



U.S. Chamber of Commerce

1615 H Street, NW
Washington, DC 20062-2000
uschamber.com

By electronic submission:

Daniel Lee
Assistant U.S. Trade Representative for Innovation and Intellectual Property
Office of the U.S. Trade Representative
Washington, DC

2025 SPECIAL 301 SUBMISSION

Submitted electronically via: <https://www.regulations.gov>

January 27, 2025



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-2024-0023; Request for Comments and Notice of a Public Hearing Regarding the 2025 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 announcement of a public hearing for the 2025 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,

Tom Quaadman
Senior Vice President
Economic Policy
U.S. Chamber of Commerce

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



Introduction

The U.S. Chamber of Commerce (“Chamber”) remains unwavering in its support for binding and enforceable international trade rules. Central to this mission is the protection of intellectual property (“IP”) rights, which are crucial for driving innovation, creativity, and economic growth. Intellectual property fuels the creative and technological advancements that propel our economy forward, ensuring that American businesses can compete on a level playing field and mitigate the adverse effects of unfair trade. As the United States and its allies navigate the complexities of international trade, it is essential to uphold stringent IP protections to safeguard the interests of American businesses and innovators.

In today’s interconnected world, the economic and national security of the United States are deeply intertwined with the integrity of our IP systems. Robust IP protections are vital for maintaining the competitive edge of American industries and securing the nation’s economic future. The Special 301 Report highlights the urgent need to address and rectify the practices of countries that fail to protect IP rights, deny fair and equitable market access, and unfairly take advantage of America’s business interests.

By holding bad actors accountable and rectifying bad policy, we can deter IP theft and ensure that American businesses are not unfairly disadvantaged in the global marketplace. This vigilance is crucial for sustaining the innovative ecosystem that underpins our economic prosperity. Similarly, the Special 301 Report underscores the importance of international cooperation in strengthening IP enforcement and addressing the challenges posed by inadequate IP regimes. By working together, we can create a more secure and prosperous global economy.

The Special 301 Report is a vital instrument in this endeavor, providing a comprehensive assessment of global IP protection and enforcement. By holding bad actors accountable and advocating for stronger IP protections, we can safeguard the economic and national security interests of the United States. The Chamber will continue to champion the cause of IP rights, ensuring that innovation and economic growth are not hindered by inadequate protections. Together, we can build a more secure and prosperous future for American businesses and the broader global economy.

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 13th edition of the Index is expected to be released in the first quarter of 2025. 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

The Importance of Trade and Enforcing Existing Trade Agreements

International trade supports more than 40 million American jobs and represents an important engine of economic growth. More than 95% of the world's consumers live outside U.S. borders, and securing trade agreements to improve our access to those markets allows American farmers, ranchers, manufacturers, and service providers to sell U.S.-made products worldwide. U.S. trade agreements have been negotiated to ensure that U.S. trade relations provide a level playing field, eliminating in a reciprocal manner all tariffs on more than 99% of all tariff lines.

In addition to these market access provisions, U.S. trade agreements establish high-standard rules that establish a level playing field for American companies, including in our innovative and creative industries. Protecting the innovations, creative works, and the intellectual property that drives American ingenuity supports good jobs and fosters wage growth. Without such protections, the very foundation of our competitive advantage is eroded, undermining the spirit of free and fair trade.



For American businesses, this means that their hard-earned innovations and creative content are safeguarded against theft. When the United States holds other economies to these principles, it fosters a critical enabling environment for U.S. business to flourish that is essential for sustainable economic growth and trade surplus.

The challenges faced by American businesses in the global market are multifaceted. They must navigate not only competitive pressures but also the risks of IP theft and unfair trade practices. Trade agreement enforcement, when coupled with robust IP protections, provide a framework within which businesses can thrive in markets abroad. These protections ensure that Americans can continue to benefit from the next generation of innovations and encouraging further investment in research and development. In this way, IP rights are integral to maintaining the competitive edge of American businesses and ensuring U.S. economic growth and trade surplus.

As the new Administration considers the appropriate trade tools to use to maintain America's economic and strategic advantages, the Chamber urges caution regarding the application of tariffs. As Chamber President and CEO Suzanne P. Clark said in the Chamber's 2025 State of American Business address, "Blanket tariffs would worsen the cost-of-living crisis, forcing Americans to pay even more for daily essentials like groceries, gas, furniture, appliances, and clothing, and retaliation by our trading partners will hit our farmers and manufacturers hard, with ripple effects across the economy. The bottom line is this: tariffs are a tax paid by Americans, and their broad and indiscriminate use would stifle growth at the worst possible time."

Tariffs will directly impact U.S. manufacturers who thrive on the back of U.S. IP-intensive goods and services. Indeed, half of all imports are materials, intermediate, and capital goods used by domestic manufacturers, and replacing these imports with domestic products in the quantities needed or at reasonable prices is simply impossible. Tariffs will also bring swift and painful retaliation against American manufactured goods, nearly half of which are destined for export markets. According to the U.S. Patent and Trademark Office, IP-intensive industries accounted for \$1.31 trillion—or 79%—of all U.S. merchandise exports while exports of IP-intensive services totaled \$154 million.¹ The Chamber is deeply concerned that levying heavy handed tariffs on our trading partners will directly undermine the ability of American IP-intensive industries to support our economic growth and global competitive advantage.

¹ <https://www.uspto.gov/sites/default/files/documents/oce-ip-econ-note-101.pdf>



Instead, the Chamber advocates for trade policies that provide access to foreign markets and uphold strong rules, including the strong protections for IP that are crucial for the long-term success of American enterprises and workers. By defending America creators and innovators—and their property rights in IP—while championing trade enforcement, we can build a more prosperous American economy.

USMCA and IP Obligations

The United States-Mexico-Canada Agreement (USMCA) incorporates critical commitments strengthening robust and enforceable IP rights. Unfortunately, more than four years after the entry-into force of USMCA, many of these critical IP and market access obligations with respect to the biopharmaceutical and biotechnological industries have yet to be faithfully and comprehensively implemented in Mexico – including patent enforcement, timely marketing authorization, patent term restoration, and regulatory data protection obligations. The United States Government (USG) has consistently raised its concerns regarding these outstanding issues through its annual Special 301 submission and its annual National Trade Estimate Report, as well as in other opportunities.

