines trust in the system and can distort competition. IPO urges USTR to advocate for transparent procedures, harmonized interpretation of treaty obligations, such as the TRIPS Agreement, and adherence to fair administrative and judicial practices that provide innovators with confidence that their rights will be treated uniformly, predictably, and with due process across all jurisdictions.

II. COUNTRY-SPECIFIC CONCERNS

ARGENTINA

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

The patent examination backlog in Argentina continues to be a challenge for innovators. In general, patent applications are resolved five years from the filing date, but pharmaceutical and biotech inventions 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 encourages efforts by the Argentina Patent Office, the Instituto Nacional de la Propiedad Industrial ("INPI Argentina"), to reduce the backlog, including its enactment of Resolution 56/2016.[44] However, a significant backlog remains and Argentina provides neither provisional nor supplemental protection to ameliorate delays during prosecution.

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[40] U.S. COPYRIGHT OFF., COPYRIGHT AND ARTIFICIAL INTELLIGENCE, PART 2: COPYRIGHTABILITY 18 (2025).

[41] Case C-5/08, Infopaq Int'l A/S v. Danske Dagblades Forening, 2009 E.C.R. I-6569.

[42] Li Su Liu (李诉刘) [Li v. Lu] (Beijing Internet Ct., 2023).

[43] Copyright, Designs and Patents Act 1988, c. 48, § 9(3); INTELLECTUAL PROPERTY OFFICE, COPYRIGHT AND AI: CONSULTATION, 2024, Cm. 1205 at 24.

[44] Resolution No. 56/2016, Sept. 12, 2016, [33464] B.O. 19, 19 (allowing the National Patent Administration to accept international prior art searches and examinations conducted by foreign offices with the same patentability requirements as Argentina).

Shifts in the Legal Framework Creating Uncertainty for Innovators

Joint Resolution 118/2012, 546/2012, and 107/2012, issued in May 2012, introduced highly restrictive patentability criteria for chemical and pharmaceutical inventions in Argentina 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.[45]

Resolution 283/2015, issued on September 25, 2015, amended the Argentina 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 provided by the TRIPS Agreement, the Patent Law No. 24,481, and its Regulating Decree.[46]

The above-referred Resolutions, which are applied together in some biotech and pharma cases, run contrary to the obligations assumed by Argentina under the TRIPS Agreement and discourage local and foreign direct investment. In particular, IPO believes that these Resolutions 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," and that "patents shall be available and patent rights enjoyable without discrimination as to the . . . field of technology . . . ."[47]

Patent owners also face substantial difficulties and delays in enforcing their rights in Argentina due to the complexity of and obstacles to obtaining temporary injunctions. Argentina Patent Law was amended in 2004 to introduce a cumbersome injunction process.[48]

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.[49] Argentina adhering to this agreement would be a positive step toward reducing extra expenses and facilitating filing strategies for individual inventors, universities, institutions, and private and public companies.

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[45] 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).

[46] Resolution No. 283/2015, Sept. 25, 2015, [33228] B.O. 16, 16–17.

[47] 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.

[48] Law No. 25859, Jan. 8, 2004 [30317] B.O. 7, 7 art. 2.

[49] *The PCT Now Has 158 Contracting States*, WORLD INTELL. PROP. ORG., https://www.wipo.int/pct/en/pct_contracting_states.html (last visited Nov. 26, 2025).

Lack of Regulatory Data Protection

Argentina does not provide protection for regulatory testing data, which is inconsistent with its obligations under TRIPS Article 39.3.[50] Specifically, Law 24,766 and Decree 150/92 permit Argentine officials to rely on data submitted by biopharmaceutical originators to approve competitor's requests to market similar products.[51]

Piracy and Counterfeiting

The level of enforcement against piracy and counterfeiting of protected works and goods is very weak in Argentina. Preventative measures taken by local courts, police, and customs officials are often ineffective. Federal courts have also made little effort to combat counterfeiters, thus encouraging an increase in illegal activity.

However, it should be highlighted and commended that in 2025, Argentinian authorities imprisoned the owner and collaborators of the country's biggest counterfeit product market, known as "La Salada." In the same year, the Chief of Government of Buenos Aires collaborated with local police to reduce the sale of counterfeit products by street sellers, locally known as "manteros." IPO is encouraged by these efforts and hopes to see a continued upward trend of stronger enforcement.

Framework for a United States–Argentina Agreement on Reciprocal Trade and Investment

On Thursday November 13, 2025, the White House issued a briefing and statement that the U.S. and Argentina had agreed to a framework to deepen bilateral trade and investment cooperation.[52] The statement further informed that Argentina has committed to address structural challenges cited in the USTR's 2025 Special 301 Report, including patentability criteria, patent backlog, and geographical indications, and that it will work towards aligning its intellectual property regime with international standards.[53] The agreement is expected to be finalized in 2026. IPO looks forward to implementation of this agreement and further cooperation between Argentina and the U.S. on intellectual property rights.

AUSTRALIA

Australia's Onerous Best Method Requirement for Patents

An unusual feature of Australian patent law is its "best method" requirement, an independent ground of invalidity that requires the patent specification describe the best method of performing the invention known to the applicant (not the inventors) at the date

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[50] *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.

[51] Law No. 24766, Dec. 20, 1996, [28553] B.O. 3; Decree No. 150/1992, Jan. 20, 1992, [27311] B.O. 2.

[52] Press Release, White House, Joint Statement on Framework for a United States-Argentina Agreement on Reciprocal Trade and Investment (Nov. 13, 2025).

[53] Press Release, White House, Joint Statement on Framework for a United States-Argentina Agreement on Reciprocal Trade and Investment (Nov. 13, 2025).

of filing (as opposed to the priority date).[54] This complicates matters for applicants because failure to disclose the best method can invalidate an entire application, despite there being sufficient disclosure, and it cannot be remedied later via amendment.[55]

There is a serious open question of whether the entire patent, or only certain claims, will be invalidated if the best method is not disclosed. The Federal Court also has conflicting case law governing what constitutes the relevant "filing date" of the complete application, specifically, whether it is the "date of the patent" (i.e., the ultimate filing date of the first complete application in a patent family) or the local filing date of any divisional application.[56] The former understanding creates significant issues, as adding new information to the divisional specification to include the best method could also affect the priority date of any claims that rely on the added matter. Already-granted divisional patents could also 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.

Australia's Support Requirement

IPO continues to monitor the Australian requirement for claims to be "supported" by matter disclosed in the specification.[57]Although enacted to promote international harmonization, the differences between the Australian support requirement and U.S. enablement and written description requirements can present challenges for applications originating from the U.S.[58]

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[54] *Les Laboratoires Servier v Apotex Pty Ltd* [2016] FCAFC 27 (8 March 2016) ¶ 12. For a summary of the relevant factors to be considered in deciding the best method requirement, see *Dyno Nobel Asia Pac Pty Ltd v Orica Explosives Tech Pty Ltd* [2025] FCA 767 (14 July 2025) ¶ 543.

[55] The best method requirement was recently reaffirmed by the Full Federal Court of Australia, which found that even though a patent satisfied the enabling disclosure requirement, it did not include the "best method" because the specification disclosed broad ranges from which the preferred concentrations of the vaccine-at-issue could be discovered through further research and testing. *Zoetis Servs LLC v Boehringer Ingelheim Animal Health USA Inc* [2024] FCAFC 145 (15 November 2024) ¶ 48.

[56] *Dometic Austl Pty Ltd v Houghton Leisure Prods Pty Ltd* [2018] FCA 1573 (19 October 2018) ¶ ¶ 229, 233 (holding that the best method requirement was based on what was known by the applicant at the filing date of the divisional application and not the filing date of the earlier parent (PCT) application); *The NOCO Co v. Brown & Watson Int'l Pty Ltd* [2025] FCA 887 (7 August 2025) ¶ ¶ 375–376 (holding the best method should be assessed as of the date that the first complete application was filed and for which a monopoly would be granted for the invention—that is, the ultimate complete filing date).

[57] *Patents Act 1990* (Cth) s 40(3); *Merck Sharp & Dohme Corp v Wyeth LLC (No 3)* [2020] FCA 1477 (14 October 2020) ¶ 547 (holding 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); *see also Cytec Indus Inc v Nalco Co* [2021] FCA 970 (19 August 2021) ¶ 136; *TCT Grp Pty Ltd v Polaris IP Pty Ltd* [2022] FCA 1493 (14 December 2022) ¶ 241.

[58] Explanatory Memorandum, Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 (Cth) 48–49. 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 UK to the Australian support requirement and 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. [2023] FCAFC 178 (13 November 2023) ¶ 186 (citing *Regeneron Pharms. Inc. v. Kymab Ltd.*

It is becoming increasingly more difficult to obtain broad antibody claims in Australia, predominantly because of the Australian Patent Office's strict implementation of the support and enablement requirements, of which there has been little judicial consideration in relation to therapeutic antibodies. In a typical scenario where an antibody is raised against a known antigen, it must now be claimed by reference to all six complementarity-determining region sequences ("CDRs"), the segments that determine antigen-binding specificity. Although in some instances it might be possible to avoid reciting all six CDRs, the majority of applications are constrained by these relatively narrow claims.[59]

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 Patent Prosecution Highway ("PPH"). Such unpredictability has been to the detriment of those who innovate in this space.

Subject matter eligibility is assessed under the UK Statute of Monopolies' "manner of manufacture" test, which, as previously implemented by the Australian Patent Office, dismissed the contribution of well-known claim features and gave undue weight to inventive features, foreclosing patentability to many computer-implemented inventions mischaracterized as ineligible "schemes."[60] However, the Full Court recently adopted a lower threshold for the manner of manufacture, stating that the patent's characterization should reflect the features of the claim as a whole, encompassing both inventive and non-inventive elements.[61] In relation to whether a particular computer-implemented invention is a manner of manufacture, the Full Court devised a new test which asked whether the subject matter is: (1) an abstract idea which is manipulated on a computer; or (2) an abstract idea which is implemented on a computer to produce an artificial state of affairs and a useful result; with the latter being eligible and the former not.[62] The Full Court emphasized that this technology-neutral approach aligned with the policy need for the Patents Act to encourage invention and innovation.[63]

The Australian Patent Office has updated the Patent Manual of Practice and Procedure to reflect this decision but the Manual still includes consideration of the state of the art in assessing manner of manufacture.[64]

[2020] UKSC 27, [56] (appeal taken from Eng.) (UK)). 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." *Calix Ltd v Grenof Pty Ltd* [2023] FCA 378 (28 April 2023) ¶ 128.

[59] It may be possible to not cite all six CDRs 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).

[60] Statute of Monopolies 1623, 21 Jac. c. 3, § IV. (Eng.).

[61] *Aristocrat Techs Austl Pty Ltd v Comm'r of Pats* [2025] FCAFC 131 (16 September 2025) ¶ 131.

[62] *Aristocrat Techs Austl Pty Ltd v Comm'r of Pats* [2025] FCAFC 131 (16 September 2025) ¶ 131.

[63] *Aristocrat Techs Austl Pty Ltd v Comm'r of Pats* [2025] FCAFC 131 (16 September 2025) ¶ 134.

[64] IP Australia, *Patent Manual of Practice and Procedure* (2025) vol 2, s 5.6.8.1.

Market-Size Damages

The Australian pharmaceutical benefits scheme (PBS) imposes automatic and irreversible price cuts on medicines as soon as a competing brand first enters the market, but does not provide a corresponding mechanism of automatic compensation to innovators for a PBS price cut triggered by an infringing product being launched prematurely; the innovator must instead seek to recover those losses from the infringing generic as part of its damages claim.

Australia's Department of Health has continued to implement its policy of seeking damages from biopharmaceutical innovators that have obtained preliminary injunctions in proceedings that are ultimately unsuccessful on the merits.[65] Those damages are designed to compensate the PBS for any delay in the reduction of prices during the period of the preliminary injunction, which, given the value of subsidies under the PBS, could amount to damages in the hundreds of millions Australian dollars.[66]

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

IPO also believes the Australian Government should take steps to increase the notice period to a patent holder regarding entry of a generic competitor 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 five years of RDP 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.[67] 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 puts pharmaceutical innovators at a potential disadvantage in Australia compared to other developed countries. After expiry of the initial five-year period, generic competitors can rely on innovators' clinical data to obtain abridged approvals

[65] Department of Health, Disability and Ageing, *Annual Report 2024-25* (Report, 2025) 276.

[66] 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) ¶ 440, *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)).

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

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

The Australian Government is currently considering legislation based on the results of a 2023 request for comments that proposed expanding protection for virtual, incremental, and partial designs.[68] Implementing such legislation would 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 its users.[69] Australia should be encouraged to make the changes needed to join the Hague System.

The proposal to allow virtual designs is a welcome shift. IP Australia currently takes the position that Australia's design registration system is geared towards protecting "the overall appearance of physical products."[70] This can create difficulties when seeking design protection for 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 traditional display screens.[71] 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.

Additionally, 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).[72] This differs from IP Australia's current position, which requires design registrations to exist in relation to "products" and does not expressly include partial products.[73]

Removal of IP Rights Exemption from Australian Competition Law

IPO is concerned about the removal of 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

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[68] *See Enhancing Australian Design Protection*, IP AUSTL., https://consultation.ipaustralia.gov.au/policy/enhancing-australian-design-protection/ (last visited Jan. 17, 2026).

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

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

[71] 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) (revoking DRiV IP's designs for an "electronic device including a display screen" and "display screen.").

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

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

competition law prohibitions, was repealed on September 13, 2019.[74] With the repeal of the exemptions, licensors and licensees may be held criminally liable for breaching cartel prohibitions, unless the anti-overlap provisions apply when the contract includes price, territorial, or quota restrictions.

Recent Judicial Decisions Adverse to Trademark Owners' Rights

Several recent decisions published by the Australian courts have endangered long-standing protections for trademark holders. IPO believes that Australia should revisit these issues to ensure greater protection for brand owners.

The Australian Federal Court's 2017 decision in *Pham Global Pty. Ltd. v. Insight Clinical Imaging Pty. Ltd.* made clear that a trademark application filed under the name of an individual or entity that does not own the mark cannot be later remedied by amendment or assignment.[75] This allows a mere clerical error to render a mark invalid at the outset and sets a complicated precedent for brand owners trying to protect their rights in Australia.

More recently in 2023, the Australian Full Federal Court cast doubt on a longstanding principle that allowed applicants to rely on the Nice Classification of Goods when determining the scope of a trademark's goods and services, and refused to register the mark in Class 30 for coffee due to a likelihood of confusion with a similar mark in Class 32 for non-alcoholic beverages based on a similarity of goods.[76] The need to assess the likelihood of consumer confusion across classes creates more uncertainty and unpredictability for applicants filing in Australia.

In another recent unanimous judgment, the Australian High Court clarified that a trademark's reputation should not be taken into account when assessing deceptive similarity under the infringement provision of Section 120(1) or the prosecution provision of Section 44(1) of the Trade Marks Act 1995 (Cth).[77] This decision has wide-reaching implications for owners of reputable or famous marks in terms of mitigating infringement risks.

Increased Scam Activity Relating to Trademarks

IP Australia has experienced an increase in scam activity affecting trademark rights holders. This includes unauthorized third parties fraudulently impersonating actual registered attorneys or law firms. IPO encourages IP Australia to continue to take steps to address scam activity and appreciates efforts already introduced, including new multi-factor identification for access to accounts.

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[74] *Competition and Consumer Act 2010* (Cth) comp 119 s 51(3); *see Treasury Laws Amendment (2018 Measures No. 5) Act 2019* (Cth) sch 4; Australian Competition & Consumer Commission, *Guidelines on the Repeal of Subsection 51(3) of the Competition and Consumer Act 2010 (Cth)* (2019).

[75] [2017] FCAFC 83 (26 May 2017).

[76] *Energy Beverages LLC v Cantarella Bros Pty Ltd* [2023] FCAFC 44 (22 March 2023).

[77] *Self Care IP Holdings Pty Ltd v Allergan Austl Pty Ltd* [2023] HCA 8 (15 March 2023).

Inconsistent or Biased Trademark Examination

IPO members report Australian trademark applicants are experiencing inconsistent and sometimes lower quality examination of their applications, with some cases receiving new citations raised late in subsequent reports with no extension of the acceptance deadline, examiners applying tests derived from superseded case law, and inconsistent training and supervision of new examiners. IPO members have also noticed more stringent examinations being conducted on cases filed by overseas applicants versus those by local applicants.

BRAZIL

Brazil Enacts Clear Regulations for Acquired Distinctiveness in Trademarks

For the first time, Brazil's Patent and Trademark Office, the Instituto Nacional da Propriedade Industrial ("INPI Brazil") established rules for acknowledging the secondary meaning, or acquired distinctiveness, of a trademark. Effective November 28, 2025, the new regulation allows requests for recognition of acquired distinctiveness to be submitted at the time of filing a trademark application, within 60 days of its publication, within an appeal of a rejection, or in response to pre-grant or post-grant oppositions.[78] For pending cases, requests will be exceptionally accepted within 12 months from the effective date of the new rules.[79]

Once recognition is requested, applicants will have 60 days to provide evidence of (1) at least three years of continuous use of the trademark and (2) its exclusive association with the applicant's goods or services by a relevant portion of Brazilian consumers.[80] INPI Brazil may issue office actions to request additional information and rejections can be appealed.

IPO supports this new regulation, the clarity it brings for trademark owners in Brazil, and the expanded means for securing trademark rights.

Brazil Enacts Regulations on the Potential Suspension of Intellectual Property Rights Amid Trade Disputes

In April 2025, the Brazilian government issued Decree No. 12,551/2025 to clarify and regulate the enforcement of the Reciprocity Act (Law No. 15,122/2025), which provides the legal basis for Brazil's reciprocal actions against countries or economic blocs that impose restrictive or discriminatory trade measures and authorizes the suspension of intellectual property rights as a response to unilateral trade actions against Brazil.[81]

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[78] Portaria No. 15, de 03 de Junho de 2025, Revista da Propriedade Industrial de 10.06.2025, art. 84-D(III).
[79] Portaria No. 15, de 03 de Junho de 2025, Revista da Propriedade Industrial de 10.06.2025, art. 96-A.
[80] Portaria No. 15, de 03 de Junho de 2025, Revista da Propriedade Industrial de 10.06.2025, arts. 84-E, 84-F.
[81] Decreto No. 12.551, de 14 de Julho de 2025, Diário Oficial da União [D.O.U.] de 15.7.2025; Lei No. 15.122, de 11 de Abril de 2025, Diário Oficial da União [D.O.U.] de 14.4.2025.

Decree No. 12,551/2025 establishes a dedicated committee responsible for monitoring, recommending, and overseeing the implementation of such measures.[82] The regulation outlines two distinct procedures: an expedited procedure for provisional measures, and an ordinary procedure—featuring detailed studies and stakeholder consultations—for definitive actions.[83] Any provisional measure must eventually undergo the ordinary procedure to be confirmed.

Brazil has historically held this type of reciprocal authority since introducing Law No. 12,270/2010 during a World Trade Organization (WTO) dispute over cotton subsidies (DS267).[84] While this earlier law allows for the suspension of intellectual property rights in response to non-compliance with multilateral obligations, it has never been exercised in practice. IPO will continue to monitor this situation.

