U.S. Chamber of Commerce

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By electronic submission:

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2024 SPECIAL 301 SUBMISSION

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Daniel Lee
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Office of the U.S. Trade Representative
600 17th Street NW
Washington, DC 20508

Re: ***Docket Number USTR-2023-0014; Request for Comments and Notice of a Public Hearing Regarding the 2024 Special 301 Review***

Dear Mr. Lee:

The U.S. Chamber of Commerce ("Chamber") is pleased to submit the attached comments in response to the Office of the U.S. Trade Representative's Request for Comments and Notice of a Public Hearing for the 2024 Special 301 Review. As in years past, the 2024 Special 301 Review enables a thorough examination of, and shines a much-needed spotlight on, the state of intellectual property protection and enforcement worldwide. We encourage the U.S. government to use this analysis, along with other available mechanisms, to secure meaningful action by our trading partners to improve their respective IP environments. The Chamber looks forward to working with the U.S. government to achieve this goal.

Sincerely,

David Hirschmann
Executive Vice President, U.S. Chamber of Commerce
President and CEO, Global Innovation Policy Center

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

Introduction

During the transformative period commencing in 2020 with the onset of the COVID-19 pandemic, a monumental vaccination effort successfully curtailed what could have been an even more dire and prolonged global health crisis, paving the way for a return to normalcy and economic stability. Intellectual property-intensive industries, integral to this victory, provided the innovative technologies and services that played — and still do play — a crucial role in sustaining the worldwide health and productivity that we enjoy today.

However, as the world resumes its regular course, the United States —traditionally a global promoter and enforcer of robust IP rights — has weakened its own authority on the international stage, inviting the erosion of IP rights. This shift has implications for various industries, including pharmaceutical, agricultural, technological, financial, and the arts. As the United States repositions itself, various economies and multilateral organizations worldwide have initiated a comprehensive assault on intellectual property rights in these diverse sectors.

The U.S. Chamber of Commerce ("Chamber"), representing these and other cutting-edge industry sectors from local enterprises to global leaders, has been at the forefront of bringing attention to and responding to these assaults, and has committed itself to being a voice for industry globally and for the innovators who sustain our economic ecosystems. The Chamber also recognizes the vital role played by its members in creating and discovering innovations that enhance lives across the globe and is proud to stand by their sides. Ongoing challenges, including technological advancement, climate resilience, and global health, underscore the need for continued reliance on IP-intensive industries for sustained economic recovery and expansion, as well as global health and sustainability.

To assist foreign governments in strengthening their IP ecosystems, the Chamber's International IP Index annually assesses national IP frameworks. The findings highlight the tangible economic benefits of robust IP protection, including increased access to venture capital, early availability of innovative therapies, promoting collaboration, and significant private sector investment in research and development.

Additionally, and in conjunction with the IP Index, the Chamber in September 2023 published its "IP Principles" paper declaring the Chamber's beliefs regarding intellectual property and its role in the 21st Century and urges policymakers of all stripes to "take affirmative steps to ensure that intellectual property rights in America remain strong both domestically and the gold standard globally." Specifically, the Chamber affirms the need to:

- Protect America's global innovation leadership;
- Lead the world in critical and emerging technologies;
- Foster America's creativity and provide global inspiration;
- Hold bad actors accountable for IP crimes; and

- Unleash the full potential of American entrepreneurial ingenuity.

America, and its business ecosystem, is a force for global good. But we know that in a globalized society, it takes cooperation, collaboration, and good faith efforts by its allies and trading partners to deliver on these principles and hope that the economies listed in this Special 301 report — and beyond — can draw inspiration from these affirmations and incorporate their ideals into policy.

The Chamber's Special 301 submission, covering 16 representative markets, underscores the critical role of U.S. leadership in resolving IP-related challenges, and identifies what it and its members see as glaring shortcomings in global IP positions, in addition to identifying the specific market practices that deny adequate and effective IP to American innovators. When the U.S. takes the lead on IP policy, it ensures that Americans, as well as global citizens, benefit from innovation. U.S. leadership on IP creates U.S. jobs, fosters American innovation and competitiveness, and safeguards America's national security. The Chamber urges the U.S. government to reaffirm its global leadership on IP protection, expressing concern over proposals such as the WTO TRIPS Waiver expansion and proposed language in the WHO Pandemic Treaty negotiations, which may undermine American innovation.

The Chamber remains committed to collaborating with the U.S. government and global partners to ensure that IP continues to be a force for good in 2024 and beyond. This commitment aligns with the goal of advancing the global ecosystem for innovation and creativity, fostering a collaborative approach to address challenges on the international stage.

Section A: Measuring IP and Access

The 2024 Chamber International IP Index

Now in its 12th 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 economies. The Index maps the IP ecosystem in 55 global economies (over 90% of global GDP) across 50 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 12th edition of the Index is expected to be released in early 2024. As a result, the Chamber's Special 301 submission will cite the 11th edition of the report, which has been public since February 2023.

Section B: Global Trends

Artificial Intelligence

The Chamber recognizes the complexities of the rapidly evolving global debate around the development, training, and use of artificial intelligence, including concerns regarding patentability, disclosure requirements, protection of copyrighted works, and commercialization of assets derived from AI-generated content. Along with its members, the Chamber stands ready to help lead the discussion on how to best adapt and adopt common sense policies and procedures that maximize innovation and creativity while protecting the intellectual property rights of creators and inventors and maintaining the safety and security of users.

United States Chamber of Commerce Commission on AI

In January 2022, the Chamber launched its Artificial Intelligence ("AI") Commission on Competition, Inclusion, and Innovation to study the effects of and advance U.S. leadership in the use and regulation of AI technology. Co-chaired by former Reps. John Delaney (D-MD) and Mike Ferguson (R-NJ), the Commission convened thought leaders with experience in government, industry, and civil society to address the advancement and challenges of adopting AI in communities across the country and its impact on a wide range of industries, national security, and the US and global economies. Commissioners met over the course of a year with over 87 expert witnesses during five separate field hearings across the country and overseas. They also received written feedback from stakeholders answering three separate requests for

information posed by the Commission. After collecting feedback from relevant stakeholders, the Commission released its much-anticipated report that stressed the need for five key pillars in AI formation, including efficiency, collegiality, neutrality, flexibility, and proportionality. Expanding on these themes, the Commission recommended focusing on using AI to:

- Prepare the workforce in training, re-skilling, and attracting high skill talent;

- Bolster global competitiveness by developing good global governance, protecting IP rights, and protecting innovation and ingenuity; and

- Protect national security, with an emphasis on supporting human rights and streamlining acquisitions.

The Chamber notes that these findings and recommendations are not exhaustive, and it welcomes the insights of others who may contribute to the AI policy debate, particularly as it relates to the protection of IP and IP-protected assets. The Chamber stands ready to collaborate with policymakers to address these issues that are of utmost importance to the United States and the economic wellbeing and safety of the global community.

International AI Development

Additionally, the Chamber was encouraged to see recent language from the G7 as part of the "Hiroshima AI process," was comprised of an 11-point code, which "aims to promote safe, secure, and trustworthy AI worldwide and will provide voluntary guidance for actions by organizations developing the most advanced AI systems, including the most advanced foundation models and generative AI systems."

The code also urges companies to institute appropriate measures to identify, evaluate and mitigate risks across the AI lifecycle, as well as identify and respond to patterns of misuse after AI products have been placed on the market. As noted, the Chamber stands ready to assist our global partners in the private and public sectors in developing robust and enforceable AI standards that protect innovators, enforce IP standards, and protect safety and national security.

The Chamber also strongly encourages USTR and the United States government to closely follow and monitor international AI developments, ensuring that American industry's voice is heard as various economies debate a path forward that enhances AI capabilities while protecting IP rights.

USMCA and Transition Periods

Top of mind for members and indeed the broader Chamber is the faithful implementation of the USMCA and other trade agreements, in particular, provisions protecting

and enforcing intellectual property. U.S. lawmakers of both parties, joined by the Chamber and other business organizations, have long insisted that U.S. trade agreements are not worth the paper they are printed on if they are not enforced. Indeed, enforcement of trade agreements is a principle that enjoys essentially universal support in Congress, across Administrations, and throughout industry.

However, as has become increasingly clear as USMCA transition period deadlines in 2025 for IP provisions rapidly approach, Mexican authorities have — in multiple circumstances — failed to implement many basic provisions of their IP obligations into domestic law. This includes, among other issues, the exclusion of "computer programs" as patentable subject matter, the lack of a comprehensive and practical system of biopharmaceutical patent enforcement, the lack of a period of restoration or additional sui generis protection for delays caused by the drug registration and marketing approval process, lack of clear regulatory data protection for pharmaceutical products such as biologics, unclear language regarding ISP liability for infringing content, and ongoing constitutional challenges to copyright provisions promulgated in 2020.

As always, 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.

The International IP Landscape in Multilateral Organizations

Ongoing Challenges at the U.N. and Other Agencies

Specialized agencies in the United Nations (U.N.) framework create a critical venue to advance conversations on fostering innovation and creativity in the global context. While the standards for IP protection and enforcement vary significantly in global markets — as evidenced by the Index — the multilateral rules-based system can expand participation in the global innovation ecosystem if the institutions' agreements embrace a more effective and positive framework for IP-driven innovation.

The Chamber is deeply concerned about the narrative, broadly calling for IP waivers and forced technology transfers, which has taken hold across multilateral institutions and UN agencies. As noted below, proposals for the WHO Pandemic Accord call for further such exceptions, or outright rejections, of core IP rights. Additionally, the UN Secretary General has suggested that renewable energy technologies should be public goods. This narrative goes together with a broader effort to force technology transfer and undermine trade secrets across the multilateral system. For example, India recently introduced in the WTO mechanisms to promote access to patented green technologies through forced technology transfer. Likewise, the International Health Regulations suggest a need for involuntary technology transfer. The Chamber is concerned that these efforts will dismantle the global framework that has supported IP-driven private sector investment in innovation to date.

For this reason, the Chamber urges the U.S. government to reassert its long-standing global leadership position within the multilateral rules-based system to preserve the framework that has delivered transformative innovation and creativity for the global community.

WTO TRIPS Waiver and USITC Report

The Chamber remains highly concerned with the ongoing negotiations to expand the waiver of WTO members' TRIPS obligations for IP rights related to COVID-19 technologies and welcomed USTR's efforts to gather further data on the extension of the TRIPS Waiver through the USITC report. The Chamber believes the report rightly acknowledges several points:

- Real barriers to access: The Chamber supports multilateral organizations' efforts to expand access to healthcare technologies in low- and middle-income countries. The USITC report notes the many real barriers to access, including slow regulatory approvals, limited government budgets for healthcare expenditures, last mile delivery issues, a waning focus on COVID-19, competing healthcare priorities, trade barriers, export restrictions, and issues with customs and border inspections. The WTO, along with the UN agencies in Geneva, have a role to play in addressing trade-related barriers and existing gaps in healthcare systems. Proceeding with an IP waiver for therapeutics and diagnostics will diminish the world's ability to prepare for and respond effectively to the

next pandemic, while doing nothing to addressing the real barriers that prevent the supply of treatments and diagnostics to those who still need them.