Additionally, the U.S. patent-intensive industry remains concerned that Canada has yet to implement a comprehensive patent term adjustment (PTA) mechanism, as stipulated under USMCA – with an implementation deadline of January 1, 2025. Unfortunately, current Canadian proposals are flawed, running PTA concurrently with Patent Term Restoration (PTR) and imposing restrictive limits and third-party opposition. These deficiencies mean Canada's PTA system will not meet its USMCA commitments, preventing innovators from receiving adequate remedies for patent office delays. Moreover, Canada is pursuing a series of policies for the online marketplace that curb U.S. access to the market and discriminate against U.S. companies. These include Canada's digital services tax and the Online Streaming Act. These laws mandate that U.S. companies subsidize Canadian industry, contrary to Canada's obligations under the USMCA.

Regarding copyright, the U.S. creative industry welcomes Mexico's passage of key laws implementing that country's USMCA commitments and enhancing copyright enforcement. While a constitutional challenge in Mexico delayed implementation of these laws, the creative industry applauds the recent Constitutional Court ruling that upheld these critical provisions. With the constitutionality of these provisions upheld, Mexico should ensure their full implementation, including through the promulgation of any necessary regulations.



The USMCA also included several copyright commitments for Canada, including with respect to national treatment, and the creative industry welcomes their implementation. However, the USMCA also included the so-called cultural industries carveout, which the Trump Administration and creative industry jointly opposed.

The Trump Administration is already preparing to begin the joint review of USMCA due by July 2026. The Chamber and its members support USMCA and encourages all parties to achieve a successful joint review that continues the success the benefits of the Agreement. As such, the Chamber and its members believe that protecting and enforcing robust IP protections, including the implementation of the aforementioned obligations above (and detailed more within this report), should be addressed through the review process.

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 U.S. government engagement in the World Trade Organization (WTO), World Health Organization (WHO), and World Intellectual Property Organization (WIPO) is of vital importance. We encourage the U.S. government to reassert its long-standing global leadership position with the multilateral system to preserve the framework that helped protect American innovative and creative goods and services abroad and helped raise the bar for IP protection globally.

This includes driving an affirmative agenda in these and other international organizations to advance IP protection and enforcement through data-driven engagement that demonstrates the economic contributions of creativity and innovation and the importance of the protection and enforcement of copyright, technological protection measures, patents, trademarks, and other forms of IP. Likewise, the U.S. government should oppose efforts to diminish IP protection, including to resist overbroad IP exceptions, that not only undermine IP rights, but do harm to the contributions of our creative and innovative sectors to the American economy, employment and trade surplus. Along these lines, the Chamber strongly supports the U.S. government's leadership at the WTO with the IP and Innovation



coalition in the Council on the Trade-Related Aspects of Intellectual Property Rights (TRIPS), which has advanced a robust pro-IP agenda that has successfully countered anti-IP messaging for over a decade.

WTO Art. 71 TRIPS Review

The WTO TRIPS Council is currently conducting an Article 71.1 review of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement to review Member States' implementation of the TRIPS Agreement. While the Chamber is not opposed to an examination of Members' implementation of the TRIPS Agreement, we believe it is critical that review first does no harm to the IP protection and enforcement mechanisms included in the 30-year-old agreement. The Chamber supports the TRIPS Council's approach to conduct the review article-by-article to ensure it remains focused on the strict implementation of the existing provisions. The Chamber urges the U.S. government to reject any attempts by certain WTO members to utilize the review to re-open the provisions included in the TRIPS Agreement, which was intended to serve as a floor for global IP protection, and continues to incentivize innovation, enable access to that innovation, and foster competition. We look forward to working with the U.S. delegation to the WTO to ensure review preserves the IP principles inherent in the original Agreement.

WHO Pandemic Agreement

The multilateral rules-based system plays a critical role in advancing global health objectives through effective IP standards and enforcement. International organizations, like the WHO, can enable voluntary licensing and collaboration that is critical to supporting health systems worldwide.

As the WHO continues to negotiate the Pandemic Agreement, the Chamber is concerned with provisions that condition pathogen access on benefits sharing (PABS), which could undermine efficient R&D efforts and unnecessarily delay the development of life-saving pandemic-related products. Existing access and benefit sharing laws have blocked or delayed pathogen samples for a number of viruses, from Zika to influenza.¹ Creating a PABS system through the Pandemic Agreement would only exacerbate these delays. As a result, it is critical to decouple access to pathogens from equitable access and prioritized unrestricted data sharing as a baseline.

Additionally, the Chamber stresses the importance of ensuring that technology transfer and licensing are conducted through voluntary licensing and collaboration, and on the basis on mutually acceptable terms. We believe a reliance on voluntary and mutually agreed upon mechanisms effectively enables the innovative community to



arm local partners with the information and know-how needed to safely produce medicines while also protecting the underlying trade secrets and other IP critical to the investment in their development. We are grateful for the U.S. government's opposition to forced technology transfer and its advocacy for technology transfer on voluntary and mutually agreed terms.

Given the recent Executive Order on WHO withdrawal, the Chamber is concerned that absent U.S. leadership, the WHO will conclude the Pandemic Agreement against American interests. The U.S. government can be instrumental to ensuring that the Pandemic Agreement safeguards IP and voluntary licensing, and we believe it is critical that the U.S. government continue to uphold strong IP standards through engagement over the next year at the WHO.

WIPO Treaty on IP, Genetic Resources, and Associated Traditional Knowledge

In May, WIPO agreed to a new Treaty of IP, Genetic Resources (GR), and Associated Traditional Knowledge (aTK). The Chamber is concerned that the Treaty's patent disclosure requirements could both increase the cost of patent procurement and exacerbate delays in countries' patent systems, as evidenced by the impact disclosure requirements had on patent procurement in Brazil and India.² Additionally, ambiguity around the scope of the disclosure requirement creates significant legal uncertainty for innovators as to which patents can be granted and enforced across global markets. Finally, the Chamber is concerned that the Treaty does not specifically exclude human genetic material, which forms the basis of many biotechnology inventions and are pivotal to the conduct of clinical trials and other fundamental aspects of health-related research and development. While we are deeply grateful for the U.S. government's long-standing, active involvement in the Intergovernmental Committee. The Chamber urges the U.S. to carefully consider the negative implications of patent disclosure requirements when considering whether to sign on to the Treaty.

WIPO Intergovernmental Committee on Traditional Knowledge and Traditional Cultural Expressions

As the WIPO Intergovernmental Committee (IGC) continues to convene discussions on Traditional Knowledge (TK) and Traditional Cultural Expressions (TCE), the Chamber urges the U.S. government to ensure the integrity of the copyright system. While we support the goal of greater incorporation of native and indigenous

² See [Economic Impact of Disclosure Requirements in Patent Applications for 'Genetic Resources'-Based Innovation. IFPMA, 2018.](#)



creators into the broader creative community, the model put forth by proponents at IGC contravenes the international copyright system. Specifically, the chair's text should not be a basis for further work, as it does not represent the consensus position of WIPO members, and incorporates obligations imported from outside international IP law, with no analog in any other WIPO or other multilateral copyright treaty. Proponents are seeking to grant perpetual, enforceable IP rights to undefined subject matters that are not subject to qualification requirements or to the public domain. This model will encroach on freedom of expression and create significant challenges for creators. Additionally, the Chamber believes that policies on traditional culture must maintain the fundamental right to freedom of expression.