Brazil Issues Draft Guidelines on AI-Related Patents

INPI Brazil released its "Draft Guidelines for Patent Examination of AI-Related Inventions" for public comment on August 20, 2025.[85] The initiative addresses the rising number of AI filings in Brazil and provides clarity on how such inventions will be examined. The draft is established around the following pillars:

- Exclusions: Mathematical models, algorithms, statistical methods, business methods, and computer programs "as such" remain outside patentability. Inventions autonomously generated by AI are also excluded, as inventorship must always be attributed to a natural person.[86]
- Sufficiency of disclosure: Specifications must provide enough detail for reproduction, including datasets, model architecture, parameters, and how AI interacts with technical components.[87]
- Claims drafting: Claims cannot be directed solely to an AI model or training method. They must clearly define the technical application of the AI (e.g., "method for facial recognition using a neural network").[88]
- Non-obviousness: Routine automation, substitution of models, or parameter adjustments will not confer non-obviousness. By contrast, non-obviousness may

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[82] Decreto No. 12.551, de 14 de Julho de 2025, Diário Oficial da União [D.O.U.] de 15.7.2025, art. 2.

[83] Decreto No. 12.551, de 14 de Julho de 2025, Diário Oficial da União [D.O.U.] de 15.7.2025, chs. IV–V.

[84] Lei No. 12.270, de 24 de Junho de 2010, Diário Oficial da União [D.O.U.] 25.6.2010; Request for Consultations by Brazil, *United States–Subsidies on Upland Cotton*, WTO Doc. WT/DS267/1 (Oct. 3, 2002).

[85] Consulta Pública No. 3, de 16 de Agosto de 2025, Diário Oficial da União [D.O.U.] de 18.8.2025; INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, EXAME DE PEDIDOS DE PATENTE RELACIONADOS A INTELIGÊNCIA ARTIFICIAL (2025) [NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY, EXAMINATION OF PATENT APPLICATIONS RELATED TO ARTIFICIAL INTELLIGENCE].

[86] INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, EXAME DE PEDIDOS DE PATENTE RELACIONADOS A INTELIGÊNCIA ARTIFICIAL ART. 2 (2025).

[87] INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, EXAME DE PEDIDOS DE PATENTE RELACIONADOS A INTELIGÊNCIA ARTIFICIAL ART. 3 (2025).

[88] INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, EXAME DE PEDIDOS DE PATENTE RELACIONADOS A INTELIGÊNCIA ARTIFICIAL ARTS. 3.13–3.16 (2025).

> be recognized when AI delivers unexpected technical effects, such as adaptive real-time control or feedback loops in industrial processes.[89]

The Draft Guidelines' proposed sufficiency of disclosure requirements are too rigid and not aligned with the flexible legal standard of Art. 24 of the Brazilian Patent Act or the practices of other jurisdictions such as the European Patent Office and the U.S. Patent and Trademark Office.

Referring to the "black-box" nature of some AI systems, the Draft Guidelines require that the descriptive report provides all the technical details necessary for a person skilled in the art to reproduce the proposed solution without undue experimentation.[90] Specifically for AI models or techniques (where the contribution lies in the model itself), a detailed description of the architecture, functions, parameters, and training method is required.[91] For AI-based inventions, the Draft Guidelines require a description of the dataset that effectively enables the AI system's success, a clear correlation between input and output data, and non-exhaustive details on data processing, algorithms, hyperparameters, training, and model evaluation.[92] Additionally, the Draft Guidelines suggest that, for AI-assisted inventions, the descriptive report must show that the expected technical effects have indeed been achieved, to mitigate the possibility of "algorithmic hallucination."[93]

IPO encourages INPI Brazil to emphasize that the legal standard for sufficiency of disclosure is the reproduction of the technical effect without undue experimentation, not a complete description of every internal step or parameter, and extraneous details unrelated to the technical improvement should not be required. Concerning training data, INPI Brazil should recognize that it is not always necessary to provide the specific dataset itself (which can be voluminous or proprietary) and clarify that it should be sufficient to describe the defining characteristics and methodology used to create or curate the training dataset. Finally, IPO encourages INPI Brazil to remove the additional requirement for evidence of technical effect for AI-assisted inventions, as that would create an unnecessary burden as compared to purely human inventions.

Brazilian Patent Office Proposes New Guidelines on Medical Use Claims

On July 29, 2025, INPI Brazil published a notice of intent to approve a new chapter of its Chemistry Guidelines that addresses the examination of patent applications directed to new medical uses of known substances, making it even more difficult to obtain patent protection on these important inventions, and, in essence, introducing additional

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[89] INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, EXAME DE PEDIDOS DE PATENTE RELACIONADOS A INTELIGÊNCIA ARTIFICIAL ART. 4.4 (2025).

[90] INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, EXAME DE PEDIDOS DE PATENTE RELACIONADOS A INTELIGÊNCIA ARTIFICIAL ARTS. 3.2 –3.3 (2025).

[91] INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, EXAME DE PEDIDOS DE PATENTE RELACIONADOS A INTELIGÊNCIA ARTIFICIAL ART. 3.7 (2025).

[92] INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, EXAME DE PEDIDOS DE PATENTE RELACIONADOS A INTELIGÊNCIA ARTIFICIAL ART. 3.9 (2025).

[93] INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, EXAME DE PEDIDOS DE PATENTE RELACIONADOS A INTELIGÊNCIA ARTIFICIAL ART. 3.12(A) (2025).

restrictions on the acceptance of medical use claims.[94] Key proposed changes include: (a) more rigorous criteria for enablement, demanding at least in vivo data from validated animal models; (b) no room for supplemental data, even if aimed at corroborating information already disclosed in the specification, contrary to what is established in the "General Patent Applications Examination Guidelines" for inventive step and removing the excerpt indicating that in vitro data could be substantiated by supplemental information; and (c) support is only recognized for the exact compounds tested, extrapolations on structural similarities are unacceptable.[95]

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 as 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.[96] 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.[97]

Compulsory Licensing Laws and Forced or Pressured Technology Transfer

Brazil's 2021 modifications to the rules governing compulsory licenses were concerning to IPO members.[98] Forced technology transfer provisions were also proposed during the legislative process but were ultimately vetoed by the Brazilian President.[99]

IPO strongly opposes compulsory licensing of IP rights with respect to all industries and technologies and believes that licensing of IP rights is best accomplished through voluntary efforts. Further, forced technology transfer could jeopardize IP rights and violate international treaties. As explained in the USTR's 2025 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

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[94] Consulta Pública No. 02, de 24 Julho de 2025, Diário Oficial da União [D.O.U.] de 29.7.2025; INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, MINUTA DAS DIRETRIZES DE EXAME DE PEDIDOS DE PATENTE: ASPECTOS RELACIONADOS AO EXAME DE PEDIDOS DE PATENTE NA ÁREA DE QUÍMICA (2025) [NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY, DRAFT GUIDELINES FOR THE EXAMINATION OF PATENT APPLICATIONS: ASPECTS RELATED TO THE EXAMINATION OF PATENT APPLICATIONS IN THE FIELD OF CHEMISTRY].

[95] INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, MINUTA DAS DIRETRIZES DE EXAME DE PEDIDOS DE PATENTE: ASPECTOS RELACIONADOS AO EXAME DE PEDIDOS DE PATENTE NA ÁREA DE QUÍMICA 10, 12 (2025).

[96] Geneva Act, July 2, 1999, WIPO Lex. No. TRT/HAGUE/006; Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks, Nov. 12, 2007, WIPO Lex. No. TRT/MADRIDP-GP/001.

[97] Portaria No. 36, de 06 de Setembro de 2023, Diário Oficial da União [D.O.U.] de 4.9.2023; INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, MANUAL DE DESENHOS INDUSTRIAIS (2024) [NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY, Industrial Design Manual].

[98] Projeto de Lei No. 12/2021, de 5 Junho de 2021.

[99] *See* Veto No. 48/2021, de 02 de Setembro de 2021; Mensagem No. 432/2021, de 03 de Setembro de 2021.

local manufacturers, distributors, and retailers, and slow the pace of innovation and economic progress."[100]

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, would-be patent owners, and potential competitors by complicating investment decisions; impairing access to critical funding, especially for smaller companies; 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, like PPH agreements; and leveraging examination of foreign counterpart applications.[101] 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, INPI has implemented the changes necessary to comply with international standards, and trademarks are now being granted in 14 months on average.

In September 2025, as part of ongoing efforts to further reduce trademark examination backlogs, INPI introduced a single-fee system for trademark registrations, under which applicants pay one fee at the outset of the process, eliminating the need for a subsequent confirmation step following payment of a final fee.[102] This change streamlines the procedure and ensures that trademark rights are secured without requiring an additional deadline for fee payment. INPI also reduced fees by up to 60% for micro and small businesses, innovation entities, and nonprofits.[103]

Proposed Patent Term Adjustment for INPI Delay

Brazil should reinforce the above-described efforts to reduce the patent examination backlog by establishing a patent term adjustment ("PTA") mechanism to restore patent term lost due to unreasonable delays in the patent examination process. 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.[104]

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[100] OFF. OF THE U.S. TRADE REPRESENTATIVE, 2025 SPECIAL 301 REPORT 25 (2025).

[101] The Brazilian National Institute of Industrial Property ("INPI") has significantly reduced patent pendency 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. INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, STRATEGIC PLAN: 2023-2026 22 (version 2.0, 2023). INPI has also reported a substantial reduction of the patent backlog, from 15,134 pending applications in October 2022 to only 1,052 in March 2025. *Evolução do Plano de Combate ao Backlog de Patentes* [*Evolution of the Patent Backlog Reduction Plan*], INSTITUTO NACIONAL DA PROPRIDADE INDUSTRIAL, https://www.gov.br/inpi/pt-br/servicos/patentes/plano-de-combate-ao-backlog/historico-do-plano-de-combate-ao-backlog-de-patentes (Jan 16, 2026).

[102] Portaria No. 110, de 5 de Maio de 2025, Diário Oficial da União [D.O.U.] de 9.5.2025.

[103] Portaria No. 110, de 5 de Maio de 2025, Diário Oficial da União [D.O.U.] de 9.5.2025, art. 4.

[104] *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.

In July 2022, a bill was submitted at the Brazilian House of Representatives to amend the patent statute towards establishing a PTA system based on INPI Brazil's delays during examination.[105] According to the bill, patentees would be able to request PTA when INPI Brazil took more than 60 days to issue decisions; the adjustment would be limited to an additional five years of patent protection.[106]

Changes in Patent Examination Queue

On December 17, 2023, INPI Brazil published Technical Note No. 27, which proposed that the order of the examination queue for patent applications be changed from filing date to examination request date.[107] INPI Brazil stated 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.[108] INPI Brazil believed that the 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.[109] 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 examination had already been requested, although INPI had informally stated that this new rule would 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.[110] 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.[111] In other words, adding new matter from the specification to the rejected claim set 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.

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[105] Projeto de Lei No. 2056/2022, de Julho de 2022.
[106] Projeto de Lei No. 2056/2022, de Julho de 2022.
[107] Nota Técnica No. 27, de 17 de Dezembro de 2023 § 1.
[108] Nota Técnica No. 27, de 17 de Dezembro de 2023 § 8.
[109] Nota Técnica No. 27, de 17 de Dezembro de 2023 § 24.
[110] Parecer No. 00016/2023/CGPI/PFE-INPI/PGF/AGU, de 12 de Dezembro de 2023, Revista da Propriedade Industrial [Industrial Property Magazine] de 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.
[111] Parecer No. 00019/2023/CGPI/PFE-INPI/PGF/AGU, de 12 de Dezembro de 2023, Revista da Propriedade Industrial de 12.12.2023.

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.[112] 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 ensure 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.[113] 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.[114] Also, INPI formerly 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.

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.

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[112] Lei No. 10.603, de 17 de Dezembro de 2022.

[113] Decreto No. 8.772, de 11 de Maio de 2016, Diário Oficial da União [D.O.U.] de 12.5.16.

[114] Portaria No. 26/2023, de 07 de Julho de 2023, Diário Oficial da União [D.O.U.] de 13.6.23; Portaria No. 27/2023, de 7 de Julho de 2023, Diário Oficial da União [D.O.U.] de 13.6.23; *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.

CANADA

Lack of Adequate Trade Secret Protection

Pursuant to its obligations under the United States-Mexico-Canada Trade Agreement ("USMCA"), in 2020, Canada enacted new Criminal Code provisions aimed at the intentional theft of trade secrets and requiring proof of "deceit, falsehood or other fraudulent means" and the knowing obtainment or communication of a trade secret .[115] 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.[116]

However, Canada's (excluding Québec) lack of a statutorily-granted civil right of action continues to be problematic, leaving rights holders to resort to common law causes of action for breach of confidence, which according to a leading commentator "remains a significant challenge for litigants."[117] A critical next step is for Canada to codify the basic principles of common law trade secret protection in a uniform manner to further supplement the Criminal Code protections, address Canada's continued lack of adequate enforcement, and potentially provide harmonization with the U.S. [118]

Customs Seizure of Counterfeit Goods and Pirated Works

IPO members are concerned that not enough counterfeit goods and pirated works are being seized by the Canada Border Services Agency ("CBSA"). It appears that the Canadian government could devote more resources to the inspection of imported goods. IPO is encouraged by Canada's recent commitment to hiring 1,000 new CBSA officers and hopes this will result in the increased inspection of shipments entering Canada.[119]

IPO is also concerned that Canada's legislative framework for the seizure of counterfeit and pirated goods is too cumbersome, resulting in limited usage by IP rights holders.[120] For example, placing the onus on rights holders to take legal action to seize counterfeit goods creates a disincentive for them to use the system, even though very few infringers bother to contest a seizure.[121] This inefficiency is heightened by counterfeiters often using small shipments to reduce the risk of being detected. IPO recommends that Canada amend its legislation so that the burden is placed on the importer to contest the continued

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[115] Agreement Between the United States of America, the United Mexican States, and Canada, art. 20.71, July 1, 2020; Canada-United States-Mexico Agreement Implementation Act, S.C. 2020, c. 1, art 36–37; Criminal Code, R.S.C. 1985, c. C-46, art 391(1).

[116] Criminal Code, R.S.C. 1985, c. C-46, art 391(3).

[117] 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).

[118] *See e.g.,* 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).

[119] Press Release, Can. Border Servs. Agency, CBSA is Strengthening the Border: 2025 Results and Accomplishments (Dec. 9, 2025).

[120] Combating Counterfeit Products Act, R.S.C. 2014 c. C-42.

[121] Combating Counterfeit Products Act, R.S.C. 2014 c. C-42, art 44.02.

seizure or destruction of such goods, once the relevant rights holder has confirmed the goods in question are counterfeit or pirated.

Patented Medicine Prices Review Board (PMPRB) Regulations

Canada's *Patent Act* mandates and gives authority to the Patented Medicine Prices Review Board ("PMPRB") to ensure that patentees do not sell patented medicines at excessive prices within the regulatory framework provided by the "Patented Medicines Regulations."[122]

IPO members have expressed concerns about the most recent amendments to the "Patented Medicines Regulations," which came into force on July 1, 2022.[123] In particular, section 4(1)(f)(iii) of the Regulations revised the list of country-specific prices patentees are required to report to the PMPRB as references for setting the median international price of each medicine marketed in Canada, an ultimate consideration in the product price ceiling.[124] The updated country list, known as the PMPRB11, added Australia, Belgium, Japan, Netherlands, Norway, and Spain, and removed the U.S. and Switzerland.

It is concerning that Canada would not include two of its largest trading partners, the U.S. and Mexico, in the PMPRB11, but select countries that generally 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 leading pharmaceutical and biotechnology research companies, sending a message that Canada is interested in the benefits of that research, but not in subsidizing or incentivizing the development behind it.

The PMPRB implements the Regulations through its Guidelines, which are intended to provide predictability for innovative manufacturers by giving guidance on when patented drugs are at risk of being excessively priced. Since 2022, the PMPRB was operating under interim policies, without Guidelines in place. On June 30, 2025, the PMPRB published new Guidelines, which came into effect on January 1, 2026.[125]

Unfortunately, the new Guidelines do little to resolve ongoing issues of price uncertainty experienced by the innovative pharmaceutical industry in Canada. The Guidelines state the PMPRB will conduct continuous (annual) reassessments of prices throughout the

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

[123] 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; Regulations Amending the Patented Medicines Regulations, 151 C. Gaz. 4497 (2017); Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), SOR/2019-298, 5945–46, 5957–58. Regulations Amending the Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), No. 5, SOR/2022-162.

[124] Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), SOR/2019-298 s. 4(1)(f)(iii).

[125] PATENTED MED. REV. BD. CAN., GUIDELINES FOR PMPRB STAFF: ADMINISTRATIVE PROCESS FOR EXCESSIVE PRICE HEARING RECOMMENDATION (2025).

lifetime of a patent, wherein the prices are determined based on the highest international price (HIP) of the PMPRB11.[126] If a patentee exceeds the PMPRB11 HIP benchmark in any year or receives a pricing complaint from a public insurer, the PMPRB will conduct an in-depth investigation of the drug product, during which it may consider factors including the price of similar therapies and generic medicines.[127] This could mean that even if an initial price review concludes that a price is non-excessive, a future review could reverse that determination even if a patentee restricts its list price increases to the consumer price index. This continued price erosion of patented medicines is very concerning.

IPO is concerned that the PMPRB's use of patent statutes 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, and in fact, do abandon patents to avoid coming under the jurisdiction of the PMPRB. Other manufacturers, particularly smaller entities who are often involved with therapies for rare diseases, may choose to withdraw from or elect to not enter the Canadian market. Drug prices/rebates are highly negotiated with public and private drug plans in Canada and heavily regulated at the provincial level, making the additional burden of federal regulation by the PMPRB particularly troubling and seemingly unnecessary.

Weak Patent Enforcement Through the Patented Medicines (Notice of Compliance) Regulations

The "Patented Medicines (Notice of Compliance) Regulations" (the "PMNOC Regulations") establish Canada's linkage system between patented medicines and generics, whereby a patentee may apply for a Notice of Compliance (NOC) from Health Canada and to list its product on the Patent Register to prevent a generic manufacturer from entering the marketplace.[128] If a generic manufacturer applies for an NOC covering or referencing a drug that has already been issued an NOC, the generic must file and serve upon the patentee a Notice of Allegation (NOA) asserting its rights.[129] The patentee may then bring an infringement action in Federal Court against the generic.[130]

The PMNOC Regulations include deficiencies that weaken Canadian patent enforcement, including: providing insufficient time for final patent determinations in a single proceeding; increasing liability for damages under section 8 (i.e., granting damages in excess of 100% of the total generic market); and establishing a separate litigation track for some types of patents due to their ineligibility for listing on the Patent Register (i.e., arbitrary timing requirements).

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[126] PATENTED MED. REV. BD. CAN., GUIDELINES FOR PMPRB STAFF: ADMINISTRATIVE PROCESS FOR EXCESSIVE PRICE HEARING RECOMMENDATION 16 (2025).

[127] PATENTED MED. REV. BD. CAN., GUIDELINES FOR PMPRB STAFF: ADMINISTRATIVE PROCESS FOR EXCESSIVE PRICE HEARING RECOMMENDATION 16 (2025).

[128] Patented Medicines (Notice of Compliance) Regulations, SOR/93-133.

[129] Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 5.

[130] Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 6(1).

The PMNOC Regulations bar infringement proceedings that are not brought within 45 days after a patent is listed on the Patent Register and an NOA has been served, unless the innovator had a reasonable basis for not bringing the action in response to the NOA.[131] This provision revokes a statutorily granted right of action due to a missed deadline and puts the onus of showing a justifiably irregular reason for failing to sue at first instance on the patentee.

