U.S. Chamber of Commerce

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Daniel Lee
Assistant U.S. Trade Representative for Innovation and Intellectual Property
Office of the U.S. Trade Representative
600 17th Street NW
Washington, DC 20508

Re: *Docket Number USTR-2025-0243; Request for Comments and Notice of a Public Hearing Regarding the 2026 Special 301 Review*

Dear Mr. Lee:

The U.S. Chamber of Commerce is pleased to provide the attached comments in response to the call of the Office of the United States Trade Representative for input and the related announcement of a public hearing for the 2026 Special 301 Review. This annual review continues to offer a comprehensive evaluation and highlights the critical state of intellectual property protection and enforcement globally. We urge the United States government to leverage this analysis, along with other available tools, to prompt significant improvements in the IP frameworks of our trading partners. The Chamber is eager to collaborate with the United States government to achieve these objectives.

Sincerely,

Marty Durbin
Senior Vice President, Policy
President, Global Energy Institute
U.S. Chamber of Commerce

John Murphy
Senior Vice President and Head of International Affairs
U.S. Chamber of Commerce

Introduction

Section A: Measuring IP and Access

The 2025 Chamber International IP Index

Now in its 13th edition, the Chamber's International IP Index ("Index") creates a roadmap for markets large and small to leverage IP protection and become 21st century, knowledge-based innovation economies. The Index maps the IP ecosystem in 55 global economies (accounting for over 90% of global GDP) across 53 unique indicators in nine categories of protection: patents, copyrights, trademarks, design patents, trade secrets, commercialization of IP assets, enforcement, systemic efficiency, and membership and ratification of international treaties.

Additionally, the Index includes a robust statistical annex demonstrating the strong, positive correlation between the strength of a country's IP system and different widely shared socio-economic goals. The data demonstrates that countries with more effective IP frameworks are more likely to receive positive benefits, including increased innovative and creative output, greater access to innovative and creative goods, increased job creation in knowledge-intensive industries, and greater access to venture capital. The 14th edition of the Index is expected to be released in the first quarter of 2026. The Chamber, however, has offered the most up-to-date statistics in this year's Special 301 from the 13th edition.

Section B: Overview of High-level Concerns and Developments

International IP Landscape in Trade

Trade and IP

Intellectual property protections have long played a central role in U.S. trade agreements, ensuring fair competition for American innovators and creators globally. Including strong IP provisions in bilateral deals is essential to drive innovation, creativity, and economic growth. As new trade frameworks are developed, robust IP rules are necessary to protect American ingenuity and maintain a competitive, creative economy.

Embedding IP protections in bilateral agreements sends a powerful signal about U.S. leadership in innovation. These provisions not only protect American businesses but also set high standards that encourage partners to strengthen their own IP regimes consistent with a reciprocal approach to trade that, creating a more predictable, fair, and transparent global marketplace. Trade negotiations should

advance rules-based frameworks that foster innovation and creativity, while protecting proprietary technologies, rather than compromising these principles for short-term gains. By prioritizing IP in trade frameworks, the U.S. can foster deeper economic ties, promote cross-border collaboration, and ensure that the benefits of innovation and creativity are widely shared.

The Importance of IP-Enabled Trade

The economic benefits of IP-intensive industries are well-known, with IP-intensive industries accounting for 44% of U.S. employment and 41% of domestic economic output.[1] IP has also been a key driver in supporting U.S. exports. Specifically, trade in IP-intensive services has increased from $60 billion in 1999 to $285 billion in 2023, becoming a growing source of export revenue for the U.S. economy.[2] According to the Chamber's 2025 study, *From Innovation to Employment: IP's Role in Job Growth*, in 2024, over $5 trillion of existing IP assets supported jobs in all industries, every state, and for businesses of all sizes. More specifically, when adding up across all 50 states, the study found that approximately 10.9 million jobs are directly and indirectly supported by IP-intensive R&D activities. All of this translates to roughly $140.36 billion in IP-related exports in 2024.[3]

IP likewise supports trade in innovative and creative goods and services with our trading partners. Notably, the majority of the world's top 10 exporters of creative services lead the way in the rankings of the Chamber's International IP Index, with 9 of the top 10 exporters achieving an Index score of 80% or more.[2] This creates a mutually beneficial cycle: stronger IP standards lead to greater innovation and creativity, which in turn drives trade flows and economic development. The Chamber has consistently argued that IP is not a barrier to trade but a catalyst for it. By embedding robust IP protections in trade agreements, policymakers can ensure IP remains a cornerstone of the U.S. economy while also creating a level playing field for innovators and creators worldwide.

Impact of Unfair Trade Practices on Market Access for U.S. Innovators

In addition to the substantive IP challenges noted in markets below, the Chamber is also concerned about provisions that undermine market access for U.S. innovators in foreign markets. The Chamber provided input for USTR's investigation into "unfair trade practices" announced by the Trump Administration in 2025 and support vigorous action to address these ongoing challenges. Many of thee practices we identified have a disproportionate and non-reciprocal impact on innovative

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[1] See Intellectual property and the U.S. economy: Third edition. United States Patent and Trademark Office. May 1, 2022.
[2] See 2025 Thirteenth Edition International IP Index Statistical Annex. U.S. Chamber of Commerce. 2025.
[3] See From Innovation to Employment: IP's Role in Job Growth. U.S. Chamber of Commerce. April 9, 2025.

industries that rely on IP protection. For example, as noted in the country-specific sections below, unfair practices in the life sciences including clawbacks, strict price controls and other measures that unfairly place a disproportionate burden on American patients and taxpayers to fund global research and development for new pharmaceuticals and other healthcare products. These policies exacerbate concerns about "freeloading" in foreign markets and, when coupled with shortening or eliminating IP protection, create barriers both for U.S. innovators as well as the global patient population that needs these life-saving technologies.

Tariffs

Recently imposed broad-based tariffs have harmed the economic growth and export success that IP-intensive industries support. Broad-based tariffs have increased the cost of imported goods, disrupting domestic supply chains and undermining U.S. export competitiveness. The additional financial burden placed on companies will also negatively impact investment in innovation by diminishing the revenue companies have available to invest in the next generation of research and development. Moreover, industry remains concerned that rising costs induced by tariffs will lead to an increase in counterfeiting as consumers seek out lower-priced goods, in turn undermining trademark protection and brand integrity. The continued imposition of tariffs risks diverting attention from the real challenges posed by counterfeiting, piracy, and inadequate enforcement against dangerous, substandard goods.

The utilization of broad-based tariffs could also inspire retaliatory measures that target the IP landscape. For example, the Brazilian government has implemented statutory legislation which authorizes the government to override and suspend the protection of existing IP protection as a "response to unilateral measures adopted by a country or economic bloc that negatively impact Brazilian international competitiveness." We urge the U.S. government to closely monitor this legislation—and similar legislative efforts in other markets—which seek to target American innovative companies by suspending their IP rights in response to tariffs.

More broadly, tariffs threaten to undermine the certainty and predictability provided by IP rights and upon which U.S. companies rely when investing in global markets. Strong IP protections thrive in a rules-based system that promotes predictability and openness. Broad-based, reciprocal tariffs have the potential to undermine these principles by creating a volatile market environment where innovation-based economic partnership becomes more difficult. For example, industry is concerned that tariffs will disrupt cross-border licensing agreements, which are key to facilitating voluntary technology transfer between stakeholders in global markets. The Chamber has consistently emphasized that trade policy should advance—not

hinder—innovation, and tariffs run counter to that goal by eroding trust and cooperation among nations.

The Chamber believes that a competitive economy depends on strong IP protections supported by open markets, and broad tariff-driven policies jeopardize both goals. The Trump Administration has successfully reasserted U.S. leadership on IP protection, pressing for effective IP protection with our trading partners and in international organizations to create a level playing field for U.S. businesses. To maintain U.S. leadership in innovation, we urge this Administration to abandon broad-based tariffs that undermine the strength of America's innovation ecosystem and utilize trade policy to reinforce strong IP standards and enforcement globally.

The International IP Landscape in Multilateral Organizations

Overview

U.S. leadership in international organizations is critical to advancing pro-IP priorities globally. While the standards for IP protection and enforcement vary significantly across global markets—as evidenced by the Index—the multilateral system is a critical mechanism to ensure that countries uphold IP protection and enforcement.

For this reason, the Chamber believes that strong U.S. government engagement in the World Trade Organization (WTO) and World Intellectual Property Organization (WIPO) is of vital importance. We encourage the U.S. government to reaffirm its longstanding global leadership position within the multilateral system to preserve the framework that protects American innovation and creativity abroad.

We specifically encourage U.S. government engagement on the below listed issues.

World Trade Organization

The WTO plays a pivotal role in upholding strong IP standards worldwide. By establishing a rules-based framework through multilateral agreements, the WTO requires that member countries adhere to IP standards, creating a more predictable global environment for investment in innovation and creativity. Unfortunately, many WTO members have failed to comply with their IP obligations under the TRIPS Agreement. Moreover, recent measures to weaken IP commitments—such as the TRIPS wavier—threatened to undermine this critical framework, jeopardizing the innovation ecosystem and the economic benefits it delivers. The Chamber is grateful for the Administration's strong opposition to efforts to waive IP rights at the WTO,

reversing course on the harmful position taken by the Biden Administration. We share this Administration's view that the U.S. must work with its trading partners to help address public health matters while also maintaining the IP systems that supported the development of innovative technologies.[4] We look forward to working with the Administration to ensure that future IP discussions at the WTO focus on promoting full compliance with the TRIPS Agreement.

As the WTO seeks to identify outcomes for the 14th Ministerial Conference (MC-14), we encourage U.S. government engagement on two specific issues:

- **LDC Waiver:** In July 2025, the least-developed countries (LDC) group tabled a proposal, *WTO Smooth Transition Support Measures in Favour of Countries Graduated from the LDC Category*.[5] Upon graduation from LDC status, the proposal seeks to extend for six years countries' waiver of their Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. The Chamber encourages the U.S. government to take a strong stance against the LDC waiver and encourage graduated countries to fully integrate into the global IP ecosystem through the adherence to their TRIPS commitments. Doing so will help these countries to attract new investments in innovative industries and raise incomes by fostering value-added industries.

- **E-commerce Moratorium:** The WTO's e-commerce moratorium is a commitment by members not to impose customs duties on electronic transmissions, first adopted in 1998 and renewed at every successive ministerial conference. We appreciate that the U.S. government has prioritized the moratorium and called for making it permanent, and we urge its renewal at MC-14 to avoid digital fragmentation and increased costs for consumers and businesses.

World Intellectual Property Organization

As the international organization with a mandate to promote IP protection, WIPO plays a key role in shaping international IP policies, promoting effective enforcement mechanisms, and ensuring that IP frameworks support the needs of creators and innovators worldwide. The Chamber is deeply grateful for the U.S. government's engagement at WIPO and continued leadership to oppose proposals to weaken IP rights through various WIPO committees. We encourage the U.S. to maintain a robust presence at WIPO to ensure that the U.S. can protect American innovators and creators, champion policies that uphold the integrity of the global IP

[4] See 2025 Special 301 Report. Office of the U.S. Trade Representative. April 29, 2025.
[5] See WTO Smooth Transition Support Measures in Favour of Countries Graduated from the LDC Category Pursuant to Paragraph 3, WT/MIN (24)/34; WT/L/1189. World Trade Organization. July 11, 2025.

system and encourage other nations to adopt strong IP standards that drive investment and economic development. The Chamber encourages the U.S. government's ongoing engagement on the below priorities at WIPO:

- **Secure Effective WIPO Leadership and Staff:** The 2026 WIPO election provides a renewed opportunity to ensure that all WIPO leadership positions continue to be held by personnel with significant technical experience in protecting, enforcing, managing, or administering intellectual property rights. While a strong Director General is critical, having qualified candidates fill the Deputy Director General (DDG) and Assistant Director General (ADG) positions will be equally important to the ensuring that the WIPO Secretariat adheres to its core mandate to promote the protection and enforcement of IP rights. We encourage the U.S. government to work closely with like-minded countries to ensure that WIPO staff have the appropriate IP experience to effectively carry out their responsibilities.

- **Facilitate Implementation of Existing Treaties:** The Chamber supports WIPO's work to facilitate Member States joining and fully implementing foundational WIPO treaties that support its core mandate, including the WIPO Copyright Treaty, the WIPO Performances and Phonograms Treaty, the Patent Cooperation Treaty, the Madrid Protocol, and the Hague Agreement. We encourage the U.S. government to work with WIPO to ensure that the United States' trading partners are adhering to their international commitments in order to promote more fulsome participation in the global IP ecosystem.

- **Support for Member-State Driven Work:** The Chamber supports efforts by member states to advance work in line with WIPO's core mission. We commend the work of Committee chairs to facilitate Member State dialogue and report out on the consensus reached at meetings. However, text and workplans should be the result of consensus, rather than driven by the chair. We encourage the U.S. government to push back on attempts by Committee chairs to advance their own agenda through the Standing Committees' work.

- **Advance Technical Assistance in Member States:** WIPO plays a crucial role supporting technical assistance to advance the growth of more effective IP frameworks in Members States. However, the technical assistance funded by WIPO must be coordinated with WIPO's substantive teams. We believe it is critical that the offices utilized for technical assistance have substantive expertise in IP matters and promote the protection of IP in member states. We encourage the U.S. government to work with the WIPO Secretariat to ensure that the offices utilized for technical assistance have substantive expertise in IP matters and promote the protection of IP in Member States.

- **Support an Affirmative Agenda:** As the international organization responsible for the promotion of IP rights, WIPO plays a pivotal role in encouraging the adoption of strong IP frameworks in WIPO Member States. We encourage the U.S. government to work with industry and like-minded governments to identify new opportunities to strengthen IP rights through WIPO Committees including: the Intergovernmental Committee on IP and Genetic Resources, Traditional Knowledge, and Folklore; the Standing Committee on Copyrights and Related Rights; the Standing Committee on Patents; and the Advisory Committee on Enforcement. Likewise, we urge the U.S. government to remain vigilant against attempts to undermine IP rights through ongoing discussions in each of these forums.

Other Countries of Concern

In Australia, the government has failed to implement a patent linkage system in accordance with the 2005 Australia-U.S. Free Trade Agreement (AUSFTA) and has been continuing to approve generic/biosimilar products within an innovator's patent term. Australia also does not provide timely notice to innovators about generic/biosimilar request for regulatory approval, as required by AUSFTA. Moreover, The Australia government should enhance its regulatory data protection consistent with broader developed-market norms so as to ensure adequate and effective protection of proprietary data.

Additionally, In May 2025, Israel's Ministerial Committee for Legislation approved an updated Broadcasting (Communications) Bill that imposes an investment obligation to both domestic and international content providers in violation of the U.S-Israel Free Trade Agreement. The legislation requires content providers with annual revenues over 40 million shekels to invest 6.5 percent of revenues in "high-quality genre" through "local production" and for content providers not previously subject to an investment obligation, the rate will phase in. The status of this proposed investment obligation is unclear, however, as it was accompanied with language indicating that the provision was subject to consultations with the United States.

Furthermore, in Thailand, the process of amending the Thai Patents Act has been ongoing for a number of years (since 2018) and still has not been completed and should be completed as soon as possible to streamline the patent registration process and to reduce patent backlog and pendency. In late 2024, a new proposal was presented by the national IP office, the DIP. While the DIP and Thai authorities should be commended for seeking to update what is now almost a half a century old piece of legislation, unfortunately, the proposed new Act does not address long-standing challenges mentioned above.

Finally, in the United Kingdom in 2025, the UKIPO undertook a consultation process on proposed regulatory interventions related to standard essential patents (SEPs) which included a streamlined Rate Determination Track for SEP royalties and a UK-specific searchable SEP database. Both proposals could dramatically reshape a licensing ecosystem in ways that would devalue the intellectual property of innovative US companies. The Rate Determination Track proposal would establish the value of IP without providing due process to the right holder and without safeguards to prevent misuse. Likewise, a UK-specific SEP database built on self-declared essentiality would impose significant administrative burdens, legitimize inaccurate patent-counting valuation methodologies, and create opportunities for misuse—contradicting the UKIPO's stated goal of improving transparency. The US government should urge the UK government to refrain from adopting regulatory measures that would introduce uncertainty into SEP licensing markets and instead promote evidence-based, market-led solutions while ensuring any future reforms remain proportionate, transparent, and aligned with global best practices to safeguard innovation and competitiveness.

Section C: Developed Market Profiles

CANADA

Patents and Related Rights

Index Stat: Canada's score falls short of many high-income economies in the Index patent indicators, ranking behind the leading economies in Asia, Europe, and the United States.

Patent Term Adjustment: As part of commitments made under the USMCA, Canada agreed to introduce a patent term adjustment (PTA) mechanism to compensate patent applicants for any undue delay in prosecuting the patent application. While Canada's PTA system came into effect on January 1st, 2025, PTA has been difficult, if not impossible, to obtain for most applicants largely due to its treatment of an applicant's normal prosecution steps as applicant delays. Moreover, any PTA granted runs concurrently with a separate and distinct form of term restoration, namely, supplementary protection for biopharmaceutical patents, effectively compromising the ability of innovators to receive the full benefits to which they are entitled.

While PTA is used to account for unreasonable delays in patent prosecution, certificates of supplementary protection (CSP) for biopharmaceutical patents are meant to restore time lost during the marketing authorization process for new medicines and biopharmaceutical technologies. As such, these forms of patent term

restoration are independent from each other, which is reflected in the separate commitments of the parties to the USMCA under Articles 20.44 and 20.46. There is therefore no justification for running the PTA and CSP periods concurrently: they should run sequentially in order to properly compensate patentees for prosecution delays at the patent office on the one hand and/or delays in the authorization of a medicine on the other.

Additionally, the PTA application process lacks clear timelines for critical steps along the way, while also allowing for deducting delays that cannot be avoided by the innovator despite their best effort (e.g. due to insufficient time offered to respond to information requests from CIPO). Moreover, where applicants are granted shorter patent term adjustments and wish to apply for redetermination, the Commissioner for Patents can only either shorten the adjustment term or dismiss the application. Therefore, the only meaningful remedy available is to initiate costly and lengthy judicial proceedings.

- Chamber Recommendation: The Chamber encourages the U.S. government to ensure that Canada implements a PTA system satisfying the requirements of Article 20.44 of USMCA, independently from its separate CSP system. The PTA should have a clear and transparent calculation methodology, with reasonable timelines to allow cooperation and not penalize normal prosecution interactions with the patent office during the process, while also providing an effective redetermination procedure that can also result in upwards adjustments to the granted PTA, where duly justified.