The Chamber is concerned that overly broad legal frameworks could limit creators' abilities to utilize elements based in traditional culture, essentially undermining freedom of expression. Copyright protection remains the most universal and time-tested mechanism for the protection of expressive works. Undermining that system will likely lead to a weakening of the proponents' objectives and result in less protection and more uncertainty for all creators, including the proponents. The Chamber looks forward to working with the U.S. government to ensure that can both protect traditional culture and prevent misappropriation, while also bolstering legal certainty in the creative ecosystem.

WIPO Standing Committee on Copyrights and Related Rights

While the WIPO's Standing Committee on Copyrights and Related Rights (SCCR) is a critical venue to advance discussions on an effective framework for copyright protection and enforcement globally, the Chamber is concerned with some of the SCCR's discussion topics. For example, the SCCR has deliberated a limitations and exceptions agenda that purposefully weakens the legal certainty enshrined in copyrights. Concerning provisions on limitations and exceptions have been included in policy toolkits intended to help member states implement their IP framework. Such tool kits effectively become soft law that ultimately undermine copyright protection in many nations. Additionally, the Chamber is concerned with the ongoing discussions and proposals on copyright in the digital environment, which rests on a false premise, while lacking sufficient data to support its conclusions. The Chamber is deeply grateful for the U.S. delegation's work to ensure that the SCCR can advance the framework for strong global copyright protection and look forward to supporting efforts to advance an affirmative agenda in the SCCR that spotlights the immense contributions of creators to economic development. Likewise, we urge you to remain vigilant to attempts to undermine copyright protection through ongoing discussions on limitations and exceptions and copyright in the digital environment.



The International IP Landscape in Enforcement

Effective and consistent IP enforcement is crucial for creating a rule of law environment that encourages investment in IP-valued creations across industries. However, many global economies lack practical and fully utilized enforcement options, with judicial and administrative routes often overloaded and under-resourced. Effective border measures are also lacking, as not all economies grant customs authorities the power to seize counterfeit goods without a formal complaint. This volatility in the global enforcement environment affects U.S. Chamber members' ability to protect their IP and sustain American jobs, especially given the rise in global trade, which reached an estimated \$33 trillion in 2024.

The technological revolution and booming e-commerce environment have made it increasingly difficult to enforce against counterfeit and pirated goods. Lax overseas enforcement at the national level means U.S. consumers are vulnerable to fake, sub-standard, and counterfeit goods from sources such as China's Temu and SHEIN, where considerably lower standards of transparency, accountability, and seller vetting are in evidence. Criminals and transnational organizations use sophisticated strategies to sell illicit products online, mirroring tactics used in physical marketplaces. Despite significant investments by legitimate businesses, counterfeiters continue to infiltrate the global supply chain. To protect consumers and trusted brands, it is imperative that law enforcement authorities have the necessary resources and tools to combat online counterfeiters.

IP infringement is complex and globalized, requiring sophisticated investigatory tools and cross-border data transfers. Data localization measures and restrictions on data transfer hinder the ability to investigate and counteract transnational IP infringing activities. The Chamber supports global initiatives to combat transnational criminal networks that produce and sell counterfeit goods, such as the OECD illicit trade taskforce. The U.S. government plays a critical role in combating the sale of IP-infringing goods online, and the Chamber supports efforts like the USTR's annual notorious markets report to identify platforms that allow counterfeit and pirated products. The rise of counterfeit medicine sales is a significant public health issue, with dangerous consequences for consumers.

In 2021, U.S. Customs and Border Protection (CBP) and the Chamber signed a historic Memorandum of Understanding (MOU) to facilitate information-sharing on anti-counterfeiting efforts. The MOU was renewed in 2023. The information-sharing program has led to the seizure of millions of dollars' worth of IP-violative goods in the U.S., serving as a model for public-private partnerships in global enforcement. The program has significantly improved CBP's ability to detect and seize counterfeit



pharmaceutical products and medical devices, thanks in part to international training sessions organized by the secondee. In 2024, successful trainings in Mauritius and Türkiye helped customs officers spot counterfeit medicines, enhancing American consumer safety. These collaborative efforts demonstrate the effectiveness of public-private partnerships in combating illicit trade and protecting IP rights.

We appreciate the focus of the Office of the U.S. Trade Representative in protecting the IP rights of creators and innovators, and especially appreciate the attention being paid to the public health threat of counterfeit medicines. Illicit markets offer a refuge to sellers of infringing goods and those who lure consumers to—and exploit them through—digitally pirated content. The persistently high levels of global counterfeiting and digital piracy demonstrate that government and industry must be equally relentless in meeting the challenge.

Section C: Developed Market Profiles

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. Additionally, the proposed changes included in the EU General Pharmaceutical Legislation could lead to nearly a 10% score decrease in the life sciences-related Index indicators for EU economies, demonstrating the negative impact of such measures on the EU's global standing as an innovation leader.

General Pharmaceutical Legislation: In April 2023, the European Commission proposed a new Directive and Regulation to revise the EU's General Pharmaceutical Legislation. The Commission's initial proposals and the position of the European Parliament contain alarming proposals to undermine long-standing IP protection in Europe for U.S. innovators, including through: reducing the term of RDP and conditioning such protection on criteria beyond control of the right holder, and perhaps even more concerning, expanding (really, redefining) the *Bolar* exemption to include commercial activities that not only would undermine IP enforcement but appear to contradict the basic obligations of European countries under the WTO TRIPS Agreement. In response, the Chamber has encouraged the EU to consider the following recommendations as they seek to pass the GPL in the coming years.

- Maintain or enhance the current 8 (+2) years RDP baseline.



- Maintain existing structure for additional years of RDP protection.
- Broaden the “unmet medical need” definition and provide an added year of RDP.
- Preserve the existing scope of the Bolar exemption.
- Retain a 10-year market exclusivity for orphan medicines.

Chamber Recommendation: The Chamber encourages the U.S. government to collaborate with its EU counterparts to ensure the GPL creates a pharmaceutical landscape that prioritizes groundbreaking innovation and the health and wellness of patients, remains fully consistent with the EU’s international obligations, and bolsters Europe’s competitive environment for U.S. investors in innovative technologies.