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, or patentees, in an infringement action to be jointly and severally liable for losses suffered by the defendant, or the generic, for profits lost during the period in which the generic could have marketed the product if not for the patentee staying their being granted an NOC.[132] However, the PMNOC Regulations do not require all defendants in NOC proceedings related to the same patented medicine to bring their section 8 claims together. Furthermore, courts are unable to consider multiple section 8 claims together or make findings related to multiple generic companies entering the market outside the PMNOC Regulations. As a result, when innovators face multiple section 8 claims, there is a risk that they will be subject to cumulative damage.[133]

Section 8 also does not limit the period of a patentee's liability. Thus, generics may be able to claim losses suffered beyond the date of any dismissal or discontinuation of proceedings, risking "windfall" damage awards contrary to the traditional compensatory function of damages. Situations in which 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.[134]

The PMNOC Regulations continue to prevent rights holders from listing their patents on the Patent Register thorough certain, seemingly arbitrary, timing requirements that are not present in the U.S. Hatch-Waxman Act.[135] Even when patents are eligible for listing, subsequent entrants are provided with expanded opportunities to circumvent the Patent Register by selectively relying on unmarketed strengths and dosage forms of otherwise marketed innovative drug products.[136] This wrongly denies pharmaceutical innovators access to statutorily-granted enforcement procedures.

Certificate of Supplementary Protection (CSP) Restrictions

In a positive move, Canada has recently begun to provide for restoration of patent terms for pharmaceutical inventions, under certain circumstances, by means of a Certificate of Supplementary Protection ("CSP"). However, IPO is concerned that certain types of

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[131] Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, ss. 6(1), 6.01.
[132] Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 8(2).
[133] *See, e.g.,* Apotex, Inc. v. Sanofi-Aventis, 2014 FCA 68; Teva Can. Ltd. v. Sanofi-Aventis Can. Inc., 2014 FCA 67.
[134] Patent Act, R.S.C. 1985, c. P-4, s. 60(1).
[135] Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 4(6).
[136] *See e.g.,* AbbVie Corp. v. Canada (Health), 2022 FC 1209.

innovations are still barred from CSP eligibility, resulting in the exclusion of otherwise worthy patents from receiving a CSP and likely discouraging innovation.[137] In addition, it is overly restrictive to require that innovators seeking CSP file a complete new drug submission in Canada within a year of filing in the U.S., Europe, or several other smaller markets, especially with respect to smaller companies who do not have the resources to file in multiple jurisdictions before knowing whether their submission is sufficient to receive approval.[138] Both of these burdensome requirements are not necessary for patent term restoration in other jurisdictions.

Canada's term for a CSP is capped at two years of the possible five—an unduly restrictive time limit, well outside the global norm that applies, for example, in the U.S. and Europe.[139] The CSP also provides 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. This exception deprives patent holders of the full bundle of patent protections during the CSP period.

Patent Term Adjustment Restrictions

On June 22, 2023, Canada passed legislation on its first ever PTA regime to compensate patentees for "unreasonable delays" by the patent office in issuing a patent.[140] IPO is concerned about several aspects of the PTA framework and believes that Canada should reconsider certain provisions to ensure that its implementation is compliant with the remedial objectives of the USMCA.

Canada has taken a very strict and minimal approach in adopting PTA, only meeting the basic requirements of the USMCA.[141] The accompanying Patent Rules further render most patents ineligible for PTA by deducting extensive time periods from any potential eligible term.[142] Overall, there are 38 categories of excluded periods that will be subtracted in the PTA term calculation to account for delays attributed to the applicant rather than CIPO.[143] Additionally, any third party can request shortening the PTA potentially available to a patentee. PTA is also not granted automatically as it is in the

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[137] *See* Certificate of Supplementary Protection Requirements, SOR/2017-165, ss. 2–3. (excepting the invention of new processes and formulations from grant of CSP).

[138] Certificate of Supplementary Protection Requirements, SOR/2017-165, s. 6(1).

[139] Certificate of Supplementary Protection Requirements, SOR/2017-165, s. 6(1).

[140] Bill C-47, An Act to implement certain provisions of the budget tabled in Parliament on March 28, 2023 (assented to June 22, 2023); Patent Act, R.S.C., 1985, c. P-4, as amended.

[141] Agreement Between the United States of America, the United Mexican States, and Canada, art 20.71, July 1, 2020.

[142] Patent Rules, SOR/2019-251, as amended, s. 117.03(1).

[143] Some examples include: (a) all days between the issuance of a notice requiring applicant action and the applicant's response; (b) all days relating to a judicial appeal of the Canadian Intellectual Property Office's ("CIPO") refusal to register a patent application; (c) the period when an applicant makes a request for continued examination and ending on the day the final fee is paid; (d) 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 (e) The days taken to pay the required fees, including maintenance and late fees. Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act, SOR/2024-241, ss. 15(117.03)(1)(d), (m), (p), (w), (z.1).

U.S., but instead, applicants are required to apply for PTA within three months from the patent's issuance or they lose this benefit.[144]

Finally, IPO is concerned about the narrow scope of Canada's proposed implementation of PTA. Notably, unlike in the U.S., Canada's PTA term runs concurrently, not consecutively, with any CSP term granted to pharmaceutical patentees.[145] This is inconsistent with the different remedial objectives of CSPs and PTA, as CSPs are intended to compensate for patent term lost over time spent in research and development and regulatory approval.

Introduction of the Promise Doctrine into Allegations of Overbreadth

Under the promise doctrine, a court identified the utility alleged to be "promised" in the patent specification and then measured the utility of the invention against those promises, i.e., any statement in the patent's specification on what the invention did or could do became the threshold for utility.[146] The Supreme Court of Canada unanimously overturned this approach, calling the doctrine "unsound" and "excessively onerous" on patentees as it improperly imported disclosure requirements into the utility analysis by 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.[147]

Despite this decision, the Court further held that the "scheme of the Act treats the mischief of overpromising in multiple ways," including, *inter alia*, overly broad claiming.[148] In Canada, a claim is overbroad if it is broader than the invention disclosed in the patent's specification or the invention made by the inventor.[149] 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 and IPO is concerned that Canadian courts are introducing a version of the promise doctrine into determinations of overbreadth, thereby reintroducing uncertainty into the law and lowering the threshold for findings of overbreadth without any statutory basis.[150]

Elevated Disclosure Requirement for Patents

The Federal Court recently found a patent invalid because it omitted certain preferred elements from embodiments that were described in the disclosure and did not describe

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[144] 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).

[145] Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act, SOR/2024-241, ss. 27–28.

[146] AstraZeneca Can. Inc. v. Apotex Inc., 2017 SCC 36, paras. 29–31.

[147] AstraZeneca Can. Inc. v. Apotex Inc., 2017 SCC 36, paras. 44, 36, 37, 46.

[148] AstraZeneca Can. Inc. v. Apotex Inc., 2017 SCC 36, para. 46.

[149] W. Oilfield Equip. Rentals Ltd. v. M-I L.L.C., 2021 FCA 24, para. 128.

[150] A recent Federal Court decision has been interpreted as inviting zealous lawyers to read a patent specification in such a way as to persuade a court to look at the nature of the "core of the invention." Seedlings Life Sci. Ventures, LLC v Pfizer Can. ULC, 2021 FCA 154 at paras. 54, 60. This introduces a similar approach, and therefore similar uncertainties and burdens on patentees, as the rejected promise doctrine. *See also e.g.,* Mylan Pharms. ULC v. Pfizer Can. Inc., 2012 FCA 103, para. 57; Aux Sable Liquid Prods. LP v. JL Energy Transp. Inc., 2019 FC 581 at paras. 58–60, 65–66.

how to make embodiments other than the preferred embodiment.[151] This novel increased disclosure requirement appears to place an unmanageable burden on inventors to disclose all embodiments of an invention and could invalidate patents where an inventive improvement falls within the scope of the claims but the embodiment containing such improvement was not originally disclosed.[152]

Overly Stringent Due Care Standard for Reinstatement of Patent Rights

As with most other jurisdictions, Canada requires applicants and patentees to pay maintenance fees to keep pending applications and issued patents in force.[153] In Canada, such fees are due annually on the anniversary of the patent/application's filing date. If a maintenance fee is not paid by the deadline, CIPO issues a notice informing the applicant/patentee, or its patent agent, and provides a prescribed time period to submit the missed payment along with a "late fee." If the applicant/patentee fails to do so within the provided time period, the application/patent is deemed abandoned. A request to reinstate an abandoned case may be submitted within 12 months of the abandonment date, however, the request must include a detailed explanation of the facts that led to the abandonment.[154] More importantly, reinstatement is only permitted if the request satisfactorily shows the applicant/patentee did not reply to the notice despite exercising "due care."

CIPO has taken the position that this due care requirement extends to all parties involved in the handling of the payment, including not only the applicant, but all agents and annuity services associated with the matter. Additionally, CIPO has not provided clear direction on what constitutes "due care" and has refused the vast majority of filed reinstatement requests. Even "administrative errors" that lead to an applicant/patentee failing to respond to the CIPO notice may result in irrevocable loss of valuable patent rights. This position was recently upheld by the Federal Court of Appeal, despite that it puts Canada out of place with other jurisdictions that accord reinstatement of an application or patent where the abandonment was the result of a mistake or administrative error.[155]

Other Concerns

IPO believes that the Government of Canada should take a more progressive approach to amending its laws by better defining boundaries to create greater certainty for businesses operating in Canada. For example, Canada's policy of allowing transfer of prior user

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[151] Seedlings Life Sci. Ventures, LLC v. Pfizer Can. ULC, 2021 FCA 154 at paras. 68, 71 ("[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.").

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

[153] *Pay Maintenance Fees – Applications and Patents*, CANADIAN INTELL. PROP. OFF., https://ised-isde.canada.ca/site/canadian-intellectual-property-office/en/patents/maintain-your-patent-application-or-granted-patent/pay-maintenance-fees-applications-and-patents (Apr. 28, 2025).

[154] *Pay Maintenance Fees – Applications and Patents*, CANADIAN INTELL. PROP. OFF., https://ised-isde.canada.ca/site/canadian-intellectual-property-office/en/patents/maintain-your-patent-application-or-granted-patent/pay-maintenance-fees-applications-and-patents (Apr. 28, 2025).

[155] Canada (Att'y Gen.) v. Matco Tools Corp., 2025 FCA 156.

rights to third parties establishes an unstable foundation for reliable patent protection.[156] Canada's file wrapper estoppel rules have also been unfairly applied retroactively and have created a significant disruption in existing patent proceedings.[157] Canada's data protection practices are also a concern due to court challenges calling into question the scope of protection provided for test data. Notably, when the Government of Canada has sought public comments on new proposals, the deadlines for comment are sometimes extremely short and, in IPO's view, do not allow sufficient time for a thoughtful perspective to be provided. Innovators would like Canada to take steps to provide stronger protections for innovation.

CHILE

Pending Fármacos II Bill

Chile has developed a leading health and innovation ecosystem but is at risk of reversing its progress by proposing anti-IP laws and unhelpful modifications to its regulatory affairs process. Amendments submitted 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.[158] These proposed amendments would also excessively broaden the scope of compulsory licenses and incorporate vague and discretionary elements such as the "shortage" or the "economic inaccessibility" of pharmaceutical products into the law.[159] They are further not consistent with internal legislation or with the international treaties Chile has signed.

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 the packaging's main faces.[160] Medicines may also only have a "fantasy" name on the container that does not exceed 50% of the size used for the international common name.[161] Requiring qualified professionals to prescribe drugs using

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

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

[158] 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].

[159] 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.

[160] 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].

[161] 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.

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.

CHINA

Trade Secrets: Positive Developments and the Need to Upgrade

Trade secret law in China is fragmented, with protection provided under several different legal and administrative provisions, including those involving anti-unfair competition, criminal, contract, and labor laws. Although some recent developments are promising, trade secret owners still face significant challenges to protecting their confidential information in China, such as high evidentiary burdens, limited discovery, inadequate damages, and requirements to submit confidential details to government agencies. Although IPO is encouraged by updates such as Section B of the Phase I Economic and Trade Agreement, more needs to be done.[162]

However, there have been several promising developments in these differing regimes during this decade that indicate China's desire for stronger enforcement against trade secret misappropriation and continue a trend of expanded enforcement of trade secret rights. In 2020, 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" to clarify the procedure for litigating trade secret theft in civil actions.[163] In 2025, the Anti-Unfair Competition Law ("AUCL") was amended to increase administrative fines for trade secret infringers and China's State Administration for Market Regulation ("SAMR") announced draft revisions to the "Several Provisions on the Protection of Trade Secrets" to keep up-to-date with the evolving digital economy and multilateral trade agreements.[164]

The recent revision of the AUCL presents both opportunities and continuing challenges for foreign entities that must be addressed to improve China's IP protection landscape. Crucially, the AUCL, as amended, fails to close substantive loopholes in trade secret protection and to ensure digital competition standards align with global principles. Specifically, the definition of trade secret infringement should be clarified to ensure that the "use" of a trade secret explicitly includes modifying the acquired information or using

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[162] 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.

[163] 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).

[164] Shangye Mimi Baohu Guiding (Zhengqiu Yijian Gao) (商业秘密保护规定 (征求意见稿)) [Regulations on the Protection of Trade Secrets (Draft for Comment)] (announced by the St. Admin. For Mkt. Regul. Apr. 25, 2025); 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] (adopted by the Standing Committee of the Eighth Nat'l People's Cong., Sept. 2, 1993, rev'd June 27, 2025).

the modified trade secrets. Allowing misappropriators to rely on modification as a defense undermines protection and the objective of promoting innovation.

Under China's criminal law, whether a misappropriation of trade secrets can be prosecuted is determined by losses caused to the rights holder, as opposed to the act of theft itself, or even the value of the information.[165] In civil proceedings, 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.[166] Like its criminal counterpart, the current civil law discourages early intervention to minimize damages.

While more preliminary injunctions in the form of conduct preservations have recently been granted by Chinese courts in trade secret actions, such relief remains uncommon and unpredictable, due to the high burden of proof and judicial policy, which together discourage trade secret owners from seeking relief.

The joint venture and data localization requirements for internet, cloud, medical technology, pharmaceutical, and biopharmaceutical companies to submit technical and functional features of their products, including confidential test data, for access to the Chinese market presents further challenges for protecting confidential business information.[167] Regulatory laws, such as environmental, pharmaceutical, and medical device approval requirements, can 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).

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

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[165] 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. A threshold loss of RMB 500,000 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).

[166] 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] (adopted by the Standing Committee of the Eighth Nat'l People's Cong., Sept. 2, 1993, rev'd June 27, 2025) ch. 4.

[167] Zhonghua Renmin Gongheguo Wangluo Anquan Fa (中华人民共和国网络安全法) [Cybersecurity Law of the People's Republic of China] (adopted by the Standing Comm. of the Twelfth Nat'l People's Cong., Nov. 7, 2016, rev'd Oct. 28, 20225) art. 39.

information, including trade secrets.[168] IPO members are concerned with the significant risk of trade secret disclosure that could result from administrative investigations and enforcement absent proper safeguards. Although China promised at the 2014 Joint Commission on Commerce and Trade ("JCCT") to hold government officials with access to confidential business information accountable and to otherwise shield the details from public disclosure, the impact of any changes has yet to be felt.[169]

Jurisdictional Overreach

Article 40 of the revised AUCL claims broad extraterritorial jurisdiction over acts committed outside China that disrupt its market competition order.[170] This expansive approach lacks crucial limitations necessary for a predictable international legal system, such as "minimum contacts" requirements and judicial "reasonableness" factors. Without these constraints, Article 40 could unduly stifle legitimate global competition and create compliance risks for international operators. Moreover, the administrative penalty regime for severe IP infringements, such as trade secret violations, often relies on the vague definition of "serious circumstances" to impose maximum fines of up to RMB 5 million (over USD 700,000). China must provide clearer guidance, ideally defining seriousness based on the "totality of circumstances" to ensure transparent and predictable enforcement standards for businesses operating within the country.

China Lacks a Meaningful Grace Period for Design Applications

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

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

[169] *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. 27, 2026).

[170] 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] (adopted by the Standing Committee of the Eighth Nat'l People's Cong., Sept. 2, 1993, rev'd June 27, 2025) art. 40.

WTO Disputes[171]

Since August 2020, Chinese courts have unilaterally determined the value of global patent portfolios and issued anti-suit injunctions (ASIs) 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.[172]

On July 6, 2021, the EU filed an Article 63.3 request at the WTO for further information on four standard essential patent ("SEP") cases in China. China rebuffed the EU's request and failed to make those decisions public.[173] Japan, Canada, and the U.S. joined in the Article 63.3 Consultation process and the EU requested that a panel be set up by the Dispute Settlement Body to examine the matter.

The dispute (DS611) concluded with a significant arbitral decision on July 21, 2025, that found China's ASI policy that "empowers Chinese courts to impose a range of possible prohibitions at the request of implementers in the context of SEP litigation, which can be enforced through the imposition of cumulative daily fines" was inconsistent with its WTO obligations and violated Article 28.1 and 28.2 of the TRIPS Agreement by "frustrating" the ability of patent owners to exercise their exclusive patent rights in other WTO member jurisdictions and allowing the implementer to obtain an ASI without any inquiry into the SEP holder's right to conclude licensing contracts.[174] In addressing

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[171] 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/.

[172] *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.

[173] 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).

[174] Award of the Arbitrators, *China—Enforcement of Intellectual Property Rights*, ¶¶ 4.5, 4.107, WTO Doc. WT/DS611/ARB25 (July 21, 2025). ("[t]he Panel confirmed the European Union's argument that the ASI policy empowers Chinese courts to impose a range of possible prohibitions at the request of implementers in the context of SEP litigation, which can be enforced through the imposition of cumulative daily fines, and which is a policy elaborated and promoted by the SPC and endorsed by the NPC Standing Committee. As such, the ASI policy establishes a course of action that frustrates the exercise of the

China's systemic transparency failures, the arbitrators rejected China's narrow argument that only "guiding cases" must be published and ruled that its failure to publish "typical cases" that serve as "persuasive authority" also violated its TRIPS obligations.[175] While China's Ministry of Commerce has stated it will implement the decision despite its "dissatisfaction," this outcome provides a new, binding benchmark for holding China accountable.[176] Details of some of China's ASI cases have been made available through filings and reports in DS611, including: *Xiaomi v. InterDigital*;[177] *OPPO v. Sharp*;[178] and *Samsung v. Ericsson*.[179]

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exclusive right of a patent owner to prevent the use of the subject of its patent without its consent, as conferred on it by another WTO Member under Article 28.1 of the TRIPS Agreement."); *see id*. at ¶¶ 4.95, 4.106, 4.154–164 ("[t]his is significant because, through their FRAND undertaking, SEP holders conditionally waive their right under Article 28.2 to not conclude a licensing agreement, so long as SEP implementers engage in good faith negotiations over FRAND terms. . . . By contrast, under the ASI policy, an ASI can be obtained at the request of a SEP implementer without any inquiry into the SEP holder's ability to exercise the 'right … to conclude licensing contracts' in light of the FRAND undertaking made in respect of that 'right'. . . . In summary, for the reasons outlined in this section, we find that the European Union has demonstrated that the ASI policy is inconsistent with Article 28.2, read in conjunction with Article 1.1, first sentence, of the TRIPS Agreement concerning patents in China and outside of China.").

[175] Award of the Arbitrators, *China—Enforcement of Intellectual Property Rights*, ¶¶ 4.5, 4.107, WTO Doc. WT/DS611/ARB25 (July 21, 2025).

[176] Press Release, Shangwu Bu Xinwen Bangongshi (商务部新闻办公室) [Information Office of the Ministry of Commerce], Shangwu Bu Tiaoyue Falu Si Fuze Ren Jiu Shimao Zuzhi Gongbu Zhong'ou Youguan Shimao Zhengduan Anjian Shangsu Zhongcai Caijue Shi Da Jizhe Wen (商务部条约法律司负责人就世贸组织公布中欧有关世贸争端案件上诉仲裁裁决事答记者问) [A Spokesperson for the Department of Treaty and Law of the Ministry of Commerce Answered Reporters' Questions Regarding the WTO's Publication of the Arbitration Award on the Appeal of a WTO Dispute Between China and the EU] (July 22, 2025).