Certificates of supplementary protection (CSP): Canada amended the Patent Act to introduce a CSP mechanism in an effort to adhere to its commitments under the Comprehensive Economic and Trade Agreement (CETA) with the EU. The relevant amendments (Sections 106-134) provide a maximum restoration period of two years which is considerably shorter than the five-year maximum period that can be restored in the United States. Indeed, a five-year period is the global norm and is also available in the EU and Japan. Furthermore, the effective availability of this term of restoration was severely restricted through several technical carve-outs.

First, under Section 116(4), the Canadian government retained the right to reduce the term of protection at its discretion. Second, the implementing regulations contained a non-treaty “Timely Submission Requirement” that limits the availability of a CSP eligibility to medicines for which a new drug submission is made within one year from the first regulatory submission in a set of “prescribed economies” (i.e. EU, UK, U.S., Australia, Switzerland and Japan). Thus, the availability of a CSP was made contingent on timely comparative market entry. Additionally, the eligibility for CSP excludes

certain new drug submissions if they are based on a list of variations of medicinal ingredients, an exception that is absent from the U.S. system. Finally, the law also contained an export carve-out, with Section 115(2) effectively exempting the infringement of CSP protection if the activity is for the exclusive purpose of export. Such an exemption is not foreseen in the USMCA and results in the CSP not having an equivalent protection to the underlying patent than the underlying patent toto which it relates.

- **Chamber Recommendation:** The Chamber encourages the U.S. government to work with their Canadian counterparts to provide restoration of term up to five years and remove the limitations on eligibility tied to timely regulatory submission requirements and variations of medical ingredients. The CSP, as a sui generis right should provide the same level of protection as the underlying patent, eliminating the export manufacturing waiver.

Patent Enforcement: Article 20.78 of the USMCA requires parties to ensure that their laws include enforcement procedures, including "expeditious remedies to prevent infringements and remedies that constitute a deterrent to future infringements." Canada's damages system under Section 8 of the PM(NOC) regulations provides for excessive damages against patentees and deters innovators from adequately enforcing their rights by seeking an order to prevent generic or biosimilar product manufacturers from obtaining a Notice of Compliance where they deem that the product is covered by a valid patent. Section 8 allows generic or biosimilar product manufacturers to seek damages for the lost profits due to the innovator's enforcement action where the patent is subsequently found invalid. The very principle of allowing for damages in such cases is flawed as damages would only be justified if the innovator did not act in good faith by initiating the action while knowing that the patent is invalid or is not infringed. Additionally, Canadian courts are interpreting the provisions of Section 8 in a way that allows for granting excessive damages that go beyond the damage actually incurred or the total value of the generic market.

- **Chamber Recommendation:** The Chamber encourages the U.S. government to use the USMCA joint review to engage with Canadian counterparts and limit 1) the scope of the damage provisions to cases where the right holder willingly acts in bad faith, and 2) the amount of the damages so it cannot be higher than the actual profits lost, which should be established in relation to the generic market value.

Patent Linkage: A properly designed patent linkage framework is critical to protecting and promoting innovative drug development in Canada while facilitating timely generic entry upon patent expiry. Article 20.F.16 of the USMCA requires Canada to provide to the innovator (1) a notice if a generic/biosimilar company relies on the

safety and efficacy of a "previously approved" innovator's product and (2) adequate time and sufficient opportunity for the innovator to seek appropriate remedies before the marketing of the allegedly infringing generic/biosimilar product. However, Canada has been allowing generic/biosimilar companies to rely on "previously approved," although not yet marketed, innovator products for generic/biosimilar approval without providing the innovator with any prior notice or opportunity to seek appropriate remedies and therefore fails to fulfil its USMCA obligation and compromises the delicate balance created by the patent linkage framework under USMCA.

In addition, Article 20.F.16 of the USMCA requires adjudication of any patent "claiming the approved product or its approved method of use" prior to generic/biosimilar approval. However, Canada has unilaterally limited the eligible patents for adjudication to only those that are granted before the generic/biosimilar regulatory filing.

- Chamber Recommendation: The Chamber recommends that the U.S. government encourage the Canadian government to implement an effective patent linkage framework to ensure innovators receive notice of a generic or biosimilar product's intention to enter the market so long as it references to a previously approved innovator product. The framework should be designed to allow sufficient time for innovators to pursue appropriate remedies in the case of potential infringement. Additionally, the Canadian government should remove limitations on the types of patents eligible for adjudication during the patent linkage proceeding to comply with its USMCA obligations.

Copyrights and Related Rights

Index Stat: In the copyright indicators, Canada scores ahead of some South Asian and Middle Eastern economies, such as Malaysia and Israel, but falls behind many high-income developed economies.

Online Streaming Act: Canada's Online Streaming Act (Bill C-11), which entered into force in April 2023, updated Canada's Broadcasting Act to regulate online streaming services and provided discretion to the Canadian Radio-television and Telecommunications Commission (CRTC) on how to implement it. On June 4, 2024, the CRTC issued a decision to require foreign, largely U.S.-based, music and audiovisual streaming service providers to pay 5% of their gross in-country revenue to certain Canadian cultural funds. In addition to the levy, the CRTC is designing additional discriminatory measures that target U.S. companies and content, including narrow definition of what qualifies as a "Canadian Program" and content discoverability mandates. The CRTC may also increase the financial levy to as high as

30%. In total, the Online Streaming Act could cost U.S. industry as much as $7 billion by 2030. The OSA violates multiple provisions of the USMCA including non-discrimination of digital products, national treatment of investments, and the prohibition on performance requirements.

- **Chamber Recommendation:** The U.S. government should work with their Canadian government counterparts to fully repeal the Online Streaming Act, while in the meantime securing a reversal of existing discriminatory implementation decisions, such as the 5% financial levy, and a commitment that future decisions will not impose a raise the levy on foreign streaming services or otherwise impose discriminatory obligations on U.S. companies, including local content quotas and discoverability requirements.

Trade Secrets and the Protection of Confidential Information

Index Stat: In the trade secrets and protection of confidential information indicators, Canada outperforms its percentage of overall score in other Index categories. Canada achieves 85% of the overall score in the trade secrets indicators, while it receives 68.43% in the copyright indicators and 78.33% in the patent indicators.

Standard for Disclosure of Confidential Business Information (CBI): In November 2014, Canada enacted legislation to update its Food and Drugs Act (Bill C-17). Provisions in that law granted the Health Minister discretion to disclose a company's CBI without notice to the owner of the CBI. Additionally, the disclosure of CBI in Bill C-17 is inconsistent with Canada's USMCA obligations, which requires that CBI be protected against disclosure except where necessary to protect the public. Under these provisions, it is not necessary that there be a serious risk of injury to justify the disclosure; rather the provisions merely require that the Minister believes the disclosure to be necessary. The Act allows the Minister to disclose CBI to individuals involved in "the protection or promotion of human health or safety of the public," though there is no necessity requirement for this disclosure to occur. USMCA does not refer to disclosure for the promotion of health, but rather to disclosure needed to protect the health of the public.

- **Chamber Recommendation:** The Chamber encourages U.S. government to work with the Canadian government to ensure that the regulations and guideline documents to implement the Food and Drugs Act are consistent with Canada's USMCA obligations on confidential business information.

Market Access

Artificial Devaluation of Innovative Medicines & Regulatory Delays: Despite being one of the largest and most advanced economies in the world, Canada maintains policies that artificially devalue innovative medicines developed in the United States and limit and delay patient access to these medicines. The Patented Medicines Prices Review Board (PMPRB) reviews the prices of all patented medicines sold to public or private payers by assessing whether they are "excessive", using a threshold based on a basket of reference countries. Canada is the only jurisdiction worldwide that has a federal price regulator of this kind, making it out of step with international norms. In 2022, Canada removed the United States and Switzerland from the reference basket of countries, and added several lower-priced countries, thereby artificially lowering prices and exacerbating the situation where Canada fails to pay its fair share for innovation.

Additionally, it takes approximately two years following regulatory approval for a medicine to reach patients insured on public drug plans. This is due to lengthy sequential administrative processes, including health technology assessments (HTA) through Canada's Drug Agency (CDA) and Quebec's Institut national d'excellence en santé et en services sociaux (INESSS), and federal-provincial pricing negotiations through the pan-Canadian Pharmaceutical Alliance (pCPA) before individual jurisdictional funding agreements. In particular, CDA continues to use outdated economic evaluation tools, such as cost-effectiveness thresholds, that under-value pharmaceutical innovation, leading to protracted downstream negotiations and unrealistic pricing expectations at the pCPA.

These measures deprive U.S. innovators of revenue and market access and allow Canada to benefit from U.S. pharmaceutical innovations without paying its fair share for those innovations. USTR should use the USMCA Joint Review in a manner consistent with the President's May 12, 2025, directive to eliminate foreign government policies "forcing American patients to pay for a disproportionate amount of global pharmaceutical research and development, including by suppressing the price of pharmaceutical products below fair market value[.]"

Chamber Recommendation: The Chamber encourages the U.S. government to work with the Canadian government to introduce the following reforms:

- Sunset the PMPRB or put the U.S. back in the reference country basket and continue to apply the PMPRB International Price Comparison Test using the Highest International Price standard;

- Reduce administrative steps between pCPA pricing agreements and inclusion on public formularies of provinces and territories to accelerate patient access;

- Require HTA evaluators – the CDA and INESSS – to modernize how they consider the economic and clinical value of innovative therapies and avoid using outdated cost-effectiveness thresholds;

- Expand accelerated funding pathways currently being piloted by the pCPA and Ontario (i.e., the FAST initiative) to all new medicines and jurisdictions; and

- Ensure pCPA recognizes the value of innovation and reflects this in its pricing agreements.

EUROPEAN UNION

Patents and Related Rights

Index Stat: While the landscape for patent protection varies across the EU, even the leading EU economies score behind Singapore, the U.S., Switzerland, South Korea, and Japan in the Index patent rights indicators.

General Pharmaceutical Legislation: In April 2023, the European Commission proposed a new Directive and Regulation to revise the EU's General Pharmaceutical Legislation. In December 2025, the Parliament and the Council of the EU reached an agreement on the final legislation. Despite efforts to improve the Commission's flawed original proposal, the outcome includes provisions that weaken the IP framework in the EU, exacerbate concerns about European "freeloading" on American innovation, and create an unlevel playing field for American businesses seeking to invest in Europe. While awaiting the final negotiated text, the Chamber is particularly concerned with aspects of the agreement that have been announced by the EU institutions which are reported to change the IP-related provisions as follows:

- **RDP:** The deal includes eight years of data protection and, one year of market protection, i.e. a baseline of 8+1 years. This decreases market protection from two years to one year and will weakens the EU's RDP framework. The agreement also conditions the restoration of lost RDP terms on criteria such as conducting clinical trials in multiple EU Member States or seeking marketing authorization in the EU within 90 days of first global submission. The deal includes a cap of 11 years on the combined RDP.

- **Market Access:** The agreement also introduces unprecedented new access obligations, in principle allowing all Member States to require companies to launch a newly authorized medicinal product on their national market within three years of the granting of the marketing authorization (MA) "within the limits of their responsibility" (an undefined term). If companies do not comply,

and cannot invoke “exceptional circumstances” that are fully outside their control, they can lose regulatory data protection (two years earlier validation and assessment (but not granting) of generic/biosimilar MA applications) and market protection in that Member State.

- **Bolar Exemption:** The final legislative agreement will also expand the scope of the Bolar exemption that could include pre-commercial and commercial activities—such offering for sale or marketing that may occur during as health technology assessments, pricing and reimbursement procedures, and tender applications. Including commercial activities in the exemption is unprecedented and contradicts original intent of the Bolar exemption. This change is inconsistent with both standard practice in the rest of the world and the EU’s commitments under the WTO TRIPS Agreement. Moreover, the expanded Bolar scope would appear to render effective patent enforcement more difficult and, at least in some cases, essentially impossible, as innovators currently can demonstrate the “imminent infringement” required by European courts through evidence of acts that, once implemented, may no longer be considered infringing.

- **Orphan Exclusivity:** The final agreement also reduces Market Exclusivity for Orphan Medicines from 10 years to 9 years. In addition, 2 additional years are now given in case of a breakthrough orphan medicinal product.

Chamber Recommendation: The Chamber encourages the U.S. government to utilize the ongoing trade dialogue or other trade tools to obtain commitments from the European Union to clarify TRIPS compliance by not exempting commercial activities from its Bolar exemption, rescind any changes that go beyond international law and practice, and to create a pharmaceutical landscape that prioritizes groundbreaking innovation, remains fully consistent with the EU’s international obligations, and bolsters Europe’s competitive environment for U.S. investors in innovative technologies.

Patent Package: In April 2023, the Commission released a Patent Package which contained a series of legislative proposals related to compulsory licensing, standard essential patents, and supplementary protection certificates. The compulsory licensing legislation has now been finalized. While it includes notable improvements to the Commission’s original proposal—including exclusion of the forced disclosure of trade secrets—the creation of a pan-EU compulsory licensing mechanism is concerning and counterproductive, particularly when IP rights are being inappropriately leveraged to advance industrial policy goals in many countries. Also, while originally included in the Patent Package, the Standard Essential Patent (SEP) Regulation was withdrawn in February 2025. The European Parliament is currently

pursuing legal action against the Commission in response to the Commission's decision to withdraw the proposal. Discussions over the Supplementary Protection Certificate (SPC) Regulation are continuing in the Council. Moreover, the proposals include a simplified, centralized procedure to grant SPCs—versus the current separate national processes—and a unitary SPC process to align with European unitary patent.

- **Chamber Recommendation:** The Chamber encourages the U.S. government to work their EU counterparts to ensure that new pre-grant opposition mechanisms are not added back into the final SPC legislation and to ensure that changes to the EU's SPC regime preserve the legal certainty provided by SPC rights.

EU Health Data Space: The EU Health Data Space (EHDS) Regulation establishes a framework to facilitate the use and exchange of health data across the European Union, aiming to enhance healthcare delivery and support research and innovation. While the Chamber supports the goal of fostering a more secure and unified system for electronic health data, we remain concerned that the EHDS contradicts the EU's existing framework for the protection of IP rights and trade secrets. For example, data holders do not have the ultimate right to refuse data sharing, even when doing so could result in the disclosure of trade secrets and significant economic harm to the innovator. Additionally, the EHDS does not specify that commercially sensitive information cannot be utilized to create a competing product. It is critical that the EHDS is implemented in a manner which respects and safeguards innovators' IP rights including patents and regulatory data protection and ensures that they can retain control over their trade secrets.

- **Chamber Recommendation:** The Chamber recommends that the U.S. government encourage the EU to engage in meaningful dialogue with stakeholders to ensure that data holders can retain control over their IP and trade secrets and have the right to refuse access to their confidential commercial information or data.

<u>Market Access</u>

Pharmaceutical Pricing: Several large EU member states—including Italy and France—impose clawback mechanisms on pharmaceutical and medical device companies, requiring firms to return revenue if healthcare spending exceeds often underfunded healthcare budget limits. When clawbacks are applied retroactively after contracts are awarded, they can distort the actual value of those contracts and undermine the integrity of the procurement process. This is particularly relevant in the

context of the most-favored nations (MFN) policy, as clawbacks reduce the net prices companies receive, making EU list prices an unreliable benchmark for U.S. pricing policy. Additionally, these unpredictable financial penalties disproportionately impact U.S. firms, creating uncertainty, undervaluing innovation, and discouraging long-term investment. If expanded, these policies could result in essentially a tax of billions of dollars on U.S. life sciences companies and exacerbate the discrepancy between what foreign and U.S. patients pay for American-financed innovation.

- Chamber Recommendation: The Chamber encourages the U.S. government to encourage the European Commission to assess whether national clawback mechanisms conflict with EU procurement rules, which are designed to ensure transparency, fairness, and predictability in public purchasing. The U.S. government must also encourage Member State governments to more effectively balance fiscal policies with the need for medical innovation, ensuring that clawback schemes do not create excessive burdens on industry.

JAPAN

Patents and Related Rights

Index Stat: Japan is tied for second in the 55 global economies in the patents and related rights Index category, ranking alongside South Korea, Switzerland, and the United States, but behind Singapore.

Patent Linkage: In 2024, Japan's Ministry of Health, Labor and Welfare (MHLW) set up a research team to consider amending the patent linkage system. They proposed introducing an Expert Committee (EC) system where experts opine on patent infringement based on information submitted by innovative and generic manufacturers and when MHLW is unable to determine if a follow-on product falls within the scope of the innovator's patents. The proposed system risks delaying approvals and increasing legal uncertainty and litigation. Regardless of the expert opinion outcome, it does not offer a legally binding resolution for patent disputes. In November 2025, MHLW issued a notice of Trial Implementation of the EC system and started it.

- Chamber Recommendation: The Chamber encourages U.S. government to work with the Japanese government to establish a formal patent linkage system to help timely resolve patent disputes between innovators and generic/biosimilar companies. This would help ensure MHLW cannot adjudicate legal disputes between innovative and generic manufacturers, including through experts, and should instead leave legal matters for the courts. Any formal patent linkage system should clarify the scope of patents

covered by the system and include the following features at a minimum: a patent listing requirement, public disclosure of patent listings, notice of generic marketing applications, a set stay period if litigation is initiated, and market authorization at the end of the stay period or after a final court decision (whichever comes first).

Regulatory Data Protection: Japan does not have a formal framework for regulatory data protection. Instead, Japan relies on an *ad hoc* reexamination system that, as a *de facto* matter, provides similar periods of exclusivity. However, such a system has a different purpose and may be changed in a manner that reduces protection underscoring the need for a more formal legal system for protection of regulatory data in line with global best practice.

- **Chamber Recommendation:** The Chamber urges the US government to work with the Japanese government to implement a formal regulatory data protection framework that provides protection at highest international standards, namely at least 10-year protection for small molecule drugs and at least 12-year protection for biologics.

<u>Copyrights and Related Rights</u>

Index Stat: Japan ranks 10th out 55 global economies in the copyrights, related rights, and limitations Index category, behind Singapore and the Republic of Korea (ROK) in Asia.

Copyright Law Reform: While the Japanese Copyright Act was amended in 2019, several key forms of copyright protection have been omitted from the legislation. For example, the Copyright Act does not include a public performance right for artists and sounds recording producers. Likewise, the Japanese making transmittable right does not correctly implement the WIPO Performance and Phonograms Treaty's (WPPT) making available right and is narrower than the making transmittable right in other territories. For example, the making available right only covers scenarios where the copies are stored in the jurisdiction and made available from Japan.