Compulsory Licensing: In April 2023, the Commission released a proposed regulation to revise the framework for compulsory licensing of patents. The Parliament and the Council subsequently adopted their positions in March 2024 and June 2024, respectively. The Council’s approach included several improvements to the Commission’s initial approach, including the judicial review of compulsory licenses by the Court of Justice of the EU, the introduction of a “last resort” condition, and the protection from disclosure of trade secrets.

- **Chamber Recommendation:** As the compulsory licensing regulation heads to interinstitutional negotiations, the Chamber encourages the U.S. government to work with its EU counterparts to ensure that the CL framework provides legal certainty, due process, an independent review of CL decisions, protects confidential information for innovators, and sustains our shared global competitiveness.

EU Standard Essential Patent (SEP) Regulation: In April 2023 the European Commission (EC) released a draft Regulation that would change current practice relating to SEPs and licensing negotiations. The current proposal, which continues to undergo alterations, would establish the EUIPO as a SEP ‘competence center’ tasked with overseeing and maintaining a register of SEPs and functioning as an arbiter and evaluator of essentiality and various forms of “royalty determination”.

SEP-based technologies are central to future innovation and economic growth in the EU and globally. Many of the cutting-edge industries that are loosely labeled as making up the “Fourth Industrial Revolution” - the Internet of Things, artificial intelligence, robotics, and 3-D printing – will rely on SEPs to function. It is critical that incentives around the process of standardization are appropriately balanced both for those that hold patents and those that will seek licenses. In short, SEP policy is deeply complex, incredibly consequential, and is often heavily fact specific on a case-



by-case basis. The EC attempts to regulate must preserve the incentive structure necessary to form SEPs, retain case-specific flexibility, avoid government price-setting, and prevent adoption of a regulatory approach that could lend itself to abuse by countries such as China.

JAPAN

Patents and Related Rights

Index Stat: Japan ranks 5th out of 55 global economies in the patents and related rights Index category.

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 the Expert Opinion Inquiry (EOI) system where experts decide opinions on patent infringement based on opinions submitted by innovative and generic manufacturers. Under the EOI system, MHLW would confirm patent infringement in reference to the experts' opinion and approves generic drugs if MHLW confirms that generic drugs do not infringe any patents.

- **Chamber Recommendation:** MHLW should not adjudicate legal disputes between innovative and generic manufacturers, including through experts, and should instead leave legal matters for the courts. Any amended patent linkage system should 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).

Copyrights, Related Rights, and Limitations

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

Copyright Law Reform: A public performance right for artists and sound recording producers should be introduced. Likewise, the Japanese making transmittable right, which does not correctly implement the WPPT's making available right and is narrower than the making available right in other territories, should be corrected to cover not only the point of uploading but also subsequent transmissions. For example, the



making available right only covers scenarios where the copies are stored in the jurisdiction and made available from Japan.

- **Chamber Recommendation:** Japan should also refrain from adopting overbroad exceptions to copyright and remove any existing overbroad exceptions. To more adequately combat online piracy, Japan should: (1) introduce a clear and express legal basis for injunctive-style relief, in line with international best practices outlined in the IP Index;³ and (2) improve the inadequate online liability framework and notice and action provisions of its law.

Copyright Enforcement: As a result of a combination of the making transmittable right and the lack of injunctive-style relief, right holders 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. Cyberlockers and sites and apps that link to infringing content, including to sites or servers hosted or operated from outside of Japan, are also popular. Other issues include unlicensed content on UUC services.

- **Chamber Recommendation:** The Chamber urges the U.S. government to work with the Government of Japan to address the above-mentioned deficiencies in Japan's legal system and enforcement apparatus to ensure adequate and effective protection of copyright and to combat copyright piracy online.

Market Access

Patient Access Report Stat: The pricing and health technology assessment system used in Japan have resulted in decreased access to innovative medicines in the market. For example, 48% of new medicines launched in the U.S. or EU between 2012 and 2021 have not yet begun development in Japan.

Revisions to the Price Maintenance System: The FY2024 Drug Pricing System Reform includes some positive changes to Japan's drug pricing system. These include an expansion of the product eligibility criteria for the PMP, the abolishment of the PMP company criteria, and price maintenance during the premium-eligible period, aimed at rewarding innovation and eliminating drug-lag/loss issues in Japan. However, there have not been any major improvements in the Market Expansion Repricing System, especially in spill-over repricing rules, which lack predictability and make investment decisions for additional indications difficult.

³ <https://www.uschamber.com/intellectual-property/2024-ip-index>



- **Chamber Recommendation:** The Chamber believes that these repricing rules penalize and undervalue breakthrough therapies in an attempt to manage budget impact, and strongly requests the abolishment of spill-over repricing rules. The Chamber also encourages the U.S. government to work with their Japanese government counterparts to ensure that the Drug Pricing system adequately acknowledges the value of innovative medicines to Japanese patients.

Health Technology Assessment Changes: In April 2019, the Japanese government made permanent a new Health Technology Assessment (“HTA”) system, which operates as a price adjustment tool after price listing, rather than for making for reimbursement decisions. Unlike HTA mechanisms in many other economies, the Japanese system is narrowly based on achieving price efficiencies and expenditure control for only selected high-cost and financially significant products with limited systematic effort to understand or map the greater health and socio-economic value of an appraised product. For example, the Japanese government introduced a new price adjustment scheme for LEQEMBI using an ICER threshold which is inconsistent with the drug pricing system and has the high degree of uncertainty in analysis. While the 2024 HTA guidelines introduced some changes to clarify comparator choice criteria and the Quality of Life value, the Chamber remains concerned that the HTA system in Japan increasingly does not allow for a reasonable return of fair value for innovation, with Japanese patients suffering less access as a result.

- **Chamber Recommendation:** The Chamber encourages the U.S. government to engage its Japanese counterparts to ensure that the HTA system reform is implemented in a way that promotes a pro-innovative HTA framework, rewards innovation, and ensures patient access in Japan.

REPUBLIC OF KOREA (ROK)

Patents and Related Rights

Index Stat: The Republic of Korea ranks 4th out of 55 global economies in the patents and related rights Index category.

Patent Term Extension (PTE): On December 27, 2024, the Korean legislature (the National Assembly) passed the Patent Act Amendment Bill which would require no more than one patent to be eligible for patent term extension. In comparison, under the current law, multiple patents are eligible for patent term extension. Accordingly,



under the current law, a patentee can get patent term extensions not only for the first-approved indication, but also indications approved in the future if there are additional patents covering those future approved indications. However, under the Patent Act Amendment Bill, a patentee would not be able to obtain any patent term extension for patents covering future approved indications if such patentee has already obtained a patent term extension for a patent covering the first approved indication. This would be inconsistent with international norms, including the U.S. and Europe, and discourage research and investment for additional indication approvals in Korea.