- Collaboration across the innovation ecosystem: Innovation occurs along a lifecycle and across a multi-stakeholder ecosystem of private industry, financial markets, government agencies, research universities, and scientific institutions. Public-private sector collaboration across the ecosystem is critical to ensuring that the fruits of the innovation ecosystem are realized and reach end-users to save and transform lives. The USITC rightly notes the many R&D collaborations — underpinned by effective IP standards — between business and actors across the innovation ecosystem throughout the pandemic enabled the rapid discovery of COVID-19 technologies. An expansion of the waiver will undermine the framework that supported these successful partnerships and enabled the delivery of vaccines, therapeutics, and diagnostics to markets around the world.

- Pivotal role of the private sector: According to the National Science Foundation, three-quarters of R&D taking place throughout the U.S. innovation ecosystem is performed by the private sector, whose investment relies on effective IP laws and supporting regulatory frameworks backed by a commitment to the rule of law. The USITC report accurately describes the unique role the private sector plays in both the R&D process and bringing innovative products to market, stating "the U.S. government and universities have played an important role in some of the R&D underlying diagnostic and therapeutic discoveries. Governments and universities, however, generally do not commercialize new products." Proceeding with a further waiver of IP rights will undercut the business community's ability to continue to do so for the next major global challenge, be it a future pandemic or climate change.

- Waning demand: With the conclusion of the public health emergency, the USITC appropriately acknowledges that demand for products has declined, and that supply meets current demand, noting that "governments with limited budgets for healthcare expenditures must balance their responses to COVID-19 with efforts to combat other diseases." Expanding the waiver of IP rights while the global health emergency wanes will only leave the global community less prepared to respond to other health threats by stifling the innovation needed to combat them.

We appreciate the U.S. government's acknowledgement of each of these points. However, we note the following concerns with the continued debate over the waiver's expansion, which were largely left unaddressed by the USITC report:

- Impact on U.S. leadership: Over all 11 editions of the Index, the U.S. has ranked first overall due to its long-standing dedication to a legal and regulatory framework that supports IP-driven innovation. The strength of the U.S. IP framework supports investment in innovation and creativity across wide-ranging sectors. Support for the COVID-19 vaccine waiver marked a radical departure from the U.S. government's long-

established position on global IP policy, to the detriment of the U.S. economy and American innovators, creators, and workers. Support for the waiver not only undermines our leadership on IP-driven biopharmaceutical innovation but also in emerging industries including digital, climate change, and agriculture-related technologies.

- Impact on U.S. national security: The existing waiver gives away America's technology to create innovative vaccines to its economic competitors. Expanding the waiver to therapeutics and diagnostics further compounds this threat. While the waiver is intended to solely apply to technology for COVID-19 treatments, there is no guarantee that our economic competitors, including China, would refrain from using that technology to support technological advancements in other therapeutics areas. An expansion of the waiver will give the keys to our success in the innovative industry to our foreign competitors.

- Impact on the U.S. economy: Effective IP policy empowers America's comparative advantage in the innovative and creative industries. The biopharmaceutical industry supports over 4.4 million U.S. jobs and adds $14 trillion to the U.S. economy. Proceeding with an expansion of the waiver will endanger the jobs and economic contributions sustained by IP-enabled innovation.

- Impact on the framework for marketplace competition: Well-functioning markets can promote competition while safeguarding the underlying IP framework needed to sustain investment in innovation. The Chamber is concerned that reliance on IP waivers as a misguided means to enhance access will undermine the existing framework that has enabled competition in the marketplace and negatively impact our fragile economic recovery.

- Impact on future innovation: As the global community moves beyond the global health emergency the Chamber is concerned about the impact an expansion of the waiver will have on the future pipeline for innovation. An expansion of the waiver to therapeutics and diagnostics not only begins to dismantle the framework for IP protection but also jeopardizes future investment in the next generation of innovation, both in the biopharmaceutical sector and beyond.

As the U.S. government considers its position on an expansion of the waiver, we urge USTR to consider the far-reaching and negative implications such an expansion would have on not just the biopharmaceutical and healthcare-related industries, but almost every other creative and innovative ecosystem in the world. Rather than continue negotiations on this unnecessary waiver, the Chamber calls on the U.S. government and like-minded multilateral stakeholders to re-double global efforts to focus on the real barriers to access, and to promote IP education and capacity-building, which will be critical to the global capacity to respond to the next pandemic or other crisis requiring innovative technological solutions.

WHO Pandemic Accord

While the debate continues over the TRIPS Waiver at the WTO, the Chamber is concerned to see the anti-IP narrative spill over into the debate on the WHO's Agreement on Pandemic Prevention, Preparedness, and Response ("Pandemic Accord"). The WHO's Intergovernmental Negotiating Body ("INB") is currently considering negotiating text for the Pandemic Accord, and the October 2023 draft includes harmful provisions which will further undermine the ecosystem for biopharmaceutical innovation. Chief among the Chamber's concerns are the provisions that call for "time bound waivers" of intellectual property rights. The text also reiterates the call for countries to use the "TRIPS waiver on compulsory licensing to ensure access to medicines for all."

The U.S. Chamber deeply appreciates the U.S. government's re-acknowledgement that waiving intellectual property protection will not strengthen preparedness for the next global pandemic. We align our position with the recent U.S. government statement at the INB where U.S. Ambassador Hamamoto noted that "[e]liminating intellectual property protections will not effectively improve equitable access during pandemic emergencies and will in fact harm the systems that have served us well in the past. The United States believes strongly in IP protections which serve to fuel investment and innovation. We agree that more timely access to these innovations should be central to our discussions and are exploring options to prioritize the availability of medical countermeasures for developing countries during future pandemic emergencies."

Likewise, we appreciate the U.S. government's continued focus on voluntary technology transfer — emphasis on "voluntary." The global innovative ecosystem thrives when the innovative community has legal certainty that their inventions will be protected. This ecosystem relies upon mechanisms to disclose information safely and voluntarily with trusted partners on the development and manufacturing of those innovations, which is made possible by effective IP protection. The Chamber looks forward to working with the U.S. government to ensure that the final Pandemic Accord preserves the IP rights and framework for voluntary collaborations that were pivotal to the shared global response to COVID-19.

WIPO Diplomatic Conference on IP and Genetic Resources

The World Intellectual Property Organization ("WIPO") plans to host a Diplomatic Conference to Conclude an International Legal Instrument on IP, Genetic Resources, and Traditional Knowledge Associated with GR from May 13-24, 2024, in Geneva. Depending on the outcome, such a legal instrument could upend American innovators' continued ability to research and develop products related to genetic resources.

The Chamber and indeed industry are deeply concerned with the patent disclosure requirements proposed in the Chair's text which could inhibit innovation using genetic resources ("GR") and associated traditional knowledge ("TK") and the failure to exclude Human

Genetic Resources from the scope of any such text – consistent with the scope of the Convention on Biological Diversity. The Chair's text sets a minimum patent disclosure obligation but allows for significant discretion to the Member States to put in place more expansive requirements than those required by the legal instrument, which creates significant legal uncertainty for innovators as to which patents can be granted or enforced across global markets.

Additionally, the Chamber is concerned that the disclosure requirements will delay the patent application process. For example, research by IFPMA and CropLife International found that disclosure requirements could delay the patent application process in Brazil and Indian by 1-4 years. In Brazil, while INPI has taken steps to address the patent backlog, the estimated backlog remains at 20,000 applications.[3] Industry is concerned that the disclosure requirements proposed in the Chair's text will exacerbate the already lengthy delays innovators face during patent review in some emerging markets.

Furthermore, the Chair's text does not specifically exclude human genetic material, which form the basis of many biotechnology inventions. Human genetic resources are pivotal to the conduct of clinical trials and other fundamental aspects of health-related research and development. Recent experience with restrictive requirements in China concerning mandatory requirements for IP sharing related to use of Human Genetic Resources shows that such an approach carries great risk to pharmaceutical and other healthcare-related industry research and development. The measures in China have added significantly to the timeline for completion of clinical trials and disproportionately burdens U.S. companies who may need to export samples and data to complete their clinical trials, and this should not be exported globally.

The Chamber urges the US government to take these concerns seriously and continue opposition to inclusion of new patent disclosure requirements for genetic resources and related traditional knowledge and any inclusion of "human genetic resources" within the scope of the Diplomatic Conference. Instead, WIPO should focus on measures relating to genetic resources to improve patent quality, such as prior art databases to streamline patent examination burdens, and measures to facilitate mutually agreed terms between providers and users of genetic resources.

We believe the upcoming Diplomatic Conference will set the tone for the subsequent Diplomatic Conference on traditional knowledge and traditional cultural exceptions. The Chamber appreciate the U.S. government's long-standing engagement on the IGC, and we stand ready to continue to collaborate ahead of the Diplomatic Conferences.

The International IP Landscape in Enforcement

Background

A rule of law environment for innovators and creators, marked by effective, sustained, and consistent IP enforcement, is foundational to the legal certainty that enables investment in IP value creation across all industry sectors. Unfortunately, in many global economies effective enforcement options are not practically available or fully utilized. Judicial and administrative routes of enforcement are often overloaded and under-resourced. With respect to effective border measures, not all economies grant their customs authorities, border guards, and/or other designated officials *ex officio* authority to seize suspected counterfeit and pirated goods, including goods in transit, without a formal complaint from a given rightsholder.

Volatility of the global enforcement environment greatly affects U.S. Chamber members' ability to create, use and protect their IP both at home and abroad, and correspondingly their capacity to create and sustain American jobs. The lack of effective enforcement efforts is an increasingly significant problem given the rise in overall levels of global trade. In 1990, the value of world trade in goods was an estimated USD 3.5 trillion. As the most recent data from 2022 shows, the value of global trade in goods is over seven times that amount at an estimated USD 25.05 trillion;[1] and this is not counting trade in services which has also grown exponentially.

The technological revolution of the past three decades has helped foster international trade growth, most keenly evinced by a booming e-commerce environment. It is estimated that by 2024, 21.2% of retail sales will occur online.[2] While this development has enabled large, medium, and small businesses alike the ability to reach consumers in foreign markets that a generation ago would have been inaccessible, the resulting increase in volume and value of global trade has complicated IP enforcement efforts to a degree insurmountable by some global economies as they are currently structured and has 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.