Chamber Recommendation: The U.S. government should encourage the Japanese government to pursue the following reforms:

- Introduce a public performance right for artists and sound recording producers;

- Update the Japanese making transmittable right to cover not only the point of uploading but also subsequent transmissions; and

- Refrain from adopting overbroad exceptions to copyright and remove any existing overbroad exceptions.

Copyright Enforcement: As a result of a combination of the making transmittable right and the lack of injunctive-style relief, rightsholders have no meaningful recourse against popular sites which are operated from or host infringing content outside Japan. Stream ripping is the dominant music piracy issue: there were more than 21 million visits to stream ripping sites from Japan in Q2 2024 to download music. Research from the University of Electro-Communications and Photonic Systems Solutions Inc. indicates that, including all audiovisual piracy sites, there were 1,886 piracy sites with more than 100,000 visits per month, with an average of about 300 million monthly piracy visits in 2024. Authorities recognize that many notorious piracy services of Japanese content are located outside Japan, and the authorities are accordingly realigning their efforts to tackle piracy by building strategic international partnerships. Other issues include unlicensed content on user-uploaded content (UUC) services.

Chamber Recommendation: To more adequately combat online piracy, the U.S. government should encourage the Japanese government to:

- Introduce a clear legal basis to effectively address online piracy, in line with international best practices outlined in the IP Index;[6]

- Improve the inadequate online liability framework and notice and action provisions of its law.

Market Access

Pharmaceutical and Medical Devices Pricing and Reimbursement Policies: Frequent pharmaceutical price revisions, the continued use of off-year adjustments, and other cost-containment measures have created a commercially challenging environment in Japan for U.S. pharmaceutical, medical devices, and medical technology companies. Moreover, the current pricing system in Japan has failed to keep pace with inflation and higher costs for companies, as well as the incredible breakthroughs in science and technology associated with new pharmaceutical and medical technology products.

In December 2024, Japan announced its decision to expand the off-year price revision impacting American-made medicines, including innovative, long-listed products (LLPs) as well as generics, effective April 1, 2025. The reduction in biopharmaceutical revenues from these price cuts is estimated to be JPY 247 billion (approximately USD

[6] https://www.uschamber.com/intellectual-property/2024-ip-index

1.73 billion). Moreover, under the current budget plan, drug price cuts account for 46% of the funds raised to curb the growth of overall social security spending and to support policies outside of healthcare.

MHLW also plans to verify the current cost-effectiveness evaluations (Japanese HTA) system in early FY2026 and subsequently aims to expand the HTA, including a price adjustment range, system reform, and implementing market expansion re-pricing in the FY2027 off-year drug price revision. U.S. industry is deeply concerned that the value of innovative medicines will be reduced further due to the expansion. Furthermore, these latest proposals contradict Japan's efforts to address its drug lag and drug loss and could significantly discourage biopharmaceutical R&D investment and hinder the timely market presence or launch of innovative medicines in Japan, as well as the continued availability of medicines already in the market.

Chamber Recommendation: The Chamber encourages the U.S. government to work with their Japanese government counterparts to pursue the following reforms:

- Abolish the off-year price revision;

- Establish a bilateral public-private healthcare dialogue to improve timely and continued access to U.S. innovative and high-quality medical products. This dialogue should include the participation of relevant U.S. agencies and Japanese ministries/entities (e.g., MHLW, Chuikyo, PMDA, Ministry of Finance), as well as companies representing all segments of the pharmaceutical and medical devices/technologies market so they can be consulted to provide data-driven insights into access, supply sustainability, and therapeutic value;

- Restore market-based incentives for continued investment in life sciences and medical technology innovation and reduce the frequency of price revisions to help maintain the commercial viability of the life sciences sector in Japan;

- Consider modifying the existing Japanese HTA system, such as modifying the criteria for evaluating "additional benefits" and creating different evidence acceptance criteria; and

- Consider eliminating the price differential for long-listed products to help ensure U.S. companies' competitiveness and continued presence in the Japanese market.

Lack of Transparency and Due Process in Japan's Pricing Decisions: The lack of transparency and formal consultation facilitating due process in Japan's reimbursement system for health products, including pharmaceuticals and medical

devices, hampers healthcare innovation and creates significant commercial uncertainty. As Japan has introduced substantial changes to pricing rules over the past decade, the decision-making bodies have failed to provide adequate and meaningful opportunities for industry input during the policy development and implementation. In addition, industry has very limited opportunities to testify before the Central Social Insurance Medical Council (Chuikyo). Although it makes key decisions on pricing, the Chuikyo is exempted from Japan's regulatory transparency regulations because it is classified as a government "advisory" committee. Further, some rules are not applied transparently, nor in a manner consistent with their stated purpose, to the detriment of U.S. companies.

- **Chamber Recommendation:** The Chamber encourages the U.S. government to ensure that Japanese regulators engage in meaningful, transparent, and inclusive stakeholder consultation, including with the most heavily impacted American companies, on repricing proposals. Early, meaningful engagement would help identify unintended consequences and allow for the joint development of more effective measures to balance the interests of the public and private sectors, while ensuring continued access to medicines and medical devices. Moreover, regular consultation mechanisms between Japanese regulators and industry, such as joint working groups, formal comment periods, or appeal mechanisms would foster trust and improve the transparency of pricing, regulatory, and HTA decision-making processes.

REPUBLIC OF KOREA (ROK)

Patents and Related Rights

Index Stat: The Republic of Korea is tied for second out of 55 global economies in the patents and related rights Index category, scoring alongside Japan, Switzerland, and the United States.

Patent Term Extension (PTE): In July 2025, the Patent Act Amendment Bill entered into force. The Amendment limits PTE eligibility to a single patent, creating a more restrictive system. In addition, Korea's PTE framework continues to suffer from a long-standing structural deficiency in its appeal mechanism, which predates the July 2025 Amendment and remains unaddressed. Under the current system, when the Ministry of Intellectual Property (MOIP), formerly known as the Korean Intellectual Property Office, determines a PTE duration that is shorter than the period requested by the patentee, a challenge to that determination carries the risk that, if unsuccessful, the patentee may lose the entire extension, including the portion previously acknowledged by the Patent Office. This all-or-nothing outcome significantly chills the exercise of appeal rights, deters patentees from seeking correction of erroneous

administrative calculations, and undermines procedural fairness and legal certainty. While the July 2025 Amendment substantially narrowed the scope of PTE eligibility, it did not remedy this fundamental procedural deficiency, thereby further weakening the effectiveness and reliability of Korea's PTE system

- Chamber Recommendation: The Chamber encourages the U.S. government to work with their Korean government counterparts to pursue further legislative refinements to ensure that Korea's patent framework continues to support innovation, investment, and access to new medicines. More specifically, the chamber urges that the Korean government further amend the PTE regime to align with U.S. and European practice by ensuring that the patent term extension granted to the first and only eligible patent covers all future indications approved before the expiration of the already-granted PTE, rather than limiting protection to the initially approved indication and address the long-standing all-or-nothing appeal problem through additional legislative action so that patentees are not forced to forfeit already-recognized extension periods merely for exercising their right to challenge erroneous administrative determinations.

Invalidation Decision Pre-Notification System: Separately, Korea is pursuing legislative efforts to introduce an Invalidation Decision Pre-Notification System aimed at enhancing transparency, predictability, and procedural efficiency in patent invalidation proceedings. The goal of enhancing stability within the patent system is a positive development. However, the current proposal reportedly includes industry-specific exception clauses that leave substantial discretion to the authorities, raising concerns that such discretion could be applied in a manner that disproportionately affects pharmaceutical patents. Such industry-specific carve-out undermines the core objectives of the proposed system by creating uncertainty and unequal treatment across technologies. A stability-enhancing procedural reform should apply in a neutral and technology-agnostic manner; otherwise, it risks weakening confidence in the patent system rather than strengthening it.

- Chamber Recommendation: The Chamber encourages the Korean government to ensure that the proposed Invalidation Decision Pre-Notification System Invalidation Decision Pre-Notification System fulfills its stated objective of enhancing stability and predictability by avoiding broad, industry-specific exceptions, particularly those targeting pharmaceuticals, which would undermine equal treatment and confidence in Korea's intellectual property system.

Index Stat: The Republic of Korea ranks 7th out of 55 global economies on the copyrights and limitations Index category.

Copyright Law Reform: The Copyright Law does not provide a clear legal basis for and effective application of injunctive-style relief, in line with international best practices outlined in the IP Index.[7] Moreover, the ROK's copyright liability rules regarding linking to infringing content and liability require improvement. The law also includes a burdensome pre-approval process for clearance of music videos on local services.

- **Chamber Recommendation:** The Chamber recommends the U.S. government encourage the ROK to amend its public performance right for music performances, refrain from adopting overbroad exceptions to copyright, and remove any existing overbroad exceptions.

Copyright Enforcement: The Republic continues to have high piracy rates, for foreign-based cyberlockers and stream ripping sites. Piracy sites in Korea continue to operate through routinely "hopping" domains or through hundreds of copycat domains or IP addresses. It remains unclear if injunctive-style relief is available for such sites due to the criteria imposed in practice.

- **Chamber Recommendation:** The Chamber urges the U.S. government to work with the Government of the Republic to address the above-mentioned deficiencies in Korea's legal system and enforcement apparatus to ensure adequate and effective protection of copyright and to combat copyright piracy online. The Communications and Information Network Act could help rightsholders with enforcement through similar regulations.

Market Access

Pharmaceutical and Medical Devices Pricing and Reimbursement: ROK's pharmaceutical and medical device pricing and reimbursement policies continue to undervalue U.S. IP and innovation and fail to "appropriately recognize the value of the patented pharmaceutical product" in violation of Article 5.2(b) of the U.S.-Korea Free Trade Agreement (KORUS). Korea's pricing and reimbursement scheme for pharmaceuticals is extremely complex and maintains a strict focus on cost-containment measures that remain uncoordinated. Recent policies introduced by the Korean government are not enough to appropriately value patented pharmaceutical products.

[7] https://www.uschamber.com/intellectual-property/2024-ip-index

Dual pricing policies recently announced allow separate list and net price for pharmaceuticals, but fail to address the core concerns regarding low Incremental Cost-Effectiveness Ratio (ICER) thresholds. More specifically, in late November 2025, the Ministry of Health and Welfare (MOHW) released a package of reforms to the pharmaceutical pricing system. Core elements include the introduction of a flexible pricing contract (dual pricing), exploration of indication-based and value-based pricing, and procedural improvements to facilitate timely patient access. Dual pricing separates the listed price from the actual transaction price. While this mechanism is expected to provide short-term support for the introduction of new medicines, it is not a fundamental solution. Actual prices for innovative medicines in Korea remain substantially lower than in peer OECD markets, signaling persistent undervaluation of innovation. Without appropriate recognition and reward for innovation, the medium- to long-term sustainability of supply for Korean patients is at risk.

Similarly, The Ministry of Health and Welfare (MOHW)'s "Measure to Improve Drug Pricing Systems to Reward Innovation and Strengthen Health Security" effectively excludes foreign companies from the accreditation and incentives afforded with the "innovative company" accreditation. This measure continues the discriminatory preferences to domestic companies over foreign companies. While the Korean government is working to lower thresholds so that foreign companies can obtain innovative-company certification, in practice, foreign firms still face difficulties in achieving certification, and even when certified, price advantages granted under post-listing price management remain limited for new product launches.
Altogether, these policies undermine and hinder Korea's goal to become a biotech hub and strategic partner on drug supply chain resiliency, as well as constitute a major barrier to American companies' ability to supply health products in the Korean market.

Chamber Recommendation: The Chamber urges the U.S. government to ensure that South Korea implement its KORUS FTA commitments. Both governments should restart discussions under the Medicines and Medical Devices Committee established under KORUS Article 5.7 on reforms to:

- Ensure the regulatory and reimbursement systems appropriately recognize the value of innovative technologies and grant clear, material incentives at listing/reimbursement stages for certified innovators;

- Improve transparency, predictability and due process in criteria and procedures;

- Embed quantitative innovation metrics in post-listing management so that value is consistently reflected;

- Sustain a sound science regulatory approach; and

- Incentivize investment in innovation.

These discussions must also involve relevant Korean government ministries, including the MOHW, to ensure a successful dialogue aimed at achieving concrete outcomes and practical solutions to barriers to innovation.

Delays in Korea's Regulatory System for Reimbursement: Korea utilizes a health technology assessment mechanism for all new product listings, which has resulted in lengthy reimbursement times and delayed patient access. One reason for this is that the ROK's ICER is low and outdated. The excessively low ICER threshold discourages the entry of innovative, investment-heavy drugs into the Korean market, potentially limiting patient access to new medicines. As a result, it is challenging for new products to be considered as cost-effective under the current ICER threshold, leading to lengthy review times or rejections.

Moreover, it bears noting that the announced plan to raise the ICER threshold should require clear and transparent justification regarding the magnitude and basis of the increase. For example, policymakers should specify whether the threshold will move from ~2GDP to 3GDP, and/or establish differentiated ICER bands by therapeutic class or disease severity, with explicit indicators—for instance, higher bands for severe, rare, or high-innovation categories.
In addition, Korea allocates only 13.5% of its total drugs spending to new drugs, the lowest among the OECD countries. The OECD average spending on new drugs out of total drugs spending is 33.9%.

- Chamber Recommendation: Korea's pilot program to accelerate the review process – where regulatory approval and pricing negotiations occur simultaneously – is a constructive step that needs to be expanded. The Chamber encourages the U.S. government to work with their Korean government counterparts to increase the spending on new drugs out of total drugs spending, shorten the lead time from regulatory approval to reimbursement approval, and update the ICER threshold (~100mil.KRW/QALY) for actual price. We recommend the U.S. government share best practices with Korean officials on ways to improve the process and resolve delays in market entry. Lastly, we urge Korea to create meaningful opportunities for stakeholder input regarding the approval process.

Post-Listing Pricing Management: The South Korean government has a substantial post-listing price management system that drives down the prices of U.S.

pharmaceuticals, including a current consideration to revise its international reference pricing system. Such post-listing pricing policies threaten the commercial viability of U.S. pharmaceutical in Korea.

- **Chamber Recommendation:** The South Korean government should improve the current complex and redundant post-management mechanisms. Savings generated through post-listing price management should be reinvested into the introduction of new medicines to institutionalize a 'virtuous cycle' for the national health insurance budget. In addition, Korea should set a medium- to long-term commitment on the target share of GDP allocated to new drug expenditure to improve predictability for patient access and innovation reward.

TAIWAN

Patents and Related Rights

Index Stat: Taiwan is tied for third out of 55 global economies in the patents and related rights Index category, scoring alongside the UK and several EU economies.

Patent Linkage: While the Taiwan Food and Drug Administration (TFDA) promulgated final patent linkage (PL) regulations in August 2019, the Chamber is concerned that the TFDA has excluded patents that protect new doses, new dosage forms, or new unit strengths. The exclusion of these patents fails to fully protect those innovations and makes Taiwan out of step with international best practices.

- **Chamber Recommendation:** To ensure comprehensive protection of pharmaceutical innovations, the Chamber recommends that the Taiwanese government include patents for new doses, new dosage forms, and new unit strengths in the patent linkage system, reducing legal uncertainties and enhance market stability, benefiting both innovator and generic drug manufacturers.

Patent Term Extension: Patent term extension (PTE) is a mechanism designed to restore the patent term lost due to delays in the national regulatory agency's marketing approval process. Recently, an American company has faced instances where PTE was denied in Taiwan under circumstances where it would have been granted in other major jurisdictions, including in the United States and Europe. This denial was based on the determination that the compound patent did not "cover" a hydrate form of the compound under Taiwanese law, significantly affecting the exclusivity period of these products.

These denials are a result of the 2018 Patent Examination Guidelines which impact PTE determinations. According to Example 5 in these guidelines, a patent claiming a compound does not cover a hydrate form of that compound for PTE purposes. As a result, the Taiwan Intellectual Property Office (TIPO) has denied PTE for patents claiming a compound when the marketed product includes the compound in a hydrate form.

The scope of PTE of a composition of matter (COM) patent is limited to the active ingredient and a single indication identified in the market approval. This practice is significantly different from US and Europe practice, where the scope of the PTE of a COM patent would cover all indications subsequently approved after the initial product approval.

- **Chamber Recommendation:** The Chamber encourages TIPO to revise its guidelines to align with international practices. Specifically, Example 5 should be deleted or replaced with an example that allows PTE for compound claims covering a product containing a hydrate of the compound. This change would recognize that compound claims cover mixtures, including hydrates, as is the practice in the United States, Europe, and other jurisdictions.

Market Access

Index Stat: Taiwan scores behind EU economies such as Sweden and Poland but ahead of Asian economies, including Brunei, in the commercialization of IP assets Index category.

Market Access: Several market access issues continue to persist or loom on the horizon for industry, including:

- The lack of transparency, predictability, input, and due process in Taiwan's pricing and reimbursement system—particularly in the negotiation and renegotiation of managed entry agreements (MEAs) and price volume agreements (PVAs)—creates significant barriers to patient access to innovative medicines and uncertainty for the industry.

- In 2017, the Taiwan Government imposed price adjustments to maintain spending targets that protected only compound and combination patented products from price cuts, which has in turn created an unfair pricing environment for other patented medicines.

- The National Health Insurance Administration (NHIA) plans to use international reference pricing (IRP) for price adjustments. IRP can lead to artificially low

prices, resulting in product withdrawals, launch delays, and undermining the availability of medicines in both the implementing and referenced markets.

Chamber Recommendation: As Taiwan prepares to implement amendments to its pricing and reimbursement system in January 2026, the Chamber recommends that Taiwan's government enhance transparency and stakeholder engagement in the pricing and reimbursement process to ensure fair and predictable outcomes. Additionally, reconsidering the use of IRP for price adjustments could help prevent artificially low prices and ensure the availability of innovative medicines. Finally, protecting all patented products from price cuts, not just compound and combination ones, would create a more equitable pricing environment.