[177] The Wuhan Intermediate People's Court accepted Xiaomi's request to determine the value of InterDigital's global portfolio of 3G and 4G patents (including U.S. patents), without InterDigital consent. On September 23, 2020, the court issued an ASI to prevent InterDigital from applying for and enforcing injunctions against Xiaomi in any other territory (including the U.S.) subject to a fine of RMB 1 million per day (approximately USD 145,000). Request for Consultations by the European Union, *China—Enforcement of Intellectual Property Rights*, ¶ 1.1.1, WTO Doc. WT/DS611/1 (Feb. 22, 2022).

[178] The Shenzhen Intermediate People's Court accepted OPPO's request to determine the value of Sharp's global portfolio of Wi-Fi, 3G, and 4G patents (including U.S. patents), without Sharp's consent. On October 16, 2020, the court issued an ASI to prevent Sharp from initiating new patent infringement lawsuits or applying for injunctions against OPPO in any other territory (including the U.S.) subject to a fine of RMB 1 million per day (approximately USD 145,000). On August 19, 2021, the Supreme People's Court affirmed that Chinese courts have jurisdiction over such requests and that they may unilaterally set the terms of a global license to the patent portfolio at issue. Request for Consultations by the European Union, *China—Enforcement of Intellectual Property Rights*, ¶ 1.1.1, WTO Doc. WT/DS611/1 (Feb. 22, 2022).

[179] The Wuhan Intermediate People's Court accepted Samsung's request to determine the value of Ericsson's global portfolio of 4G and 5G patents (including U.S. patents), without Ericsson's consent. On December 25, 2020, the court issued an ASI to prevent Ericsson from seeking or enforcing injunctions against Samsung in any other territory (including the U.S.), and from starting any actions to enforce its patents against Samsung or to determine the terms of a license to its patents in any other territory (including the U.S.). On January 11, 2021, the Eastern District of Texas granted an emergency anti-ASI that prohibited Samsung from enforcing the ASI against Ericsson within the U.S., and to indemnify Ericsson for any fine issued by the Chinese court. Request for Consultations by the European Union, *China—Enforcement of Intellectual Property Rights*, ¶ 1.1.1, WTO Doc. WT/DS611/1 (Feb. 22, 2022).

On January 20, 2025, the European Union initiated a request for consultations with China at the WTO (DS632) concerning China's practice of setting binding, worldwide royalty rates for SEPs without the patent owner's consent.[180] According to the EU's press release, it believes this practice "pressures European high-tech companies into lowering their rates worldwide," which it claims gives Chinese manufacturers "cheaper access" to European technologies.[181] The EU also stated, in its view, that the practice "unduly interferes with the competence of EU courts for European patent issues" and is "inconsistent with WTO standards."[182]

These developments should continue to be monitored to ensure that Chinese proceedings do not unfairly favor domestic businesses and that due process and transparency are observed.

Counterfeiting

The remedies available against counterfeiters in China compare favorably with practices in other countries. In particular, Chinese police (the "Public Security Bureaux" or "PSBs") generally act upon complaints where the trademark owners present persuasive evidence of infringements that exceed the relevant threshold for prosecution. Prosecutors have also been fairly successful in encouraging counterfeiters to settle civil claims with trademark owners incidental to plea bargaining. Meanwhile, civil damages from Chinese courts have been reasonably generous, with infringers paying judgments in most cases out of fear of so-called "social credit penalties" on individual defendants and the legal representative of corporate infringers.

All that said, IPO members report that the level of counterfeiting in China is growing substantially, and for a number of reasons explained below:

- *Economic conditions*: Chinese enterprises appear more inclined to engage in counterfeiting and other forms of IP infringement due to weak economic conditions within China and the trend of decoupling with western economies.

[180] Request for Consultations by the European Union, *China—Measures Concerning Patent Licensing Terms*, WTO Doc. WT/DS632/1 (Jan. 20, 2025).

[181] Press Release, Eur. Comm'n, EU Challenges China at WTO on Royalties for EU High-Tech Sector (Jan. 19, 2025).

[182] In addition to the cases identified above, the following demonstrate China's practice in cases where the implementer did not request an ASI; if they had, these cases would likely be in the previous list. In *OPPO v. Nokia*, the Chongqing No.1 Intermediate People's Court accepted OPPO's request to determine the value of Nokia's global portfolio of 5G patents (including U.S. patents), without Nokia agreeing to the court's jurisdiction. On November 28, 2023, the court determined OPPO should pay Nokia a royalty of $1.151 per mobile phone for sales in developed markets and $0.707 for other markets. Notably, the court determined that the lower rate applied to China. In *OPPO v. InterDigital*, the Guangzhou IP Court accepted OPPO's request to determine the value of InterDigital's global portfolio of 3G, 4G, and 5G patents (including U.S. patents). Interdigital challenged jurisdiction, which the court rejected on January 13, 2023. The Supreme People's Court denied InterDigital's appeal on September 4, 2023. In *SUNMI v. Nokia*, the Yunnan Kunming Intermediate People's Court accepted SUNMI's request to determine the value of Nokia's global portfolio of Wi-Fi, 2G, 3G, and 4G patents (including U.S. patents), without Nokia agreeing to the court's jurisdiction. Nokia immediately applied for and received anti-ASIs from the Unified Patents Court (Munich Local Division) and German courts (Munich I Regional Court and Mannheim Regional Court) to prevent SUNMI from requesting an ASI from the Chinese court.

Meanwhile, there have been credible rumors circulating that suggest national authorities in China are encouraging local governments to treat infringers more leniently. Some IPO members report that this seems to have resulted in failed raid actions, suspended prison sentences (where previously custodial sentences), and lower civil compensation awards.

- *Jurisdictional Limits on PSB Investigations*: In March 2025, the Ministry of Public Security ("MPS") issued a notice to local PSBs limiting their ability to exercise jurisdiction against infringements arising outside their regions.[183] This limitation has severely undermined the ability of brand owners to pursue counterfeiting cases in hotspot regions where protectionism is endemic and infringements otherwise exceed the capacity of local PSBs.
- *Use of Shell Companies*: Infringers in China have increasingly conducted business by relying on shell companies that frustrate investigations into online sellers and exporters by both IP owners and government authorities alike.
- *Barriers to Criminal Investigations Against Exporters of Counterfeits*: For a number of reasons—including the shell company phenomenon noted above—Chinese customs will only rarely transfer serious counterfeiting cases to local PSBs for criminal investigation. Meanwhile, Chinese customs authorities have very limited powers to investigate infringements and the penalties they impose are typically nominal and well below the levels set out in the China Trademark Law.
- *Insufficient Support from Online Trade Platforms*: While leading Chinese ecommerce companies such as Alibaba (which operates platforms such as 1688.com, Taobao, and Tmall) are lauded by many brand owners for the support they provide in conducting take-downs of advertisements for infringing goods, the overall level of counterfeiting on these and other services—including Little Red Book (aka RedNote), Pin Duo Duo and others—remains huge.
- *Lack of Cooperation in Cross-Border Cases*: Chinese customs and police remain largely uncooperative with requests by brand owners, foreign police, and customs authorities for assistance in investigating cross-border counterfeiting cases.
- *Increase in Criminal Liability Thresholds*: In April 2025, the Supreme People's Court issued a judicial interpretation intended to clarify the conditions under which infringers may be criminally prosecuted and convicted.[184] While certain numerical thresholds for criminal liability were reduced under this interpretation, the threshold was actually doubled for "extremely serious" counterfeiting cases, i.e., from RMB 250,000 to 500,000 (approximately USD 35,000 to 70,000).

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[183] Guanyu Yinfa "Gong'an Jiguan Kua Sheng She Qi Fanzui Anjian Guanxia Guiding" De Tongzhi (关于印发《公安机关跨省涉企犯罪案件管辖规定》的通知) [Notice on the Issuance of the "Regulations on Jurisdiction over Inter-Provincial Business-Related Criminal Cases Handled by Public Security Organs"] (issued by the Ministry of the Pub. Sec. of the People's Republic of China, Mar. 5, 2025).

[184] Guanyu Banli Qinfan Zhishi Chanquan Xingshi Anjian Shiyong Falu Ruogan Wenti De Jieshi (关于办理侵犯知识产权刑事案件适用法律若干问题的解释) [Interpretation on Several Issues Concerning the Application of Law in Handling Criminal Cases Involving Infringement of Intellectual Property Rights] (adopted by the Jud. Comm. of the Sup. People's Ct., Apr. 7, 2025, effective Apr. 26, 2025).

Draft SAMR Regulations on Administrative Investigations and Enforcement of Trademark Cases

On November 14, 2025, the SAMR issued draft regulations for public comment that appear intended to facilitate direct involvement of local Market Supervision Bureaus ("MSBs") in the investigation of online sellers of goods infringing registered trademark rights.[185] Depending on their implementation, these regulations could provide a novel and potentially more effective means of dealing with online infringers.

The draft regulations would allow brand owners to file complaints with local MSBs based mainly upon notarized purchases of goods verified as infringing, after which the authorities would have the power to order relevant online trade platforms to disclose transactional and logistical information that could be used to support further investigations into the location of warehouses and factories.[186] The draft rules also grant local MSBs the power to order trade platforms to take a range of new measures, including takedowns and inserting language in online ads stating that the registered addresses of online sellers operating shell companies are false, thereby educating consumers on the risks of doing business with them.[187] IPO members are eager to see these draft regulations issued and implemented without delay.

However, IPO hopes that the final regulations will also allow for the following: (a) orders by MSBs to platforms to conduct reasonable investigations into networks operating in their markets, including so-called "cluster searches," i.e., searches of other seller accounts that are clearly connected to the target seller by virtue of obvious indicators, such as the use of the same bank account, contact details, etc., and their dealings in the same infringing items; and (b) the transfer by MSBs of cases suspected of constituting a crime to local PSBs.

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[185] Dianzi Shangwu Pingtai Xiezhu Chachu Shangbiao Qinquan Anjian Guiding (Zhengqiu Yijian Gao) (电子商务平台协助查处商标侵权案件规定 (征求意见稿)) [Regulations on E-commerce Platforms Assisting in the Investigation and Handling of Trademark Infringement Cases (Draft for Comments)] (announced by the St. Admin. For Mkt. Regul. Nov. 14, 2025); *PRC – Draft SAMR Regulations on Administrative Enforcement against Online Trademark Infringements*, EAST IP (Nov. 19, 2025), https://www.east-ip.com/insights/prc-draft-samr-regulations-on-administrative-enforcement-against-online-trademark-infringements/.

[186] Dianzi Shangwu Pingtai Xiezhu Chachu Shangbiao Qinquan Anjian Guiding (Zhengqiu Yijian Gao) (电子商务平台协助查处商标侵权案件规定 (征求意见稿)) [Regulations on E-commerce Platforms Assisting in the Investigation and Handling of Trademark Infringement Cases (Draft for Comments)] (announced by the St. Admin. For Mkt. Regul. Nov. 14, 2025)

[187] Dianzi Shangwu Pingtai Xiezhu Chachu Shangbiao Qinquan Anjian Guiding (Zhengqiu Yijian Gao) (电子商务平台协助查处商标侵权案件规定 (征求意见稿)) [Regulations on E-commerce Platforms Assisting in the Investigation and Handling of Trademark Infringement Cases (Draft for Comments)] (announced by the St. Admin. For Mkt. Regul. Nov. 14, 2025).

In December 2025, the National People's Congress ("NPC") issued a draft amendment to the China Trademark Law.[188] IPO encourages the NPC to ensure that MSBs have all of the legal powers needed to pursue investigations into online infringement cases.

Restrictive Policies on Trademark Examination

Since approximately 2023, the China National IP Administration ("CNIPA")—which houses the China Trademark Office and the Trademark Review and Adjudication Department ("TRAD")—began tightening the criteria for examination of new trademark applications, apparently in an effort to reduce the number of approved trademarks in China. While the need for this was understandable, CNIPA's policies resulted in an enormous increase of rejections of new applications based upon absolute grounds and a much higher number of citations. In parallel, the TRAD began rejecting virtually all appeals based upon consent agreements between appellants and the owners of cited registrations. Regrettably, Chinese courts have by-and-large upheld TRAD decisions issued in conformity with CNIPA's new policies.

The net result for the trademark community is dramatic, with applicants forced to incur substantially greater costs to file appeals and eliminate cited marks through non-use cancellations and other means. Worse, trademark owners faced with rejections based on absolute grounds have more often than not found the door closed to appeals—even where the same mark was previously registered in China in a slightly different font or format.

IPO members hope that CNIPA will reconsider their current policies, which now pose a significant barrier to normal business while at the same time denying trademark owners the tools necessary to deal with counterfeits and other infringements of their rights in a cost-effective manner.

Planned Trademark Law Amendment

As noted above, on December 27, 2025, the NPC issued a draft revision to the PRC Trademark Law for public comment by February 9, 2026.[189] The draft offers no significant fixes to the concerns explained above, and IPO is currently considering potential comments.

Non-Traditional Trademarks Presumed Unregistrable

Under current CNIPA guidelines issued on December 29, 2023, non-traditional trademarks, including 3D designs, product designs, color combination, and sound marks, are generally presumed to be unregistrable unless proven otherwise through appeals to

[188] Zhonghua Renmin Gongheguo Shangbiao Fa (Xiuding Cao'an) (中华人民共和国商标法 (修订草案)) [Trademark Law of the People's Republic of China (Revised Draft)] (announced by the Nat'l People's Cong., Dec. 27, 2025).

[189] Zhonghua Renmin Gongheguo Shangbiao Fa (Xiuding Cao'an) (中华人民共和国商标法 (修订草案)) [Trademark Law of the People's Republic of China (Revised Draft)] (announced by the Nat'l People's Cong., Dec. 27, 2025).

the TRAD.[190] This creates obstacles for companies who wish to use and obtain protection of such non-traditional trademarks 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.[191] It is clear, however, that a relationship between indigenous innovation and government procurement has continued.[192] Therefore, although IPO is 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.[193]

Forced or Pressured Technology Transfer

China's 2020 Foreign Investment Law has provisions that, if implemented, could constitute substantial progress in dismantling policies, laws, regulations, and practices that force technology transfer.[194] 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."[195] This language might prove open to loopholes that would prevent it from being fully effective if, for example, 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. IPO is particularly concerned about regulations allowing for forced disclosure of trade secrets to administrative agencies, as discussed *supra*, and looks forward to China's implementation of Articles 1.9, 2.2, and 2.3 of the Phase I Economic and Trade Agreement, which require improvements in the protection of trade secrets and confidential business information from unauthorized disclosure by government

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[190] Guanyu Fei Chuantong Shangbiao Yingdang Juyou Xianzhu Tezheng De Zhiyin (关于非传统商标应当具有显著特征的指引) [Guidelines Regarding the Requirement for Non-Traditional Trademarks to Possess Distinctive Characteristics] (published by China Nat'l Intell. Prop. Admin., Dec. 29, 2023).

[191] *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.

[192] Examples include 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.

[193] 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.

[194] 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).

[195] 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.

authorities and prohibit forced technology transfer through administrative and licensing requirements.[196]

Patent Enforcement and Examination

The volume of utility patents filed in China remains high and, combined with the lack of patentability examination, creates substantial uncertainty for U.S. companies in the Chinese market with respect to validity of their own patents and potential challengers'.[197] CNIPA has acknowledged this problem by rejecting some utility model applications that are "obviously unpatentable" and through the use of AI searching tools, but more safeguards are needed to ensure such patents are not inappropriately used to asserts rights against innovative companies.

One positive development was the 2021 amendments to the "Patent Examination Guidelines," which harmonized Chinese patent practice with U.S. patent practice in allowing petitioners to submit new evidence of invalidity when respondent patent owners seek to amend their claims during the invalidity proceeding.[198]

IPO is encouraged by CNIPA's effort to improve the quality and examination of utility patents containing algorithmic or business method features, as indicated by the 2021 and 2025 amendments to the "Patent Examination Guidelines."[199] However, the 2025 amendment introduces confusion as to patentable subject matter for computer programs and further clarity is needed on whether an invention includes a "technical means."[200] 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.

Administrative Enforcement of Patents

Article 20 of China's Fourth Amendment to the Patent Law requires those who apply for and exercise patent rights to act in good faith and not misuse patents to "damage public

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[196] 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.

[197] *Intellectual Property Statistical Country Profile 2024: China*, WORLD INTELL. PROP. OFF., https://www.wipo.int/edocs/statistics-country-profile/en/cn.pdf (Nov. 2025).

[198] 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 St. Intell. Prop. Off., Dec. 11, 2020, effective Jan. 15, 2021).

[199] Guojia Zhishi Chanquan Ju Guanyu Xiugai "Zhuanli Shencha Zhinan" De Jueding (Ju Ling Di 84 Hao) (国家知识产权局关于修改《专利审查指南》的决定 (局令第 84 号)) [Decision of the National Intellectual Property Administration on Amending the "Guidelines for Patent Examination" (Order No. 84)] (promulgated by the St. Intell. Prop. Off, Nov. 10, 2025, effective Jan. 1, 2026).

[200] Guojia Zhishi Chanquan Ju Guanyu Xiugai "Zhuanli Shencha Zhinan" De Jueding (Ju Ling Di 84 Hao) (国家知识产权局关于修改《专利审查指南》的决定 (局令第 84 号)) [Decision of the National Intellectual Property Administration on Amending the "Guidelines for Patent Examination" (Order No. 84)] (promulgated by the St. Intell. Prop. Off, Nov. 10, 2025, effective Jan. 1, 2026).

interests or other's legal rights."[201] China has not provided details to explain this principle or guide courts and administrative agencies. Although well-intentioned, this provision could create significant uncertainty and impede the legal exploitation of patents. It also raises questions regarding consistency with TRIPS Article 30, which provides that the exceptions to the exclusive rights conferred by a patent should neither "unreasonably conflict with a normal exploitation of the patent" nor "unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties."[202]

The Fourth Amendment to the Patent Law expanded administrative enforcement of patent rights by giving hundreds of inexperienced local and provincial patent administration and enforcement offices new powers to investigate, inspect, and grant injunctive relief; impose compensatory damages, fines, and penalties for patent infringement; and even to enhance damages if the infringement is deemed willful.[203] This has led to primarily Chinese domestic entities or individuals asserting their rights before local and administrative officials, who might not be technologically or legally qualified and are without clear guidance tying any remedy or award to the value of the patent. Prior to such authority being granted, these complex patent proceedings were entrusted only to certain courts selected by the Supreme People's Court. This change fragments 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.

Judicial Transparency

Judicial transparency is critical to ensuring fairness to parties and consistent case law development. China's 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.[204] Although this increased the availability

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[201] Zhonghua Renmin Gongheguo Zhuanli Fa (中华人民共和国专利法) [Patent Law of the People's Republic of China] (adopted by the Standing Comm. of the Sixth Nat'l People's Cong., Mar. 12, 1984, rev'd Oct. 17, 2020) art. 2.

[202] *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.

[203] Zhonghua Renmin Gongheguo Zhuanli Fa (中华人民共和国专利法) [Patent Law of the People's Republic of China] (adopted by the Standing Comm. of the Sixth Nat'l People's Cong., Mar. 12, 1984, rev'd Oct. 17, 2020).