International efforts to measure the scale of counterfeit and pirated goods have increased in tandem, with the work primarily being driven by the OECD and EUIPO which have been instrumental in developing new metrics and regular assessments of levels of trade-related counterfeiting. Estimates show that the volume and scope of counterfeit and pirated goods is steadily increasing. The latest OECD estimates suggests an aggregated valuation of just under

[1] https://www.wto.org/english/res_e/booksp_e/trade_outlook23_e.pdf.
[2] https://on.emarketer.com/rs/867-SLG-901/images/eMarketer%20Global%20Retail%20Ecommerce%20Forecast.pdf.

USD 500 billion (USD 464 billion) of counterfeit and pirated goods per year, or 2.5% of global trade.[3] Similarly, U.S. Chamber of Commerce research found that global online piracy costs the U.S. economy at least $29.2 billion in lost revenue each year.[4]

Counterfeit Enforcement in an Online Environment

As the e-commerce ecosystem continues to expand and evolve, combating IP theft becomes more and more challenging, particularly in a global trade environment in which many global trade powerhouses have vastly different enforcement capabilities. Criminals and transnational criminal organizations have adopted sophisticated strategies to peddle illicit, IP violative products directly to consumers shopping online. Despite considerable investments by legitimate businesses to secure product integrity, chemical safety standards, and customer trust, the pervasiveness of counterfeiters infiltrating the global supply chain is unyielding and rapidly evolving. To protect the health and safety of consumers and the continued viability of trusted brands that employ millions of people worldwide, it is imperative that law enforcement authorities both in the United States and abroad have the resources and tools to combat counterfeiters operating in the online environment.

IP infringement is increasingly complex and globalized, requiring sophisticated investigatory tools. No IP enforcement program can be effective without the ability to trace, on a cross-border basis, counterfeiting and other illicit activities with insights and information derived from foreign source countries, distribution hubs and networks, and end-user markets. Data localization measures and unnecessary data transfer restrictions directly interfere with the ability to investigate and counteract transnational IP infringing activities. Cross-border data transfers are critical to many aspects of IP enforcement, from monitoring marketplaces, to gathering evidence of infringement in multiple locations, to researching details of illicit networks, to using administrative or judicial tools in multiple jurisdictions to preserve evidence and secure recourse.

The Chamber supports collaborative global initiatives dedicated to combating transnational criminal networks that produce and sell counterfeits, pirated works, and other illicit goods, including in the online ecosystem. For example, the OECD illicit trade taskforce continues its valuable work to study illicit trade activity, creating a foundational understanding of the significant threats illicit trade poses to our global economy and examining, through quantitative metrics, novel solutions to combat the production and sale of counterfeit goods.

The greatest source of illegally diverted drugs is the internet via the online grey market. Grey market goods are defined as genuine goods diverted from the manufacturer's authorized

[3] http://www.oecd.org/gov/risk/trends-in-trade-in-counterfeit-and-pirated-goods-g2g9f533-en.htm.
[4] Impacts of Digital Piracy on the U.S. Economy.

distribution network.[5] Illegal online transactions for prescription drugs are made through standalone websites, online marketplaces, and social media platforms. These online transactions are unregulated and dangerous for patients. Patients purchase from these online sources believing they are getting low-cost versions of FDA-approved medicines. Often, they are being deceived by criminals purely for financial gain. At best, patients receive illegally diverted drugs that arrive at their doorstep with zero regulatory oversight on how the drugs were stored, packaged, and/or shipped. At worst, they receive counterfeit medicine that can put the consumer in lethal danger. Given the internet's lack of central governance, enforcement typically lies solely with internet service providers and the platforms' willingness to enforce their own terms of use. Many do nothing after being put on notice that their services are used to illegally sell prescription drugs, creating a refuge for this type of illegal activity online. While others may take content down, their efforts fall short of having any meaningful impact on addressing the issue of illegal diversion of drugs online.

Transshipment and Small Parcels

Overseas criminals and sellers often ship counterfeit goods into the U.S. using international express mail services and airmail, such as the China-based Express Mail Service ("EMS") of the China Post. To avoid detection of counterfeit goods by U.S. Customs and Border Protection ("CBP") import specialists, remote sellers overseas may fraudulently declare small mailings individually. Depending on the size of the order, many websites will also break up shipments into several small packages, including using a fraudulent label or trademark tag, to avoid seizure. The issue of counterfeits in express and mail shipments has continued to grow. Last year, nearly 1 billion small parcels were shipped to the United States.[6] Furthermore, of all IP violative seizures of goods, small parcels made up 93% in 2018.[7] The sheer volume of such small shipments makes it impossible for customs agents in the U.S. and abroad to adequately screen and detect suspect shipments, and goods shipped domestically by first-class, priority, or express mail often are not inspected for potential IP violation without probable cause.

The Role of Public-Private Partnership to Combat Counterfeiting

In 2021, U.S. Customs and Border Protection ("CBP") and the Chamber signed an historic Memorandum of Understanding ("MOU") to implement a dedicated public-private partnership with a multi-faceted program of anti-counterfeiting work. Since its inception, the MOU has facilitated, developed, and spearheaded models for public-private information-sharing related

[5] OECD/EUIPO (2020), *Trade in Counterfeit Pharmaceutical Products*, Illicit Trade, OECD Publishing, Paris, https://doi.org/10.1787/a7c7e054-en.

[6] https://www.cbp.gov/sites/default/files/assets/documents/2022-Sep/COAC%20eCommerce%20TF%20Gov%20External%20-20220822%20%28003%29%20%282%29.pdf.

[7] OECD/EUIPO (2018), *Misuse of Small Parcels for Trade in Counterfeit Goods: Facts and Trends*, Illicit Trade, OECD Publishing, Paris, https://doi.org/10.1787/9789264307858-en.

to illicit trade. This Summer, the MOU was renewed for an additional five-year term, signaling strong commitment from CBP and the Chamber to build on progress made thus far.

A particularly fruitful component of the MOU is a program of work in which Chamber member companies, representative of highly counterfeited industries, are sharing foreign counterfeit seizure data with CBP and the National IPR Center through a designated Chamber secondee. The secondee is physically embedded at the National IPR Center and can regularly interface with data analysts and investigative agents at the Center to help comb foreign seizure data for themes or commonalities that indicate illicit activity, develop investigatory leads, fact-check sources, and use limited resources and bandwidth in the most effective fashion possible.

Furthermore, the Secondee and Chamber member participants have been able to assist in strengthening current criminal investigations by identifying additional infringing importers and exporters that were unknown to Homeland Security Investigations ("HSI"). The Secondee works with CBP to identify transshipment routes of counterfeit goods that enter the United States before its ultimate destination to another country. CBP and the Secondee analyze data provided by the U.S. Chamber's members in real time to identify transshipment routes and related information that is then utilized by CBP to conduct targeting of the counterfeit goods before they reach their ultimate destination. The information sharing program has resulted in the seizure of millions of dollars' worth of IP violative goods in the United States, and in this and many other ways, may provide a useful template for public-private partnerships in the global enforcement arena.

Digital Piracy and Copyright Infringement

A growing area of concern for the Chamber and its members is the proliferation of digital piracy and the difficulty of enforcement against infringing content found online. The growth and scale of online piracy since the late 1990s — whether through downloading, streaming or some other technology — has mirrored this growth in broadband and mobile device connectivity. This scale and volume of online infringement has resulted in a growing strain and burden on rightsholders to effectively protect their content and economic rights. However, one common tool used to protect digital copyrighted content is site blocking. As of January 2022, at least 48 countries — including the European Union ("EU") — offer legislative, judicial, or administrative frameworks for some form of site blocking for copyright infringement. The most common method is injunctive relief, which comes in three variations: static, dynamic, and live.

Static injunctions are the most common, as they are used to stop a specific instance of infringement by a specific infringer. Dynamic injunctive relief adapts to the technological advantages utilized by infringers. Often, digital pirates utilize mirror sites, a technique whereby infringing content appears on a separate site mimicking the infringing content on a main mother site. Therefore, the infringing content illegally re-enters the arena by simply being moved to a different access point online. In a purely static injunctive relief jurisdiction,

rightsholders must acquire separate injunctions for each of these sites. Dynamic injunctions provide rightsholders a singular mechanism to repeatedly block access to infringing websites, apps or platforms, regardless of their domain or IP address changes. Although live injunctive relief may also be static or dynamic, the framework here offers rapid protection against economically destructive infringement, such as in the case of live-streaming sporting events.

Areas of Note and Attention

PTE in Taiwan

The Chamber notes that industry is experiencing systematic issues in Taiwan regarding the lack of adequate and effective patent term extension ("PTE"). Currently, Taiwan's PTE practice remains out of sync when compared to global best practices, particularly in the US, Europe, and Japan. This is especially true in other major jurisdictions when considering the limitation of the API that is eligible for PTE – in relation to the particular hydrate or polymorph used in the drug application. Specifically, no major jurisdiction considers a hydrate of the API as the active ingredient for the purpose of PTE. Instead, all major jurisdictions allow a patent claiming the active ingredient (as a compound) to be eligible for PTE even though the drug application describes that the drug product contains a particular hydrate of the active ingredient compound.

Patent Law in Thailand

A particular area of note that the Chamber feels USTR should monitor is developments in the process of Thailand's amending of the Patents Act, which has been ongoing since 2018 and still has not been completed. The Chamber and industry, keenly aware of emerging opportunities in Southeast Asia, believe that these efforts should be completed as soon as possible to streamline the patent registration process and to reduce patent backlog and pendency.

Section C: Developed Market Profiles

AUSTRALIA

Overview

The Chamber is a committed stakeholder in the U.S.-Australia relationship and believes that securing strong IP protection will be critical to further strengthening ties between our two countries. The Chamber believes the U.S.-Australia Free Trade Agreement laid the groundwork for ensuring that innovative and creative industries in both countries can thrive. However, the Chamber has identified several areas where a more effective IP framework can enhance ingenuity, promote greater foreign investment, and stimulate Australia's long-term economic growth and global competitiveness. The Chamber looks forward to working with the U.S. government to address the below IP-related concerns.

Patents and related rights

Index Stat: Australia ranks 16th out of 55 economies in the patents, related rights, and limitations Index category. While Australia outperforms economies like Israel and Taiwan in the overall Index rankings, ongoing challenges for patent holders cause Australia to trail these economies in the patent rankings.