- **Chamber Recommendation:** The Chamber encourages the U.S. government to work with their Korean government counterparts to either stop enacting the Patent Act Amendment Bill, or further amend the bill to align with the U.S. and European practice such that the patent term extension granted to the first and only patent should cover all future indications that will be approved before the expiration of the already-granted patent term extension.

Copyrights, Related Rights, and Limitations

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

Copyright Law Reform: The Republic's rate setting process regarding its public performance right for music performances is dysfunctional, having led to unreasonably low payments for broadcast and public performance rights, and requires overhaul. The law also 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 Index⁴. Moreover, the Republic's copyright liability rules regarding linking to infringing content and ISP liability require improvement. Finally, its pre-approval process for clearance of music videos on local services is overly burdensome and requires removal or revision.

- **Chamber Recommendation:** The Republic should amend its public performance right for music performances, which has been inadequately implemented. The Republic should also 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. It remains unclear if injunctive-style relief is available for such sites due to the criteria imposed in practice.

⁴ <https://www.uschamber.com/intellectual-property/2024-ip-index>



- **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.

Market Access

Patient Access Report Stat: The use of price controls and heavy emphasis on cost containment in the pricing and reimbursement process have resulted in decreased access to innovative medicines in Korea. For example, Korean patients only had access to 33% of the new medicines launched between 2012-2021.

Pricing Issues: The use of government price controls creates non-tariff barriers that undermine the enabling environment needed to sustain investment in medical innovation. The Chamber has several concerns with the ROK's pricing framework, including:

- The focus on cost reduction, rather than a holistic assessment of a medicine's value, when determining medicine prices.
- The reference to other medicines in the same therapeutic class, including off-patent and generic medicines which are already subject to drastic price-reduction measures, when determining the reimbursement price for patented medicines.
- The granting of price preference to locally developed innovative medicines.
- The utilization of repetitive and excessive price cut mechanisms after reimbursement listing.
- The use of Risk Sharing Agreements ("RSA") to generate additional concessions from innovative companies, which the Chamber believes must be paired with broader reforms that recognize the true value of innovative patented medicines.

The ROK's pricing framework may be out-of-step with the transparency and due process obligations under KORUS, which requires an independent review process for those affected by pricing and reimbursement recommendations or determinations. However, Korea has taken the position that reimbursed prices negotiated with pharmaceutical companies should not be subject to the independent review because the NHIS does not make "determinations" and merely negotiates the final price at which a company will be reimbursed. This interpretation negates the original purpose of the independent review mechanism, which should apply to the negotiation process



for prices of all reimbursed medicines, particularly patented medicines. While these policies have been driven by goals of cost-savings and cost-containment, the result is reduced access to innovative medicines for Korean patients and doctors and the undermining of the principle of a fair return for innovation.

- **Chamber Recommendation:** The Chamber encourages the U.S. government work with their Korean government counterparts to help update its domestic biopharmaceutical pricing regime to ensure the pricing framework reflects fair value for the investment in innovation and is consistent with the ROK's KORUS obligations.

TAIWAN

Patents and Related Rights

Index Stat: Taiwan ranks 49th out of 55 global economies in the patents and related rights Index category.

Patent Linkage: Despite the Taiwan Food and Drug Administration (TFDA) promulgating final patent linkage (PL) regulations in August 2019, the Chamber and its members are 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: Patents, including those in Taiwan, typically offer a 20-year exclusivity period from the filing date. For pharmaceuticals, this period is effective only after marketing approval. 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 because 2018 Patent Examination Guidelines were implemented in Taiwan, affecting 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. This has led the Taiwan Intellectual Property Office (TIPO) to deny PTE for patents claiming a compound when the marketed product includes the compound in a hydrate form.

- **Chamber Recommendation:** TIPO should 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.

Commercialization of IP Assets

Index Stat: Taiwan ranks 36th out of 55 global economies 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 MEAs and 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; and
- The NHIA's plan 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: To address these market access issues, 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 IPR 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 new 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);
- 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
- Copyrightability of AI contributions and authorship where the work may include both creative input from human authors and AI generated content, appears to have changed recently in the China courts, and while such a shift may be positive it is not clear that it is consistent with international norms.

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”;
- Restrictive patentability criteria, including stringent requirement before acceptance of post-filing data to demonstrate patent eligibility despite obligation to eliminate such requirement under Article 1.10 of the “Phase One Agreement”;
- No 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;
- Enact 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;



- 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;
- 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 IPR 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 Related Rights

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

Weak Patent Enforcement on Pharmaceutical Products: In 2020, the Chamber was encouraged to see that the recently approved amendment to the Patent Law (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.
- Loopholes that allow generic companies to bypass the patent linkage mechanism and prematurely launch their products in the market

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, in a manner 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.

- **Chamber Recommendation:** The Chamber looks 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.

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.⁵ Though the panel's final report was originally scheduled to be issued in the second half of 2024, its release has been delayed to the first quarter of 2025.⁶

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 complaint⁷ with the WTO to start 2025. This ongoing expansion of Chinese courts into global rate setting is highly consequential for multinational rights holders.

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 new 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 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

⁵ https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds611_e.htm

⁶ <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/DS/611-9.pdf&Open=True>

⁷ https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds632_e.htm



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, Related Rights, and Limitations

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

Copyright Law Reform: China’s amendment to its Copyright Law (November 2020), 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, and protections for technological protection measures. Statutory damages for copyright infringement have also been increased substantially following similar changes to the Patent Law and Trademark Law.

Despite the strengthened copyright protections included in the newly amended Copyright Law, the Chamber is disappointed and concerned with the Chinese government’s continued lack of progress in the following areas:

- The lack of confirmation 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.
- The absence of new rules that address the volume of internet piracy caused by video aggregation websites and mobile apps, as well as enumerating exclusive rights under copyright.
- The lack of proactive administrative enforcement that has the capacity to close infringing websites and remove unauthorized applications.



- The absence of 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.
- Despite recent case law supporting injunctive-style relief obligations, China’s online liability framework and notice and action provisions still require improvement and consolidation.
- China should confirm the primary liability of UUC sites that store and make available user uploaded content.
- A clear and express legal basis for injunctive-style relief should be introduced.
- China should extend the term of protection for sound recordings, which is currently only 50 years.
- China should refrain from adopting any overbroad exceptions to copyright and remove any existing overbroad exceptions.
- The scope of the making available to the public right needs to be improved due to the existing “server test” element requiring that the act of making available occurs via copies stored in China. This can hinder enforcement actions in relation to unlicensed services operating outside the country.
- Updates to copyright-related implementing regulations are still required following enactment of China’s new Copyright Law in 2021, as this has given rise to inconsistency and ambiguity in practice. In keeping with this, China’s Article 15 WPPT reservation should be removed.