Section D: CHINA

Overview

The Chamber continues to advocate for greater market access and a level playing field on behalf of our members operating in the China market on a full range of issues and have forcefully encouraged the Chinese government to strengthen IP protection and enforcement across a broad array of IP policy concerns. The Chamber continues to support the full implementation of the Phase One Agreement. The agreement represents a significant achievement in ongoing efforts to advance fairness and reciprocity in the bilateral economic and commercial relationship, yet China has still failed to implement many of the IP provisions. In continuing to reform its IP regime, China has taken encouraging steps that follow through on commitments enumerated in the agreement's text, including:

- The release of a judicial interpretation clarifying when plaintiffs may request punitive damages in civil IP infringement cases, as well as specifying how Chinese courts should determine punitive damages and criteria for calculating punitive damage awards (March 2021);

- The publication of implementing regulations for China's early patent dispute resolution mechanism (i.e., patent linkage regime) by the China National Intellectual Property Administration (CNIPA) and National Medical Products Administration (NMPA), as well as corresponding provisions on the adjudication of drug patent disputes released by the SPC (July 2021);

- The acceptance of China's first civil patent linkage lawsuit by the Beijing IP Court (November 2021) and subsequent ruling that confirmed the importance of invalidation proceedings / assuaged concerns about obtaining timely remedies (April 2022);

- The release of draft amendments to Trademark Law (January 2023), proposing systemic changes such as civil liabilities over bad faith trademark applicants, mandatory transfer of bad faith registrations back to the genuine right owner, and requirement of intent to use and reporting trademark use status;

- The release of guidelines for trademark examinations and trials (November 2021);

- Strengthened efforts surrounding trademark enforcement, especially in regard to punishing bad-faith trademark applications and registrations (year-round); and

- The release of revisions to the China Patent Law Implementing Rules and Patent Examination Guidelines which include patent-term adjustments to compensate for examination delays (PTA) and for the time taken for the review and approval of new drug (PTE) (January 2024); and

Despite these positive steps to strengthen IP protections, the Chamber remains concerned about the following key issues:

- PTE appears to be limited to those products for which approval is sought in China before they are approved anywhere else in the world. This discriminates against U.S. companies and is inconsistent with Article 1.12(2)(b) of the Phase One Agreement;

- The scope of PTE of a composition of matter (COM) patent is limited to the active ingredient and a single indication identified in the market approval. This practice is significantly different from US and Europe practice, where the scope of the PTE of a COM patent would cover all indications subsequently approved after the initial product approval;

- Restrictive patentability criteria, including stringent requirements before acceptance of post-filing, supplemental data to demonstrate patent eligibility despite obligation to eliminate such requirement o under Article 1.10 of the Phase One Agreement; Moreover, the CNIPA does not grant a patent to protect inventions related specifically to a new dosage or administration regimen when the indication is already known;

- The absence of effective regulatory data protection (RDP);

- Inconsistent patent enforcement, including the continued favoring of domestically produced generics that infringe on patent protections for innovative medicines (with cases emerging even after the Phase One Agreement was signed);

- Lack of transparency around and the jurisprudence behind anti-suit injunctions (ASIs) that interfere with decisions rendered on standard-essential patents (SEPs) in global jurisdictions;

- Increased invocation of anti-monopoly remedies/administrative action in IP-related matters;

- Continued inadequate efforts to combat internet piracy, unauthorized camcording, and counterfeiting;

- The absence of effective enforcement actions with transparency against the manufacture, promotion, distribution, and exportation of Piracy Devices;

- The low application of punitive damages and preliminary injunction in IP cases; and

- Continued use of market access restrictions, data transfer and storage restrictions, administrative practices, and cyber-espionage to forcibly acquire sensitive IP and valuable proprietary information from foreign companies.

The abovementioned issues constitute serious areas of concern for our membership, which relies on the strong and consistent enforcement of IP protections worldwide to generate revenue that they re-invest in further research and development. To address these issues, the Chamber recommends that China:

- Fully implement, as a matter of urgency, all commitments included in the Phase One Agreement, including China's purchasing obligations which includes licensing for audiovisual works. In addition, China should fully implement obligations with respect to trade secrets, patents, protections for all innovative pharmaceuticals, copyrights, piracy and counterfeiting, trademarks, and judicial enforcement and penalties;
- Provide effective protection against the unfair commercial use of test data for pharmaceuticals, i.e., a term of regulatory data protection consistent with global standards made available to all medicines that are new to China;

- Eliminate unnecessarily burdensome legal provisions and other onerous requirements in the patent and trademark enforcement system;

- Eliminate discriminatory and unnecessarily burdensome data transfer restrictions and localization requirements; and

- Carry out structural reforms that increase judicial autonomy and protect companies against the unfair state-led manipulation of China's court system.

The Chamber is committed to working with the U.S. government to monitor and address China's unfair practices and lack of enforcement with respect to each of these issues. In the following sections, it offers our assessment of Chinese IP protections and practices across a wide range of areas, which we look forward to engaging further with the U.S. and Chinese governments on in the year ahead.

Patents and Limitations

Index Stat: In the patent-related indicators, China scores shortly behind Israel and Australia and ahead of Greece.

Weak Patent Enforcement on Pharmaceutical Products: The Chamber was encouraged to see that the amendment to the Patent Law (approved in October 2020) included a form of early patent dispute resolution (specifically, elements of a "patent linkage" system). However, several important provisions related to China's emerging patent dispute resolution system remain ambiguous, leading to uncertainty about their scope, implementation, and value for biopharmaceutical innovators in China and abroad. Specifically, while the July 2021 "Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes (Trial)" ("Measures") provide some necessary clarity on key issues, there remain notable gaps in the emerging system, including:

- The 9-month automatic NMPA waiting period does not appear to be extendable or contingent on obtaining a final ruling, either from a court of law or through the administrative patent trial process within CNIPA;

- The absence of an automatic waiting period for biologics; and

- Loopholes that allow generic companies to bypass the patent linkage mechanism and prematurely launch their products in the market. For example, generics can submit Category 3 Statement (i.e. promising not to market their ANDA products before OB listed patents expire) and get MA, and then request invalidation in CNIPA, thus circumventing making a Category 4 Statement

Chamber Recommendation: The Chamber urges the U.S. government to encourage China to move swiftly to implement the proposed reforms in a manner that empowers IP-intensive businesses and is consistent with its commitments in the Phase One Trade Agreement.

Loss of Patent Term Due to Regulatory Processes and Patent Office Delays: Patent Office delays and lengthy regulatory development and approval processes for pharmaceutical products result in a significant loss of effective patent term for such products. Given these current challenges, we commend the inclusion of effective patent term extension provisions in Article 1.12 of the Phase One Trade Agreement. Patent term adjustment and patent term extension provisions were included in the amended patent law and the revised Patent Law Implementing Rules and the Patent Examination Guidelines took effect on January 20, 2024. According to these guidelines, for a pharmaceutical product to qualify as a "new drug" that is eligible for PTE in China, the pharmaceutical product must be new to the world, i.e., never approved previously in another market, at the time the company seeks approval in China. This is not consistent with the best international practice. Differences in approval or launch dates around the world occur regularly and is a result of different regulatory and market access practices around the world. As such, further efforts are necessary to ensure patent term restoration effectively compensates for the loss of the effective patent term of the Chinese patent during the development and regulatory review period before NMPA and is available to all patented medicines that are new to China, i.e., not previously approved for use or launched in China, rather than new to the world. Moreover, the PTE granted in China on a compound patent covers only the indication already approved, but not future indications; and this is out of syn with other major jurisdictions such as the US, EU and Japan.

Additionally, and according to the Implementation Rules and Guidelines, the protection scope is limited to a new drug for the indication as approved during the PTE, which means the PTE of the API compound patent would not protect later approved indications of the same API. Such narrow protection scope is not consistent with the best international practices.

- **Chamber Recommendation:** The Chamber looks for forward to working with the U.S. government to ensure effective implementation of patent term extension for all pharmaceutical products, including those approved first outside of China, as well as all indications including future indications approved after the grant of the PTE.

Lack of Jurisprudential Transparency and Application of Anti-Monopoly Authorities to Standard Essential Patent (SEP) Cases: Despite past pledges to increase judicial transparency by making most court decisions publicly available, the

publication of decisions of all kinds has decreased over the last three years. This trend coincides with the ongoing WTO complaint brought by the European Union (and subsequently joined by the United States) regarding the availability of final decisions for cases in which Chinese courts issued anti-suit injunctions / cases identified as guiding materials when adjudicating royalty rates.[8] In July 2025, a WTO appeal Arbitrator found that China's policy on anti-suit injunctions was inconsistent with its commitments under the TRIPS Agreement. The Arbitrator's findings mark a potential turning point on this issue and, if implemented in full by China, could amount to a significant improvement to the licensing environment for SEPs.

As a related issue, Chinese courts have been increasingly assertive about setting worldwide royalty rates for SEPs. Though China is not the only jurisdiction to do so, the relative opacity of jurisprudence around rate setting decisions adds uncertainty to an already contentious environment. Moreover, concerns about the establishment of binding worldwide royalty rates without the consent of the patent owner have prompted the European Union to file another complaint[9] with the WTO to start 2025. Additionally, in March 2025, the Chinese government "Opinions of the State Intellectual Property Office, the Ministry of Education, the Ministry of Science and Technology, the State Administration for Market Regulation, the State Financial Regulatory Administration, the National Copyright Administration and the Chinese Academy of Sciences on further optimizing the business environment in the field of intellectual property." Notably, section II, subsection V further cements the Chinese government's role within the SEP licensing process through: the development of new SEP state-issued licensing guidelines; the promotion of "fair and reasonable licensing" of SEPs; and the prevention of "monopolistic behavior." This ongoing expansion of the Chinese state into global rate setting is highly consequential for multinational rights holders, particularly given China's record of using anti-monopoly law to promote domestic industrial policy goals

Meanwhile, China's anti-monopoly law greatly expands the government's basis for action against anti-competitive behavior and substantially increases fines and penalties. With respect to IP rights, article 68 states that the "Law applies to undertakings' abuse of intellectual property rights to eliminate or restrict competition." The law was accompanied by several new rules and draft rules. In that vein, the State Administration for Market Regulation (SAMR) released *Provisions on Prohibiting the Abuse of Intellectual Property Rights to Exclude and Restrict Competition,* which took effect on August 1, 2023. Article 19 explicitly singles out SEPs, requiring that SEP owners not violate FRAND commitments and that SEP holders not request courts to prohibit the use of their IP without having engaged in good faith negotiations. This development may presage Chinese licensees turning to

[8] https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds611_e.htm
[9] https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds632_e.htm

antitrust lawsuits as ASIs become less viable. Indeed, the Chinese judiciary has denied Chinese computing giant Lenovo an ASI, suggesting the practice may be on the wane in favor of an anti-trust-oriented approach.

Additionally, in June 2024, the State Council issued National Decree 793, the Fair Competition Review Regulations, which discuss how the Chinese government should promote and actively encourage fair competition across the entire economy. While articles 8 and 9 limit localization efforts and explicitly eliminate the discrimination of foreign or imported goods, article 12 all but nullifies the preceding provisions by allowing competition to be restricted or eliminated "to promote scientific and technological progress and enhance the country's independent innovation capabilities." In the same month, the Supreme People's Court released its view of the AML through the "Interpretation of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Civil Disputes over Monopoly." The Interpretation provides some specific references to the handling of IP rights and related disputes including in relation to the analysis of a dominant position, unfair competition practices, and potential abuse of IP rights. In November 2024, SAMR released *Antitrust Guidelines regarding Standard Essential Patents.* Article 16 *(Attaching Other Unreasonable Trading Conditions during SEP Licensing*) stipulates that *''(5)whether there is prohibition or restricting of the standard implementer's choice of dispute resolution measures and jurisdiction"* as a key consideration in finding abuse of dominance. It is concerning that that the antitrust guides could be used to limit dispute resolution to Chinese venues in a similar way that ASI were being used to restrict SEP disputes to Chinese Courts.

- Chamber Recommendation: The Chamber is concerned that the anti-competition authorities included in the AML will lead to more frequent invocation of anti-trust in IP matters that create challenges for rightsholders seeking to assert their rights on fair, non-discriminatory, and equal terms. We urge the U.S. government to track the implementation of the AML and accompanying guides and their application to intellectual property closely.

Inconsistent Application of Patent Examination Criteria: In December 2020, CNIPA issued an amendment to the Patent Examination Guidelines, stating that post-filing experimental data could be conditionally accepted to prove both sufficient disclosure and inventive step. This new language was supported by the SPC's September 2020 issuance of the "Judicial Interpretation of Some Issues in Hearing Administrative Cases of Granting and Determination of Patent Rights," in which Article 10 prescribed that the Court would review post-filing experimental data. The Chamber welcomed these positive steps, but concerns remain regarding CNIPA/SPC implementation, especially at the Patent Reexamination Board level. Industry reports suggest that thus far, the implementation has been inconsistent and largely depends on the examiner.

There are recent cases which demonstrate that CNIPA continues to impose stringent requirements and thereby refuses acceptance of supplemental data to support compliance with patentability requirements in a manner that is out-of-step with other leading global practices, including the United States, Europe, and Japan, and is inconsistent with Article 1.10 of the Phase One Agreement. At least one major blockbuster drug patent was still invalidated due to rejection of acceptance of supplemental data, despite the same patent being validated and the same data being readily accepted in Europe and other jurisdictions.

- Chamber Recommendation: The Chamber encourages the U.S. government to work with their Chinese government counterparts to resolve concerns regarding acceptance of post-filing data to fully implement requirements under the "Phase One Agreement," including through implementation of the Judicial Interpretation and underlying Patent Examination Guidelines in a manner consistent with "Phase One Agreement" and global best practices.

Copyrights and Limitations

Index Stat: China ranks on par with Kenya and marginally ahead of Ghana and Brazil in the Index copyright-related indicators.

Copyright Law Reform: China's November 2020 amendment to its Copyright Law, effective as of June 2021, broadly align with the development of China's cultural industry over the past few years. The amendments are geared towards strengthening digital copyright protections while simultaneously strengthening/increasing penalties for copyright infringement. The new law finally adopted the new legal definition of "audio-visual works" that are common in today's digital environment, including webcasts and short videos. The amendments also include the introduction of the rights of broadcasting and public performance for producers of sound recordings, as well as technological protection measures. Statutory damages for copyright infringement have also been increased substantially following similar changes to the Patent Law and Trademark Law.

Chamber Recommendation: The Chamber encourages the U.S. government to work with their Chinese government counterparts to introduce the following reforms to strengthen the Copyright Law:

- Confirm that all live television broadcasts are copyrightable works in China, which would provide the needed legal protection to prevent pirated Internet retransmissions of valuable live broadcasts;

- Introduce new rules to address the volume of internet piracy caused by video aggregation websites and mobile apps, as well as enumerating exclusive rights under copyright;

- Introduce proactive administrative enforcement measures to close infringing websites and remove unauthorized applications;

- Introduce criminalization provisions to address violations of the Anti-Circumvention Provisions for Technological Protection Measures ("TPMs"), Information Rights Management ("IRM"), and internet offenses that may lack a demonstrable profit motive but that impact rightsholders on a commercial scale;

- Improve China's online liability framework and notice and action provisions;

- Confirm the primary liability of UUC sites that store and make available user uploaded content;

- Introduce a clear and express legal basis to effectively address online piracy;

- Extend the term of protection for sound recordings, which is currently only 50 years;

- Refrain from adopting any overbroad exceptions to copyright and remove any existing overbroad exceptions;

- Improve the scope of the making available to the public right; the existing "server test" element requires that the act of making available occurs via copies stored in China, which can hinder enforcement actions in relation to unlicensed services operating outside the country;

- Update copyright-related implementing regulations following enactment of China's new Copyright Law in 2021, and remove China's Article 15 WPPT reservation.

Copyright Enforcement: Rightsholders continue to face significant challenges enforcing copyright protection in China as a result of a lack of progress to address the following areas of concern:

- Persistent high piracy rates;

- The ability of UUC platforms to avoid liability by claiming to qualify for safe harbor immunities, leading to large scale availability of unlicensed content online;

- Onerous requirements for evidence of infringements (e.g. notary needs to be involved) and the proof of title in civil and criminal proceedings; and

- Difficulty obtaining evidence to satisfy the requirement to quantify the financial gain made by an infringer for administrative and criminal actions.

Chamber Recommendation: The Chamber urges the U.S. government to work with its Chinese government counterparts to pursue the following measures to provide effective protection of copyright and to robustly combat copyright piracy online:

- Conduct sustained year-round enforcement actions to combat copyright piracy;

- Engage in copyright enforcement actions against unlicensed UUC platforms and apps to combat infringing content, which is widely made available on such platforms and apps. In the absence of clarity regarding the liability for such platforms and obligations such as 'stay down', infringements of the same content proliferate, including infringements by repeat infringers;

- Modify evidentiary requirements to remove the burden they impose that serve as a barrier to administrative and criminal proceedings;

- Refine the process for transferring administrative cases to criminal cases; and

- Bring consistency to the thresholds for local authorities to accept administrative and criminal cases across different regions.

Market Access

Market Access Restrictions on Copyrighted Content: China maintains a host of market access restrictions to U.S. copyright-protected content. In movie distribution, there is an outright ban on foreign-controlled distribution or import. This forces foreign movie producers into an artificially low revenue share with the two state-owned film distributors, subject to a quota of 34 (20 plus 14) revenue-sharing films. China further restricts the market by manipulating release dates, limiting theatrical runs, and effectively limiting the marketing of foreign movies. China also prohibits foreign streaming services from operating in its market. Moreover, China's censorship regime is opaque, unpredictable, punitive, and utilized as a tool to manage the market. China's broadcast TV sector is almost entirely closed to foreign content, except for a

small amount of licensed TV shows. China's Pay-TV sector also includes extensive measures that largely exclude foreign content.

Collectively, these policies make China one of the most closed markets in the world for foreign content. While the online media space displayed insignificant growth in market access in the years prior to 2014, China subsequently announced new limits on the use of foreign content by websites and video on demand services, including a new 30% quota and a new prior catalogue approval and censorship review regime, implemented through a fixed semi-annual process, rather than on a rolling basis. The 30% foreign content cap is additionally limited by genre and country, effectively lowering the amount of U.S. content to around 10-13%. The new regulations have substantially cut back on the percentage of total content-spending spent on foreign audiovisual films. Further, these limits penalize legal service providers to the benefit of China's vast illegal online marketplace, which freely ignores the limits.

Additionally, China continues to prohibit foreign investment or control in online video services, even though U.S. companies are the global leaders in the space. While China affirmed in the Film MOU that any properly licensed Chinese enterprise may distribute imported films, the China Film Administration (CFA) has yet to approve any new private distributors. CFA and China Film Group also determine the release dates and length of theatrical runs of foreign films, often restricting the ability of U.S. producers to obtain the full commercial value of films.

- Chamber Recommendation: The Chamber urges China to fully implement the Phase One purchasing obligations for audiovisual licensing. Moreover, China must work with the U.S. to fully implement the US-China Film MOU.