Patent Linkage and Market-Sized Damages

In October 2020, the Therapeutic Goods Administration ("TGA") concluded an 18-month consultation on prescription medicines transparency measures. As a result of the consultation, the Government announced their plan to introduce legislation to create an earlier patent notification framework. The proposed plan was set to require that applicants for the first generic and biosimilar form of an originator product notify the patent holder when their application is accepted for evaluation by the TGA. The change was designed to create an opportunity for earlier negotiation and resolution of disputes on potential patent infringements before the generic is listed on the PBS.
The Chamber was encouraged by these potential changes to the Australian system, which could increase transparency, reduce the need for costly litigation, and improve the regulatory framework for innovative companies operating in Australia. However, these changes were put on hold by the previous Government following minor concerns by the competition regulator the ACCC. Since the election in May 2022, the issue has not been prioritized by the new Government.

Chamber Recommendation: The Chamber suggests that the U.S. government work closely with their Australian government counterparts particularly within the central agencies (Finance and Treasury) to ensure that the benefits of the change are clearly understood, and the early notification system is effectively implemented to better protect IP rightsholders. Additionally, the Chamber recommends encouraging the Australian government to reverse its policy of pursuing market-sized damages from IP rightsholders aimed at compensating for a delay in the PBS price reduction during the period of provisional patent enforcement, which creates further legal uncertainty for biopharmaceutical innovators in Australia particularly as injunctive action is the only option available to an IP rightsholder to protect its patent upon learning of the entry of a competitor into the market.

Patent Term Extension

A patent term extension period of a maximum five years is allowed under the Australian Patent Act. However, rightsholders in Australia have historically faced some practical challenges to receiving the full maximum term available. Under the Patent Act, an applicant is obliged to apply for term extension within six (6) months of the approval and listing of the relevant product and corresponding patent claims on the Australian Register of Therapeutic Goods. Unlike other major jurisdictions, the Australian authorities have interpreted the start of this six-month period as beginning from the time in which any product containing the substance falling under the relevant patent claim was registered, regardless of it belonging to a

third party. In effect, this has likely precluded rightsholders from accessing their full term of the patent.

However, a 2022 Federal Court ruling clarified that if the PTE regime "has not achieved, and is not achieving, its intended policy objectives, or is providing difficulty for patentees in its application, then it is for the legislature to drive the outcomes it seeks by undertaking the necessary legislative changes."

Chamber Recommendation: The Chamber encourages the U.S. government to work with the Australian government to ensure that the availability of patent term restoration in Australia is consistent with best practices in other developed economies.

Trade secrets and related rights

Index Stat: Australia ranks 18th out of 55 economies in the trade secrets and protection of confidential information Index category. On the regulatory data protection indicator, Australia scores on par with upper-middle-income economies such as Jordan and Malaysia.

Regulatory Data Protection

Current Australian law includes five years of regulatory data protection for biologic medicines. However, the lack of RDP for new formulations, new combinations, new indications, new populations, and new dosage forms, whether for biologics or small-molecule medicines, is contrary to Article 17.10(2) of the AUSFTA. In contrast the RDP provided by Australia to certain categories of chemicals and medicines for veterinary use was increased to 10 years in 2014 as a measure to promote innovation.

Chamber Recommendation: The Chamber suggests that the Australian government consider enhancing data exclusivity protection for all medicines in line with international best practice, which is strongly in line with the government's stated industrial policy objectives with respect to biopharmaceuticals and the attraction of innovation and investment.

Commercialization of IP assets and market access

Index Stat: While Australia has a strong performance overall in the commercialization of IP assets and market access; Index indicators, reimbursement and listing uncertainty, the use of broadcast quotas, and local content obligations create significant challenges for creators operating in the market.

Reimbursement and Listing Uncertainty

Historically, innovative companies have encountered a complex regulatory framework for marketing authorization in Australia. Under Australia's statutory pricing system, innovative

products are subject to significant price reductions upon the market entry of a follow-on product. Additionally, industry has reported challenges listing new medicines on the Pharmaceutical Benefits Scheme due to significant delays between regulatory approval and reimbursement listing. On average, it takes 47 months from global launch of a product to reimbursement listing in Australia.
Furthermore, Australia's comparison of new innovative products to the lowest cost comparator (rather than the most used clinical comparator) has resulted in fewer innovative medicines being offered in the market compared to other high-income economies. For example, Australian patients only had access to 32% of the new medicines launched between 2012-2021, while patients in the U.S. had access to 85%. Similar delays are also experienced through the Medical Services Advisory Committee.

Chamber Recommendation: The Chamber appreciates the Australian government's willingness to work with industry, including through Strategic Agreement's with Medicines Australia and the current Health Technology Assessment Review. The Chamber encourages the U.S. government to work with their Australian government counterparts to build upon the Strategic Agreements to further streamline the health technology assessment and reimbursement system to improve access to innovative medicines for Australian patients. Annex 2-C, 3 of the Australia-US FTA established a Medicines Working Group to resolve issues like the above. The Group has not met since 2008. The Chamber requests that USTR make efforts to reform this group to provide a platform for officials of federal government agencies responsible for federal healthcare programs to come together on a regular basis to resolve current medicines access issues.

Broadcast Quotas

While the U.S.-Australia Free Trade Agreement capped broadcast quotas for analog TV at 55%, Australia has the right to extend the quotas to digital broadcast TV. The Chamber believes the quotas create a market access barrier for foreign creative companies operating in the market.

Chamber Recommendation: The Chamber recommends that Australia reconsider the use of broadcast quotas to open the Australian market for creative content from abroad.

OTT/VOD Local Content Obligations

According to the Australian Media Communications Authority, five Video on Demand (VOD) streaming services — Amazon Prime Video, Disney, Netflix, Paramount+, and Stan — have invested $335.1 million in Australian programming. Despite this significant investment, the Australian government is considering imposing additional local content obligations on VOD streaming services. The Chamber firmly believes in the power of free markets, and it is clear based on current private sector investment that there is not a market failure that necessitates further government intervention. The Chamber is also concerned that the additional

regulations will violate Australia's obligations under the Australia-U.S. Free Trade Agreement and the Korea-U.S. Free Trade Agreement.

Chamber Recommendation: The Chamber urges USTR to work closely with their Australian government counterparts to ensure that any additional VOD regulations for streaming services do not unfairly disadvantage the foreign creative community, which has already invested significantly in Australia.

CANADA

Overview

A unified North American IP framework will be critical to furthering global economic competitiveness for Canada, Mexico, and the U.S. alike. Faithful implementation of the United States-Mexico-Canada Agreement ("USMCA") IP chapter will result in stronger IP protection in some areas. However, the final agreement removed or omitted many IP provisions that would have strengthened the environment for innovators and creators in Canada. Given the missed opportunity the USMCA created to raise the bar for IP protection, the Chamber believes it is even more important that the U.S. government work closely with its Canadian government counterparts to address the remaining challenges outlined below.

Patents and related rights

Patent Enforcement and Resolution Mechanism

Canada's linkage system dates to 1993 and the North American Free Trade Agreement ("NAFTA") agreement. However, Canada's linkage system has several long-standing deficiencies. In 2017, the government amended the relevant secondary legislation, the Patented Medicines (Notice of Compliance) ("PMNOC") Regulations, to comply with Canada's commitments under the Canada-EU Economic and Trade Agreement ("CETA"). Unfortunately, the amendments have not effectively addressed these deficiencies.

First, while the Canadian linkage regime provides a register similar to the U.S. Orange Book that lists approved products and their respective patents, the Canadian listing requirements mean fewer patents can be included. Specifically, timing requirements and the fact that late listing is not possible limit the number of eligible patents.

Additionally, there is no 20-day or other deadline in Canada for generic producers to notify the innovator of its regulatory filing. Once a notification (notice of allegation) is given, the innovator has 45 days to file a judicial review application to resolve patent issues, triggering an automatic 24-month stay. The old PMNOC procedures did not provide patent holders (a "first person") with a right of appeal, and the judicial proceedings determining the merits of the disputed patent or patents was a summary, not full, process. This limited the rights of the

patent holder and the availability of the full term of protection. While recent amendments have replaced summary proceedings with the possibility to bring fully fledged judicial actions, procedural complexity is likely to result in cases not being resolved before the end of the 24-month stay. This issue of proceedings has long dogged Canada's linkage regime, with innovators being at a distinct disadvantage, and industry reports suggest that this continues to be a significant hurdle even with new regulatory amendments introduced because of CETA.

When infringement is not found, a generic/biosimilar producer is entitled to claim damages (so-called Section 8 damages). Yet, the approach taken by Canadian courts accounts for a disproportionate, almost punitive, liability exposure to patentees. Specifically, in 2015 the Supreme Court of Canada upheld the verdict in two important 2014 Federal Court of Appeal rulings concerning the methodology for determining damages under Section 8 of the PMNOC. These rulings (and their affirmation by Canada's Supreme Court) have in effect established a judicial precedent whereby an innovator drug company could be held to pay damages to multiple manufacturers of a follow-on generic drug product that together exceed the size of a total hypothetical generic market. The net effect is that patent holders are less vigorous in defending their rights, as failure to successfully defend these rights may result in excessive damages. Furthermore, under new amended provisions, there is no end for a Section 8 damage period, enabling generic producers to claim undefined and unlimited future losses.

Finally, innovative companies continue to face treble damages under common law theories in cases proceeding with the provincial courts. Several actions have been lodged against brand-name pharmaceutical patentees and/or licensees seeking treble damages under the U.K. and Ontario Statute of Monopolies on the basis that a patent that delayed generic market entry was declared invalid. While there has not been a decision on merits yet, life sciences innovators will be significantly impacted should these claims succeed on merits. Taken together, the common law and Section 8-related amendments create a risk of windfall damage awards. Such awards are contrary to the traditional compensatory function of damages. The Chamber recommends that the U.S. government work with the Canadian government to address the deficiencies of the PMNOC regulations and the uncertainty created by the disproportionate application of Section 8 damages.

Patent Term Restoration (PTR) and Adjustment (PTA)

Canada's IP environment would also improve significantly if it provided for a PTR, which provides additional patent life to compensate for the time lost during clinical trials and the regulatory approval process. Following the implementation of CETA, Canada introduced a new regulatory scheme allowing for some compensation for delays in obtaining marketing approval for biopharmaceutical products. The relevant amendments made to the Patent Act (sections 106-134) and implementing regulations published in the Canada Gazette provide a maximum restoration period of two years through a Certificate of Supplementary Protection (CSP) mechanism. While overall this is a positive step and an improvement in Canada's biopharmaceutical IP environment, there remain significant areas of concern. To begin with,

the maximum 2-year term of the CSP is substantially shorter than patent term extensions available in most other countries such as the U.S. and EU which provide for up to five years of additional protection. Further, under Section 116(4), the Canadian government retains the right to reduce the term of protection at its discretion. Specifically, this subsection states "the Minister may, if he or she is of the opinion that that person's [the rights-holder's] failure to act resulted in a period of unjustified delay in the process of obtaining the authorization for sale, reduce the term of the certificate when issuing it by the amount of that period." No further definition of what constitutes an "unjustified delay" has been provided in any of the relevant regulations, which leaves a broad scope for interpretation with the Canadian government.