[204] *China Judgements Online*, SUP. PEOPLE'S CT., http://wenshu.court.gov.cn/ (last visited Jan. 27, 2026); *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-

of judicial decisions, observers have concluded that Chinese courts appear to publish only around half of their patent judgments.[205] 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.

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 these decisions. Reported decisions can help bring predictability to patent law for U.S. companies and investors, allowing for greater investment and innovation in China.

Swaying Standard of a Person Skilled in the Art to Justify Arbitrary Patent Objection

While the Chinese Patent Examination Guidelines define a person skilled in the art in accordance with the international norm, in practice, examiners employ inconsistent standards in making objections against patent applications, often arbitrarily defining the abilities of the person skilled in the art.[206]

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 inventors, which IPO believes is unnecessary and might cause confusion.[207] Article 15 already requires an employer entity to give the inventor or designer a reasonable amount of remuneration, but without specifying exactly

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changes-chinese-legal-system-attractive-venue- iplitigation/id=96099/. In 2024, the Supreme People's Court Intellectual Property Court, a centralized tribunal for hearing appeals in IP cases, reported that it had closed 4,213 cases, but only about 31 were published online. *See Case Analysis*, INTELL. PROP. CT., https://ipc.court.gov.cn/zh-cn/news/more-5-20.html (last visited Jan. 27, 2026). In 2016, the Beijing IP Court embarked upon an initiative to use guiding cases in deciding IP cases, which included establishing a database and a research organization for identifying guiding cases. Such efforts reveal a desire on the part of China's judiciary to help bring transparency and predictability to the enforcement of IP rights in China, which will be further improved if a system of guiding cases can be adopted by more IP courts.

[205] 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. Even in the face of a WTO Article 63.3 request by the EU, China failed to make public the four SEP cases at issue. 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).

[206] Guojia Zhishi Chanquan Ju Guanyu Xiugai "Zhuanli Shencha Zhinan" De Jueding (Ju Ling Di 84 Hao) (国家知识产权局关于修改《专利审查指南》的决定 (局令第 84 号)) [Decision of the National Intellectual Property Administration on Amending the "Guidelines for Patent Examination" (Order No. 84)] (promulgated by the St. Intell. Prop. Off, Nov. 10, 2025, effective Jan. 1, 2026) pt. II, cs. 4, 2.4.

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

how.[208] IPO is concerned that the listed examples of incentive mechanisms could be misinterpreted as requiring share-based awards as the only acceptable type of remuneration and, thereby, limiting the employer's freedom in remunerating its employees.

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, preferably in the final "Implementing Regulations of the Patent Law."[209] 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.[210]

Unique Challenges to Pharmaceutical Protection

The U.S. and China have the potential to strengthen cooperation in the biopharmaceutical area. The Phase I Agreement should have provided such an opportunity, however, as explained further below, China has not completely fulfilled its obligations under Article 1.10 and Article 1.12, paragraph 2(b), and its implementation of the remaining provisions is questionable.[211]

The situation in China 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.

Consideration of Supplemental Data

China has not fully complied with Article 1.10 of the Phase I Agreement, which requires it to permit patent applicants to rely on supplemental data to support patentability, including sufficiency of disclosure and inventive step.[212] The provision intends to eliminate China's unique standard for the acceptance and consideration of supplemental data—which requires the technical effect demonstrated by supplemental data be

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

[209] 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 St. Council of the People's Republic of China, June 15, 2001, rev'd Dec. 11, 2023).

[210] 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 St. Council of the People's Republic of China, June 15, 2001, rev'd Dec. 11, 2023).

[211] 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. 1.10, 1.11, 1.12, Jan. 15, 2020 (covering consideration of supplemental data, effective mechanism for early resolution of patent disputes, and effective patent term extension, respectively).

[212] 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.

"obtainable" from the original specification. The unique "obtainable" standard has no basis in China patent law, but has been adopted and used by both the CNIPA and China courts as an extra requirement.[213] IPO understands that China continues to express certain policy concerns regarding supplemental data, e.g., under the first-to-file principle, but a properly developed standard for sufficiency of disclosure should be adequate to address all the policy concerns that China has relied on to justify its maintenance of the unique "obtainable" standard.

With respect to patent examination, China updated its "Patent Examination Guidelines" in 2023 to allow patent applicants to file additional biological data after the initial filing date and confirmed that the Guidelines would no longer be applied retroactively.[214] This is a welcome step, however, IPO is concerned that CNIPA appears to be imposing new and unfair or inappropriate limitations and interpretations of the new amendment on the use of post-filing data to satisfy inventive step requirements, especially at the Patent Reexamination and Invalidation Department level.

Patent Linkage

In a relatively new move for China, Article 76 of the Fourth Amendment to the Patent Law introduced a patent linkage system for pharmaceutical products.[215] IPO is encouraged by this development, but notes that a fair and effective linkage system must balance both the interests of generics and innovators while providing consistency between the courts and the range of concerned administrative agencies.

The first final patent linkage decision from the Supreme People's Court revealed the following issues, which unnecessarily complicate the decision process: (a) the generic supplier is <u>not</u> required to disclose details of the composition of the generic pharmaceuticals; and (b) it is unclear whether the generic supplier could target/choose a specific claim, regardless of independent or dependent, to challenge the brand supplier on.[216] IPO is also concerned that the Supreme People's Court 2021 "Provisions on Several Issues Concerning the Application of Law in Civil Cases of Patent Disputes

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[213] *See* Guojia Zhishi Chanquan Ju Guanyu Xiugai "Zhuanli Shencha Zhinan" De Jueding (Ju Ling Di 84 Hao) (国家知识产权局关于修改《专利审查指南》的决定 (局令第 84 号)) [Decision of the National Intellectual Property Administration on Amending the "Guidelines for Patent Examination" (Order No. 84)] (promulgated by the St. Intell. Prop. Off, Nov. 10, 2025, effective Jan. 1, 2026).

[214] Guojia Zhishi Chanquan Ju Guanyu Xiugai "Zhuanli Shencha Zhinan" De Jueding (Ju Ling Di 84 Hao) (国家知识产权局关于修改《专利审查指南》的决定 (局令第 84 号)) [Decision of the National Intellectual Property Administration on Amending the "Guidelines for Patent Examination" (Order No. 84)] (promulgated by the St. Intell. Prop. Off, Nov. 10, 2025, effective Jan. 1, 2026).

[215] Zhonghua Renmin Gongheguo Zhuanli Fa (中华人民共和国专利法) [Patent Law of the People's Republic of China] (adopted by the Standing Comm. of the Sixth Nat'l People's Cong., Mar. 12, 1984, rev'd Oct. 17, 2020).

[216] Zhongwai Zhiyao Zhushi Huishe Su Wenzhou Hai He Yao Ye Youxian Gongsi (中外制药株式会社诉 温州海鹤药业有限公司) [Chugai Pharm. Co., Ltd. v. Wenzhou Haihe Pharm. Co.] (Sup. People's Ct., Aug. 5, 2022).

Related to Drug Registration Applications" do not include a time limit for the court to issue a decision.[217]

In 2021, the National Medical Products Administration ("NMPA") and CNIPA published the "Implementation Measures for the Early Resolution Mechanism of Drug Patent Disputes" which created a patent registration system and procedure for generics seeking marketing approval of drugs based on registered patents.[218] The finalized Measures have a nine-month time limit for litigation to conclude, after which the NMPA is allowed to end the moratorium on the generic's marketing approval.[219] As the NMPA does not suspend evaluation during the moratorium, it is possible that it could issue marketing approval before the court issues a final decision. In that case, the NMPA would not revoke marketing approval, even if the court ultimately 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.

IPO is also concerned about the Measures' lack of a notice requirement.[220] The Measures provide the patentee or interested party opposing a patent statement in a generic drug application with a 45-day window to bring an action, accruing from the date NMPA makes the generic drug application public.[221] Without notification, the patentee or interested party may have very limited time to prepare for litigation.

IPO believes the relevant laws and regulations must be reformed to enable stakeholders to consider the proposed patent linkage scheme fully and holistically and to be harmonized with higher level laws and regulations.[222] It is also unduly burdensome for

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[217] Zuigao Renmin Fayuan Guanyu Shenli Shenqing Zhuce Di Yaopin Xiang Guan De Zhuanli Quan Jiufen Minshi Anjian Shiyong Falu Ruogan Wenti De Guiding (最高人民法院关于审理申请注册的药品相关的专利权纠纷民事案件适用法律若干问题的规定) [Provisions of the Supreme People's Court on Several Issues Concerning the Application of Law in Civil Cases Involving Patent Disputes Related to Registered Pharmaceutical Products] (promulgated by the Sup. People's Ct, July 4, 2021).

[218] Yaopin Zhuanli Jiufen Zaoqi Jiejue Jizhi Shishi Banfa (Shixing) (药品专利纠纷早期解决机制实施办法（试行) [Implementation Measures for the Early Resolution Mechanism of Pharmaceutical Patent Disputes (Trial Implementation)] (promulgated by Nat'l Med. Prods. Admin. and Nat'l Intell. Prop. Admin., July 4, 2021, effective July 4, 2021).

[219] Yaopin Zhuanli Jiufen Zaoqi Jiejue Jizhi Shishi Banfa (Shixing) (药品专利纠纷早期解决机制实施办法（试行) [Implementation Measures for the Early Resolution Mechanism of Pharmaceutical Patent Disputes (Trial Implementation)] (promulgated by Nat'l Med. Prods. Admin. and Nat'l Intell. Prop. Admin., July 4, 2021, effective July 4, 2021).

[220] 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. 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.

[221] Yaopin Zhuanli Jiufen Zaoqi Jiejue Jizhi Shishi Banfa (Shixing) (药品专利纠纷早期解决机制实施办法（试行) [Implementation Measures for the Early Resolution Mechanism of Pharmaceutical Patent Disputes (Trial Implementation)] (promulgated by Nat'l Med. Prods. Admin. and Nat'l Intell. Prop. Admin., July 4, 2021, effective July 4, 2021).

[222] For example, because Article 76 of the Patent Law is directed to drug marketing applications, the current versions of the Measures and Provisions should be revised to reflect the broad definition of "drug"

China to require that pharmaceutical companies file marketing approval applications in China close to or at the same time as filing applications for the same drug abroad. Further, China has excluded from the patent linkage system certain type of patents, such as polymorphs or biologic formulations, that are used in a broad range of pharmaceutical products.

Patent Term Extensions in China

China's patent term extension law is insufficient in that it only permits extensions for products that are new to the world, i.e., have not previously been approved in any other country before filed as a new drug application in China.[223] This contrasts with the international norm for patent term extension, as embodied in U.S. law, where patent holders can obtain a patent term extension for any drug which has never previously been approved in the U.S. The Chinese patent term extension rule has a prejudicial impact on U.S. companies, since most drugs introduced in China by U.S. companies have been previously approved in other jurisdictions. The rule effectively favors Chinese manufacturers, which are more likely than U.S. companies to file new drug applications first in China, due to more familiarity with Chinese regulatory requirements.

As such, China does not appear to fully comply with Article 1.12, paragraph 2(b), of the Phase I Trade Agreement, which clearly requires the term of patent extension to apply to "a new pharmaceutical product that is approved for marketing in China" and "the first commercial use of that product in China," and does not concern approval or commercialization in other countries.[224] In addition, Article 1.12 also clearly states that any patent term "shall confer all of the exclusive rights, subject to the same limitations and exceptions, of the patent claims" under the patent term extension.[225] It is indisputable that: (1) a compound patent covers all approved uses; and (2) all approved uses, regardless of whether some are approved subsequent to the others, rely on the same preclinical, pharmacological, and other information, and therefore suffer the same regulatory delay associated with the review and approval of the compound as a drug for the first time. Accordingly, under Article 1.12, all approved uses should be covered by the patent term extension of the compound patent.

There are several additional issues concerning the grant of patent term extension in China, including: (a) patent term extension can only be granted to improved small molecule drugs with esters or salts of known active ingredients, which is very restrictive and would not include small molecule drugs with improved licensed indications; and (b)

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and the wide range of relevant patents. Zhonghua Renmin Gongheguo Zhuanli Fa (中华人民共和国专利法) [Patent Law of the People's Republic of China] (adopted by the Standing Comm. of the Sixth Nat'l People's Cong., Mar. 12, 1984, rev'd Oct. 17, 2020) art. 76.

[223] 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 St. Council of the People's Republic of China, June 15, 2001, rev'd Dec. 11, 2023) art. 80.

[224] 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.

[225] 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.

it is unclear whether generic suppliers could invalidate a granted term based on a different interpretation of "innovative drug."

Requirements for Foreigners to Hire Local Patent Agencies

In China, domestic applicants may file their patent applications directly with CNIPA. Foreign applicants must appoint a patent agency to represent them before CNIPA.[226] Hiring a third party, however, can increase both the expense and the risk that confidential information is lost in the application process. For companies with significant operations in foreign countries, it is not uncommon to have in-house operations that manage the patent application process, including 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.

Obstacles to Accelerated Examination of Patent Applications

CNIPA's procedures for accelerated examination are not available, as a practical matter, to U.S. or other foreign applicants. To apply for prioritized examination, applicants need a recommendation from a local IP Office, which is very difficult to obtain in practice since foreign applicants are not under any local IP Office's jurisdiction. Similarly, to use Fast Track Examination (Fast Pre-Examination), applications need to go through a pre-examination conducted by local IP protection centers corresponding to the applicants' registered addresses. However, for foreign applicants without a registered address in China, it is practically impossible to complete the pre-examination. This has become particularly important since, as of October 1, 2025, PPH requests for accelerated examination will be denied if not in XML format, which is otherwise the only patent acceleration mechanism available to foreign applicants.

These obstacles to the use of accelerated examination by U.S. and other foreign applicants is not in accord with TRIPS Article 3, which provides in relevant part: "[e]ach Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property . . . ."[227]

Requirements for Labeling AI-Generated Content in China

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

[227] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 3, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 300.

The Cyberspace Administration of China announced "Methods for Identifying Synthetic Content Generated by Artificial Intelligence" on March 7, 2025, requiring labeling of AI-generated content, including cover text, images, audio, video, virtual scenes, and even data processed by AI platforms.[228] While it is unclear whether these requirements would cover foreign AI platforms, this could pose compliance issues to AI platforms operating in China.

Extensive, Overlapping, and Confusing Anti-Monopoly Governance

China has separate, overlapping regulations relating to monopolization that can prevent or endanger normal patent enforcement.[229] These give China many tools to regulate companies that could affect the enforcement of patent rights, including SEPs and pharmaceutical patents.

COLOMBIA

Compulsory Licenses

In June 2023, the Ministry of Health ("MoH") initiated, as a necessary step, a Declaration of Public Interest ("DPI") for the compulsory licensing of Patent 1887 for Dolutegravir, a drug used in the treatment and prevention of HIV/AIDS, owned by VIIV Healthcare Company and Shionogi & Co. Ltd.[230] 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.[231]

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[228] Rengong Zhineng Shengcheng Hecheng Neirong Biaozhi Banfa (人工智能生成合成内容标识办法) [Methods for Identifying AI-Generated Synthetic Content] (promulgated by the St. Internet Info. Office, Ministry of Indus. & Info. Tech., Ministry of Pub. Sec., and St. Admin. of Radio & Television, Mar. 7, 2025).

[229] *See, e.g.,* Zhonghua Renmin Gongheguo Fan Longduan Fa (中华人民共和国反垄断法) [Anti-Monopoly Law of the People's Republic of China] (promulgated by the Standing Comm. of the 13th Nat'l People's Cong., June 24, 2022); Jingying Zhe Jizhong Shenchz Guiding (经营者集中审查规定) [Regulations on the Review of Business Mergers and Acquisitions] (promulgated by the St. Admin. for Mkt. Reg., Mar. 10, 2023, effective Apr. 15, 2023); Jinzhi Lanyong Shichang Zhipei Diwei Xingwei Guiding (禁止滥用市场支配地位行为规定) [Regulations Prohibiting The Abuse Of Market Dominance] (promulgated by the St. Admin. for Mkt. Reg., Mar. 10, 2023, effective Apr. 15, 2023); Jinzhi Longduan Xieyi Guiding (禁止垄断协议规定) [Prohibition Of Monopolistic Agreements] (promulgated by the St. Admin. for Mkt. Reg., Mar. 10, 2023, effective Apr. 15, 2023); Jinzhi Lanyong Zhishi Chanquan Paichu, Xianzhi Jingzheng Xingwei Guiding (禁止滥用知识产权排除、限制竞争行为规定) [Regulations Prohibiting The Abuse Of Intellectual Property Rights To Exclude Or Restrict Competition] (promulgated by the St. Admin. for Mkt. Reg., June 25, 2023, effective Aug. 1, 2023); Biaozhun Biyao Zhuanli Fan Longduan Zhiyin (标准必要专利反垄断指引) [Antitrust Guidelines for Standard-Essential Patents] (promulgated by the St. Admin. for Mkt. Reg, Nov. 4, 2024, effective Nov. 4, 2024); Guanyu Yaopin Lingyu De Fan Longduan Zhinan (关于药品领域的反垄断指南) [Guidelines on Anti-Monopoly Practices in the Pharmaceutical Sector] (promulgated by the St. Council Anti-Monopoly & Anti-Unfair Competition Comm'n, Jan. 23, 2025, effective Jan. 23, 2025).

[230] Ministerio de Salud y Protección Social, Resolución 881, Junio 2, 2023.

[231] Ministerio de Salud y Protección Social, Resolución 2024, Diciembre 1, 2023.

On April 24, 2024, Colombia's Patent Office, the Superintendency of Industry and Commerce ("SIC"), cited public interest reasons to issue its first-ever compulsory license to the MoH for Patent 1887.[232] 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.[233] Under the terms of the license, the MoH must compensate the patent holders at a rate of COP 0.11 (approximately USD 0.000025) per milligram of Dolutegravir produced or imported.[234] The SIC has also permitted the MoH to use centralized purchasing mechanisms to secure the drug's availability.

Industrial Designs

In 2022, SIC issued new guidelines for filing and prosecuting industrial designs.[235] Given that the Andean Community issued the Andean Industrial Design Manual ("AIDM") in 2024, it is possible that the SIC guidelines will not be applied due to different criteria between the two.[236] Clarity on which guidelines will be applied would be helpful to stakeholders.

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 examination landscape in Colombia 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 regular cases to receive a first examination and 2020 in cases where administrative remedies were filed against a first non-final decision. IPO members have received multiple final decisions in cases that would have been directly granted prior to 2024, such as applications claiming specific antibodies defined by their CDRs or pharmaceutical compositions defined by specific concentrations (not ranges).

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[232] Superintendencia de Industria y Comercio, Resolución 20049, Abril 23, 2024.
[233] Superintendencia de Industria y Comercio, Resolución 20049, Abril 23, 2024, art. 2.2.
[234] Superintendencia de Industria y Comercio, Resolución 20049, Abril, 23, 2024.
[235] Superintendencia de Industria y Comercio, Resolución 60452, Septiembre 5, 2022.
[236] For example, the AIDM allows the use of colors in 3D designs, while the Colombian Guidelines do not. COMUNIDAD ANDINA, MANUAL PARA EL EXAMEN DE DISEÑOS INDUSTRIALES EN PAÍSES DE LA COMUNIDAD ANDINA [Andean Community, Manual for the Examination of Industrial Designs in Countries of the Andean Community] (2024). Superintendencia de Industria y Comercio, Resolución 60452, Septiembre 5, 2022.