Trademarks Rights and Limitations

Index Stat: China scores on par with a range of economies in the trademark indicators, including the UAE, Spain, Singapore, and Saudi Arabia.

Counterfeiting: The Phase One Agreement included several provisions designed to address China's substantial counterfeit economy. In particular, the Agreement:

- Requires expeditious takedowns on e-commerce platforms and penalizes notices and counter-notifications submitted in bad faith;

- Provides that e-commerce platforms may have their operating licenses revoked in the event of "repeated failures to curb the sale of counterfeit or pirated goods";

- Promises to increase enforcement actions against counterfeit pharmaceuticals and pirated and counterfeit goods in physical markets and at the border;

- Promises judicial authorities will order the forfeiture and destruction of pirated and counterfeit goods; and

- Promises to conduct third-party audits to ensure government agencies and state-owned enterprises only use licensed software.

Chamber Recommendation: The Chamber recommends that the U.S. government work with their counterparts to ensure the Phase One commitments are effectively implemented to stem the tide of counterfeiting in China.

Bad-Faith Trademark Registrations: The Chamber has taken note of CNIPA's recent initiatives to address bad-faith trademark registrations, which include having a centralized review at the early stage of trademark registration and opposition, putting together a whitelist of prominent trademarks for special protection as well as building a blacklist of notorious trademark squatters, and linking the record of bad faith filing to the social credit system. A Chinese media outlet reported that such blacklists have been sent to the examiners but not disclosed to the public.

Draft amendments to the Trademark Law released in January 2023 proposes various mechanisms to combat bad faith trademarks. Though specific standards may need clarification, it sends an encouraging signal of China's strong commitment. Under the proposed amendments:

- Rightsowners may be entitled to sue bad faith applicants for damages and reasonable expenses spent on fighting bad faith trademarks, such as legal fees spent on trademark oppositions and invalidations. Such monetary remedies are expected to be a major deterrence against bad faith trademark filings;

- Rightsowners can possibly seek transfer of bad faith registrations back; and

- Intent to use at the trademark filing stage is emphasized and trademark use reporting requirement every 5 years after registration is added. Failing to submit the use status update or give fair reasons of no-use could result in deregistration of the trademark.

Chamber Recommendation: The Chamber encourages the U.S. government to continue to monitor the implementation of amendments to the Trademark law to ensure they result in tangible measures to combat bad faith trademarks.

Trade Secrets and the Protection of Confidential Information

Index Stat: China scores behind Honduras and Colombia but ahead of Israel in the trade secrets and protection of confidential information indicators.

Regulatory Data Protection (RDP): As part of its accession to the World Trade Organization ("WTO"), China committed to providing a six-year period of RDP against unfair commercial use for clinical test and other data submitted to secure approval for products containing a new chemical ingredient. In practice, however, China does not have a mechanism to grant RDP, and relevant use criteria are inconsistent with China's commitments. For example, industry reports that China's data exclusivity is effectively illusory and does not preclude generic medicines from unfairly relying on or referencing the innovator's regulatory data. We thus strongly welcomed the draft NMPA measures on the Implementation of Drug Clinical Trial Data Protection (April 2018), which proposed up to six and 12 years of RDP for chemically synthesized medicines and therapeutic biologics, respectively. But progress stalled until March of 2025, when NMPA issued new draft measures that propose exclusivity measures between three and six years for both drug types. While these latest draft measures may put China a step closer to formally instituting RDP, we note that six-year exclusivity would be contingent on the drug not having been marketed anywhere else in the world.

- **Chamber Recommendation:** The Chamber urges the implementation of final measures that are consistent with international best practices and China's renewed commitment to provide RDP, as affirmed in the chapeau to Section C of Chapter One of the Phase One Trade Agreement. As China moves forward with implementing RDP, we believe it is critical that RDP is available to all medicines that are new to China, rather than new to the world. The Chamber looks forward to working with the U.S. government to ensure the effective implementation of RDP in China.

Enforcement

Index Stat: China receives its second poorest category score in the enforcement indicators, with an overall score of only 37%.

Intellectual Property Courts: The establishment of four specialized IP courts in Beijing, Shanghai, Guangzhou, and Hainai Free Trade Port and 27 IP tribunals around China, including one IP tribunal within SPC, has been encouraging to the Chamber and its members. We have identified various improvements and reform measures established through these IP courts and tribunals.

The Chamber notes that the court has a continuous fast-growing caseload, especially non-patent cases. The very purpose of the IP court may be somehow compromised as these courts at the intermediate level have no power to render final judgments in high-stake cases, including those judicial reviews of the Patent Review Board ("PRB") and the Trademark Review and Adjudication Board ("TRAB") decisions.

In January 2023, the Beijing IP Court announced it has closed 23,757 cases in 2022, with each judge closing 360 cases in average.[20] The Chamber hears concerns that the eagerness of closing cases, especially over trademark administrative litigation cases, may press judges to rush into judgments.

- Chamber Recommendation: While the creation of specialized IP courts was a positive development, the Chamber and its members urge continued monitoring of the IP courts cases and their outcomes.

Section E: Developing Market Profiles

ARGENTINA

Patent Rights and Limitations

Index Stat: Argentina ranks 49th out of 55 global economies in the patents rights Index category, the second worst of all Latin American economies and behind only Venezuela.

Patentability: In 2012, Argentina issued regulations that significantly restricted the patentability of chemical and pharmaceutical inventions, leading to the rejection of many applications. These regulations, which could extend to biological inventions, exclude patents for compositions, dosages, salts, esters, ethers, polymorphs, and more. The criteria go beyond the standard requirements of novelty, inventive step, and industrial application, conflicting with TRIPS and Argentina's bilateral treaty with the U.S. Despite recognition of these issues, no reforms were made. In 2015, further restrictions were imposed on biotechnological inventions, including those based on nucleotide or amino acid sequences, and genetically modified organelles. The Chamber was very glad to see that Argentina has made a commitment to address long-standing patentability criteria issues in the "Framework for an Agreement on Reciprocal Trade and Investment."

- Chamber Recommendation: To address the restrictive patent regulations, the Chamber recommends that the Argentine government align its patentability criteria with international standards, ensuring compliance with TRIPS and bilateral treaties. Specifically, Argentina should eliminate the guidelines to

allow patents for compositions, dosages, and many other important biopharmaceutical inventions. The Chamber asks that the U.S. government work with the Argentine government to prioritize resolution of this long-standing issues in full compliance with their commitments under the recently announced bilateral agreement.

Patent Backlog: Inventors and rightsholders face long delays in patent approvals in Argentina, with high-tech patent processing delays taking nearly a decade (in some cases, seven-to-eight years) due in large part to a substantial backlog of thousands of applications at INPI (with some estimates placing the number at approximately 21,000 in 2023-2024), despite efforts to streamline operations. These significant delays affect key industries, including biopharmaceuticals, chemicals, and biotechnology, hindering innovation and market entry.

The Argentine government has taken steps to alleviate the backlog, including expedited procedures for patents issued elsewhere, hiring more patent examiners, digitizing patent services with WIPO, and adhering to international cooperation and harmonization efforts. In July 2025, a decree was published to restructure INPI to modernize patent procedures and reduce the backlog. Despite these efforts, delays persist, with pharmaceutical and biotech patents still taking around 6.5 years for approval.

- **Chamber Recommendation:** The Government of Argentina should expand the Patent Prosecution Highway (PPH) mechanism to cover biopharmaceuticals and accede to the Patent Cooperation Treaty (PCT), which would streamline the patent filing and examination process. This would bring Argentina in step with over 150 different economies.

Patent Enforcement and Injunction Issues: Despite the patent law (Law No. 24,481, as amended in 2003) nominally providing for preliminary injunctions, the biopharmaceutical and life sciences industry finds obtaining injunctive relief to be time-consuming and confusing, posing a significant barrier to doing business in the country. Specifically, lengthy judicial process and inadequate damages awarded prove to be a major barrier to actualized relief.

- **Chamber Recommendation:** The Chamber asks that the U.S. government work with the Argentine government to meaningfully streamline the enforcement and judicial processes that deliver civil and criminal remedies, and to clarify the legal mechanisms intended to provide effective and expeditious relief.

Copyrights and Limitations

Index Stat: Argentina ranks 47th out of 55 global economies in the copyrights and limitations Index category – ahead of only Venezuela and Ecuador in the LatAm region.

Copyright Protection: On August 29, 2024, the Government of Argentina issued an executive decree (# 765/24) which created a highly concerning new exception to the exclusive right of communication to the public for authors, publishers, performers and producers to exclude the music played in hotel rooms and parties from performance rights licensing. Decree 765/245 will have a significant negative commercial impact on U.S. copyright holders as such licenses account for about 30 percent of total collections in the country. Moreover, as a result of the decree's imprecise drafting and the uncertainty regarding the scope of the new exception, the negative impact could be far greater. In addition, the decree was issued without any public consultation, and requests by copyright holders to the Government of Argentina to address concerns regarding the decree have been rebuffed. The decree is also inconsistent with Argentina's commitments to the United States with respect to the three-step test under international copyright treaties, including the WIPO Berne Convention and the WTO TRIPS Agreement.

- **Chamber Recommendation:** The Chamber asks that the U.S. government work with the Argentine government to resolve copyright holder concerns with Decree 765/245 and related measures.

Copyright Enforcement: Online piracy remains an issue in Argentina due to high rates of illegal downloading and streaming. Despite ongoing, sustained efforts to curb this activity, the country continues to struggle with rampant digital piracy, including torrent sites, stream-ripping, and linking sites. Argentina's internet penetration rate is one of the highest in the region, which exacerbates the problem by providing easy access to pirated content. The music industry has been heavily impacted, with Argentina having one of the highest music piracy rates globally. In 2024, Argentine law enforcement disabled access to over 50 websites offering access to pirated sports content as well as illicit content via IPTV boxes through the pan-American website "Magis". These positive efforts continued in 2025. In July of that year, access was disabled to the portal "Al AnguloTV" with the owner and proprietor arrested and taken into police custody. The website provided access to pirated live sports broadcasting.

Additionally, in early 2025, a major anti-piracy operation in Argentina dismantled a global criminal network offering illegal IPTV services to up to 8 million paying users and potentially reaching 20 million clients. The investigation, led by the Argentine judiciary with support from LALIGA, ALIANZA, NAGRAVISIÓN, Telecom Argentina, and the Motion Picture Association, targeted four office buildings in Buenos Aires.

Authorities uncovered numerous pirate platforms, including My Family Cinema, TV Express, and Weiv TV, which supplied TV boxes worldwide in markets like Argentina, Brazil, Mexico, and South Africa. The network operated through companies in multiple countries, with its hub in Argentina.

The regional rightsholders association Alianza played a pivotal role in supporting all of these local operations. The Chamber commends the Argentinian government's successful and increased efforts to address copyright-infringing content, and we encourage the government to continue to take steps to address online piracy.

- **Chamber Recommendation:** The Chamber urges Argentina to continue its coordinated, long-term antipiracy efforts at the federal and local levels to address the persistently high rates of online piracy, and consider facilitating private sector discussions on potential cross-industry cooperation to tackle online piracy more effectively. The creation of a specialized IP Prosecution Office and establishment of federal jurisdiction over copyright crimes would also improve the landscape.

Trade Secrets and the Protection of Confidential Information

Index Stat: Argentina ranks 51st out of 55 global economies in the trade secrets and the protection of confidential information Index category, behind only Venezuela, Brunei, Nigeria, and Algeria.

Regulatory Data Protection: Argentina has not fully met its obligations to protect the confidential data that biopharmaceutical innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine for marketing approval. Under Law 24,766, officials may use data submitted by originators to approve competitors' similar products, without providing protection against reliance or defining key terms like "dishonest" use.

- **Chamber Recommendation:** The Chamber recommends that the Argentine government implement regulatory data protection (RDP) in a manner consistent with international obligations. Specifically, RDP must protect against both disclosure of test data and, for a limited time, third-party reliance on the data. Further, RDP should be available for both small and biologic molecules.

Membership and Ratification of International Treaties

Plant Variety Protection / Plant Breeders' Rights - UPOV 1991: Argentina remains a party to the outdated UPOV 1978 Act and has not adhered to UPOV 1991, the international convention that establishes modern intellectual property rights for new

plant varieties by granting breeders exclusive rights over the production and commercialization of protected seeds. This has contributed to widespread unauthorized seed use in key crops, discouraging private investment in plant breeding and leading to reduced R&D, fewer competitors in the seed sector, and a slower adoption and launch of new seed technologies than seen in comparable agricultural economies. Accession to UPOV 1991 was briefly considered in early 2024 as part of the government's proposed "Bases Law," but the provision was ultimately withdrawn due to a lack of political consensus.

- **Chamber Recommendation:** The Chamber encourages the Argentine government to continue advancing toward accession to UPOV 1991 and to build the political consensus necessary to adopt implementing legislation that provides effective and enforceable plant variety protection. This would strengthen property rights for plant breeders, incentivize research and development, attract new seed technologies, and improve Argentina's competitiveness in agricultural innovation.

BRAZIL

Patents Rights and Limitations

Index Stat: Brazil ranks 42nd out of 55 economies in the patents rights Index category, ahead of only Argentina, Ecuador, and Venezuela in the Latin American region.

Patentability: In the Spring of 2021, the Brazilian Supreme Court declared that article 40 of the Industrial Property Law (Law nº 9279/96), which provided a minimum of "10 (ten) years for an invention patent and 7 (seven) years for a utility model patent" term, was unconstitutional and would no longer be available or applicable. The Court also required that the ruling be retroactively applied but only to granted patents in the biopharmaceutical and health related fields. The application of the ruling, which targeted one field of technology for disparate treatment, is a violation of article 27(1) of the TRIPS Agreement and established international principles of non-discrimination. In January 2023, a Supreme Court panel ruling found that rightsholders did not have the right to extend a patent term of protection beyond 20 years from filing, irrespective of the time of grant.

Numerous court cases have been filed but have not brought any further clarity on how the Supreme Court's ruling should be applied or interpreted. This continued in 2025 with conflicting outcomes in a case involving the sale of follow-on products to the molecule liraglutide by the Federal courts.

The outcome of the Court's decision is tangible. Brazil's patent examination backlog (more below), especially for biopharmaceutical patents far exceed the typical 2-4 years seen in other OECD economies. The lack of a Patent Term Adjustment (PTA) mechanism in Brazil further exacerbates the problem, as innovators are not protected from undue delays.

- **Chamber Recommendation:** The Chamber urges the Brazilian Government and lawmakers to immediately address these issues through mechanisms including, but not limited to, the introduction of a new statutory defined Patent Term Adjustment mechanism to compensate for unreasonable grant delays at INPI and further consider a patent validation mechanism with other major IP offices to improve predictability of IP protection in Brazil.

Patent Backlog and Review Delays: The National Institute of Industrial Property (INPI) has a backlog of patent applications approximately seven years depending on the field of technology (9.5 years for pharmaceutical applications); applications in the biopharmaceutical and ICT fields have traditionally been the most affected. The past few years have seen a growing level of commitment and efforts by INPI to address this backlog, but significant budget cuts to INPI proposed in 2022 threatened its ability to continue improvements. However, the Chamber was encouraged by an announcement to fill vacant positions at INPI to help reduce the backlog.

- **Chamber Recommendation:** The Chamber believes that continuing to hire much-needed personnel to tackle the backlog will be key to continuing Brazil's successful expansion of innovation. Further, the Chamber also strongly urges the Brazilian government to properly fund INPI so that it can meet its obligations to rightsholders and innovators alike.

Antitrust and Patent Licensing: Brazil's competition authority, CADE, has opened an ex officio investigation into alleged anticompetitive conduct related to standard essential patent (SEP) licensing. CADE raised concerns that the alleged practices, which include discriminatory pricing and refusal to license on a territorial basis, may distort competitive conditions in Brazil. These developments mark a shift from CADE's past treatment of SEP disputes as purely private matters and reflect a growing willingness to assert antitrust oversight in a way that could distort global negotiations and undermine incentives for high-value R&D.

- **Chamber Recommendation:** The US government should caution against the Brazilian government and CADE from intervening in purely private licensing disputes related to SEPs. To the extent CADE believes intervention is warranted, it should be undertaken in a manner that supports balanced, evidence-based SEP licensing practices, avoids regulatory overreach that could chill innovation incentives, and preserves predictable, globally aligned frameworks for the licensing of SEPs. Furthermore, any intervention in SEP licensing should be proceeded by a market consultation with industry participants.

Retaliatory Measures: 2025 saw the introduction of anew statutory law and regulatory powers authorizing the Brazilian Government to override and suspend the protection of existing IP protection as a "response to unilateral measures adopted by a country or economic bloc that negatively impact Brazilian international competitiveness". Together, Law 15,122, enacted in April 2025, and Decree 12,551, issued in July 2025, grant the executive branch sweeping powers to "suspend commercial, investment and concessions obligations relating to intellectual property rights". While the law and regulatory decree define and include requirements of holding public consultations prior to the issuing of any measures under the law (including with the private sector), the potential negative impact on rightsholders around the world through the potential use of these powers is immense.

- **Chamber Recommendation:** The Brazilian Government should refrain from implementing measures under Law 15,122 and Decree 12,551, as suspending IP protections in retaliation for unrelated foreign actions would undermine legal certainty, deter investment, and damage Brazil's reputation as a reliable trade partner. Instead, Brazil should pursue diplomatic and multilateral solutions that safeguard competitiveness without compromising intellectual property rights or international obligations.

Copyrights and Limitations

Index Stat: Brazil ranks 33rd out of 55 economies in the copyrights, related rights, and limitations Index category.

Copyright Law Reform: Bill PL 2370/2019 and Bill 4968/2024 introduce additional remuneration rights into the digital streaming market. Specifically, these bills introduce an additional remuneration obligation for the copyright and related-right holders of works and sound recordings used by streaming services. In addition, this problematic obligation would be subject to onerous penalties, mandatory collective

management, and contract override – thereby eviscerating underlying free market contracts between rights holders and digital service providers (DSPs). Bill PL 2370/2019 also introduces considerable confusion regarding the scope of copyright and related rights protections for broadcasting and public performance by suggesting that the separate right of making available (ie, interactive uses) is equivalent to public performance and therefore subject to mandatory collective management by ECAD, thereby downgrading the exclusive right to a mere right of remuneration. Bill 4968/2024 creates its own considerable confusion through its deficient definition of broadcasting that departs from the WIPO Internet Treaties. Moreover, it was introduced into the Senate at the very end of its 2024 session without consultations or impact assessment.