However, it should be noted that Section 116(4) is not considered to be a major problem by industry standards, as the Canadian government has never used this provision or shown, at the time of this research, any intention of doing so. Moreover, the implementing regulations contain a "Timely Submission Requirement," which limits the availability of CSP applications based on the regulatory status of a given product in a set of "prescribed economies." A CSP is not available if the regulatory filing in Canada is later than 12 months from the earliest regulatory filing in these other countries which is a condition that many smaller and medium sized companies will find hard to comply with.

Equally troubling is the law's export claw-out, with Section 115(2) effectively exempting the infringement of CSP protection if the activity is for the purposes of exports. It is unfortunate that the law has undermined a positive and necessary incentive by limiting the actual protection afforded with these additional requirements and exemptions. To fulfill the fundamental purpose of restoring patent term lost due to marketing approval delays, the patentee must be provided during the PTR term with all the rights available during the underlying 20-year patent term. Moreover, there is not a safeguard provision, such as notification to the right holder of use of such an exception, to ensure that innovators are able to enforce their rights appropriately. While the initial USMCA agreement included provisions on patent term restoration, the final agreement announced in December 2019 pared back the restoration requirements. Under the agreement, patent term restoration required was revised to include a non-exhaustive list of examples of limitations on the adjustment of patent term to compensate for regulatory delays.

Additionally, the Canadian Intellectual Property Office (CIPO) made a public request for comments on draft PTA legislation on August 7, 2023. However, the draft rules do not set out what would be considered applicant delay. Industry strongly recommends that the time reasonably needed by an applicant to act during normal course of prosecution should not count against PTA (e.g., respond to office action without extensions, paying issue fees, etc.)

Chamber Recommendation: The Chamber encourages the U.S. government to work with the Canadian government to implement a PTR and PTA system that is consistent with other frameworks implemented by developed economies.

Copyrights and related rights

Index Stat: Canada ranks 16th out of 55 economies in the copyrights, related rights, and limitations Index category.

Copyright Term

On December 30, 2022, the *Copyright Act* amendments included in Division 16 of *Budget Implementation Act, 2022, No. 1* came into force. These amendments extended the general term of copyright protection for all works to the life of the author plus 70 years (previously, life of the author plus 50 years) in accordance with Canada's obligations under the United States-Mexico-Canada Agreement (USMCA). This change to Canadian law mirrors U.S. copyright terms and will better protect all forms of creative works.

Piracy

Rightsholders continue to face unnecessary challenges protecting both physical and digital copyrighted content. For example, Canadian customs laws require rightsholders bear the costs for storage, handling, and destruction of detained goods following a request for assistance. The digital situation is equally as economically taxing. Multiple stream ripping services operate in Canada, including Loudtronix.co, Anything2mp3.cc, and YTMP2.net. In 2021, 47 million Canadian users visited YTMP2.net alone.

Although the Chamber welcomes Canada's recent anti-piracy developments, pirate sites will continue to thrive in Canada if adequate deterrents are not established. The current tools in the *Copyright Act* are insufficient to deal appropriately with the new forms of online piracy that were not present, dominant, or contemplated in 2012, such as illegal IPTV subscription services, set-top boxes configured to allow users access to infringing content, streaming sites, and cyberlocker (host) sites.

However, the Chamber welcomes Canada's judicial efforts in this arena. In *Teksavvy Solutions Inc. v. Bell Media Inc.,* the Federal Court of Appeal ("FCA") issued a site-blocking order. The ISP, TekSavvy Solutions Inc., appealed, and on March 24, 2022, the Supreme Court of Canada ("SCC") dismissed the appeal, underscoring the ability of rightsholders to obtain site-blocking orders in Canada on the basis of the courts' equitable jurisdiction to grant injunctive relief. Furthermore, in May 2022, the Federal Court in *Rogers Media Inc. v. John Doe 1* issued a dynamic site-blocking order for the "live" blocking of illegally broadcast National Hockey League ("NHL") games, the first of its kind in Canada.

While the decisions above are significant steps in the right direction, the Chamber believes the U.S. government can work with its Canadian counterparts on a number of items to improve the ecosystem for copyrighted content. First, the Chamber encourages the U.S. government to engage with the government of Canada to ensure rightsholders can expressly

obtain no-fault injunctive relief against intermediaries whose services are used to infringe copyright, including static, dynamic, and live site-blocking orders, delisting orders, and injunctions against payment processors and ad networks. Second, the Chamber encourages the U.S. government to raise with the Canadian government the need to appropriately recalibrate the knowledge standard for eligibility of safe harbor protection and codify the principle that safe harbors only apply when intermediaries act in a neutral manner (i.e. processing the information provided by the recipient of the service in a merely technical, automatic, and passive manner) with respect to copyright-protected content. Finally, the government of Canada must strengthen legal incentives for hosting providers, payment processors, advertising networks, domain registries and registrars, and all other intermediaries that fail to stand by their terms of service/acceptable usage policies (which often clearly outlines an intolerance for copyright infringing activities) and cooperate with copyright owners in accordance with international best practices.

Exceptions and Limitations to Copyright

The Chamber remains concerned about the now-dire crisis facing the Canadian market for educational materials and books. Since the 2012 passage of a "fair dealing" exception to copyright for educational purposes, licensing, sales revenues, and production of new content has declined dramatically.

In May 2019, the Standing Committee on Canadian Heritage released a report assessing the impact of the 2012 amendments as well as 22 recommendations, including harmonization with international treaty obligations, stronger efforts to combat piracy, a review of safe harbor provisions, and clarification of the educational fair dealing exception. Specifically, the report recommendations to the Canadian Government called for amending the Copyright Act to "clarify that fair dealing [exceptions] should not apply to educational institutions when the work is commercially available." The Committee also recommended that the Government "promote a return to licensing through collective societies."

In July 2019, the Standing Committee on Industry, Science, and Technology released a report with sharply different recommendations. The Committee simply recommended that the Government "consider establishing facilitation between the educational sector and the copyright collectives to build consensus towards the future of educational fair dealing in Canada." It also recommended that the Committee should itself "resume its review of the implementation of educational fair dealing in the Canadian educational sector within three years, based on new and authoritative information as well as new legal developments."

In April 2020, the Federal Court of Appeal released its judgment in the long-running case *York University v. The Canadian Copyright Licensing Agency* ("Access Copyright"). Running on for nearly ten years, the dispute centers on both the meaning of fair dealing within the context of educational institutions use of copyrighted content, as well as the extent to which York University was bound by Access Copyright's licensing terms (as a collective body representing

many rights-holders) and established royalty tariffs. A 2017 lower court decision had found that, first, York University's existing fair dealing guidelines and policy did not pass existing tests of fairness as defined and applied by the Canadian Supreme Court and, second, that the University was also bound to pay Access Copyright relevant licensing tariffs for the use of their work as defined and approved by the Canadian Copyright Board. In a departure from this decision, the Federal Court of Appeal held that York University was not bound by the existing tariff structure and Access Copyright's claims were dismissed with the Court arguing that "tariffs do not bind non-licensees." On the other hand, the Court did concur with the lower court's finding that York University's copyright guidelines did "not ensure that copying which comes within their terms is fair dealing". The verdict leaves rights-holders in a highly precarious spot as while both courts have clearly recognized that copyright has been infringed by York University, to achieve redress, rights-holders must now pursue new legal action against the University seeking damages on the basis of copyright infringement.

In June 2020, both York University and Access Copyright had filed appeals to the Supreme Court. The appeal was heard in early 2021 with a final judgment rendered at the end of July 2021. Like the Court of Appeal ruling, the Supreme Court found that York University was not bound by Access Copyright's tariff structure as it was not a licensee. As such, any legal action to be taken should be centered on an infringement action. However, given that Access Copyright is a collective society with a non-exclusive license from its members, under Canadian law it does not have standing to sue for potential copyright infringement. Instead, any legal action needs to be taken by Access Copyright's members individually as individual rightsholders which, practically speaking, means that rightsholders after a decade in court are essentially back to square one and having to restart the litigation process.

On the issue of fair dealing, both the lower courts' verdicts recognized that copyright had been infringed by York University, that the existing guidelines did not meet the relevant standards of 'fair dealing' and both courts refused to recognize York University's copyright guidelines as fair. While the Supreme Court also refused to formally grant a Declaration that York University's guidelines were fair, unlike the lower courts it did so on the basis that there "was no live dispute between the parties" and not on an assessment of the guidelines themselves. Instead, the Court stated that there were "some significant jurisprudential problems" with the lower courts' interpretation and pronouncements on the issue of fair dealing. In the Supreme Court's view, the lower courts had misunderstood the meaning of fair dealing by focusing solely on the perspective of York University as an institution and not the actual end-user of the copyrighted materials, that is, the student population. By doing so they had overlooked how the Supreme Court and Canadian jurisprudence on copyright was — both in the Court's own view as well as in the words of academic scholarship cited in the ruling — moving "away from an earlier, author-centric view which focused on the exclusive right of authors and copyright owners to control how their works were used in the marketplace" and the Court as an institution was "at the vanguard in interpreting copyright law as a balance between copyright rights and user rights". In conclusion, the Court stated that any analysis of a university's fair dealing practices should focus on "whether those practices actualize the

students' right to receive course material for educational purposes in a fair manner, consistent with the underlying balance between users' rights and creators' rights in the *Act*." However, it is unclear what this will mean in practice.

Not only does the Court's ruling not alter the long-standing negative dynamics and long-term consequences of the 2012 Copyright Act amendments and Supreme Court decisions, but it also adds even more layers of uncertainty and legal complexity to Canadian copyright law. As the Index and others pointed out following Parliament's amendments to the Copyright Act and Supreme Court decisions in 2012, at best the changes to Canada's copyright regime would lead to a higher level of uncertainty for publishers and at worst a shrinking of their industry and business model. Today, it is clear that both have occurred: Industry figures suggest that the Canadian publishing industry has suffered greatly over the last decade with estimated uncompensated copying outside of fair dealing amounting to over CAD 200 million. The net effect of the reforms and 2012 Supreme Court rulings has been a contraction in the publishing sector with the Canadian publishing industry and individual rightsholders reporting publishing income decreasing substantially. The bottom-line is that after 10 years of litigation and uncertainty, Canadian rightsholders have failed to achieve effective redress for the clear violation of their copyright or gain any further understanding of what constitutes fair dealing and what does not within the context of education.