Genetic Resources and Traditional Knowledge

Comments relating to Colombia's laws and regulations 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 India 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, that made 82 recommendations towards strengthening India's IP rights regime.[237]

On April 6, 2022, the Parliamentary Standing Committee presented Report No. 169, entitled "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" before both houses of the Parliament."[238] IPO is encouraged by India's positive response to recommendations for separate legislation protecting trade secrets and its recognition of the advantages provided by PPH programs.[239] 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 General of Patents, Designs, and Trade Marks ("CGPDTM") in refusing patents, resolution of the patentability criteria, and disqualification of incremental inventions under Section 3(d) of the India Patents Act.[240]

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[237] The report notably 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 with greater autonomy and reforms; (d) establishing 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 Controller General of Patents, Designs, and Trade Marks in declining patents; (g) enacting specific legislation to curb counterfeiting and piracy; and (h) amending legislation and regulations to enable protection of AI-related inventions. Standing Committee on Commerce, Review of the Intellectual Property Rights Regime in India (161st Report, 17th Lok Sabha) at 96, 100, 101, 102, 103–104, 111, 114.

[238] As per Report No. 169, it was recorded that out of Report No. 161's 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; and (d) one response was not received from the government. Standing Committee on Commerce, 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' (169th Report, 17th Lok Sabha).

[239] Standing Committee on Commerce, 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' (169th Report, 17th Lok Sabha) at 12, 32.

[240] Standing Committee on Commerce, 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' (169th Report, 17th Lok Sabha) at 12, 13–14.

Some of Report No. 161's recommendations concerning AI-related inventions are being indirectly and gradually implemented through amendments in practice and procedure guidelines, such as the "Guidelines for Examination of Computer Related Inventions (CRIs) 2025."[241] However, India has yet to see further progress on enactment of separate legislation for protection of trade secrets after the Protection of Trade Secrets Bill was introduced in 2024.[242]

National Intellectual Property Rights Policy

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.[243] Among other positive proposals, IPO is encouraged by the IPR Policy's recommendation to further study the protection of trade secrets and believes improving India's trade secret regime is critical to ensuring a level playing field for non-Indian innovators.[244]

Although much of the IPR Policy is still being implemented, some recommendations should be closely monitored, including items 2.16 for tax benefits linked to IP creation and commercialization; 3.9 for guidelines on technology transfer, know-how, and licensing of SEPs; 3.2 for India's accession to the Hague System and Design Law Treaty; 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.[245] The IPR Policy includes many positive actions for improving India's IP system, and the U.S. should continue to monitor its implementation as it unfolds.[246]

New AI and Data Protection Ecosystem

India has begun developing a comprehensive AI ecosystem under INDIAai, a national platform launched in 2024 with a budget outlay of INR 10,371.92 crore (approx. USD

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[241] Office of the Controller General of Patents, Designs & Trade Marks, Guidelines for Examination of Computer Related Inventions (CRIs) (issued on July 29, 2025).

[242] A summary of further proposals made by Report No. 169 can be found in the official press release. Press Release, Dep't Related Parliamentary Standing Comm. on Com., Recommendations/Observations – At a Glance (Apr. 15, 2022).

[243] Department for Promotion of Industry and Internal Trade, National Intellectual Property Rights (IPR) Policy (issued May 12, 2016).

[244] Department for Promotion of Industry and Internal Trade, National Intellectual Property Rights (IPR) Policy (issued May 12, 2016) at 10.

[245] Department for Promotion of Industry and Internal Trade, National Intellectual Property Rights (IPR) Policy (issued May 12, 2016) at 10, 12, 17.

[246] In its Report No. 161, the Parliamentary Committee recommended a review of the IPR Policy after five years, however, Report No. 169 indicates a further review is not being pursued. In July 2023, the Indian government identified and summarized impacts of the IPR Policy. Department of Science and Industrial Research, Compendium of Intellectual Property Rights (issued July 20, 2023) at 10. 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. Press Release, Ministry of Com. & Indus., Intellectual Property Rights Policy Management Framework Covers 8 Types of Intellectual Property Rights (July 21, 2023).

100 billion) over five years.[247] INDIAai aims to drive AI adoption across sectors via shared infrastructure, datasets, and innovation support.[248] Further, while some jurisdictions consider special rights for AI-generated content or datasets, the official stance in India is that current IP laws suffice.

In November 2025, the India Ministry of Electronics and Information Technology (MeitY) released the "India Artificial Intelligence Governance Guidelines," which set out a national framework for AI systems.[249] The Guidelines require AI developers and deployers to conduct risk assessments, maintain auditability, and implement safeguards proportionate to the system's potential impact, especially in sensitive sectors.[250] They also introduce strong expectations around disclosure and transparency, including clear communication when users interact with AI systems and accessible grievance mechanisms.[251] The framework requires AI systems to respect copyright and licensing conditions during training and output generation, and mandates transparency and traceability to support accountability for potential IP infringement.[252]

Significantly, on October 22, 2025, the MeitY released the "Draft Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Amendment Rules, 2025" ("Draft Rules") for public comment, proposing updates to the existing "Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Rules, 2021" ("Intermediary Rules").[253] The proposed amendments mark a significant step in India's digital-regulatory landscape by explicitly addressing the use and misuse of AI-generated or synthetically produced content.

The Draft Rules emerge amidst a rapid rise in cases involving synthetically generated media used for impersonation, fraud, and reputational harm—from celebrity deepfakes to market manipulation through fabricated statements. While courts have been developing jurisprudence around such misuse, the Draft Rules represent a structured regulatory response, aligned with international practice. Public feedback was sought until November 6, 2025, on the scope of intermediary liability for AI systems that generate content autonomously and the technical feasibility of embedding unalterable metadata identifiers.

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[247] Press Release, Press Info. Bureau, Transforming India with AI: Over ₹ 10,300 Crore Investment & 38,000 GPUs Powering Inclusive Innovation (Oct. 12, 2024).

[248] *See also* NITI Aayog, National Strategy for Artificial Intelligence (issued June 2018); Ministry of Electronics & Information Technology, India AI Governance Guidelines: Enabling Safe and Trusted AI Innovation (issued November 2025).

[249] Ministry of Electronics & Information Technology, India AI Governance Guidelines: Enabling Safe and Trusted AI Innovation (issued November 2025).

[250] Ministry of Electronics & Information Technology, India AI Governance Guidelines: Enabling Safe and Trusted AI Innovation (issued November 2025).

[251] Ministry of Electronics & Information Technology, India AI Governance Guidelines: Enabling Safe and Trusted AI Innovation (issued November 2025).

[252] This issue is already under scrutiny before the Delhi High Court. Ani Media PVT LTD v. Open AI Inc & ANR, 2024 DHC 1028.

[253] Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Amendment Rules 2025; The Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Rules 2021 (prescribing due diligence obligations that intermediaries must implement to claim safe harbor protection under Section 79 of the Information Technology Act, 2000 for third-party content hosted on their platforms).

Once finalized, the Draft Rules will demand significant policy and technological adaptation.

The Digital Personal Data Protection Rules, 2025, needed to implement the Digital Personal Data Protection Act, 2023, were published on November 13, 2025, after a lengthy comment process.[254] The Act established a comprehensive framework for protecting digital personal data, setting out obligations for entities handling such data (Data Fiduciaries) and the rights and duties of individuals (Data Principals).[255] With the Rules in place, India may begin a phased rollout of its new data protection regime that will reshape how companies, platforms and public bodies collect, use, and retain digital personal data.

Examination of Computer Related Inventions (CRIs)

In 2025, the Indian Patent Office released revised "Guidelines for Examination of Computer Related Inventions ("CRIs")."[256] First introduced in 2013, the Guidelines have undergone many revisions over the years to bring uniformity to examination across different branches of the Indian Patent Office and give full effect to statutory provisions and their judicial interpretation.

IPO appreciates that the 2025 Guidelines are elaborate and provide clarity on many aspects of claim and disclosure requirements for CRIs with supporting examples and explanations. Drawing on recent Delhi High Court rulings, the Guidelines redefine terms, such as algorithm and *per se*, and introduce multi-step frameworks for assessing mathematical methods, business methods, algorithms, and computer programs *per se* to ensure that inventions showing genuine technical contribution are not automatically rejected. The Guidelines reaffirm the Seven-Stambh (seven step) test for novelty, reiterate technical-contribution requirements for inventive step, set higher disclosure expectations (including for means-plus-function claims), and add extensive guidance for AI, machine learning, blockchain, and quantum computing, focusing on technically implemented solutions rather than abstract models.[257] For practitioners, the revised Guidelines offer clarity; the examples provided in the Guidelines will help applicants craft stronger arguments against different objections raised in office actions. Examiners, on the other hand, would be better equipped with structured tests and illustrative examples to interpret Section 3(k) of the Patents Act consistently.

IPO is concerned, however, that the Guidelines leave little room or flexibility for examiner discretion with respect to sufficiency requirements, especially considering the rate at which AI and other technologies are evolving, this concern is heightened.

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[254] Digital Personal Data Protection Rules 2025.

[255] The Digital Personal Data Protection Act, 2023.

[256] Office of the Controller General of Patents, Designs & Trade Marks, Guidelines for Examination of Computer Related Inventions (CRIs) (issued on July 29, 2025).

[257] Office of the Controller General of Patents, Designs & Trade Marks, Guidelines for Examination of Computer Related Inventions (CRIs) (issued on July 29, 2025).

Delays in Patent Examination and Pre-Grant Oppositions

Historically, serial oppositions, benami oppositions (filed by vested interests on behalf of others), and delays in issuing notices of opposition by the CGPDTM had contributed most towards delays in granting patents.[258] In fact, in its August 2022 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") to combat such delays.[259]

The Patent (Amendment) Rules, 2024, positively addressed some of these issues, by enacting the following provisions: (a) an official fee has been introduced for filing a pre-grant opposition, which may help curb frivolous oppositions; (b) the applicant is notified only if the pre-grant opposition is found to be *prima facie* maintainable, determination of which is to be carried out strictly within one month; (c) upon being served with a notice of representation, the applicant is required to file its statement and evidence within two months from notice (instead of the previous three-month timeframe); (d) if no *prima facie* case is made out, the respondent is to be provided an opportunity of hearing, if requested, and a reasoned order of refusal is to be recorded; and (e) if a *prima facie* case of pre-grant opposition is made out, the application is to be examined on an expedited basis with the FER to be issued within two to four months.[260] Further, notices currently applicable to post-grant oppositions are now also applicable to pre-grant proceedings.[261]

The August 2022 EAC-PM Report identified that while the number of examiners responsible for issuing first office actions at the Indian Patent Office appears to be adequate, there is an acute shortage of controllers responsible for further examination, hearings, and disposal of patent applications.[262] The EAC-PM Report relies upon recommendations of Report No. 161 to suggest an urgent increase in manpower, particularly controllers.[263]

The CGPDTM's August 2023 Annual Capacity Building Plan ("ACBP") included "achieving near-zero" pendency by the year 2025 under its National Priority Objectives

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[258] V.C. VIVEKANANDAN, UDAY SHANKAR & GARIMA PANWAR, HIDAYATULLAH NAT'L L. UNIV., A STUDY OF PATENT OPPOSITION SYSTEM 20, 22 (2023).

[259] Economic Advisory Council to the Prime Minister, Why India Needs to Urgently Invest in its Patent Ecosystem?, EAC-PM/WP/1/2022 (issued August 2022) at 10; Ministry of Commerce and Industry, Patents (Amendment) Rules, 2024, G.S.R. 211(E) (Notified on Mar. 15, 2024).

[260] Ministry of Commerce and Industry, Patents (Amendment) Rules, 2024, G.S.R. 211(E) (Notified on Mar. 15, 2024).

[261] As per the CGPDTM Annual Report 2024-25, the number of pre-grant oppositions filed decreased from 366 in 2023-24 to 239 in 2024-25, and 711 pre-grant oppositions were disposed of during the year. Office of the Controller General of Patents, Designs, Trademarks, and Geographical Indications, Annual Report 2024-2025 (issued 2025) at 28.

[262] Only 247 controllers were employed in 2019-22. Economic Advisory Council to the Prime Minister, Why India Needs to Urgently Invest in its Patent Ecosystem?, EAC-PM/WP/1/2022 (issued August 2022) at 4.

[263] Economic Advisory Council to the Prime Minister, Why India Needs to Urgently Invest in its Patent Ecosystem?, EAC-PM/WP/1/2022 (issued August 2022) at 5.

and relied upon the EAC-PM Report to emphasize "the shortage of workforce and procedural issues [as] major contributing factors to increased pendencies and delays."[264]

According to the EAC-PM Report, the average time for patent disposal in India is just under five years, far above the global best practice of two to three years.[265] While this is being addressed through recruitment and training drives, the Patent Office also appointed nearly three times the number of hearings between Nov. 2023 and Apr. 2024 as it did previously to clear backlogs and reduce the time taken for an application to proceed to grant.[266] Meanwhile, a "Quality Cell" has been established to ensure consistent and quality driven decision making. Thus, IPO encourages the Indian Patent Office to continue implementing measures to improve the speed and quality of patent examination through induction and training of examiners and controllers.

As noted in the Department for Promotion of Industry and Internal Trade ("DPIIT") the 2024-25 Annual Report, the Indian government currently has memorandums of understanding with 15 other jurisdictions, including, *inter alia*, the EU, U.S., Japan, Canada, Sweden, France, UK, and Singapore.[267] IPO hopes that India will enter PPH arrangements with other IP Offices.

Higher Threshold of Patentability for Pharmaceutical Inventions

The threshold for patentability of pharmaceutical compositions provided by section 3(d) of the India Patents Act appears to be higher than that allowed under TRIPS and discriminatory against pharmaceutical inventions and chemical compounds because it requires enhanced efficacy for new forms of known substances, making it difficult for drug innovators to obtain patent protection.[268] In Report No. 161, the Parliamentary Committee supported and upheld the validity and utility of section 3(d), but recommended a bilateral dialogue with the U.S. on this issue based on concerns raised by

[264] Office of the Controller General of Patents, Designs, and Trademarks, Annual Capacity Building Plan Report (issued September 30, 2023) at 13, 53 (emphasis added). It is noted that the government is fast-tracking the hiring process and internal promotions, elevating nearly 370 examiners to controllers in 2023 and welcomed 407 new examiners in 2025. Office of the Controller General of Patents, Designs, Trademarks, and Geographical Indications, Annual Report 2024-2025 (issued 2025).

[265] Economic Advisory Council to the Prime Minister, Why India Needs to Urgently Invest in its Patent Ecosystem?, EAC-PM/WP/1/2022 (issued August 2022) at 3.

[266] Consequently, more than 1,000,000 patents were granted in fiscal years 2023-24 and the time from first office action to disposal has been reduced. Press Release, Ministry of Com. & Indus., Indian Patent Office Has Granted 1,03,057 Patents in FY 2023-24 (July 30, 2024). It is also notable that 7,154 requests for expedited examination were filed with the Indian Patent Office in 2024-25, a continuing increase from 5,130 in 2023-24. Office of the Controller General of Patents, Designs, Trademarks, and Geographical Indications, Annual Report 2024-2025 (issued 2025).

[267] Department for Promotion of Industry & Internal Trade, Annual Report 2024-25, (issued August 31, 2025).

[268] The Patent Acts, 1970, §3(d).

USTR.[269] Following this recommendation, the Indian Government conducted a stakeholder's meeting, but has not provided any specific response.[270]

Further, India's law does not make available post-grant filing data that could be used as evidence to support novelty and inventiveness of such new compound forms.

Lack of Regulatory Data Protection and Patent Linkage

The Indian Regulatory Authority relies on test data submitted by innovators to other countries 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 address unmet medical needs. IPO notes that the Indian government recognizes the role of regulatory data protection in fostering innovative medicines; the government issued an October 2025 notice requesting public comment on whether India should institute regulatory data protection for innovators.[271] IPO urges USTR to advocate for India to institute regulatory data protection, and to comply with its obligations under TRIPS.

The lack of a linkage system between patent status and drug approval creates a significant risk of patent infringement. Under the current process in India, federal and state drug regulators are not required to ascertain the patent status of a new drug when considering requests for market approval. This leads to new drugs being launched that infringe valid patents. There is also no mechanism for a patent holder to be notified 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, India instituting an "information system" 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.

Compulsory Licensing

IPO appreciates that India took a positive and firm stand via affidavit to the Supreme Court of India against a plea for grant of a compulsory license, reciting that it would be "presumptuous to assume that the patent holder will not agree to more voluntary licenses."[272] However, in Report No. 161, the Parliamentary Committee recommended that India "delve into the prospect of temporarily waving patents rights and issuing

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[269] Standing Committee on Commerce, Review of the Intellectual Property Rights Regime in India (161st Report, 17th Lok Sabha) at 30.

[270] Standing Committee on Commerce, 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' (169th Report, 17th Lok Sabha) at 14.

[271] Central Drugs Standard Control Organization (Subsequent New Drugs Division), Inviting Comment to Ensure a Level Playing Field in New Drug Approval in India-reg (notified October 8, 2025).

[272] 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.

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."[273] High courts have also suggested that the government invoke compulsory licensing under the Patents Act in multiple public interest litigations, to which the government has stated that while it supports the legitimacy and validity of the compulsory licensing provisions, it chooses to rely on voluntary licenses granted by the patent owners.[274] IPO will continue to monitor developments concerning compulsory licensing provisions.

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."[275] This section creates the Technology Acquisition and Development Fund ("TADF") to help in situations where a patent holder is unwilling to license either at all or "at reasonable rates," or when an invention is not being "worked" within India.[276] TADF is empowered to request compulsory licensing from the Government of India.[277] Similarly, India's National Competition Policy requires IP owners to grant access to "essential facilities" on "agreed reasonable and nondiscriminatory terms" without reservation.[278] 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."[279] 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.

Further, clause 6 of the Draft Protection of Trade Secrets Bill, 2024 proposes granting compulsory licensing of trade secrets in case of national or extreme urgency. Compulsory licensing of trade secrets not only runs contrary to the basic principles of trade secrets protection, but is also practically not feasible.

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 facilitates the use of compulsory licenses contrary to the spirit of the TRIPS Agreement. A market with ongoing threats of compulsory licensing perpetuates an unreliable environment for patent protection and investment.

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[273] Standing Committee on Commerce, Review of the Intellectual Property Rights Regime in India (161st Report, 17th Lok Sabha) at 62.

[274] Standing Committee on Commerce, 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' (169th Report, 17th Lok Sabha) at 82–83.

[275] Ministry of Commerce and Industry, National Manufacturing Policy, §4.4.1 (issued on November 4, 2011).

[276] Ministry of Commerce and Industry, National Manufacturing Policy, §4.4.2 (issued on November 4, 2011).

[277] Ministry of Commerce and Industry, National Manufacturing Policy, §4.4.3 (issued on November 4, 2011).

[278] Ministry of Corporate Affairs, National Competition Policy, §5.1(vi) (issued on July 28, 2011).

[279] Ministry of Corporate Affairs, National Competition Policy, §5.1(vi) (issued on July 28, 2011).

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," they are often unfeasible and require a close relationship between the trade secret owner and alleged misappropriator.[280] Given India's highly skilled service center and the potential benefits of collaboration, it is in the interest of both stakeholders in the U.S. and India for India to enact stronger and more transparent trade secret protection, covering a broader range of actors.