Chamber Recommendation: The Chamber recommends that Brazil should also:

- Reject proposals to introduce additional remuneration rights into the digital streaming market, such as Bill PL 2370/2019 and Bill 4968/2024; These initiatives are consequential as they inspire foreign copycat bills proposing duplicative payments by streaming companies, such as the problematic "Tommy Rey" bill (No. 17,499-24) in Chile, which the Chamber recommends should be rejected as well.

- Ratify and faithfully implement the WIPO Internet Treaties, including making the necessary clarification of the producers' making available right in the Copyright Law;

- Reject the introduction of a definition/scoping of communication to the public and/or public performance that departs from international standard, and, in particular, those that would undermine the exclusive nature of rights related to interactive exploitations and the freedom to exercise it individually; and

- Reform its problematic collective rights management system, including by removing the default one-stop-shop collective management system for broadcasting and public performance, which is managed by ECAD. ECAD should be subject to good governance rules, in particular to guarantee fair and balanced representation in ECAD's governing bodies of all rights holders whose rights are managed by ECAD. ECAD should also cease its policy with respect to music DSPs, whereby ECAD has endeavoured to impose additional payments for neighbouring rights on interactive uses of phonograms without a mandate or clear legal basis.

Copyright Enforcement: The 2014 Marco Civil da Internet law (Law No. 12,965) section 3 and articles 18–20 established a broad safe harbor provision for internet service providers (ISPs) relating to third-party infringement of digital content. ISPs are required to act and make infringing content unavailable once a court order has been issued unambiguously finding that the content is infringing. Given that the Brazilian justice system generally suffers from long processing times and high costs of litigation, rightsholders have called for processes allowing the expeditious removal of copyright infringing content. This has now fundamentally changed with the Supreme Court's decision and reinterpretation of the constitutionality of Law No. 12,965. In June, the Supreme Court issued a precedent setting ruling defining responsibilities and legal liability vis à vis third-party content, including illicit and copyright infringing content. Up until this judgment, Brazil did not have a formalized and comprehensive mechanism in place with clear lines of responsibility for online infringement akin to a notice-and-takedown system used in other economies. This ruling comes as part of a broader effort to improve the national copyright environment.

Additionally, the Chamber strongly supports the dedicated enforcement operations to combatting copyright-infringing content through "Operation Copyright," an initiative by the Brazilian Federal Police to tackle copyright piracy, and "Operation 404" – now in its seventh iteration and expanded scope in 2025. The Chamber also applauds the Brazilian National Telecommunications Agency (Anatel) for their dedicated campaign against illicit IPTV set-top boxes. Anatel's efforts to target both the physical devices and their streaming applications online resulted in the seizure of millions of illegal set-top boxes and disabled access to hundreds of illicit access points.

Additionally, the Chamber welcomes Law 3,696/2023 which gives the National Cinema Agency (Ancine) the power to "determine the suspension and cessation of unauthorized use of protected Brazilian or foreign works."[10] In September, Ancine announced that it would be applying its new powers in two pilot applications, disabling access to the dissemination of audiovisual content and live sporting events. Finally, the Chamber also applauds the work of Brazilian enforcement authorities that have been active in tackling cases against locally operated "streaming manipulation" resellers. Brazilian authorities should also take enforcement actions against popular infringing mobile apps, including MP3 download and stream ripping apps.

- **Chamber Recommendation:** The Chamber recommends that the U.S. government and other regional partners continue their successful collaborative

[10] See Presidency of the Republic, General Secretariat, Deputy Chief for Legal Affairs Decree No. 10,543: https://www.planalto.gov.br/ccivil_03/_ato2019-2022/2020/decreto/D10543.htm

actions with the Brazilian government to ensure adequate and effective copyright protection and to ensure that copyright enforcement efforts, such as those from the National Council to Combat Piracy and Crimes against Intellectual Property (CNCP), Directorate of Integrated Operations and Intelligence (DIOPI), and Cyber Gaeco have the resources and local government support to combat all forms of copyright piracy more effectively throughout Brazil.

Trademarks Rights and Limitations

Index Stat: Brazil ranks 39th out of 55 global economies in the trademark rights Index category.

Trademark Enforcement: The sale of counterfeit goods has flourished in many Brazilian cities due to lack of criminal prosecution and coordinated enforcement. In recent years, however, the Chamber has observed successful enforcement actions through a taskforce of the City Hall of São Paulo, Customs, Federal Revenue Service (DIREP), and State Police.

Most recently, in September 2025, São Paulo's joint enforcement team, including collaboration from City Hall, Receita Federal, DIREP, and state police, initiated a widespread raid that confiscated more than 17,000 fake goods that arrived via e-commerce and small parcel shipments, underscoring the need for sustained collaboration and public awareness initiatives.

- **Chamber Recommendation:** To support these efforts, the Chamber recommends that the National Congress approve legislation that would bring criminal penalties and fines for trademark infringement in line with those already established for copyright infringement, as well as legislation that allows for the *ex officio* seizure and destruction of infringing goods—which would represent a major advancement in Brazil's enforcement regime.

Trade Secrets and the Protection of Confidential Information

Index Stat: Brazil ranks 37th out of 55 global economies in the trade secrets Index category and is in the bottom tier of Latin American economies.

Regulatory Data Protection: Brazilian Law currently does not provide regulatory data protection for pharmaceuticals made for human use. The lack of regulatory data

protection is not consistent with Brazil's obligations under the TRIPS Agreement. Moreover, the lack of an appropriate protection term for data supporting the marketing approval of pharmaceuticals for human use exacerbates the challenges regarding unpredictability of IP for biotechnology companies operating in Brazil. However, industry was encouraged when, in May 2024, Brazil's Senate Committee on Science, Technology, Innovation, and Informatics held two public hearings focused on the implementation of Regulatory Data Protection (RDP) for human-use pharmaceutical products.

- **Chamber Recommendation:** The Chamber encourages the U.S. government to work further with the Brazilian government, including the Brazilian Health Regulatory Agency (ANVISA), and the National Data Protection Authority (ANPD) to ensure adequate and effective regulatory data protection for pharmaceuticals.

Market Access

Index Stat: Brazil ranks 38th out of 55 global economies in the commercialization of IP assets and market access Index category, ahead of only Colombia, Ecuador, and Venezuela.

Local Content/Forced Localization: Enacted Legislation alters Brazil's Pay-TV Law to reinstate local content requirements until 2038, which directly affect creative content and ICT sectors. The Pay-TV Law obligates "qualified channels" to air at least 3.5 hours of Brazilian programming per week. It also requires that half of the content originate from independent local producers and that one-third of all qualified channels included in any PAY-TV package must be Brazilian. These localization policies limit the content that Brazilian consumers can access and has an unfortunate effect of increasing illegal consumption of content.

Additionally, theatrical quotas were renewed until 2033 through Law 14.814/2024, which reinstated Brazil's traditional screen quotas and include an obligation on theaters to exhibit a minimum percentage of Brazilian works, in an amount proportional to the number of screens in each complex and requires annual presidential decrees to define detailed rules. A different amount of work must also be shown simultaneously, also proportional to the number of screens, and complexes with 3 or more screens cannot exhibit the same work in over 50% of the screenings in a day. This screen quota is designed to prevent large theatrical releases from playing

continually and limits consumer choice; thereby pushing consumers toward illegitimate content sources.

- **Chamber Recommendation:** The Chamber encourages the U.S. government to work with the Brazilian government to introduce policies that help stimulate innovation and creativity across the local content sectors — through industry training programs and tax incentives — rather than local content requirements.

COLOMBIA

Patents Rights and Limitations

Index Stat: Colombia ranks 31st out of 55 global economies in the patents rights Index category.

Pharmaceutical Patent Enforcement: The U.S.-Colombia FTA requires a patent linkage system, but current provisions lack key elements and effective enforcement. The National Institute of Drug and Food Surveillance's (INVIMA) 2013 mechanism, while not required or obligated to notify patent holders, creates an informational system for patent holders of potentially infringing applications through implementing regulations, but patent holders must pursue prosecution themselves. Colombia does not provide legal grounds for litigation based on drug registration or suspension of marketing authorization, leading to the approval of follow-on products despite existing patents. This situation undermines patent protection and market exclusivity for original drug developers.

- **Chamber Recommendation**: The Chamber urges the U.S. to work with Colombia to align their patent enforcement framework with FTA commitments.

Compulsory Licenses: In June 2023, Colombia's Ministry of Health and Social Protection (MSPS) issued Resolution No. 881 to explore compulsory licensing for an HIV treatment containing DTG due to rising infections and high costs. In October, Resolution No. 1579 declared it in the public interest to allow compulsory licensing for Patent No. 07115501A, emphasizing Colombia's legal obligations and the failure of voluntary measures. The license will remain valid until April 28, 2026, with financial compensation set at 3.5% of the generic product's value. Five entities, including the MSPS and four private companies, applied for the license. While the private sector companies have yet to produce the patented medicines due to their lack of manufacturing capabilities, MSPS obtained a CL for governmental use and there is public information that the first batches of the purchased generic product had been distributed within the Colombian health system.

Throughout 2025, credible reports emerged that the Colombian Ministry of Health was preparing to issue a resolution to declare a hepatitis C molecule patented by an American company as a matter of public interest (DPI), clearing the path for the grant of compulsory licenses. On separate occasions in 2025, the Colombian Ministry of Commerce communicated written assurances to the U.S. government and a bilateral industry coalition, respectively, that no active compulsory license initiative was under consideration. Notwithstanding these assurances, the Ministry of Health has continued to vocally promote its interest in issuing a DPI.

Colombia's compliance with TRIPS Agreement obligations regarding the issuance of the compulsory license is questioned under Articles 31(h) and 31(a). Article 31(h) requires adequate remuneration for patent holders, but the stipulated payment of $0.11 Colombian pesos per milligram of DTG may be insufficient, failing to reflect the economic value of the compulsory license (CL). Additionally, Article 31(a) mandates individual merit consideration for CLs, yet Colombia's focus on reducing costs for DTG, particularly for Venezuelan migrants, suggests a broader cost-saving motive rather than a case-by-case assessment, potentially undermining the spirit of the TRIPS Agreement.

Subsequently, the Colombian Minister of Health has publicly indicated considerations to use CLs or the threat of CLs to negotiate prices despite existing access policy options already available that would not also maintain IP protection. Compulsory licenses create a harmful global precedent that IP rights will be discretionary when a government no longer wishes to pay the cost previously agreed to with the innovative company. Innovator firms seeking to expand access to new markets require the commercial certainty that their products will be protected under that government's regulatory and legal framework. Unilaterally reducing prices in the name of meeting the budgetary constraints of a universal health care system undermines investor confidence necessary to produce new cures.

- **Chamber Recommendation:** The Chamber encourages the U.S. government to work with the Colombian government to help enable access to the newest innovative treatments while complying with its TRIPS Agreement and FTA obligations and reject the use of price negotiations to undermine IP protections.

Copyrights and Limitations

Index Stat: Colombia ranks 38th out of 55 global economies in the copyrights and limitations Index category.

Copyright Enforcement: Colombia made significant strides to improve copyright enforcement with a landmark judgment in May 2024 that disabled access to several infringing websites, including "SkyLatinaTV," and introduced a dynamic element for updating orders without restarting legal proceedings. This was followed by a September order disabling access to "Latinos IPTV" and "Redcol IPTV." These judgments affirmed the right to injunctive relief online and streamlined the process for updating enforcement actions. The orders build on a 2021 case where the national copyright office DNDA disabled access to infringing material, including unauthorized publication of a scientific article and unauthorized broadcasting by IPTV Colombia Premium. Reports suggest that these efforts continued successfully in 2025. These developments highlight Colombia's evolving approach to copyright protection and enforcement.

- **Chamber Recommendation**: The Chamber urges the U.S. government to work with its Colombian government counterparts in continuing to provide adequate and effective protection of copyright and to robustly combat copyright piracy online.

Trade Secrets and the Protection of Confidential Information

Index Stat: Colombia ranks 23rd out of 55 global economies in the trade secrets and the protection of confidential information Index category.

Regulatory Data Protection: Decree 2085/2002 provides for a five-year period of regulatory data protection for both pharmaceuticals and agrochemicals in Colombia. Although less than international best practices, this is in line with Colombia's commitments under the U.S.-Colombia FTA. However, there are no additional protections for subsequent modifications, label extensions, pediatric indications, new pharmaceutical forms, and, to some uncertain extent, biologics.

- **Chamber Recommendation:** Colombia should extend regulatory data protection to cover subsequent modifications, label extensions, pediatric indications, new pharmaceutical forms, and biologics. This enhancement would align Colombia's framework with international best practices.

Market Access

Index Stat: Colombia ranks 48th out of 55 global economies in the commercialization of IP assets and market access Index category, ahead of only Ecuador and Venezuela.

Pharmaceutical Procurement: In 2024, the National Commission on Drug and Medical Device Prices (CNPMDM) issued Circular 18 with the new drug price

regulation methodology. It maintains the international comparison of prices with drugs (active ingredients and pharmaceutical forms) that have Health Registration in Colombia or that are produced by the same laboratory. It incorporates as a new control parameter, the National Reference Price (PRN), which will be established at the 90th percentile of the last year's data. Additionally, Circular 19, also issued in 2024, updated the maximum sales prices for medicines already subject to the direct price control regime.

In this way, the control price will be established for monopolistic products at the lowest price between the PRI and the bidder's price, and in the case of competitive markets, at the lowest price between PRI and PRN. New reference countries were added: Germany, Greece, India, Italy and South Africa, but China was not included.

Finally, the price adjustment parameter was modified and from now on it will be the exchange rate and not inflation.

On December 26, 2025, a draft circular was published for public consultation to amend, and update the maximum sale price of medicines subject to direct price control. The draft defines the relevant markets that comprise Group A and prioritizes those related to medicines for the treatment of orphan diseases, HIV, vital non-available medicines, and/or high-cost medicines, given their impact on public health and the financial sustainability of the General System of Social Security in Health (SGSSS). Additionally, it updates five hundred thirty-four (534) relevant markets using the nominal daily exchange rate of the reference countries' currencies, expressed in COP and published by Colombia's Central Bank (Banco de la República). The simple average of the percentage variations in these exchange rates is –5.78% for the reference period January 1 to December 31, 2024.

The circular will take effect two (2) months after its publication in the Official Gazette.

- **Chamber Recommendation:** The Chamber urges the CNPMDM to adopt best practices and internationally agreed standards for pricing, and more specifically the need for comparability with products registered in Colombia and the inclusion of countries with favorable innovation frameworks.

INDIA

Patents Rights and Limitations

Index Stat: India ranks 47th out of 55 global economies in the patents rights, and limitations Index category.

Patentability: Indian patent law imposes an additional requirement under Section 3(d) beyond novelty, inventive step, and industrial applicability. This "fourth hurdle" limits patentability for certain pharmaceutical and chemical inventions unless the applicant proves enhanced therapeutic efficacy over the closest known compound. Courts have consistently interpreted Section 3(d) to deny protection for new forms and new uses of known substances. As a result, many patents have been rejected or revoked over the years. In 2025, the Indian Patent Office revoked protection for the heart medication Entresto under this provision. This additional requirement is inconsistent with TRIPS Article 27, which does not include such exclusions, and conflicts with the non-discrimination principles of TRIPS and WTO rules. Additionally, Section 3(i) excludes method of treatment claims, discouraging U.S. biotechnology companies from entering the Indian market.

Other patentability requirements in India are also out of sync with global norms and demand unreasonably high standards with frequent reliance on impermissible hindsight. It has become routine that a pharmaceutical compound invention is found patentable in all other major jurisdiction including the US, EU, Japan and China, but found unpatentable or invalid in India.

- **Chamber Recommendation:** To align with TRIPS requirements and encourage biopharmaceutical innovation, it is recommended that India amend Section 3(d) of the Patents Act to remove the "enhanced efficacy" criterion and ensure non-discriminatory patentability standards. Additionally, revising Section 3(i) to allow method of treatment claims would more fairly reward U.S. biotechnology innovation and create a level playing field for U.S. companies in the Indian market, while fostering the availability of life-saving products for Indian patients. Finally, India needs to re-adjust its overall patentability standards to align with global norms and become more diligent to prevent the use of impermissible hindsight when assessing inventive step.

Price Controls: At the beginning of 2019, the Ministry of Chemicals and Fertilizers provided for an exemption under DPCO 2013, Paragraph 32 to orphan medicines and patented medicines from price controls for a period of five years "from the date of commencement of its commercial marketing by the manufacturer in the country." While this is a welcome step, it keeps the door open for price controls—potentially even compulsory licenses — to be imposed on patented medicines after the five-year mark. Just one month later, the National Pharmaceutical Pricing Authority (NPPA) kicked off a pilot program to cap trade margins on 42 oncology medicines — some of which were protected by patents. As of December 29, 2023, ceiling prices of 131 anti-cancer formulations (including palliative care), have come into effect.

In a notable decision recently, the NPPA, after its full Authority meeting on October 8, 2024, invoked extraordinary powers under Para 19 of the DPCO, 2013, to approve a 50% increase in the ceiling prices of 11 scheduled formulations of 8 drugs, citing larger public interest.

Policies like this frustrate the ability of innovative companies to further invest in life-saving treatments. The market price of a medicine does not reflect solely the cost of developing that medicine — they reflect a company's multi-year research and development pipeline, all the related costs of sustaining a corporate infrastructure, and factoring in a competitive return on an oftentimes risky investment.

- Chamber Recommendation: To encourage continued investment in life-saving treatments, it is recommended that India extend the exemption from price controls for orphan and patented medicines beyond five years and avoid imposing compulsory licenses. Additionally, reconsidering the cap on trade margins for oncology medicines would better reflect the true costs of pharmaceutical innovation and support the sustainability of biopharmaceutical advancements.

Patent Term Restoration: Current Indian patent law provides for a 20-year term of protection from the filing date, but it does not include provisions to compensate for delays in the patent prosecution process. Patent term restoration provides additional patent life to compensate for the time lost during clinical trials and the regulatory approval process.

- Chamber Recommendation: To enhance the protection of pharmaceutical innovations, the Chamber recommends that India introduce a patent term restoration mechanism. This would compensate for time lost during clinical trials and regulatory approval processes, aligning India's patent system with international standards, and encouraging further investment in drug development.

Patent Opposition: In 2024, India introduced notable improvements to its patent opposition proceedings, including defined timelines and granting the Controller General discretion to accept opposition filings based on a "prima facie" case. The updated Patent Rules also introduced filing fees for opponents and changed the Form 27 filing requirement from annual to every three years, removing the need to report the approximate value of the patented technology. Unfortunately, most of these improvements have not been fully implemented, and many patent applicants are still facing lengthy delays caused by duplicative or frivolous pre-grant oppositions, which delays often effectively eradicate any meaningful patent term.