Copyright Enforcement:

- High piracy rates continue to exist in China. China authorities should conduct sustained year-round enforcement actions to combat copyright piracy.
- China should engage in copyright enforcement actions against unlicensed user uploaded content (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.
- UUC platforms seek to avoid liability by claiming to qualify for safe harbor immunities, leading to large scale availability of unlicensed content online. UUC platforms should be denied immunity, and face liability, for copyright piracy.
- Copyright holders face onerous requirements in China in relation to evidence of infringements (e.g. notary needs to be involved) and regarding the proof of title in civil and criminal proceedings.



- Right holders face significant difficulty obtaining evidence to satisfy the requirement to quantify the financial gain made by an infringer for administrative and criminal actions. Such evidentiary requirements should be modified to remove the burden they impose that serve as a barrier to administrative and criminal proceedings.
- China should refine the process for transferring administrative cases to criminal cases.
- China should bring consistency to the thresholds for local authorities to accept administrative and criminal cases across different regions.

Chamber Recommendation: The Chamber urges the U.S. government to work with its Chinese government counterparts to address the absence of the above-listed measures to provide adequate and effective protection of copyright and to robustly combat copyright piracy online.

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 and punitive, 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. And 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 and Related Rights

Index Stat: China scores on par with India and Brazil on the protection of well-known marks Index indicator.

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 SOEs 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 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.

The latest 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

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 report 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. While this draft measure represented a strong first step toward reform in this area, it appears reform efforts have stalled. China has yet to grant RDP for any product containing a new chemical.

- **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

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 eager 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

Patents and Related Rights

Index Stat: Argentina ranks 49th out of 55 global economies in the patents and related 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. Despite having included this issue in its Special 301 for several years, USTR did not include this issue in its 2024 report, sending the wrong message to Argentina and others.

- **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. This includes eliminating the guidelines to allow patents for compositions, dosages, and biotechnological inventions. Additionally, we urge the government to engage with industry stakeholders to develop a balanced framework that fosters innovation while protecting public health. The Chamber asks that the U.S. government work with the Argentine government to prioritize resolution of this long-standing issues.

Patent Backlog: Inventors and rightsholders face long delays in patent approvals in Argentina, with high-tech patents taking nearly a decade 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. 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: Even when innovators secure patent protections in Argentina, enforcing these rights is challenging. Preliminary injunctions, introduced in 2003 under Law 25.859, are crucial but difficult to obtain. Remedies for infringement include pre-trial mediation, seizure of infringing products, injunctions under TRIPS, and criminal sanctions. Patentees can also seek damages through civil suits. However, the pharmaceutical 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 awards 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.

Copyrights, Related Rights, and Limitations

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

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 a significant issue in Argentina, with high rates of illegal downloading and streaming. Despite 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. Thankfully, Argentina made significant strides in copyright enforcement. In 2023, federal court ordered the disabling of access to several copyright-infringing websites, including a dynamic element to update and apply the order to new URLs as they appear. This dynamic injunction effectively addresses the issue of mirror sites and prevents infringing content from re-entering the public domain. In 2024, Argentine law enforcement disabled access to over 50 websites offering access to pirated sports content through the joint effort with Brazil called "Operation 404." This was followed up by a raid and the arrest of a suspect. The Chamber commends the Argentinian's governments efforts successful, 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 increase resources and political backing for a coordinated, long-term antipiracy agenda at the federal and local level to address the persistently high rates of online piracy. Moreover, the government should 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 regulatory test data, as data exclusivity and patent term extensions for regulatory delays are currently unavailable. Additionally, there are no clinical results for competing generic products or information to support efficacy claims. 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 data exclusivity and patent term extension for



regulatory delays. Additionally, the government should ensure transparency and more clearly define key terms in Law 24,766.

Commercialization of IP Assets and Market Access

Index Stat: Argentina ranks 29th out of 55 global economies in the commercialization of IP assets and market access Index category, behind only Chile and Mexico.

Pharmaceutical Reimbursement: In 2015, Argentina established a reimbursement program favoring locally made generic and biosimilar products, requiring Health Insurance Agents to prioritize these products if they have the same active ingredient or are significantly cheaper than foreign products. However, key terms in the regulations remain undefined, causing uncertainty for the industry. This program conflicts with global biosimilar guidelines and Argentina's WTO obligations. In 2020, Argentina adopted international reference pricing for high-cost medicines, and in late 2021, the government froze medicine prices until January 2022. In August 2023, another price freeze was implemented due to hyperinflation, with the health sector experiencing a 15.1% inflation rate.

- **Chamber Recommendation:** The Chamber recommends that the Argentine government clearly define key terms in the regulations to provide transparency and certainty for the industry. Additionally, the government should align its policies with global biosimilar guidelines and WTO obligations to ensure fair competition. Finally, the Chamber urges the government to develop a sustainable pricing strategy that balances affordability with the economic viability of the biopharmaceutical industry.

BRAZIL

Patents and Related Rights

Index Stat: Brazil ranks 42nd out of 55 economies in the patents and related 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. The bottom line is that, despite Brazil's National Institute of Industrial Property (INPI) efforts to enhance patent processes, rightsholders continue to face legal uncertainty on whether they will be able to secure a meaningful patent term in Brazil.

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 historically had a backlog of patent applications ranging from 10 to 13 years depending on the field of technology; 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. While there remain roughly 800 vacancies left to be filled, the Chamber is pleased by INPI's public desire to fill roughly 400 in the coming year.

- **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.

Compulsory Licensing: The Industrial Property Law 9.279/96 provides a broad basis for compulsory licensing beyond the use of this mechanism solely for public health emergencies that do not involve commercial consideration. Moreover, this mechanism also includes a domestic manufacturing criterion that can form the basis for the issuing of a compulsory license. These sections have been used in the past during price negotiations with foreign biopharmaceutical innovators to reduce their prices considering the threat of approving the manufacturing of local generic versions of patented medicines. In late 2021, several amendments to the Industrial Property Law were enacted, including provisions broadening the Government's emergency powers and authority to issue compulsory licenses, setting the percentage of royalties to be paid in licensing fees and expanding the compulsory licensing mechanism to also cover patent applications.