However, in 2022, the federal Government appears to have finally recognized the dire impact of the 2012 amendments and subsequent Supreme Court rulings. In the 2022 budget *A Plan to Grow Our Economy and Make Life More Affordable* the Government stated plainly that it would "work to ensure a sustainable educational publishing industry, including fair remuneration for creators and copyright holders, as well as a modern and innovative marketplace that can efficiently serve copyright users."

Chamber Recommendation: The Chamber appreciates the Canadian Government's acknowledgement that more must be done to protect the publishing industry in Canada and encourages the U.S. government to continue to work with its Canadian government counterparts to address the uncertainty created by the Supreme Court ruling to better protect copyrighted content in Canada.

Trade secrets and related rights

Index Stat: Canada ranks 9th out of 55 economies in the trade secrets, related rights, and limitations Index category, in large part thanks to efforts in creating precedent-setting dynamic injunction orders and longer copyright terms, new criminal sanctions for theft and misappropriation of trade secrets, and ex officio authority for border action against in-transit goods.

Criminal Sanctions for Trade Secrets Theft

Historically, Canadian law has not provided a statutory definition or criminal sanctions for the theft or misappropriation of trade secrets with any potential criminal prosecution needing to rely on other parts of the legal code. As part of its implementation of the USMCA, Parliament passed new criminal provisions for the theft and misappropriation of trade secrets through the Canada–United States–Mexico Agreement Implementation Act. Section 391 of the Criminal Code now contains a maximum 14-year prison term for anyone who "by deceit, falsehood or other fraudulent means, knowingly obtains a trade secret or communicates or makes available a trade secret." The Chamber applauds this positive development, which will help better protect IP rightsholders in Canada, and encourage the U.S. government to work with the Canadian government to ensure the provision is effectively enforced to maintain compliance with Canada's USMCA commitments.

Commercialization of IP assets and market access

Index Stat: Canada ranks 14th out of 55 economies in the commercialization of IP assets Index category.

Patented Medicines Prices Review Board ("PMPRB")

The PMPRB sets maximum prices for patented medicines in Canada. These prices are not the prices that are paid—they are a maximum ceiling. American companies must submit new medicines to health technology assessment agencies then negotiate with government-funded drug plans through a buying coalition (the pan Canadian Pharmaceutical Alliance or pCPA) – a process that yields even lower net prices. In addition, net price negotiation is becoming more common in the private insurance market. For many years, the PMPRB's decisions have diminished the value of American IP and innovation. On July 1, 2022, the Canadian government issued amendments Canada's Patented Medicines Regulations ("PMRs") that discriminate against U.S. innovators to reduce the cost of innovative medicines in Canada at the expense of U.S. health care consumers and future innovation. Notably, the amendments remove the U.S. and Switzerland from the basket of comparator countries that the PMPRB uses to set drug prices, adding instead six new countries, including: Australia, Belgium, Japan, the Netherlands, Norway, and Spain. However, the Canadian government reduced the harm of its regulatory package by dropping regulatory amendments that would have required patentees to report price and revenues, net of all price adjustments (e.g., confidential rebates) and created excessive price regulatory factors wherein the PMPRB would consider a medicine's market size.

The entry into force of the amended PMRs has triggered a consultation on implementing rules (the PMPRB Guidelines). On October 6, 2022, draft Guidelines were released for a 60-day written consultation. The draft Guidelines represent a completely new and experimental approach to federal regulation of patented medicine prices, the core features of which have not been consulted on previously. The established system of voluntary compliance with transparent price tests has been replaced by "investigation triggers", making it difficult for manufacturers to predict an allowable price. Moreover, the investigation triggers

are misaligned with the PMPRB's legislative mandate and the direction of the courts on preventing excessive pricing. A 60-day written consultation is not sufficient to address these significant concerns.

The PMPRB regulations and draft guidelines exacerbate concern in what is already a challenging market entry environment and risk aggravating the established trend of fewer new innovative medicines entering the Canadian market. Between 2017 and 2021, the number of new innovative medicines launched in Canada declined each year and lagged the number launched globally, and particularly in the United States. Fewer than 60% of the medicines introduced in the US since 2017 were launched in Canada. This is a dramatic decline from the five years prior, when Canada launched more than 80% of the medicines introduced in the US. In addition, Canadian launches occurred after a median delay of 2.1 years following the first global launch.

Notably, in July 2021, the Canadian Government launched a new Biomanufacturing and Life Sciences Strategy in recognition of the strategic nature of the research-based biopharmaceutical industry. Pillar 5 of this Strategy – "Enabling Innovation by Ensuring World Class Regulation" – seeks to make Canada a more "attractive destination for leading life sciences firms to establish and grow." Adequate pricing and reimbursement policies will be critical to creating an enabling environment where biopharmaceutical innovation can thrive. To build a more robust innovation ecosystem in Canada – which would benefit patients across North America – the Chamber encourage the U.S. government to continue to work with the Canadian government to ensure that Canada is sufficiently respecting the rights of American IP owners through its domestic pricing policies.

Enforcement

Canadian border officials have historically not had *ex officio* powers to search and seize goods suspected of infringing IP rights, and a court order has been required for seizure and detaining of suspected goods by customs officials under both the Copyright Act and the Trade-Marks Act. However, Chapter 20 of the USMCA includes a clear requirement that border agents be granted *ex officio* authority to detain any and all suspected counterfeit goods, including goods in transit. As part of its implementation of the USMCA in 2020, Parliament passed new provisions relating to goods in transit through the Canada–United States–Mexico Agreement Implementation Act. Section 51.03 of the Trademarks Act now includes reference to transshipped goods and goods in transit. The section states that such goods "while being shipped from one place outside Canada to another, are in customs transit control or customs transshipment control in Canada are considered to have been imported for the purpose of release."

The Chamber applauds this positive development which will help protect American consumers from dangerous counterfeit goods entering the United States.

Chamber Recommendation: The Chamber encourages the U.S. government to collaborate with their Canadian government counterparts to ensure the new provisions of the Trademarks Act are effectively implemented.

CHILE

Overview

Despite maintaining OECD membership and a "very high" human development index score (0.8.55as of 2023—the highest in Latin America), innovative and creative companies continue to face a challenging environment in securing effective IP protection in Chile.

While the Chamber has outlined longstanding concerns below, the Chamber urges the U.S. government to leverage its FTA with Chile—and OECD membership—to address outstanding gaps in the country's IP protection and enforcement regime.

Despite efforts that have traditionally undermined IP in response to COVID-19, Chile took more-recent steps to strengthen its IP framework over the last several years, including, most notably, the implementation of a package of reforms amending Law 19,309 on Industrial Property Implementation of these new regulations were published in May 2022, when the new law came into effect. The law includes a series of positive changes to strengthen Chile's IP ecosystem, which, according to INAPI, "[seeks] to favor users by making more efficient and modern the processes that are intended to access the protection of trademarks and patents," and industry looks forward to working with the U.S. and Chilean governments to ensure the law is effectively implemented and address the outstanding issues in Chile's IP framework noted below.

Patents and related rights

Index Stat: Chile ranks 30th out of 55 economies in the Index's overall findings but fall to 37th out of 55 economies in the patents, related rights, and limitations Index category. While Chile ranks in the bottom tier internationally, including behind China and all EU economies, it remains in the top third of Latin American economies.

Compulsory Licensing

Although no compulsory licenses have been granted, the Chilean government has deliberated on multiple pieces of domestic legislation to expand the basis for compulsory license applications, with such proposals having gained traction during the global COVID-19 pandemic. In March 2020, the Lower Chamber unanimously passed a resolution calling for compulsory licenses on any products, diagnostics, medical devices and other medical paraphernalia. This March 2020 resolution was followed up with a legislative proposal and a set of amendments, Bulletin 13,572-11, which introduced sweeping changes to Chile's compulsory

licensing regime, and the Minister of Health's Resolution 399 (and subsequent Resolution 68 issued by the Chamber of Deputies) allowing for direct request of compulsory licenses for hepatitis C medicines. Finally, Senate Bill 12,135-03, published in the national gazette and promulgated in July 2021, included provisions on compulsory licensing for non-commercial public use and broadens the procedural discretion for compulsory licensing petitions.

Additionally, the Chilean Congress discussed Drug Act II (Ley de Farmacos II), also known as Bulletin 9914-11, as part of Chile's National Drug Policy. The bill includes provisions that would greatly extend the reach of non-voluntary licenses—incorporating discretionary elements such as "shortage" or "economic inaccessibility" of products as a legitimate ground for issuing such licenses—and severely limits the prescription of medicines based on their trademarked names, requiring the International Non-Proprietary Name (INN) be used instead. This would considerably limit the right to use a registered trademark in a way that is inconsistent with Chilean and international law. As of November 2023, the bill remains stuck in the Joint Commission following the rejection of amendments, where it has remained since July 2022.

Chamber Recommendation: The Chamber strongly encourages the U.S. government to work closely with the Chilean government to ensure that IP is respected in the global pandemic.

Patent Linkage

Chile has not yet instituted a patent linkage mechanism, despite its commitment to do so in its free trade agreement ("FTA") with the U.S. This is particularly concerning given that the FTA went into force in 2004. Article 17.10.2 requires Chile to "make available to the patent owner the identity of any third-party requesting marketing approval effective during the term of the patent" and "not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner." However, infringing products are known to be approved, and resolution of patent disputes is often severely delayed.

During 2023, public procurement processes led by the Ministry of Health resulted in several patent infringements. The lack of a proper process to verify the existence of patents allows infringing third parties to obtain tender adjudication to supply products to the public health system despite compound patent holders still having exclusivity rights in Chile. Although some relevant stakeholders have expressed concern, until effective action is taken, this new trend could impact seriously the intellectual property ecosystem.

Chamber Recommendation: The Chamber recommends that the U.S. government continue to work with the Chilean government to ensure effective implementation of Chile's patent-related FTA commitments.

Patent Term Restoration ("PTR")

The Ley Corta No. 21,355, entered into force in May 2022, establishes equal treatment for a patent application filed under the Paris Convention and for those filed under the Patent Cooperation Treaty agreement when the rightsholder asks for the restoration of the right of priority. While Law 21,355 includes many positive elements such as the aforementioned inclusion, one glaring negative feature of the new legislation is the introduction of a much shorter period under which rights-holders can apply for "supplementary protection," from six months to 60 days. This period of term restoration would account for delays on part of INAPI in processing an application and for biopharmaceutical products and technologies due to the lengthy sanitary drug registration process, or, in other words, provided an unjustified administrative delay is demonstrated. Similarly, the period under which rights-holders must pay any relevant fees for the restoration granted has now been changed from falling within a period of six months prior to the expiration of the original exclusivity period to, under the revised article, a period of thirty days. The shortened time-periods will only lead to the application process becoming more bureaucratic, convoluted and, ultimately, inaccessible. As industry has noted, TDPI ("Industrial Property Court") has chosen to adhere to a very stringent standard for patent term restoration, concluding that many of the delays incurred by the Institute of National Health are not "unjustified administrative delays."