- **Chamber Recommendation:** The Chamber recommends that the Government of India fully implement its 2024 rule changes and continue to build on the positive momentum of 2024 to streamline the patent opposition mechanism and focus on tangibly reducing prosecution timelines and eliminating frivolous or repeated opposition filings.

Patent Linkage: In May 2024, the Calcutta High Court issued a judgment in which the petitioner challenged the vires of Section 53 of the Patents Act. The court reiterated that patent linkage would only be granted if the patentee could demonstrate that the remedies under the Patents Act, 1970, were insufficient to address their legal issues.

- **Chamber Recommendation:** India must implement a patent enforcement system that provides notice to patent holders when third parties apply for marketing approval of follow-on products, gives patent holders adequate time and opportunity to seek provisional remedies prior to the marketing of the allegedly infringing products, and facilitates timely resolution of patent disputes prior to the expiration of the provisional remedies.

Biological Diversity: The Biological Diversity Act, 2002, as amended by the Biological Diversity Act, 2023, and the new Biological Diversity Rules, 2024, introduces significant changes that impact the process of seeking IP protection for inventions based on Indian biological resources. One of the key changes is the requirement to obtain prior approval before seeking IP protection for any invention derived from research or information, including Digital Sequence Information (DSI), on Indian biological resources. Additionally, entities must register and/or seek prior approval before sharing or transferring research results related to an Indian biological resource or associated traditional knowledge with a foreign entity. This requirement applies to research use, commercial use, and obtaining IP rights. Foreign entities must also inform the National Biodiversity Authority about the grant of a patent application using an Indian biological resource, including DSI. These new requirements impose additional burdens on researchers and innovators, which were not contemplated by the TRIPS agreement.

- **Chamber Recommendation:** The Chamber recommends that the National Biodiversity Authority streamline the approval process by implementing a fast-track system for research and innovation projects and establish clear guidelines to ensure transparency and efficiency. Additionally, fostering international collaborations through bilateral agreements could help align the new requirements with global standards, reducing the burden on researchers and innovators.

Indian Patent Office Improvements: The Indian Patent Office has been actively working on reducing its backlog and enhancing internal efficiencies. A notable reduction in the time to grant patents after the submission of examination requests has been observed. In 2023-24, the Indian Patent Office granted the highest number of patents in any given year.

- **Chamber Recommendation:** The Indian Patent Office should continue to expand its capacity and further reduce the time required to review patent applications.

Court Enforcement of Patent Rights: The establishment of IP Divisions in the Delhi, Chennai, and Kolkata High Courts is a positive development. The IP Division of the Delhi High Court has issued several judgments that have strengthened the enforcement of patent holders' rights. It has also worked to expedite trials by penalizing defendants found guilty of using delaying tactics and has issued orders to improve the quality of examinations at the Indian Patent Office. Despite these improvements, India's patent litigation timelines remain lengthy and unpredictable across much of the country. According to publicly reported judicial data, the average duration of a patent infringement trial in India is approximately 18 months in fast-track forums such as the Delhi High Court, but trial duration varies widely in other jurisdictions, where multi-year pendency remains common, and cases can extend well beyond three to five years before final resolution. These extended timelines create significant uncertainty for innovators, as prolonged infringement proceedings undermine the value of exclusivity and delay injunctive relief. These delays erode the commercial viability of patented technologies, particularly in fast-moving sectors such as semiconductors, pharmaceuticals, and advanced communications.

- **Chamber Recommendation:** To improve predictability and enhance the deterrent value of India's patent enforcement system, the Chamber encourages the U.S. government to urge India to adopt nationwide judicial-efficiency reforms modeled on the Delhi IP Division. Strengthening judicial capacity and institutionalizing expedited procedures across jurisdictions would help ensure that patent holders have access to timely and effective remedies consistent with India's obligations under the TRIPS Agreement.

Copyrights and Limitations

Index Stat: India ranks 37th out of 55 global economies in the copyrights and limitations Index category.

Copyright Law Reform: In 2012, Indian law was amended to establish a statutory license under Section 31D of the Copyright Act for the use of musical works and

sound recordings for radio and TV broadcasting. In 2016, the Indian Government issued a memorandum outlining its plans to broaden the Section 31D statutory license to include Internet transmissions, such as streaming. Following proposed amendments by the Indian Parliament to expand Section 31D to include Internet transmissions, two decisions by the Indian courts confirmed that Section 31D applies only to radio and TV broadcasting and does not apply to Internet transmissions. On August 21, 2024, the Government of India formally withdrew the 2016 Memorandum. The Chamber strongly welcomes this important action by the Government of India and urges that any renewed calls for statutory licensing of copyright protected works and sound recordings to be extended to Internet transmissions be rejected.

Chamber Recommendation: The Chamber urges the U.S. government to work with its Indian Government counterparts to reject any renewed calls for statutory licensing of copyright protected works and sound recordings to be extended to Internet transmissions. Additionally, The Government of India should also engage in the following copyright law reforms:

- Improve the inadequate online liability framework and enforcement mechanisms, including by providing clearer liability for UUC services that store and make available users' uploaded content alongside notice and stay down;

- Resolve concerns regarding collective management, including the lack of registration of PPL India and sub-par tariffs related to radio broadcasting;

- Refrain from adopting any overbroad exceptions to copyright and remove any existing overbroad exceptions;

- Extend the term of protection for sound recordings (currently only 60 years); and

- Strengthen protections against the circumvention of technical protection measures.

Copyright Enforcement: India has seen a rise in online piracy with the increase in broadband and mobile phone use, but its laws on notice and takedown systems remain unclear. Despite this, rightsholders have found success in defending their copyrights through injunctive relief, with courts issuing orders to disable access to infringing websites since 2012. The Delhi High Court's "dynamic" injunctions, which address mirror sites, have been particularly effective and are becoming a global best practice. In 2023, the Delhi High Court issued its first orders against stream-ripping websites and future audiovisual content infringement. The government has also introduced the Cinematograph (Amendment) Bill, 2023, to combat film piracy with

stricter penalties. Additionally, the Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Rules, 2021, include provisions related to IP rights, though their interaction with existing laws remains uncertain.

India should expand and enhance the coordination of law enforcement authorities dealing with IP enforcement. India should also combat the prevalence of pirated content on UUC video platforms and apps, which are extremely popular. These services claim immunity from piracy enforcement under unclear safe harbor provisions to avoid obtaining a license on fair terms (or at all), and rightsholders must report individual infringements at scale. These unlicensed UUC services must be held accountable under Indian law. Further, we commend the Maharashtra Cyber Police for its positive collaboration but underscore the need for the expansion and coordination of law enforcement authorities dealing with IP enforcement. Finally, copyright holders continue to face a lack of compliance to blocking orders. Accountability measures should be considered to ensure compliance with legal mandates.

- **Chamber Recommendation:** The Chamber recommends that the Government of India continue leveraging dynamic injunctions and strengthen legal frameworks like the Cinematograph (Amendment) Bill, 2023, to impose stricter penalties. Additionally, clarifying the interaction between the Information Technology Rules and existing copyright laws will help ensure better enforcement and protection of intellectual property rights. Finally, the Chamber recommends that the above-listed concerns are addressed in order to robustly combat copyright piracy online.

Trade Secrets and the Protection of Confidential Information

Index Stat: India ranks 49th out of 55 global economies in in the trade secrets and protection of confidential information Index category.

Regulatory Data Protection: India is currently not in compliance of its TRIPS Article 39.3 obligations in that is does not provide a specified term of protection for regulatory data submitted by for marketing approval within which generic copies cannot be approved. Additionally, in India, if a pharmaceutical product has already been approved by a regulatory authority in another country, regulatory authorities often require limited clinical data, and when considering approval for generic or biosimilar products approved in another country, industry has reported instance in which Indian authorities have waive the data submission requirement entirely.

Additionally, the Law Commission of India, in its report dated March 5, 2024, recommended the enactment of independent legislation to safeguard trade secrets.

The Bill defines what constitutes a 'trade secret', introduces an alternative adjudication mechanism through Commercial Courts for trade secret misappropriation, and outlines exceptions for whistleblower protection, compulsory licensing, government use, and matters of public interest. However, the Commission categorically stated that data exclusivity should not fall within the scope of the proposed trade secrets legislation

- **Chamber Recommendation**: To align with TRIPS Article 39.3 obligations, India should enhance its IP framework and provide regulatory data protection to ensure the protection of innovators' data submitted for marketing approval. This includes requiring comprehensive clinical data submissions for all pharmaceutical products, regardless of prior approvals in other countries, and eliminating waivers for generic or biosimilar products. RDP must be granted solely based on data submitted to CDSCO, independent of regulatory filings in other jurisdictions, patent status, or global launches.

Enforcement

Index Stat: India currently ranks 44th out of 55 global economies in the enforcement Index category.

Effective Border Measures and Remedies: Under Indian law, the Central Board of Excise and Customs handles IP rights enforcement, with the authority to confiscate and prohibit counterfeit or pirated goods. However, customs authorities lack the training and resources needed for effective enforcement. The process for rightsholders to register copyrights and trademarks with Customs is complex and costly, and they must file a civil action to complete the seizure process if the importer does not abandon the goods. Additionally, rightsholders must secure substantial bank guarantees, which are burdensome for U.S. companies operating in India.

- **Chamber Recommendation**: The Chamber recommends that India invest in training and resources for customs authorities. Simplifying the registration process and reducing costs for rightsholders to register copyrights and trademarks with Customs would improve efficiency. Additionally, revising the requirement for substantial bank guarantees would alleviate the burden on companies, particularly those from the U.S., and streamline the seizure process.

INDONESIA

Patents Rights and Limitations

Index Stat: Indonesia ranks 46th out of 55 global economies in the patent rights and limitations Index category.

Patent Law and Patentability: Indonesia enacted a new Patent Law (Law No. 65/2024) with amendments in October 2024, reflecting the positive changes stipulated on the Job Creation Law and broaden the scope of patentable products and technologies, however, some stipulations on compulsory licensing remain overly broad, enabling government use of patent for "public interest" and if product is "expensive."

The amendments also include potentially important changes to patentability requirements. Specifically, the amendments have eliminated the heightened efficacy requirement targeting biopharmaceutical products which had outlawed second use claims and so-called incremental innovation.

In addition, the Omnibus Job Creation Bill that came into effect in 2023, included changes to article 20 of the 2016 Patent Law which makes the granting of a patent conditional on localizing manufacturing and/or R&D in Indonesia. Although the final passed version of the Omnibus law did not eliminate the working requirement, article 107(2) defined the use and 'implementation' of patents in Indonesia as including domestic creation, importation, or the licensing of the relevant invention. This version of the Law remains in effect today.

In a positive development for rightsholders, the amendments to the Patent Law clarify that innovations where software plays a role in achieving a technical solution or effect can be patented. However, for Article 20 on the use of the patent, the new law stipulates that the holder of the granted patent must submit a statement of patent implementation in Indonesia to the patent office by the end of each year. While the Chamber is disappointed that Indonesia maintains a working requirement, it will be paying close attention as to whether if importation and licensing is truly satisfying the working implementation requirement.

- **Chamber Recommendation:** To address the concerns with Indonesia's new Patent Law, the Chamber recommends the revision of the provisions on government use of patents for imported pharmaceutical products to ensure they align with international patent standards and determine, again, if importation and licensing is truly satisfying the working implementation requirement. Additionally, the Indonesian government should narrow the criteria for compulsory licensing to align with obligations under the TRIPS Agreement. This will help balance the protection of patent holders' rights with the need for public access to essential medicines. In relation to the new requirement that the holder of the granted patent must submit a statement of

patent implementation in Indonesia to the patent office by the end of each year, the Chamber encourages the U.S. government to work with the Indonesian Government to ensure that the new requirement minimizes the compliance burden and that the implementation details are promptly released to rightsholders.

Compulsory Licensing: In 2023, the Government enacted the Health Omnibus Law (Law No. 17) which includes provisions related to compulsory licensing. Articles 314 and 326 of the Law reiterate the Government's responsibility, and right, to override patent protection using compulsory licenses to "ensure the sustainability of the supply chain." The new Health Omnibus Law also strengthens the long-standing drive to localize biopharmaceutical production. These developments further weaken what was already a highly challenging national IP environment for biopharmaceutical rightsholders.

Additionally, the amendments to the Patent Law also include changes to relevant articles relating to compulsory licensing and government use. The insertion of article 84A vests considerable authority to override duly granted patent rights to the national competition authorities (the Business Competition Supervisory Commission, KPPU). Specifically, the article states that the standard process for considering and issuing a compulsory license can be exempted if the KPPU finds "the implementation of a patent is proven to have resulted in monopolistic practices and/or unfair business competition."

- **Chamber Recommendation:** The Chamber believes that compulsory licenses are a true measure of last resort, and the Government should focus on voluntary arrangements with individual companies as the need for new products arise. Furthermore, the Chamber urges the U.S. government to work with the Indonesian government to amend the regulations to bring the compulsory licensing requirements in line with international best practices.

Copyrights and Limitations

Index Stat: While Indonesia is 51st out of 55 in the overall Index rankings, Indonesia ranks 35th out of 55 in copyright indicators. Notwithstanding this progress, online piracy continues to present a challenge for rightsholders.

Copyright Enforcement: Indonesian law currently allows for a 25-year reversion of rights mechanism, which interferes with the freedom of contract and the legitimate enjoyment of producers' rights, and rights acquired by rightsholders. Indonesia also has, as of 2025, failed to resolve long-standing concerns regarding its highly-

problematic collective management system. Complicating rights for the creative industry, Indonesia only has a term of protection for sound recordings at 50 years.

- Chamber Recommendation: Indonesia should abolish its 25-year reversion of rights mechanism. Indonesia should also resolve long-standing concerns regarding its highly problematic collective management system. It should also extend the term of protection for sound recordings. Indonesia should also refrain from adopting any overbroad exceptions to copyright and remove any existing overbroad exceptions. Certain exclusive rights should be clarified to ensure adherence to international treaties, and the restricted list of uses of sound recordings that require payment of royalties should be removed. Finally, Indonesia should also make much-needed improvements to its inadequate online liability framework and enforcement mechanisms. The Chamber urges the U.S. government to work with its Indonesian government counterparts to address the above-listed concerns in order to provide adequate and effective protection of copyright.

Injunctive-Style Relief: Since 2015, the Directorate General of IP has operated an online notification system whereby rights-holders can file a notice of infringement and request for the disabling of access to suspected websites, which has helped legitimate services operate in the Indonesian marketplace. Unfortunately, the scale of piracy in Indonesia remains a challenge, with sites like IndoXXI, LK21, and Nonten continuing to pervasively promote pirated content online by domain hopping to avoid the government's injunctive-style relief requests.

- Chamber Recommendation: The Chamber encourages the government of Indonesia to consider updating its regulations to allow for the dynamic blocking of such mirror sites. The Chamber also hopes that the U.S. government will work with the Indonesian government to improve the capabilities of law enforcement agencies to effectively address the three major piracy platforms.

Piracy: Levels of piracy remain high across Indonesia, involving a mix of domestic and internationally operated pirate sites. Stream ripping sites – including those which are locally operated – are a particularly dominant form of piracy. Indonesia should introduce efficient and transparent enforcement procedures to ensure that actions against pirate services operated from Indonesia are effective.

- Chamber Recommendation: The Chamber urges the U.S. government to work with its Indonesian government counterparts to prioritize the concerns above to enhance its copyright enforcement apparatus and to meaningfully combat copyright piracy in Indonesia.

Trade Secrets and the Protection of Confidential Information

Index Stat: Indonesia ranks 48th out of 55 global economies in the trade secrets and protection of confidential information Index category.

Regulatory Data Protection: Indonesia is not in compliance with obligations under the TRIPS Agreement as it does not currently offer regulatory data protection for pharmaceuticals.

- **Chamber Recommendation:** The Chamber encourages the U.S. government to highlight the importance of RDP for innovative biopharmaceutical products in their engagement with the Indonesian government.

MEXICO

Patents Rights and Limitations

Index Stat: Mexico ranks 30th out of 55 global economies in the patent rights and limitations Index category.

Patentability Requirements: Historically, obtaining protection for computer programs, software, and computer-implemented inventions (CIIs) in Mexico has been challenging, with Article 19 section 3.4 of the old Industrial Property Law excluding computer programs as patentable. Despite the USMCA's clear provisions for patenting all inventions, Mexico's revised Industrial Property Law still explicitly excludes computer programs. IMPI's inconsistent policies on patent prosecution, particularly regarding voluntary cascade divisionals, have further complicated matters. The Federal Law for the Protection of Industrial Property (FLPIP) prohibits voluntary cascade divisionals unless a lack of unity objection is issued, but IMPI has recently stopped accepting these divisionals for applications filed before November 5, 2020. This abrupt change has impacted several cases, highlighting the need for clearer guidelines and consistent practices.

- **Chamber Recommendation:** The Chamber encourages the U.S. government to work with the Mexican government to ensure the full implementation and application of the USMCA requirements in Mexican law, and to ensure that IMPI procedures remain consistent with applicable law.

Patent Linkage and USMCA Compliance: Under the USMCA, Mexico is required to establish robust patent enforcement mechanisms to prevent the approval of generic or biosimilar products that infringe on existing patents before those patents expire.

In 2025 the national IP office IMPI and COFEPRIS announced that they had formalized and agreed on a technical working arrangement to introduce an updated system of patent linkage in line with Mexico's commitments under the USMCA and the 2020 revised Industrial Property Law. The agreement, published in the Federal Gazette in March 2025 and now in effect, requires IMPI and COFEPRIS to regularly publish lists of in-force biopharmaceutical patents and market authorization applications by manufacturers of generic and biosimilar biopharmaceuticals. In the event that there are any in-force IP rights violated by any of the follow-on applications published by COFEPRIS, articles 9 and 10 of the agreement provide patent holders with a maximum period of 10 days to object in writing.

While it is a positive step that IMPI and COFEPRIS have finally sought to comply with Mexico's outstanding treaty commitments, this mechanism does not constitute an early notification or adjudication system, nor does it comply with the requirements of USMCA article 20.50. Article 20.50 clearly requires that the contracting parties provide "a system to provide notice to a patent holder or to allow for a patent holder to be notified prior to the marketing of such a pharmaceutical product, 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…[and]adequate time and sufficient opportunity for such a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies.