- **Chamber Recommendation:** The Chamber encourages the Brazilian government to ensure that its CL rules are compatible with its WTO obligations and, if so, that the CL framework provides legal certainty and due process for innovators and sustains our shared global competitiveness.

Copyrights, Related Rights, and Limitations

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

Copyright Law Reform: Brazil should reject proposals to introduce additional remuneration rights into the digital streaming market, such as Bill PL 2370/2019 and Bill 4968/2024. These highly concerning bills constitute a fundamental departure from copyright law, exact a stark deprivation of contractual freedom, and impose a systemic threat to the creative industry in Brazil. 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 mandatory collective management, contract override – thereby eviscerating underlying free market contracts between rights holders and digital service providers (DSPs) – and onerous penalties. Bill PL 2370/2019 also introduces considerable confusion regarding the scope of copyright and related rights protection for broadcasting and public performance 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, Bill 4968/2024 was introduced into the Senate at the very end of its 2024 session without consultations or impact assessment. Brazil should reject these proposals.

Chamber Recommendation: The Chamber recommends that Brazil should also:

- Ratify and faithfully implement the WIPO Internet Treaties, including to make 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 depart from international standard, and, in particular 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: Given that the Brazilian justice system generally suffers from long processing times and high costs of litigation, the need for a court order stands in the way of a practical and workable mechanism ensuring the expeditious removal of infringing content. Similarly, there has historically been no dedicated or defined administrative or judicial pathway in place to provide injunctive style relief for copyright rightsholders.

However, the Chamber supports the dedicated enforcement operations to combat 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 2024. The Chamber also notes that in February 2023, the Brazilian National Telecommunications Agency (Anatel) launched



a 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 almost 1.5 million 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."⁸ 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. These efforts build on the positive actions taken by Anatel in 2023. Additionally, Law 14,815/2024 granted Ancine the authority to suspend and prevent future showings of any unauthorized use of protected audiovisual works. Unfortunately, Ancine has delayed implementing this regulatory mechanism as of October 2024.

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 infringing mobile apps, which are popular, including MP3 download and stream ripping apps.

- **Chamber Recommendation:** The Chamber recommends that the U.S. government collaborate with Brazilian government colleagues to ensure adequate and effective protection of copyright 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 and Related Rights

Index Stat: Brazil ranks 38th out of 55 global economies in the trademarks and related rights Index category.

⁸ 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



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.

- **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 and related rights 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.

- **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.

Commercialization of IP Assets and 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 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. 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 and Related Rights

Index Stat: Colombia ranks 31st out of 55 global economies in the patents and related 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 notifies patent holders of potentially infringing applications, 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. By September, the Interagency Technical Committee recommended compulsory licensing for two patents (07115501 and 07115501A), highlighting the high HIV prevalence among Venezuelan migrants and the high cost of DTG. 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. On January 31, 2024, the Superintendence of Industry and Commerce (SIC) detailed the terms for the compulsory license, requiring applications by February 14, 2024, and stipulating DTG's exclusive government use and for exports. 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. However, the compulsory licenses have not been utilized due to its lack of manufacturing capabilities, and MSPS could import the product.

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 the 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, Related Rights, and Limitations

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

Copyright Enforcement: In 2024, Colombia made significant strides to improve copyright enforcement with a landmark judgment in May 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 2024 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. These developments highlight Colombia's evolving approach to copyright protection and enforcement. Because piracy of audiovisual content represents a major challenge to rightsholders in Colombia, the government should continue this great work by codifying these digital protections in its copyright statute. Such acts offer greater assurances to rightsholders and show that Colombia is taking steps towards meeting its obligations under the U.S.-Colombia FTA.

- **Chamber Recommendation:** The Chamber urges the U.S. government to work with its Colombian government counterparts to address the above-listed concerns in order 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



protection 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. In addition, according to AFIDRO, the local R&D pharma association, 30 % of the requests between 2017 and 2024 were denied by INVIMA.

Commercialization of IP Assets and 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: 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.

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: 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.

- **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 and Related Rights



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

Patentability: Section 3(d) of the Indian Patents Act adds a fourth criterion of "enhanced efficacy" to the TRIPS requirements, creating an additional hurdle for patentability, particularly for pharmaceuticals. This provision presumes that various derivatives of known substances are not patentable unless they show significant therapeutic efficacy, placing an unreasonable burden on innovators. This 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.

However, the Chamber notes that the judiciary has been helpful in clarifying Section 3(d), with High Courts outlining the need for applicants to provide robust data and explanations to prove enhanced therapeutic efficacy for patent eligibility and providing guidelines on the issue and the expectations from the applicants. While these judgments offer some relief to applicants, a more comprehensive resolution to the issue remains necessary.

- **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.

Price Controls: The Chamber notes the importance of drug pricing policies that properly value innovation. 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 for extending this term 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. While more comprehensive reforms would have been ideal, these changes are positive steps forward.



- **Chamber Recommendation:** The Chamber recommends that the Government of India 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 opposition filings.

Patent Linkage: In an important case decided in April 2022, *Kanishk Sinha And Another vs. The Union Of India And Another*, concerning the issue of patent linkage in a non-pharma sector, the division bench of Calcutta High Court refused to grant patent linkage to the Appellant holding that doing so in whatever form would give a controlling handle to the writ petitioners beyond the legal remedies available to them under the current Patent Act. The court held that a grant for patent linkages would be subject to an assessment by the courts and will only be granted where a patentee can demonstrate clearly that the remedies under Patents Act, 1970 can truly not address the legal issues arising out of their case.

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:** To ensure clarity and consistency in patent enforcement, it is recommended that the Indian government provide detailed guidelines on for notification or resolution of patent disputes prior to marketing approval of generic products. Additionally, enhancing the existing remedies under the Patents Act, 1970, could supplement – in the meantime – a more comprehensive patent linkage mechanism, ensuring that patentees have adequate legal recourse within the current framework.

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.

Copyrights, Related Rights, and Limitations

Index Stat: India ranks 37th out of 55 global economies in the copyrights, related rights, 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.

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, should be resolved;
- 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.

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, and to address the above-listed concerns in order to provide adequate and effective protection of copyright.

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 also 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 to immunity from piracy enforcement unclear safe harbor provisions to avoid obtaining a license on fair terms (or at all), and right holders 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 from ISPs to blocking orders. India should require ISPs to report back once website blocks have been implemented.

- **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 it 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 regulatory framework 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.

Enforcement

Index Stat: India currently ranks 43rd 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 and Related Rights

Index Stat: Gaps in Indonesia's patent framework result in Indonesia scoring behind all its regional counterparts in the patent category, with the exception of Thailand.