Chamber Recommendation: The Chamber encourages the U.S. government to work with the Chilean government to address all the above listed patent-related challenges to strengthen Chile's innovation ecosystem.

Trade Secrets and related rights

Index Stat: Chile ranks 36th out of 55 economies in the trademarks, related rights, and limitations Index category as a result of challenges in securing and enforcing trademark protection.

The FTA requires that Chile provide a five-year term of regulatory data protection to biopharmaceutical products. Article 89 of Chilean Law 19,039 states that "undisclosed test data or other information regarding the safety and efficacy of a pharmaceutical which utilizes a new chemical entity" may not be "disclose[d] or utilize[d]" to grant sanitary registration to a product without consent for a period of five years. However, Article 91 of the same law creates a potentially significant exception under which data protection can be denied based on "reasons of public health, national security, non-commercial public use, national emergency or other circumstances of extreme urgency," or if the product is subject to a compulsory license. Law 23,335 redefines the meaning of 'trade secret,' changing the former term "business" secret with the newer "trade" secret, which conforms to the definition established under international standards set forth within the TRIPS Agreement.
Under this standard, to constitute a trade secret, the information must be secret, have commercial value, and have been subject to reasonable measures to keep it confidential. However, the use of compulsory licensing, most recently enshrined in new laws and regulatory

schemes in Chile in response to the COVID-19 pandemic, has raised concerns that trade secrets and related rights generally protected under "reasonable confidentiality measures" will face exploitation under the newer standards of "reasonable measures of protection" criteria for health emergencies as listed above.

Chamber Recommendation: The Chamber recommends that the U.S. government work with the Chilean government to address the outstanding FTA obligations to create an IP framework more closely aligned with international best practices.

Copyrights and related rights

Index Stat: Chile ranks 41st out of 55 economies in the copyrights, related rights, and limitations Index category due to the lack of a comprehensive framework to comply with Chile's FTA commitments in protecting copyright-protected materials.

Copyright-related FTA Commitments

Piracy in Chile remains a long-standing challenge in large part due to outstanding U.S. FTA commitments that — some 17 years after generous transition periods — continue to await implementation into domestic law. Because of this, gaps in the copyright law mean that the creative industries in Chile are inadequately protected. Chief among these is Chile's lack of a basic anti-piracy mechanism: a system to remove infringing content online expeditiously and efficiently (also required by the FTA). Currently, ISPs are only required to remove infringing content upon receiving a court order. Even when a court order comes, a service provider would likely qualify for broadly applied safe harbor if it didn't have "effective knowledge" of IP infringement on its service. There exist no consequences for ISPs that fail to act if they learn of infringement without a court order, and requests to block a site can be easily derailed by charges that non-infringing content is also present.

Additionally, there are no special rules in Chilean Law that address nor remedy foreign-owned or foreign-operated websites that infringe on copyright. With regards to injunctive style relief, there is a possibility of achieving an injunction through a court order but there is no defined or practical enforcement route — whether administrative or judicial — available to rightsholders. The availability of injunctive style relief is hampered by the same lack of clear and practical rules and procedures that affects other forms of copyright enforcement in Chile. With respect to TPM and DRM, despite ratification of the WIPO Internet Treaties and the U.S.-Chile FTA, copyright law still only protects against the circumvention of, or interference with, by ISPs. Circumvention by other parties is not illegal, nor is the manufacture, distribution, and sale of circumvention devices. Chile also does not have FTA-compliant provisions establishing deterrent-level statutory damages for copyright infringement. Meanwhile, civil ex parte inspections are often undermined by a requirement that investigation requests be submitted and publicly available on an online database. Despite this well-intentioned attempt at transparency, disclosures like this can sabotage the authorities' ability to perform an effective

search. Chile also lacks rules on criminal sanctions for the camcording of motion pictures in movies theaters—a major deterrent to source piracy.

Chile has also failed to enact any meaningful legislation to crack down on circumvention devices to "work around" technological measures protecting legitimate content online. This activity is particularly pronounced in the video game industry, where copier devices, modified/unlocked consoles, and pre-street-date titles are available through online auction and e-commerce sites. These activities continue even though the FTA requires Chile to provide for liability for any person who knowingly circumvents TPMs and that "knowledge may be demonstrated through reasonable evidence taking into account the facts and circumstances surrounding the alleged illegal act." The FTA even provided a five-year transition period to implement this obligation, but the Chilean law still lacks specific protections.

Lastly, industry reports that no authority has been able to meaningfully enforce a November 2018 law to criminalize the commercialization and distribution of Pay-TV signals without legal authorization as well as the importation and commercialization of illegal devices for this purpose. Even though the law was intended to address outstanding FTA commitments, the fact that it hasn't been successfully implemented is concerning. Because of this, the Chamber notes that the illegal commercialization of Pay-TV signals has continued in Chile — severely affecting the Pay-TV and content industries in the highly influential and prominent market.

Chamber Recommendation: Given the scale and timespan of Chile's piracy problems and commitments, the Chamber encourages the U.S. government to continue constructive engagement to bring Chilean law into compliance with its 17-year-old FTA commitments.

EUROPEAN UNION

Overview

The U.S. and EU have traditionally been the global leaders in protecting IP rights in their markets as well as through efforts to advance IP protection in third countries. The U.S. Chamber's International IP Index illustrates that the U.S. and the EU stand side-by-side as global IP leaders, with U.S. and EU member states comprising seven of the top ten economies in the rankings. Policies introduced in the U.S. and the EU are often mirrored in third countries, making it even more important that the U.S. and the EU continue to support robust and effective IP policies at home.

The Chamber is proud to co-host the Transatlantic IPR Working Group Stakeholder Consultation which provides a critical venue to further discussions on strengthening IP protection in third countries. The Chamber thanks the U.S. and EU delegations for their support for continued intersessional bilateral engagement on IP issues and looks forward to continuing to support the bilateral dialogue to advance IP protection.

At the same time, the Chamber is concerned with recent legislative proposals that threaten to undermine the EU's longstanding leadership position on global IP policy and dismantle the framework for IP-driven innovation and creativity in the EU. The Chamber encourages the U.S. government to highlight how proposed reforms are likely to undermine American investment in the EU and its member states. The Chamber looks forward to working with the U.S. government and their European government counterparts to address the below concerns.

Patents and related rights

Index Stat: The landscape for patent protection varies across the EU, with Member States tied for ranking between third and sixth in the Index patent category. However, the initial estimate is that the proposed changes included in the EU General Pharmaceutical Legislation could lead to nearly a 10% score decrease on the life sciences-related Index indicators for EU economies, demonstrating the negative impact of such measures of the EU's global standing as an innovation leader.

EU General Pharmaceutical Legislation

In April 2023, the European Commission proposed a new Directive and Regulation to revise the EU's General Pharmaceutical Legislation. This legislative revision purportedly seeks to create a 21st century life sciences landscape in Europe that fosters innovation, enhances access to innovative therapies for European patients, and elevates Europe's competitive stature. While the Chamber strongly supports these goals, it is concerned that the current trajectory of the GPL is likely to inadvertently repel the investments in innovations Europe is seeking without improving access, availability, or affordability of innovative medicines for patients.

The Chamber has encouraged the EU to consider the following recommendations as they seek to pass the GPL in 2024:

- **Maintain or enhance the current 8 (+2) years RDP baseline:** RDP is crucial to ensuring innovators have ample time to realize a return on the R&D investment needed to generate safety and efficacy data required for marketing approval. The EU should avoid the Commission's proposed scaling back of the existing framework of 8 (+2) years and instead consider enhancing this baseline to 9+2 years as proposed in the Draft Report from Rapporteur Weiss to enhance incentives to drive Europe's competitiveness in global life sciences.

- **Maintain existing structure for additional years of RDP protection:** The Chamber is concerned with the GPL's proposal to condition RDP on external factors beyond companies' control, such as launch of new products in every member state within 2 years. This approach fails to consider factors that determine market access within

individual European countries outside the control of companies, such as disparate pricing and reimbursement timelines.

- **Broaden the "unmet medical need" definition and provide an added year of RDP:** Expanding the definition of "unmet medical need" and providing an additional year of RDP is vital to driving the development of treatments for underserved conditions.

- **Preserve the existing scope of the Bolar exemption:** The Chamber believes that expanding the Bolar exemption to include commercial or pre-commercial activities prior to patent expiry contradicts the original rational of the exemption, violates the obligations of the EU under the TRIPS Agreement, and could undermine the enabling environment that drives innovation and a level playing field for US investment in the EU. The Chamber suggests the GPL maintain the current Bolar exemption for activities solely related to seeking regulatory approval, with a prohibition on commercial exploitation after regulatory approval until the relevant patents and SPCs expire.

- **Retain a 10-year market exclusivity for orphan drugs:** The Chamber believes the GPL should maintain the baseline of 10 years of market exclusivity for orphan drugs and consider additional incentives based on objective criteria to effectively target unmet medical needs.

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 US investors in innovative technologies.

Compulsory Licensing

In April 2023, the Commission released a proposed regulation to revise the framework for compulsory licensing of patents, which seeks to create a framework to enable an EU-wide compulsory license. While the Chamber appreciates the Commission's intent to respond to future crises, it has significant concerns with several aspects of the proposed regulation:

- The regulation undervalues voluntary agreements, which provide a critical tool to enhance access while also preserving the underlying IP that enabled the development of innovative solutions.

- The regulation is unclear on the term "good faith" and its potential misuse; the implications for forced sharing of trade secrets and suspension of regulatory data protection and its compliance with the TRIPS Agreement; the constitution and role of the proposed advisory body; an adequate opportunity for the rightsholder to be heard; and the eventual procedure to determine CL grant.

- The proposal also suggests a CL grant per product as opposed to per patent.

- The post-CL grant phase does not include the right to damages in case of an unlawful CL grant.

- The proposal gives the Commission the power to grant CL. The Chamber believes that a grant by the Commission itself conflicts with the right to an effective remedy before a tribunal. It is imperative that the proposed EU CL regulation preserve the due process mechanisms enshrined in current national frameworks and provide meaningful judicial review.

Chamber Recommendation: The Chamber encourages the U.S. government to work with its EU counterparts to ensure that an EU-wide compulsory license is needed and compatible with the EU's WTO obligations and, if so, that the CL framework provides legal certainty and due process for innovators and sustains our shared global competitiveness.