As currently designed, it is not clear that the mechanism applies to all types of patents (even the promising step of including use patents in the October 2026 Linkage Gazette needs to be codified in implementing legislation); there is no direct notification to rightsholders; and the time limit of 10 days for rightsholders to take action is exceedingly short. Additionally, the mechanism does not provide patent holders with sufficient information to adequately present their case to IMPI before the follow-on product receives authorization.

Finally, recent court precedents have undermined patent usage by preventing their publication in the patent linkage gazette. As a result, COFEPRIS has issued numerous marketing authorizations for generic versions of patented protected products, occurring at least 11 times in 2023 and 2024 alone.

- Chamber Recommendation: Mexico must implement effective patent enforcement mechanisms which (1) provide adequate notice to patent holders when third parties apply for marketing approval of follow-on products; (2) make clear, through implementing legislation, that any patent granted to an allopathic medicine product, including compound, formulation, and use patents, is covered under the "patent linkage" regime; (3) give patent holders

adequate time and opportunity to seek provisional remedies (e.g., stays and preliminary injunctions) prior to the marketing of the allegedly infringing products; and (4) facilitate timely resolution of patent disputes prior to the expiration of the provisional remedies.

Patent Term Restoration (PTR): Mexico is one of the few members of the OECD that does not provide patent term restoration for effective patent term lost during the lengthy regulatory approval process, as required under Article 20.46.2 of the USMCA. While the USMCA provides a transition period to grant Mexico additional time to implement patent term restoration, the transition period expired on January 1, 2025, when Mexico is obligated to be in full compliance with these measures. While on September 16, 2025, the Mexican Government submitted to Congress a bill amending the Federal Law for the Protection of Industrial Property and introducing a supplementary certificate extending the patent term for a maximum of five years, key details regarding the PTR system remain outstanding.

- **Chamber Recommendation:** Mexico must implement measures, which were due on January 1, 2025, to restore the patent term for inappropriate marketing approval delays consistent with USMCA provisions. Specifically, the bill currently under discussion should be further amended to provide clarity on how the term extension is calculated, the eligibility requirements, while also providing for an effective application process that supports the timely grant of supplementary certificates before the expiry of the underlying patent.

Copyrights and Limitations

Index Stat: Mexico ranks 20th out of 55 global economies in the copyrights and limitations Index category, the highest of all Latin American economies.

USMCA Implementation (for Copyright): In May 2024, Mexico's Supreme Court upheld critical amendments to the Federal Law on Copyright, introducing a notice-and-staydown system. This decision aligns with Mexico's commitments under the USMCA. Historically, Mexico has faced challenges in copyright enforcement, but this development marks a significant step forward.

Additionally, while amendments to Mexico's Federal Law on Copyright clarify that ISPs are not liable for damages from copyright infringement if they act quickly and in good faith to remove infringing content, subsection V of the Law adds ambiguity by stating that failure to meet these requirements alone does not generate liability. Despite the Supreme Court's positive ruling in 2024, no implementing regulations or further guidance have been issued on the aforementioned issue, leaving responsibilities and legal expectations unclear. However, the 2024 ruling should provide a pathway for the

necessary regulatory processes to make the notice-and-takedown mechanism operational, addressing a long-standing gap since the USMCA's conclusion.

- **Chamber Recommendation:** To ensure the effectiveness of the notice-and-staydown mechanism, Mexican authorities should promptly issue clear implementing regulations and guidance on responsibilities and legal expectations. Additionally, these regulations should also amend Mexico's Copyright Law, the Industrial Property Code, the Criminal Code, and the Criminal Procedure Code to ensure Mexico is in compliance with its USMCA obligations.

Traditional Cultural Expressions Initiative: Mexico's Federal Law for the Protection of the Cultural Heritage of Indigenous and Afro-Mexican Peoples and Communities entered into force in 2022. The law aims to protect traditional cultural expressions (TCE) in a manner like copyrighted works, with the goal of combatting cultural appropriation and plagiarism of indigenous designs and expressions. The measure aims to register, classify, and document the TCEs of indigenous communities while also broadening the scope of protection and economic rights for these expressions.

In September 2024, the Senate approved the presidential constitutional amendment to Article 2 on Indigenous Communities, which establishes TCE protection as these communities' right and expressly establishes that indigenous people hold collective copyright over their TCEs. Consequently, both federal and local governments must create a legal framework for protecting and promoting this right. Secondary regulations will be critical for the implementation of this reform. This constitutional reform, coupled with the 2022 Law, increases legal uncertainty in Mexico regarding audiovisual investments.

- **Chamber Recommendation**: To clear legal uncertainty for a range of creative industries, the Mexican authorities should implement these reforms with transparency and legal clarity and in alignment with Mexico's USMCA commitments.

Trade Secrets and the Protection of Confidential Information

Index Stat: Mexico ranks 29th out of 55 global economies in trade secrets and protection of confidential information Index category.

Regulatory Data Protection: Article 20.48 obligates Mexico to provide regulatory data protection, for at least five years, for both small molecule and biologic drugs. This provision is subject to a five-year transition period that expired on July 1, 2025, and thereby Mexico was expected to be in full compliance with these obligations at that

time. Currently, Mexico only provides regulatory data protection in non-binding guidelines, but the protection is not automatically granted upon marketing approval and often requires litigation to obtain it.

- **Chamber Recommendation**: Mexico must implement binding regulations, to provide regulatory data protection consistent with Article 20.48 that were supposed to be effective no later than July 1, 2025. To ensure the effectiveness of Article 20.48, the protection should be made available for both small molecules and biologics and should be granted automatically.

Market Access

Index Stat: Mexico ranks 23rd out of 55 global economies in the market access Index category.

Patented Medicines Procurement: Since Mexico's medicines procurement process was centralized under the Ministry of Finance (SHCP) in 2019, the system has been plagued by a lack of transparency, and inconsistent rules, and ever-changing processes and associated entities. This centralization has raised concerns about compliance with Mexico's public procurement rules and international obligations, potentially limiting competition and causing supply issues. Additionally, the outsourcing of procurement to UNOPS – which lost its procurement authority in 2022 due to transparency and predictability issues – and now to BIRMEX and the Ministry of Health has led to continued complications in transparency, risking patent infringements and violating international agreements like the USMCA and TRIPS.

On June 2, 2025, the new Mexican Government introduced a Presidential Decree requiring suppliers of medicines to have a manufacturing plant or other investments in Mexico to be able to participate in the public procurement process and on September 26, 2025, Mexico proposed amendments to the General Health Law that grants preferential and expedited marketing authorization to locally produced products. These new requirements, exclusive for medicines, appear to be inconsistent with Mexico’s obligations under the USMCA that grant national treatment and explicitly prohibits the use of “offsets” as a condition for public procurement.

- **Chamber Recommendation**: The Chamber reiterates the need to work with the Mexican government to ensure that an effective and meaningful patent linkage system is introduced in Mexico to improve the framework for biopharmaceutical innovation.

Effective Border Measures and Remedies: Mexico has long faced challenges in combating illicit trade and counterfeit goods. The current Customs Law only grants

authorities the power to initiate measures, without the ability to seize or destroy IP-infringing items. Each suspected shipment requires an order from the Attorney General's Office for inspection and detention. While administrative procedures can be useful for targeting known infringers, they are costly and time-consuming. Consequently, rightsholders are increasingly turning to the Attorney General's Office's Specialized Unit for criminal actions. However, budget cuts have diminished this unit's effectiveness in conducting raids and seizures.

With respect to USMCA, the agreement has ex officio enforcement authority as a requirement but neither the revised Industrial Property Law nor the revised Customs Law provides a clear, unambiguous power of ex officio authority for border enforcement to act against suspected IP infringing goods. The revised Industrial Property Law retains the emphasis and power of seizures with IMPI and the Customs Law simply states that any action taken by customs officials will be undertaken as an "auxiliary" to IMPI. Additionally, Mexico's National Customs Agency (ANAM) has encountered difficulties in fully exercising and applying broad ex officio authority in practice, often needing to notify other governmental entities before making final decisions on infringement cases.

- Chamber Recommendation: The Chamber urges the U.S. government to collaborate with Mexico to improve its enforcement framework in line with USMCA Chapter 20. Additionally, the Chamber encourages Mexican legislators to introduce anti-counterfeiting legislation to empower Customs to independently seize and destroy counterfeit goods and address the threat of small parcels and online counterfeit sales.

SAUDI ARABIA

Patents Rights and Limitations

Index Stat: Saudi Arabia ranks 28th out of 55 global economies in the patents rights Index category, behind only Jordan and Israel in the Middle Eastern region.

Pharmaceutical Patent Enforcement: In 2022, the Saudi FDA and the Saudi Authority for Intellectual Property (SAIP) introduced a new procedure for registering generic products, requiring follow-on applicants to affirm that their application does not infringe existing IP rights. This includes a "Freedom to operate" analysis and certification by a licensed IP agent. In late 2025, this Procedure was updated with a new version ("Version 2"). The production of this Procedure and the subsequent work that has gone into updating it is a positive move by the Saudi FDA and SAIP. Unfortunately, neither the original Procedure nor the 2025 update provide a true 'linkage' regime, whereby a drug regulatory authority conditions the approval of a

follow-on biopharmaceutical product on their being no relevant period of market exclusivity in place for the underlying reference product. For example, the Procedure still does not contain a notification mechanism to the relevant rightsholder or an automatic stay period ensuring a period of time in which any dispute can be resolved prior to the approval and launch of the follow-on product.

- **Chamber Recommendation:** Saudi Arabia should implement a robust linkage system that conditions the approval of follow-on products on the exclusivity status of the reference product. This system should include a notification mechanism for rightsholders and an automatic stay period to resolve disputes before the follow-on product's approval. Such measures would protect innovators' IP rights, reduce potential damages for follow-on manufacturers, and provide patients with greater treatment certainty.

GCC Patent Office: After announcing in January 2021 that it would not be accepting patent applications, the Chamber was pleased to see that, as of January 1, 2023, the GCC Patent Office would begin handling national patent applications on behalf of the requesting GCC country. However, despite the cooperation of Qatar, Kuwait, and Bahrain, there still, as of 2025, has been no indication as to whether Saudi Arabia will participate in the GCC system and forward national filings to be handled by the GCC patent office.

- **Chamber Recommendation:** The Chamber will continue to monitor the evolution of the GCC Patent Office and encourages Saudi Arabia to continue its participation in the GCC system, which provides a critical venue to harmonize patent protection across the region.

Copyrights and Limitations

Index Stat: Saudi Arabia ranks 23rd out of 55 global economies in the copyrights, and limitations Index category, behind Israel, and the UAE.

Copyright Enforcement: Over the last several years, SAIP has aimed to strengthen the enforcement of IP rights in Saudi Arabia through both institutional improvements and increased levels of transparency and engagement with rightsholders. In 2024, standing committees continued to publish judgments relating to copyright infringement through the “Committee for Review of Violations of the Copyright Protection System.” The publication of these decisions shows that, first, there continues to be an increase in the number of cases considered for IP violations and, second, damages are being more consistently awarded.

Additionally, the authority has keenly worked towards enforcing IP of digital content and e-commerce in cooperation with cyberspace intermediaries to block violating sites and remove digital content that violates IP systems and regulations. Additionally, in-person inspections continue to target counterfeit goods in the physical marketplace. According to SAIP's annual report for 2024, 3.6 million counterfeit items were seized and approximately 34,000 infringing websites blocked. These efforts were supported by 20,000 inspection tours across 51 cities in the Kingdom. These numbers are expected to increase as enforcement continues.

- Chamber Recommendation: The Chamber commends SAIP for these efforts and encourages the Kingdom to continue working closely with industry leaders, content creators, and entrepreneurs to enforce mechanisms against online piracy copyright infringement, as well as continuing their cross-collaborate efforts with the relevant enforcement authorities

Trade Secrets and the Protection of Confidential Information

Index Stat: Saudi Arabia ranks 27th out of 55 global economies in the trade secrets and protection of confidential information Index category.

Regulatory Data Protection: Saudi Arabia established a five-year protection term for clinical research data submitted for biopharmaceutical market registration. This regulation mandates that Saudi authorities protect such information against unfair commercial use for at least five years from the approval date. However, there is uncertainty about the actual availability of this protection, as reports suggest follow-on products have been approved using indirect reliance on submitted data. In 2020, the SAIP released draft regulations that were criticized for not aligning with international standards, particularly by linking protection terms to the first global launch date and excluding new indications. These draft regulations, if implemented, would undermine incentives for innovation and investment. Despite these issues, the SAIP and Saudi FDA reaffirmed their commitment to regulatory data protection in 2022.

- Chamber Recommendation: Saudi Arabia should align its regulations with international standards by eliminating indirect reliance on submitted data and providing clear protection terms. Additionally, SAIP should avoid linking protection periods to the first global launch date and include provisions for new indications to foster innovation and investment.

SOUTH AFRICA

Patents Rights and Limitations

Index Stat: South Africa ranks 52nd out of 55 global economies in the patents rights Index category, ahead of only Algeria, Russia, and Venezuela.

Patentability: South Africa's Patent Act provides a 20-year term of protection, with annual renewal fees starting from the third anniversary of filing. The government's IP Policy aims to introduce stricter patentability standards, compulsory licensing changes, parallel importation for medicines, and pre- and post-grant opposition mechanisms. However, the Policy's broad and undefined criteria for patentability raise concerns about limiting innovation and biopharmaceutical investment. This uncertainty could hinder future growth prospects in South Africa's biopharmaceutical sector.

Most concerning is that the IP Policy states that TRIPS Article 27.1 (and related articles) allows South Africa the "flexibility to interpret and implement the patentability requirements in a manner consistent with its constitutional obligations, developmental goals, and public policy priorities," including adopting patentability criteria that addresses the country's "industrial policy objectives." However, the IP Policy does not definitively outline what these "constitutional obligations, developmental goals, and public policy priorities ... [and] concerns" are. Defining patentability under such broad policy terms and goals certainly seems to be outside the scope of existing international practices as used, for example, in Europe or the United States.

- **Chamber Recommendation**: The Chamber recommends that South Africa clearly define its constitutional obligations, developmental goals, and public policy priorities within the IP Policy to provide transparency and predictability. Additionally, South Africa should align its patentability criteria more closely with international best practices.

Patent Term Extension: As of 2025, the South African government is continuing to evaluate the efficacy of the Bolar exception under the 2002 Patents Act and in conjunction with ongoing legislative changes. No legislation has yet included patent term extension or adjusted the Bolar exception.

- **Chamber Recommendation**: The Chamber recommends that South Africa adopt a comprehensive patent term extension mechanism that protects the base IP incentive represented by the 20-year patent term from inappropriate erosion caused by bureaucratic or political delay.

Compulsory Licensing: Sections 55 and 56 of South Africa's Patents Act establish grounds for issuing compulsory licenses, which can be obtained if a patent cannot be

practiced due to a prior patent or in cases of patent rights abuse. The IP Policy aims to ensure a workable compulsory licensing system to promote affordability and restrain anti-competitive practices. However, the Policy's purpose remains unclear, particularly regarding its alignment with TRIPS Article 31 and the Doha Declaration, which frames compulsory licensing as a last resort for public health emergencies. The chairman's statement accompanying the General Council decision emphasizes that these provisions are not intended for industrial or commercial objectives. There is uncertainty about how the policy will achieve both sustainable and affordable supply in public health or national emergencies. This ambiguity raises concerns about the policy's effectiveness in addressing these critical issues.

- Chamber Recommendation: The Chamber encourages the South African government to utilize its TRIPS flexibilities only as a measure of absolute last resort.

Patent Opposition: Section 7.1.3 of the IP Policy expresses a desire to introduce third-party opposition procedures as a cost-effective alternative to revocation hearings, incorporating multiple layers of administrative opposition both before and after a patent is granted. However, this proposed system could create uncertainty for both innovative and generic producers regarding the patent life of any given product from grant to expiration. The potential benefits of third-party opposition to the South African patent system remain unclear without further details on its implementation. This lack of clarity makes it challenging to determine whether the proposal will ultimately be advantageous.

- Chamber Recommendation: The Chamber encourages South Africa to consider alternative patent opposition measures.

Copyrights and Limitations

Index Stat: South Africa ranks 40th out of 55 economies on the copyrights and limitations Index category.

Copyright Act Amendments Bill and Performers' Protection Amendment Bill: Over the past decade, South Africa engaged in a copyright law amendment process. While this initiative began with the goal of implementing South Africa's international treaty obligations, that goal was marginalized. Instead, the two bills that emerged became vehicles to perpetuate gaps in copyright protection, limit contractual freedom, and diminish copyright protection through expansive fair use-style exceptions. In addition to the systemic substantive concerns with the bills, the legislative process suffered from numerous procedural deficiencies, including the lack of: (1) meaningful

stakeholder consultation; (2) full review by both houses of the South African legislature; and (3) an economic impact assessment.

Significantly, following passage of the two bills by the South African legislature, in 2020 President Ramaphosa of South Africa refused to sign the two bills due to constitutional concerns, and returned them to the legislature to remedy those concerns. The bills were once again passed by the legislature in 2024, virtually unchanged *vis-à-vis* the versions returned by the President. In October 2024, President Ramaphosa decided not to sign the bills into law and instead referred them to the Constitutional Court, where (at the time of writing) the bills are currently under review. The South African and international creative communities welcomed President Ramaphosa's decision.

- Chamber Recommendation: The Chamber encourages the U.S. government to work with their South African counterparts to ensure that all of the concerning provisions of the two bills are dropped.

Market Access and Localization: For many years, South Africa has focused on developing its domestic economy through localization policies, enforcing local content rules for public procurement across various industries. The government's Audiovisual Industry Strategy, released in 2020, aims to facilitate access to diverse content but includes mandates for local content and must-carry requirements for sports broadcasts. For example, in 2021, the Independent Communications Authority of South Africa reinstated local content quotas for television. In January 2025, the Authority published a Supplementary Discussion Document expanding the market definition to include over-the-top services as well. The strategy also addresses enforcement challenges like signal piracy and recommends an inter-ministerial task force. However, the Chamber is concerned that these policies may adversely affect the creative industries and create legal uncertainty in South Africa's copyright environment. Conditioning market access on local partnering, investment, and technology transfer requirements presents significant trade barriers and investment impediments.

- Chamber Recommendation: The Chamber recommends that South Africa streamline its localization policies to reduce trade barriers, improving market conditions, and clarifying legal uncertainties, particularly in the creative industries. Additionally, enhancing collaboration with international stakeholders can help address enforcement challenges and support the growth of a diverse and accessible content market.