IPO believes that India should adopt 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. For over a decade, India has taken steps suggesting the country might value such an approach.[281]

In a positive move, the 22nd Law Commission of India issued a report titled "Trade Secrets and Economic Espionage" on March 5, 2024, to recommend a *sui generis* legal framework to adjudicate claims related to trade secret disclosure.[282] Overall, the Commission contemplated the broad framework of potential legislation, including provisions on exceptions, limitations, remedies, and a draft bill titled "The Protection of Trade Secrets Bill, 2024" annexed to the report to codify acquisition, use, disclosure of trade secrets, and legal proceedings thereof.[283]

The Commission noted that trade secrets are conceptually not akin to other types of intellectual property, since there are no definite monopoly rights attached to them and no disclosure of information to the public domain.[284] The Commission also found that because trade secrets are expansive in nature, they should be defined as per Article 39 of the TRIPS Agreement, wherein secrecy, commercial value, and reasonable steps are the qualifying criteria for trade secret protection.[285] Finally, the Commission determined that negative covenants on post-employment restraints shall not be permitted as they violate the Contracts Act prohibition against agreements in restraint of trade and information that

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[280] 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).

[281] There is also a growing body of academic literature originating within India that agrees that improving trade secret protection is critical, 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).

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

[283] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 198–204 (2024).

[284] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 4–5, 29 (2024).

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

is already in the public domain cannot be protected by way of confidentiality or secrecy provisions in non-disclosure agreements.[286]

As to exceptions, the Commission recommended incorporating provisions to protect whistleblowers because illegal activities under the guise of trade secrets cannot be exempted by law and any non-disclosure agreements to that end would be void under Section 23 of the Contracts Act.[287] On remedies for misappropriation, the Commission proposed granting interim, *ex parte*, and permanent injunctive relief, as well as other ancillary reliefs ordinarily available under IP statutes in case of groundless threats of legal proceedings.[288] However, as per the Commission, criminal action may only be taken under the applicable criminal law provisions of various existing statutes.[289]

The Commission observed that because trade secrets are commercial assets, the procedure under the Commercial Courts Act, 2015, shall be applicable to suits for misappropriation of trade secrets and Article 113 of the Limitation Act, 1963, shall be applicable wherein the statute of limitations starts three years from when the right to sue accrues.[290] The Commission was silent on whether a violation by virtue of misappropriation of trade secrets would give rise to a continuing cause of action. It had also proposed built-in confidentiality provisions for proceedings pertaining to misappropriation of trade secrets, such that disclosures to the Court could be given without any apprehension.[291] The Commission had specifically recommended not including a trade secret board or registry; it would be counter-intuitive, onerous, and practically difficult, coupled with the apprehension that rights holders may have in sharing protected information.[292]

Commentators observe that a law such as that proposed by the Commission would offer companies clarity on protection of confidential information, increase industry confidence, enable technology transfer to India, and facilitate negotiation of free trade agreements, whereas the absence of a clear law on trade secrets is often a point of concern.[293] IPO believes that it would be beneficial to the innovation ecosystem for India to have a clear

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[286] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 181 (2024).
[287] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 182–83 (2024).
[288] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 190 (2024).
[289] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 190 (2024) (such as damages, rendition of accounts or profits, delivery up, surrender, and destruction).
[290] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 191 (2024).
[291] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 192–93 (2024).
[292] LAW COMM. OF INDIA, TRADE SECRETS AND ECONOMIC ESPIONAGE 142 (2024).
[293] The 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 2024 FICCI-USPTO Roundtable on Trade Secret Protection Challenges and Solutions, provided a useful platform for in-depth discussions. Fed'n of Indian Chambers of Com. & Indus., *FICCI – USPTO Roundtable on Trade Secret Protection Challenges and Solution*, 13 IP UPDATE 5 (2024). 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. Delhi High Court Intellectual Property Division, Second Annual Report 2023-24 (issued November 2024).

law on trade secrets, but IPO would want to comment on the specifics of any legislation once proposed.

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.[294] IPO believes that removing the working requirement altogether from existing law would be best for the innovation ecosystem. IPO notes, however, that, 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.[295] The Rules also relaxed obligations 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.[296]

Additionally, a delay in filing the Statement can be condoned or an extension can be sought by request.[297] Further, under the Jan Vishwas Act, 2023, the penalty for failure or refusal to file Form 27 has been significantly reduced.[298] These changes reflect an effort to streamline reporting requirements and reduce the burden on applicants while ensuring patent holders continue to fulfill their legal obligations.[299] Nonetheless, this unnecessary burden remains.

Foreign Filings Disclosure and Permissions

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."[300] Non-compliance provided an independent ground for pre- and post-grant opposition, as well as revocation.[301] Furthermore, in the absence of clarity

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[294] The Patent Acts, 1970, § 84(1)(c).

[295] Ministry of Commerce and Industry, Patents (Amendment) Rules, 2024, G.S.R. 211(E), §7(v)(2) (Notified on March 15, 2024).

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

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

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

[299] 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).

[300] The Patents Act, 1970, § 8(1).

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

regarding the meaning of "substantially the same invention," it was often difficult to ascertain full compliance with this obligation.

This disclosure requirement was 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 Centralized Access to Search and Examination ("CASE"), this cumbersome compliance requirement should be done away with, at least for PCT national phase applications.[302] 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.[303]

India's Patents Act requires that owners of inventions patented in India and naming Indian inventors must obtain a Foreign Filing Permission ("FFP") from the Indian Patent Office prior to applying for patents elsewhere in the world.[304] Non-compliance with this requirement results in a monetary fine, jail term, or both.[305] While the routine FFPs are granted very expeditiously, inventions determined by the Patent Office to contain subject matter relevant for defense purposes or atomic energy are referred to the Ministry of Defense for prior consent, which, in some cases, may take up to two years. 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.[306] 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.[307] Further, even when the biological material does not originate from India, the applicants are required to identify the specific location or city of origin, which is onerous and unwarranted. 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.

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[302] Economic Advisory Council to the Prime Minister, Why India Needs to Urgently Invest in its Patent Ecosystem?, EAC-PM/WP/1/2022 (issued August 2022) at 11.

[303] 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, the 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).

[304] The Patents Act, 1970, § 39.

[305] The Patents Act, 1970, § 118.

[306] The Patents Act, 1970, § 10(4)(d)(ii)(D).

[307] Office of the Controller General of Patents, Designs, and Trademarks, Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material (issued 2017) at 2.

As discussed further above, India has created an NBA to regulate use of the genetic resources of India.[308] A non-Indian person or company requires NBA approval to access or include the genetic resources in a patent application in India.[309] 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.[310] Further, regulations issued in 2025 clarified that India's genetic resources disclosure rules apply to the use of digital sequence information (DSI) that is derived from genetic resources.[311] DSI is typically obtained from secondary sources, such as publicly available databases, many of which do not reference the source of the DSI. The result will be disclosure requirements that are extremely burdensome or impossible to comply with, thereby discouraging innovation relying on DSI. The new Indian regulation will further discourage U.S. innovators from using DSI information for which the source cannot be identified.

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

On February 24, 2022, the Delhi High Court published "The High Court of Delhi Rules Governing Patent Suits, 2022" ("Patent Suit Rules") and "The Delhi High Court Intellectual Property Rights Division Rules, 2022" ("IPD Rules") after a few rounds of comments from stakeholders.[312] 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.[313] Matters from the now-abolished IPAB are listed before the IP divisions.

Under the IPD Rules, a court may consolidate multiple proceedings concerning the same trademark or patent towards a common trial to save judicial time and costs for litigants.[314] A court may also seek the assistance of independent experts, whose persuasive and technically competent opinions enable well-reasoned judgments while addressing

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[308] The Biological Diversity (Amendment) Act, 2023, ch. II.

[309] The Biological Diversity (Amendment) Act, 2023, § 3(1)(2).

[310] The Biological Diversity (Amendment) Act, 2023, § 6(2).

[311] Biological Diversity (Amendment) Rules 2025.

[312] 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).

[313] 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).

[314] 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).

nuanced questions in IP rights disputes.[315] The rules also grant the intellectual property division ("IPD") benches supervisory jurisdiction over the India IP offices, enabling the courts to enhance the overall function of the offices while hearing appeals of office decisions.

The recent NITI Aayog conference, held on April 20, 2025, aligned with the government's "Viksit Bharat 2047" initiative to focus on modernizing India's patent system.[316] The event brought together judges, academics, lawyers, Indian Patent Office officials, bureaucrats and other stakeholders to explore how India's patent regime can better support innovation and development goals. Key themes included the modernization of the litigation ecosystem, proposals for a national patent bench framework, greater judicial specialization, and procedural uniformity across High Courts. There was also acknowledgment of the growing need for a coordinated legislative and judicial strategy that balances robust enforcement with public interest. The framing of this event itself signals a shift: Patent enforcement is increasingly seen not as a compliance burden but as a strategic lever for national growth.

Decriminalization of IP Offenses

Through the "Jan Vishwas (Amendment of Provisions) Act, 2023," India decriminalized minor IP offenses by imposing only a monetary penalty.[317] For instance, the offense of falsely representing a trademark as registered now has a penalty of 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 (USD 5,462.38), whichever is less. Likewise, if a person falsely represents that any article they sell is patented in India or is the subject of an application for a patent in India, they will be liable for a penalty that may extend to INR 10 lakh (USD 10,924.76), and in case of a continuing claim, a further penalty of INR 1,000 (USD 10.92) for every subsequent day during which such claim continues. Decriminalized IP offenses should be counter-balanced by stricter laws, policies, and standards for enforcement to deter infringers and counterfeiters.

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 on the merits, is still very lengthy.

The India Trademark Office has taken steps to resolve the backlog and strengthen its manpower.[318] The Delhi High Court's direction to the Office of the CGPDTM to resolve

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[315] 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).

[316] *Meetings of Governing Council*, NITI AAYOG, https://niti.gov.in/about-us/niti-governing-council-meetings (last visited Jan. 28, 2026).

[317] The Jan Vishwas (Amendment of Provisions) Act, 2023.

[318] The India Trademark Office added 200 additional posts in 2025, including 120 examiner and senior examiner positions. Office of the Controller General of Patents, Designs, Trademarks, and Geographical Indications, Annual Report 2024-2025 (issued 2025).

the trademark opposition backlog and continuous monitoring of the same has been a positive step, though progress is slow. However, in continuing its commitment to address stakeholder concerns and resolve IP related issues in a timely manner, the Office of the CDPDTM launched an Open House Helpdesk Portal for grievance redressal in February 2024 and an AI and machine learning-based trademark search tool in September 2024.[319]

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 marks.[320] 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.[321]

It is notable that Indian Courts are gearing towards granting higher damages in IP infringement matters. In *Amazon Technologies Inc v. Lifestyle Equities CV & ANR*, the Delhi High Court granted unprecedented damages of about INR 340 Crore (approx. USD 37 million) against Amazon for selling apparel that infringed Beverly Hill's registered polo trademark.[322] Courts have also recently appeared more amenable to granting dynamic injunctions against counterfeit websites and online piracy.

Inconsistent Trademark Examination

There appears to be an increase in inconsistent trademark 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 blunt 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.

Stakeholder Consultation to Discuss Key Issues Related to Trademarks in India

The Ministry of Commerce and Industry, through the DPIIT, has initiated a move to bring greater clarity and uniformity to India's trademark registration and dispute

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

[320] Ministry of Commerce and Industry, G.S.R. 199(E), §124 (notified on March 6, 2017).

[321] Tata Sia Airlines Ltd. v. Union of India, W.P.(C)-IPD 64 of 2021, Decided on May 25, 2024 (Delhi H.C.), 21.

[322] Amazon Technologies Inc v. Lifestyle Equities CV & ANR, 2025 DHC 11 (granting the highest damage award in an Indian IP case to date).

resolution processes.[323] The Office of the CGPDTM has called upon trademark attorneys, agents, applicants, and other stakeholders to submit their suggestions for drafting comprehensive guidelines aimed at streamlining procedures across different stages of trademark application filing.[324]

On a related note, India's Trademark Office accepted its first-ever olfactory trademark on November 21, 2025, for a "floral fragrance / smell reminiscent of roses as applied to tyres," filed by Sumitomo Rubber Industries Ltd.[325] The decision marks a landmark shift; India now officially recognizes smell as a valid "mark," opening the door for non-traditional trademarks and scent-based brand identity.

India Lacks a Meaningful Grace Period for Design Applications

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

Stakeholder Consultation to Discuss Key Issues Related to Designs in India

On November 26, 2025, the CGPDTM, in conjunction with DPIIT, conducted a stakeholders' meeting to discuss issues and provisions related to protection of industrial designs and invited comments from attendees. The meeting discussed: (a) an entirely new framework for protection of industrial designs in India, wherein the substantive examination occurs only upon request; (b) grace period; (c) deferred publication; (d) registration of user interface designs, such as GUIs, projected designs, etc.; (e) dual protection of designs under designs and copyright law; (f) accession to Design Law

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[323] Kirtika Suneja, *Trademark Rules' Recast in Works to Speed up Approvals*, ECON. TIMES (July 17, 2025), https://economictimes.indiatimes.com/news/economy/policy/trademark-rules-recast-in-works-to-speed-up-approvals/articleshow/122589762.cms?from=mdr.

[324] Controller General of Patents, Designs, and Trade Marks, Inviting the Submissions from Trademarks Attorney / Agents for Drafting Different TM Guidelines, CG/F/CGPDTM/DL-05/1019 (notified September 9, 2025). Issues taken up in the latest round of discussions included: global benchmarking of the definition of marks and trademarks to recognize non-conventional and futuristic marks; according statutory recognition to expedited examination process; introducing a time-bound, evidence-backed, and efficient opposition process; simplifying registration and renewal procedures and ensuring an efficient management of rights; introducing statutory damages for efficient and fair IP enforcement; fuller alignment with the Madrid Protocol; registration of security interests (as there is no mechanism to record charges, mortgages, pledges, or other security interests over registered trademarks); and establishing professional standards and accountability in trademark practice.

[325] Ayushi Shukla, *India's Trademark Registry Accepts its First Smell Trademark for Japanese Company's Rose Scented-Tyres*, LIVELAW (Nov. 21, 2025), https://www.livelaw.in/ipr/india-first-smell-trademark-sumitomo-rubber-rose-fragrance-tyres-310803?utm_source=chatgpt.com.

Treaty (DLT); (g) statutory damages; (h) single application for multiple designs; and (i) international filing mechanisms under the Hague System.[326]

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.[327]

INDONESIA

Genetic Resources and Traditional Knowledge

Despite amendments in 2024, Indonesia's Patent Law still imposes patent disclosure requirements regarding the source and origin of genetic resources or traditional knowledge related to inventions.[328] Such requirements introduce uncertainties into the patent system that inhibit innovation in relevant technologies and undermine the potential of benefit-sharing.

Compulsory Licensing

In 2020, Indonesia issued Presidential Regulation No. 77/2020, which broadly enables government agencies to request compulsory licenses for pharmaceutical products to address emergency needs in the public interest, despite efforts in 2019 to address and revise existing compulsory license regulations to align more appropriately with global norms and best practices.[329] If a compulsory license is granted and the government is unable to implement the patent, it may appoint a third party to do so. In 2021, Indonesia issued compulsory licenses for antiviral COVID-19 therapeutics despite one of the rights holders entering into a voluntary licensing agreement with generic manufacturers to supply the Indonesian market.[330] This new regulation, the process by which it was developed and issued, and the subsequent compulsory licenses, send a troubling signal to innovators.

Additionally, in August 2023, Indonesia enacted the Health Omnibus Law, Articles 314

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[326] A similar stakeholders meeting was conducted earlier on August 1, 2024, when 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.

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

[328] Undang-Undang Republik Indonesia Nomor 65 Tahun 2024 Tentang PERUBAHAN KETIGA ATAS UNDANG-UNDANG NOMOR 13 TAHUN 2016 TENTANG PATEN [Law of the Republic of Indonesia Number 65 of 2024 on THIRD AMENDMENT TO LAW NUMBER 13 OF 2006 CONCERNING PATENTS], art. 26 (2024).

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

[330] 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).

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."[331]

Forced Localization Requirements

The 2023 Omnibus Health Law emphasizes prioritization for use of locally made products, while other forced localization requirements still remain in Decree 1010.[332] IPO hopes additional measures will address outstanding concerns regarding Decree 1010 and other ministerial regulations to ensure that Indonesian patients have access to new medicines.

Patent Working Statement Requirement

Following amending legislation in October 2024, the Indonesia Patent Law now requires all patent holders to file an annual patent working statement.[333] However, implementing regulations are long overdue and desperately needed to clarify uncertainty over critical aspects such as the scope of the requirement, the actual deadline for submission, whether a grace period exists or not, and the consequences of noncompliance, among others. Further, IPO believes that removing the working requirement altogether from existing law would be best for the innovation ecosystem.

Trademark Protection

Indonesia's trademark system remains imbalanced in favor of the applicant, including those who act in clear bad faith. An appeal mechanism for unsuccessful oppositions should be implemented to help address this issue and detailed regulations establishing criteria for determining the presence of bad faith are urgently needed.

Customs

Due to strict requirements for the recordation of IP with Indonesian Customs, such as permanent local presence and large deposit requirements, this option remains out of reach for many rights holders. These requirements should either be loosened considerably or eliminated outright.

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

[332] 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).

[333] Undang-Undang Republik Indonesia Nomor 65 Tahun 2024 Tentang PERUBAHAN KETIGA ATAS UNDANG-UNDANG NOMOR 13 TAHUN 2016 TENTANG PATEN [Law of the Republic of Indonesia Number 65 of 2024 on THIRD AMENDMENT TO LAW NUMBER 13 OF 2006 CONCERNING PATENTS] (2024).

MEXICO

Issues Surrounding Divisional Applications

Provisions for divisional applications changed in the new Federal Law for the Protection of Industrial Property ("LFPPI"), effective November 5, 2020.[334] 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 the Mexican Patent Office, the Instituto Mexicano de la Propidad Industrial ("IMPI"), such as a lack of unity objection.[335] 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.[336] Thus, voluntary divisional applications deriving from divisional applications (cascade divisionals) are not allowed unless the IMPI requests further division through a lack of unity objection. LFPPI Article 100 also states 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.[337]

These changes should not be a problem for divisional applications that derive from a divisional filed before November 5, 2020, since it is clear under Mexico's law and Constitution that statutes and statutory provisions cannot be applied retroactively.[338] 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, and despite the fact that LFPPI contains transitional articles that specifically state patent applications filed under the former law should be prosecuted under the former law (in which cascade divisional applications had no restrictions whatsoever).[339]
In the last weeks of August and first weeks of September 2023, IMPI began to issue substantive office actions, such as lack of inventive step, lack of clarity, etc., rejecting cascade divisionals that were previously accepted and complied with all formal requirements. In some of these cases, IMPI rejected the application based on Federal Court jurisprudence that provides it is not possible to file divisional applications once the

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[334] 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.

[335] Ley Federal de Protección a la Propiedad Industrial [LFPPI] art. 100, Diario Oficial de la Federación [DOF] 01-07-2020.

[336] Ley Federal de Protección a la Propiedad Industrial [LFPPI] art. 100, Diario Oficial de la Federación [DOF] 01-07-2020.

[337] Ley Federal de Protección a la Propiedad Industrial [LFPPI] art. 100, Diario Oficial de la Federación [DOF] 01-07-2020.

[338] 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.

[339] Ley Federal de Protección a la Propiedad Industrial [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). 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, have not accepted any voluntary cascade divisionals where the parent case was allowed and issued as a patent or was abandoned.

prosecution of the parent case has been finalized.[340] 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 criteria 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 have been filed and granted since 1991, the year in which the former law entered into force.

IPO members report another worrisome practice in which IMPI is refusing to issue lack of unity objections in divisional applications so applicants will file all divisional applications when they receive an objection in the parent case, rather than filing a single divisional containing more than one invention (e.g., all of the non-elected claims).[341] Thus, examiners are only examining the invention that is mentioned first in the divisional and not any remaining inventions. This practice is not supported by the LFPPI and is contrary to Article 100, under which an examiner may request the applicant file a cascade divisional if there is a lack of unity issue. Mexican law firms are currently challenging this wrongful practice through replies to office actions; however, at this moment, no case has reached the courts.