Patent Law: Indonesia enacted new Patent Law (Law No. 65/2024) in October 2024, reflecting the positive changes stipulated on the Job Creation Law and broaden the scope of patentable products and technologies. However, the new law still includes a problematic provision enabling government use of patents for imported pharmaceutical products despite importation being considered as part of patent



implementation. In addition, some stipulations on compulsory licensing are overly broad, enabling government use of patent for “public interest” and if product is “expensive.”

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. The new law is also silent on how this new requirement will be implemented.

- **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 to 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 encourage 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 draft amendments to the Patent Law also include changes to relevant articles relating to compulsory licensing and government use. The amendments include a new article 84A which 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.” Should this article stand as written, it would potentially undermine and all but nullify all granted patent rights in Indonesia.

- **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, Related Rights, and Limitations

Index Stat: While Indonesia is 50th out of 55 in the overall Index rankings, Indonesia ranks 32nd out of 55 in copyright indicators. Notwithstanding this progress, online piracy continues to present a challenge for rightsholders.

Copyright Law Reform: Indonesia should abolish its 25-year reversion of rights mechanism, as it interferes with the freedom of contract and the legitimate enjoyment of producers’ rights, and rights acquired by right holders. 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, which is currently only 50 years. 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. Indonesia should also make much-needed improvements to its inadequate online liability framework and enforcement mechanisms.

- **Chamber Recommendation:** 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.

Copyright Enforcement: 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 in order 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 scores behind its regional counterparts Malaysia and Vietnam on the regulatory data protection indicator, given that both Malaysia and Vietnam offer a 5-year term of RDP.

Regulatory Data Protection: Regulatory data protection provides innovators with time to realize a return on the R&D investment needed to generate safety and efficacy data required for marketing approval. 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 and Related Rights

Index Stat: Mexico ranks 29th out of 55 global economies in the patents and related rights Index category – the third highest in the Latin American region.

Patentability Requirements: Historically, obtaining protection for computer programs, software, and computer-implemented inventions (CII) 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. Annex 20-A of the agreement allows Mexico to continue using its current system, which involves coordination between the Mexican Institute of Industrial Property (IMPI) and the Federal Commission for the Protection against Sanitary Risk (COFEPRIS), to block the marketing of patent-infringing pharmaceuticals. Consequently, Mexico must notify patent holders when a third party applies for marketing approval of a follow-on product and give them a fair chance to present their case regarding the relevant patents before any such product is authorized.

While COFEPRIS has published applications for follow-on products on its website, the Chamber and its members believe that this measure is insufficient and does not satisfy USMCA requirements. This is due to the fact that it does not allow patent holders to present their case to IMPI concerning all relevant patents before the follow-



on product receives authorization. However, the Chamber and industry appreciates the close consultation between the COFEPRIS and the U.S. government throughout as Mexico seeks to create an effective patent enforcement framework that is fit for purpose within the Mexican system.

- **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 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 USMCA. While USMCA provides a transition period to grant Mexico additional time to implement patent term restoration, Mexico did not come into compliance with its USMCA obligation ahead of the expiration of the transition period on January 1, 2025. The absence of patent term restoration is exacerbated by the ongoing delays of COFEPRIS in approving medicines, resulting in significant patent term lost due to no fault of the inventor or patent owner.

- **Chamber Recommendation:** Mexico must implement measures, prior to January 2025, to restore the patent term for inappropriate marketing approval delays consistent with USMCA provisions.

Copyrights, Related Rights, and Limitations

Index Stat: Mexico ranks 20th out of 55 global economies in the copyrights, related rights, 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. For any notification system to be effective in addressing online infringement, it must be clear what the responsibilities and legal expectations are for each affected party. 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-takedown mechanism, Mexican authorities should promptly issue clear implementing regulations and guidance on ISP responsibilities and legal expectations.

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 regulation 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: USMCA's Article 20.48 obligates Mexico to provide regulatory data protection, for at least five years, for both small molecule and biologic medicines. This provision is subject to a five-year transition period that expires on July 1, 2025.

- **Chamber Recommendation:** Mexico must implement measures, including secondary regulations, to provide regulatory data protection consistent with Article 20.48 that are effective no later than July 1, 2025.

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. 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.

Since January 2023, Mexican regulatory authorities have issued at least ten marketing authorizations for patented pharmaceutical products, despite the existence of active patents. This action violated the IP rights of the patent holder and Mexico's obligations under international agreements like the USMCA. The Instituto de Salud para el Bienestar (INSABI) allowed these products to participate in an open tender, further complicating the situation. Industry representatives met with regulatory officials, leading to a decision to either award the tender to the patent holder or withdraw it entirely. Officials claimed to have been unaware of the three active patents, which raised concerns about the transparency and effectiveness of the regulatory process.

- **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.

- **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 and Related Rights

Index Stat: Saudi Arabia ranks 28th out of 55 global economies in the patents and related 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. While this is a positive step, the procedure does



not establish a 'linkage' regime, which would condition the approval of follow-on products on the exclusivity status of the reference product. It also lacks a notification mechanism for rightsholders and an automatic stay period to resolve disputes before the follow-on product's approval and launch.

- **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 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, Related Rights, and Limitations

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

Copyright Enforcement: SAIP has over the last three years aimed to strengthen the enforcement of IP rights in Saudi Arabia through both institutional improvements as well as increased levels of transparency and engagement with rightsholders. In 2024, standing committees continued to publish judgements 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. This includes removing approximately 16,300 individual pieces of infringing content and blocking approximately 4,500 violating websites included displaying and downloading copyrighted audiovisual works and broadcasting encrypted channels.

- **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.

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 and Related Rights

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



Patentability: South Africa's Patent Act provides for a 20-year term of protection, with annual renewal fees starting from the third anniversary of filing. The government's new 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 the South African government evaluates the efficacy of the Bolar exception under the 2002 Patents Act, the government should look to enhance its patent system to include a mechanism similar to patent term extension and support the entry of generics into the marketplace while also creating a system which supports the innovator’s patent rights.

- **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, Related Rights, and Limitations

Index Stat: South Africa ranks 40th out of 55 economies on the copyrights, related rights, 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 diminish copyright protection, including through expansive fair use-style exceptions, to perpetuate gaps in copyright protection, and to limit contractual freedom. In addition to the systemic substantive concerns with the bills, the legislative process suffered from numerous procedural deficiencies, including with respect to 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 such 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 creative community of South Africa and internationally 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. Additionally, it is estimated in 2025 a Final White Paper could be published recommending the imposition of local content quotas for video on demand providers. 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.

THAILAND

Patents and Related Rights



Index Stat: Thailand ranks 50th out of 55 global economies in the patents and related rights Index category.

Patents Act: Thailand's 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.