As a separate issue, 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 compliance of the remaining patentability requirements (novelty, inventive step, etc.) only for this main invention.[342] In this case, IMPI will require the applicant to limit the claims to the main invention and, if needed, to file corresponding divisional 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.[343]

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[340] 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).

[341] For example, if lack of unity objection is issued identifying four inventions, the applicant must keep invention 1 in the parent case and file a divisional for each of inventions 2 to 4, rather than a single divisional directed to all inventions 2 to 4.

[342] Ley Federal de Protección a la Propiedad Industrial [LFPPI] art. 113, Diario Oficial de la Federación [DOF] 01-07-2020.

[343] There have been cases in which applicants receive a lack of unity objection in a first office action and limit the claims of the parent case to one of the other inventions identified by the examiner instead of the first invention. However, in the second office action, the examiner may state that according to Article 113, the applicant is obligated to limit the claims 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 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 state either that the applicant is obligated to limit the scope of the parent case to the first invention mentioned or 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 an invention which at that time may no longer be of commercial interest to them.

In April 2024, the Mexican Supreme Court of Justice considered the issue of legal standing to file invalidity actions against patents.[344] The Court held that being a commercial 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.[345]

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 the enforcement 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."[346] 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. This 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 greatest burden for the applicant will 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 do so without expense to the applicant.

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[344] 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, Pfos. 56–58.

[345] 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.

[346] Ley Federal de Protección a la Propiedad Industrial [LFPPI] art. 131, Diario Oficial de la Federación [DOF] 01-07-2020.

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.[347] However, the health law regulations have not yet been amended accordingly and should be so amended for consistency with the LFPPI.[348]

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.[349] This limitation was not present in previous law and is concerning.

Proposed Amendments to the LFPPI

On September 13, 2025, an initiative to amend the LFPPI was submitted to the Mexican Senate by the executive branch.[350] Among other things, the proposed amendments would: (a) establish maximum time limits for IMPI to issue a first office action in procedures related to patents and distinctive signs; (b) implement the "affirmative silence" provision, under which submitted applications will be deemed granted if IMPI fails to respond and an additional fifteen-day period elapses; and (c) promote the adoption of compliance frameworks in industrial property matters in connection with the upcoming 2026 review of the USMCA.

Regarding inventions, the following amendments are being proposed: (a) to introduce the concept of provisional patent applications to strengthen the IP rights of inventors that request preliminary patent protection in Mexico; (b) to clarify the rules on publication for patent applications, allowing applicants to request early publication before the current 18-month term established by the law; (c) to include the concept of patent term compensation for unreasonable reductions in the effective term of the patent caused by the pharmaceutical marketing authorization process, which shall not exceed more than five years (i.e., PTE).

Regarding distinctive designs, the following amendments are being proposed: (a) to recognize new categories of non-traditional trademarks including position marks, multimedia marks, and motion marks; (b) to modify additional grounds for refusal of

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[347] *See* Ley Federal de Protección a la Propiedad Industrial [LFPPI], Diario Oficial de la Federación [DOF] 01-07-2020.

[348] 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.

[349] Ley Federal de Protección a la Propiedad Industrial [LFPPI] art. 116, Diario Oficial de la Federación [DOF] 01-07-2020.

[350] Iniciativa con Proyecto de Decreto por el que se reforman, adicionan y derogan diversas disposiciones de la Ley Federal de Protección a la Propiedad Industrial en Materia de Transferencia de Technología y para Simplificar el Proceso de Protección de Patentes y Registros [Initiative with a Draft Decree that amends, adds to, and repeals various provisions of the Federal Law on Industrial Property Protection regarding Technology Transfer and to Simplify the Process of Patent and Trademark Protection], 13-09-2025.

trademark registration, particularly: eliminating copyright "reservas de derechos" as a basis for refusal and prohibiting the registration of cultural heritage belonging to indigenous and Afro-Mexican peoples and communities; and (c) regarding designations of origin and geographical indications, it is proposed to reduce the opposition period from two to one month.

Regarding litigation, the following amendments are being proposed: (a) to implement online modality for administrative infringement procedures; (b) to include a cause of action against the infringing use of AI with respect to inventions and distinctive signs; and (c) in connection with the FIFA World Cup 2026, the draft introduces a new ground for infringement that sanctions ambush marketing practices and classifies them as acts of unfair competition.

The proposed amendments are generally positive and aim to have the LFPPI more closely aligned with the USMCA. However, it is still disappointing that the "LFPPI Implementing Regulations" are still pending with no tentative publication date and there is a more restrictive practice on divisional applications.

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.

The proposed amendments to LFPPI are encouraging, among other things, because they would allow the restoration of the right of priority and reinstatement of rights in connection with patents, utility models, and industrial designs when the applicant fails to take the necessary steps to secure priority, such as failing to submit a translation of the international application or pay the corresponding fees.

Constitutional Judicial Reforms in Mexico

In a very short period, a constitutional judicial reform act was approved by the Mexican Congress, most of the state legislatures, signed by the President, and published in the Official Gazette of the Federation, taking effect on September 16, 2024.[351] This reform entails the following substantial modifications to the country's judicial system including:

[351] 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.

- Election of Justices, Magistrates, and Judges by popular vote: This will be implemented gradually, beginning in 2025 and concluding in 2027;
- Qualifications changed: Candidates only need to be Mexican citizens, hold a professional law degree, and have had a minimum GPA of 8 of 10 in the subjects related to the position for which they are applying during their bachelors, specialty, masters, or doctorate degree programs. This change opens the door to new profiles within the judiciary, with the potential risk of a lack of specialization;
- 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
- New electoral organization: The National Electoral Institute will be responsible for organizing elections for judicial positions.[352]

The impact of this reform on the IP field will be clearer in the next few years.

Patent Term Extension

Mexico does not grant patent term extensions for patents covering innovative pharmaceutical, to accord for the lack of patent term caused by the regulatory delay associated with obtaining marketing approval by the Mexican drug regulatory agency COFEPRIS. This is in violation of Mexico's commitment in the USMCA to institute a patent term extension law. However, the proposed amendments to the LFPPI include introducing a five-year PTE.[353] IPO encourages Mexico to implement this proposal.

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 a country's health administration to support the safety and efficacy of a drug candidate. Regulatory Data Protection ("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.[354]

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[352] 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 art. 96(IV), Diario Oficial de la Federación [DOF] 15-09-2024.

[353] Iniciativa con Proyecto de Decreto por el que se reforman, adicionan y derogan diversas disposiciones de la Ley Federal de Protección a la Propiedad Industrial en Materia de Transferencia de Technología y para Simplificar el Proceso de Protección de Patentes y Registros, 13-09-2025.

[354] 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.

RDP is particularly important for biologics submissions, but Mexico does not provide RDP for biologics upon marketing approval. Innovators must file suit against COFEPRIS in an effort to obtain data protection for biologics. This is contrary to the requirements of Article 39 of TRIPS, and 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."[355] IPO offers the following comments regarding Russia, expecting that this limitation 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.[356]

Russian Law Fails to Provide Adequate Trade Secret Protection

Russia offers nominal and weak protection for trade secrets, leaving little security 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.[357] Although this law sounds similar to the "reasonable steps" employed by TRIPS and many other 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 submitting 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, a complete inventory might be impossible to maintain, 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 like 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, Russia should implement the Asia-Pacific Economic Cooperation

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

[356] *See Russia Trade Summary*, OFF. OF THE U.S. TRADE REP., https://ustr.gov/countries-regions/europe-middle-east/russia-and-eurasia/russia (last visited Jan. 28, 2026).

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

("APEC") Best Practices for Trade Secret Protection and Enforcement, which it endorsed as part of a 2016 APEC declaration.[358]

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 the patented antiviral medicine Remdesivir.[359] The patent holder challenged the Decree in the Supreme Court of the Russian Federation, arguing that it breached the owner's IP rights and contradicted applicable national legislation and international conventions. In May 2021, the Court ruled against the patent holder, confirming the validity of the Decree.[360] 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 national security.[361] 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.[362] 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."[363] 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.[364] In combination with the possibility of importing

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[358] *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).

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

[360] 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.

[361] 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.

[362] 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.

[363] Postanovlenie, 2022, No. 299.

[364] Postanovlenie o Tovarakh (Gruppakh Tovarov), v Otnoshenii Kotorykh Ne Mogut Primenyat'syaotdel'nyye Polozheniya Grazhdanskogo Kodeksa Rossiyskoy Federatsii Ozashchite

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.

TÜRKIYE

Requirement for Birthdates

In Türkiye, an applicant is required to submit the birthdate for all inventors. This new requirement is inconsistent with other jurisdictions and IPO encourages Türkiye to eliminate this requirement.

Translation of Priority Document

When a design application is filed under the Hague System and designates Türkiye, Türkiye 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. Türkiye is 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.

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.

Andean Decisions 391 and 486 currently govern issues relating to genetic resources and traditional knowledge, and particularly regarding inventions based on such genetic resources or derivatives thereof in the Andean countries (Bolivia, Colombia, Ecuador, and Peru).[365] To date, the only requirement established in said decisions for patent applications claiming subject matter that comes from accessing genetic resources is the

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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.

[365] *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).

subscription of an access contract between the applicant and the corresponding National Authority, namely the Environmental Ministry in each country.[366]

Even though the applicant is required to obtain said contract when investigation starts or during prosecution of a later filed application (typically during the formal examination stage), neither Decision 391 nor Decision 486 oblige the applicant to in any way 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 started requiring a disclosure, similar to the one established in the WIPO Treaty.[367] 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.

IPO will be following whether, and how, the 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.[368]

EUROPEAN UNION

Compulsory Licensing

On April 27, 2023, the European Commission 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.[369] On May, 21, 2025, the European Parliament and EU government negotiators reached a provisional agreement on this proposal, stating that "[t]he new rules will ensure the EU will be able to secure the necessary supply of crisis-relevant products and technologies that are otherwise protected

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

[367] *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.

[368] *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.

[369] *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).

by patents."[370] The Council of the European Union adopted the new Regulation on December 16, 2025, which entered into force 20 days after its publication in the Official Journal of the EU.[371]

Under the new Regulation, the granting of a compulsory license is subject to four cumulative conditions, namely: (a) a crisis or emergency mode has been declared; (b) the use of a protected invention which concerns crisis-relevant products is required to secure the supply of those products in the EU; (c) means other than an EU compulsory license, including voluntary agreements, could not be achieved within a reasonable timeframe and could not ensure access to the products; and (d) the rights holder concerned was given the opportunity to provide comments to the Commission and the competent advisory body.[372] The Regulation purports that the granting of compulsory licenses is a measure of last resort if "voluntary agreement" between IP owners and manufacturers "could not ensure access to" "crisis-relevant products."[373] It is not clear what standards are applied before such a conclusion is made and public intervention is deemed necessary.

With respect to procedure, experts from intellectual property offices and national authorities responsible for granting compulsory licenses must now be involved in advisory body discussions on intellectual property.[374] The European Parliament can also participate, as an observer, in the relevant meetings of the competent advisory body, including the ad hoc advisory body.[375]

The Regulation states the European Commission should consider preliminary information gathered under the relevant EU crisis or emergency mechanism when deciding whether to initiate the procedure for granting a Union compulsory license.[376] Where the Commission's decision to grant a compulsory license departs from the opinion of the

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[370] Press Release, Eur. Parliament, Deal on Patent Rules Exception to Ensure the Supply of Critical Products (May 21, 2025).

[371] Regulation 2025/2645 of the European Parliament and of the Council of 16 December 2025 on Compulsory Licensing for Crisis Management and Amending Council Regulation No 816/2006, O.J. L, 2025/2645, 30.12.2025, ELI: http://data.europa.eu/eli/reg/2025/2645/oj.

[372] Regulation 2025/2645 of the European Parliament and of the Council of 16 December 2025 on Compulsory Licensing for Crisis Management and Amending Council Regulation No 816/2006, art. 4, O.J. L, 2025/2645, 30.12.2025, ELI: http://data.europa.eu/eli/reg/2025/2645/oj.

[373] Regulation 2025/2645 of the European Parliament and of the Council of 16 December 2025 on Compulsory Licensing for Crisis Management and Amending Council Regulation No 816/2006, art. 1, O.J. L, 2025/2645, 30.12.2025, ELI: http://data.europa.eu/eli/reg/2025/2645/oj.

[374] Regulation 2025/2645 of the European Parliament and of the Council of 16 December 2025 on Compulsory Licensing for Crisis Management and Amending Council Regulation No 816/2006, art. 6, O.J. L, 2025/2645, 30.12.2025, ELI: http://data.europa.eu/eli/reg/2025/2645/oj.

[375] Regulation 2025/2645 of the European Parliament and of the Council of 16 December 2025 on Compulsory Licensing for Crisis Management and Amending Council Regulation No 816/2006, art. 6, O.J. L, 2025/2645, 30.12.2025, ELI: http://data.europa.eu/eli/reg/2025/2645/oj.

[376] Regulation 2025/2645 of the European Parliament and of the Council of 16 December 2025 on Compulsory Licensing for Crisis Management and Amending Council Regulation No 816/2006, art. 7, O.J. L, 2025/2645, 30.12.2025, ELI: http://data.europa.eu/eli/reg/2025/2645/oj.

advisory body, it must indicate the reasons why.[377] Where the Commission decides not to grant a Union compulsory license, a notice must be published in the Official Journal of the European Union to provide information on the decision.[378]

In addition to the overall broad concern regarding EU-wide compulsory licensing, there are many issues with specific aspects of the Regulation. While the Regulation refers generally to examples of "crisis mechanisms" to improve the EU's "resilience to crises or emergencies affecting the Union," 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 also ambiguity as to when a rights holder will be notified of a compulsory license or the potential thereof.

Article 2 of the Regulation states that it "does not impose any obligation to disclose trade secrets."[379] The possibility remains, however, that parties may be pressured to "voluntarily" share their confidential information. The Regulation also creates complexity around appropriate notification of rights holders and adequate compensation; for example, whether it will 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. Also, the "adequate" remuneration provided for by the Regulations may be materially insufficient for some situations.[380]

In terms of the Advisory Board's constitution, members from the innovative industry should be represented. In addition, the Compulsory Licensing Regulation overall is opaque on process and lacks independent judicial oversight. The processes described throughout the Regulation do not seem to be subject to any independent scrutiny, and although Recital 37 addresses the judicial review of the EC's decision to grant an EU compulsory license, the articles do not address it.[381]

On a positive note, the list of crisis instruments triggering the compulsory licensing scheme no longer includes the Chips Act and the Gas Supply Security Regulation and defense-related products are explicitly excluded from the scope of the proposal. It is noteworthy, though, that an evaluation clause was included for the list of relevant crisis

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[377] Regulation 2025/2645 of the European Parliament and of the Council of 16 December 2025 on Compulsory Licensing for Crisis Management and Amending Council Regulation No 816/2006, art. 7(7), O.J. L, 2025/2645, 30.12.2025, ELI: http://data.europa.eu/eli/reg/2025/2645/oj.

[378] Regulation 2025/2645 of the European Parliament and of the Council of 16 December 2025 on Compulsory Licensing for Crisis Management and Amending Council Regulation No 816/2006, art. 7(9), O.J. L, 2025/2645, 30.12.2025, ELI: http://data.europa.eu/eli/reg/2025/2645/oj.

[379] Regulation 2025/2645 of the European Parliament and of the Council of 16 December 2025 on Compulsory Licensing for Crisis Management and Amending Council Regulation No 816/2006, art. 2, O.J. L, 2025/2645, 30.12.2025, ELI: http://data.europa.eu/eli/reg/2025/2645/oj.

[380] Regulation 2025/2645 of the European Parliament and of the Council of 16 December 2025 on Compulsory Licensing for Crisis Management and Amending Council Regulation No 816/2006, O.J. L, 2025/2645, 30.12.2025, ELI: http://data.europa.eu/eli/reg/2025/2645/oj.

[381] Regulation 2025/2645 of the European Parliament and of the Council of 16 December 2025 on Compulsory Licensing for Crisis Management and Amending Council Regulation No 816/2006, O.J. L, 2025/2645, 30.12.2025, ELI: http://data.europa.eu/eli/reg/2025/2645/oj.

instruments with the possibility of assessing new and existing instruments and with a specific reference to semiconductors for medical equipment.[382]

In conclusion, 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.[383]

Geographical Indications

As of December 2025, craft and industrial products fully benefit from an EU-wide geographical indications (GIs) protection under Regulation (EU) 2023/2411. GIs are an intellectual property protection that links specific products, which are European, local, and authentic, to their geographical origin, ensuring that these products possess qualities, reputation, or characteristics that are inherently tied to that location.[384] This protection will extend beyond the EU to 59 countries under the 2015 Geneva Act of the Lisbon Agreement.[385] 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 European Commission tabled a number of proposals to revise long-standing EU rules on medicinal products for human use.[386] In its most recent move, the European Council submitted its proposed Critical Medicines Act to the European

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[382] Regulation 2025/2645 of the European Parliament and of the Council of 16 December 2025 on Compulsory Licensing for Crisis Management and Amending Council Regulation No 816/2006, art. 25, O.J. L, 2025/2645, 30.12.2025, ELI: http://data.europa.eu/eli/reg/2025/2645/oj.

[383] 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.

[384] 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.

[385] 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.

[386] *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).

Parliament on November 26, 2025.[387] 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 drugs.[388] 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.

EU Copyright Protection for Applied Arts

The European Court of Justice has modified the criteria to judge the originality of works to be considered protectable under copyright rules.[389] There are a significant number of relevant and interesting decisions from European courts.[390] IPO continues to monitor this issue.

European Commission's Packaging and Packaging Waste Regulation

The EU, through the Commission'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.[391] 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.[392]

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[387] *Commission Proposal for a Regulation of the European Parliament and of the Council Laying a Framework for Strengthening the Availability and Security of Supply of Critical Medicinal Products as Well as the Availability of, and Accessibility of, Medicinal Products of Common Interest, and Amending Regulation (EU) 2024/795*, COM (2025) 102 final (Nov. 3, 2025); Note (EC) No. 15503/2025 of 26 November 2025 ("[t]he Council is invited to reach a general approach on the text as set out in the Annex of this document at its meeting on 2 December 2025.").

[388] *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).

[389] *See* Case C-683/17, Cofemel – Sociedade de Vestuário SA v. G-Star Raw CV, 2019 E.C.R 721.

[390] Bundesgerichtshof [BGH] [Federal Court of Justice] Feb 20, 2025, I ZR 16/24 (finding Birkenstock sandals were not protected art); Joined Cases C-580/23 and C-795/23, Mio AB v. Galleri Mikael & Thomas Asplund Aktiebolag, USM U. Schärer Söhn AG v. Konektra GmbH, 2025 E.C.R.

[391] 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. The Regulation came into force in February 2025 and takes effect in August 2026. *See* Jay Sattin et al., *New EU Packaging Regulation: Obligations for Importers and Distributers*, MASON HAYES & CURRAN (Feb. 20, 2025), https://www.mhc.ie/latest/insights/new-eu-packaging-regulation-obligations-for-importers-and-distributors.

[392] 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.

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 trade dress 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.

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.[393]

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.

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[393] 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).

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 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. When this is the case, the evidence will show that IP facilitates innovation, as well as voluntary and successful partnerships, that help, not hinder, society's efforts to meet global challenges.

IPO thanks the USTR for permitting IPO to provide comments and would welcome any further dialogue or opportunity to provide additional information to assist your efforts in developing the 2026 Special 301 Report.

Sincerely,

John J. Cheek
President