European Health Data Space

In May 2022, the EU released a proposal for a new regulation on the European Health Data Space ("EHDS"). The proposal aims to create a public facing dataset catalogue which will include available data sets provided by data holders. The Chamber believes the proposed Regulation will create a forced disclosure model which will mandate the sharing of IP and trade secrets. Specifically, Article 33 of the proposal notes that "[e]lectronic health data entailing protected intellectual property and trade secrets from private enterprises shall be made available for secondary use."

The Chamber is concerned that this proposed forced disclosure mechanism may be inconsistent with the trade secrets protection embodied in Article 39.2 of the TRIPS Agreement, which states that holders of confidential information retain the right to prevent "information lawfully within their control from being disclosed to, acquired by, or used by others without their consent." Further, the Chamber believes the proposed EHDS regulation may require the disclosure of confidential data and trade secrets without the data holder's consent.

Chamber Recommendation: The Chamber encourages the U.S. government to work with its EU counterparts to ensure that changes to the EHDS safeguard confidential information and trade secrets.

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.

Commercialization of IP assets and market access

Patient Access Report Stat: The EU Member States' pricing and reimbursement policies have resulted in delayed access to innovative medicines and less choice for European patients. For example, while 85% of new medicines launched between 2012 and 2021 were available in the U.S., only 61% were available in Germany and 52% in France and Italy, respectively.

Market Access

The Chamber is concerned that EU member states' pricing and reimbursement practices limit patient access to innovative medicines, undervalue the benefits that these treatments, and jeopardize biopharmaceutical competitiveness. The use of restrictive government pricing and reimbursement mechanisms force American innovative companies to shoulder the burden of these measures, which undermine the framework that promotes robust R&D and leads to the developing of cutting-edge treatments and cures.

The Chamber is particularly concerned with the delays in the launch of medicines that result from the length of time required for countries to make national pricing and reimbursement decisions. According to the European Federation of Pharmaceutical Industries and Associations, delays for medicines launched in Europe average 511 days and are particularly significant in some European countries. Furthermore, data collected by IQVIA reveals that many new health technologies and medicines are never launched in economies with strict price and reimbursement controls in place. While the EU requires transparent and timely processes for national pricing and reimbursement decisions, it is clear that the processes must be improved to improve patient access across Europe.

Specific concerns in EU Member States include:

- International reference pricing in the Czech Republic, Denmark, Finland, the Netherlands, Switzerland, and Romania

- Mandatory claw backs in France, Greece, Hungary, Italy, and Poland

- An array of cost containment measures in Austria, Belgium, the Czech Republic, Denmark, Finland, Italy, the Netherlands, Poland, Romania, and Spain

Chamber Recommendation: The Chamber encourages the U.S. government to collaborate with its EU counterparts to ensure the market access environment fairly recognizes the value of innovation while also enhancing access for European patients.

JAPAN

Overview

While Japan has consistently been a global leader on IP protection — ranking in the top six economies included in the report — the Chamber has longstanding concerns with the Japanese government's policy on the pricing of medicines. The current pricing system risks undermining its broader pro-innovation regulatory regime and suggest a retreat from its traditionally strong record of IP enforcement. The Chamber looks forward to working with the U.S. government and its Japanese government counterparts to address the concerns noted below.

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, Japanese patients only had access to 51% of the new medicines launched between 2012-2021.

Revisions to the Price Maintenance System

The significant changes for PMP criteria were added in 2018, which created additional market access barriers for biopharmaceutical companies operating in the market and resulted in reduced access to innovative medicines in Japan. The FY2024 Drug Pricing System Reform includes some positive changes to 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.

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 January 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. The Chamber remains concerned that the new 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 increase the Japanese government's support of global R&D on innovative medicines and to ensure that U.S. business has an opportunity to contribute its views on any new policy reforms in this area.

REPUBLIC OF KOREA ("ROK")

Overview

The Republic of Korea ("ROK") consistently ranks in the top 12 economies benchmarked in the Chamber's Index. Despite the relatively robust ecosystem for IP protection and enforcement, the Chamber is concerned that the ROK's drug pricing policies devalue U.S. IP and seemingly favor Korea's own pharmaceutical industry at the expense of U.S. companies. These barriers for patients and industry alike are described in detail below.

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 the following concerns with the pricing framework use in the ROK:

- The two-step process to determine drug prices in the ROK is primarily on cost reduction, rather than a holistic assessment of a drug's value.

- The Health Insurance Review and Assessment Service PE analysis recommends reimbursement prices for patented drugs by referencing other drugs in the same therapeutic class, including off-patent and generic drugs which are already subject to drastic price-reduction measures in the ROK.

- The ROK grants price preference to locally developed innovative medicines. As a result, only a small proportion of medicines designated as innovative are made by foreign companies.

- The ROK utilizes repetitive and excessive price cut mechanisms after reimbursement listing, including biannual Actual Transaction Pricing investigations, Price-Volume Agreements ("PVAs"), listing of first generic and expanding reimbursement scope with new indications or change of treatment guidelines.

- The National Health Insurance Service ("NHIS") requires Risk Sharing Agreements ("RSA") to generate additional concessions from innovative companies. While the Chamber supports voluntary RSAs which can facilitate greater flexibility on pricing and patient access, it believes they must be paired with broader reforms that recognize the true value of innovative patented medicines.

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.

Transparency and Due Process Concerns with KORUS Implementation

Repeated changes to the ROK's pharmaceutical pricing and reimbursement have adversely impacted the ability of innovative pharmaceutical companies to operate in the market and raises concerns that the ROK's transparency and due process obligations under KORUS are not being met. KORUS 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 drugs, 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 to work with its counterparts in the ROK to ensure ROK's policy is consistent with its KORUS obligations.

Patents and related rights

Index Stat: While Korea is tied for second place in the Index's patent category, limitations on patent rights place aspects of the ROK's patent system outside international norms.

Patent Term Restoration (PTR)

While patent term restoration is available in the ROK, there are three significant issues that undermine its effectiveness. While reforms to the PTR were introduced in the National Assembly in April 2023, the proposal does not address the below listed concerns.

- The PTR calculation should include all relevant essential clinical trials used for the approval of the Korean product, including essential clinical international trial that are submitted as a part of the Korean dossier for approval of the product.

- When a patent holder challenges the duration of PTR and loses, no PTR is granted. This "all-or-nothing" approach significantly undermines a patentee's right to appeal, effectively deterring appeals of erroneous calculations, thereby leading to uncertainty in the term of protection.

- The scope of PTR in the ROK is unduly narrow and inconsistent with the legislative intent and international best practices.

Chamber Recommendation: The Chamber encourages the U.S. government to work with their ROK counterparts to ensure patent holders can receive the full PTR term and have an effective right to appeal.

SWITZERLAND

Overview

Despite Switzerland's strong overall score on the Index, online piracy remains high as Switzerland serves as a base for registered companies, computer servers, torrents, and cyberlockers distributing infringing content. While Switzerland has taken steps to improve its

copyright law, the Chamber notes continued gaps in the legislative framework for copyright protection. As the U.S. Government continues to engage with its counterparts in Switzerland, the Chamber strongly urges that these issues be raised and where possible resolved expeditiously.

Copyrights and related rights

Index Stat: While Switzerland ranks in the top 10 economies in the overall Index rankings, Switzerland ranks 17th out of 55 in the copyright indicators, ranking behind several upper-middle-income economies including Costa Rica, Mexico, and Malaysia.

Copyright Law Amendments

In 2020, the Swiss government's new copyright law amendments became law. The amendments included a number of improvements to the Swiss framework for copyright protection, including requirements that ISPs both remove and keep infringing content off their servers. The Swiss Federal Institute of Intellectual Property has publicly stated that this requirement amounts to a requirement for a "stay down" mechanism. However, the amendments did not include any requirement or option for the disabling of access to illegal content whether through the judiciary or an administrative mechanism. Additionally, the law did not change the existing dynamic with respect to defined personal and private use exceptions to copyright.

The Chamber believes the reforms remain a real missed opportunity for rightsholders in Switzerland and internationally. While the amendments address some of the shortcomings in the existing legal framework, the reforms did not fundamentally change the dynamics of copyright enforcement and online piracy in Switzerland.

Chamber Recommendation: Over the last decade major economies — including EU Member States, the UK, India, Singapore — have begun using judicial, administrative mechanisms, and dynamic injunctions to effectively disable access to infringing content. The Chamber encourages the U.S. government to work with the Swiss government to introduce a similar framework to better protect copyrighted content online. Additionally, the Swiss government should consider further reforms to the copyright law to engage ISPs — including access providers — in the fight against online piracy; affirm that current law does not permit copying from unauthorized sources; and implement adequate civil and criminal enforcement tools, including access blocking.

Compliance with International Agreements

Chamber Recommendation: In addition to further reforms to the Copyright Act, the Chamber urges the U.S. government to work with Swiss authorities to ensure that it come into

compliance with the Berne Convention, TRIPS Agreement, WIPO Internet Treaties, and internationally acceptable enforcement standards.

Section D: China

Overview: A Rapidly Shifting IP Regime with Lingering Concerns

The U.S. Chamber of Commerce and its member companies have long been and remain committed to balanced and mutually beneficial U.S.-China economic and commercial engagement. 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.

Since the U.S. and China concluded their Phase One Economic and Trade Agreement (the "Phase One Agreement") in January 2020, significant legislative and regulatory developments have impacted the full range of IP assets:

- The PRC Patent Law was amended in October of 2020 with revisions that took effect in June of 2021.

- The China National Intellectual Property Administration ("CNIPA") issued new rules on trademark usage that took effect on January 1, 2022.

- The PRC Copyright Law was amended in November of 2020 with revisions that took effect in June of 2021.

- The State Administration of Market Regulation circulated draft revisions to the PRC Anti-Unfair Competition Law in November of 2022.

- The PRC Anti-Monopoly Law was amended in June of 2022 with revisions that took effect in August of 2022.

- The State Administration of Market Regulation amended Provisions on Prohibiting the Abuse of Intellectual Property Rights to Exclude and Restrict Competition with revision that took effect in August of 2023.

- The Patent Law Implementing Rules and the Patent Examination Guidelines were amended in December of 2023 with revisions that will take effect in January of 2024.

The Chamber continues to support the full implementation of the Phase One Agreement as a significant achievement in ongoing efforts to advance fairness and reciprocity in the bilateral economic and commercial relationship. 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:

- Patent term restoration is ineffective by relying on regulatory approval process outside China 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 o 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 drugs (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;

- A lack of recognition for live sports event broadcasts as copyrightable audio-visual works through the copyright law implementation regulations;

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

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

- The elevated standard for property preservation, especially for foreign-funded enterprises applying for property preservation against Chinese private enterprises; and

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

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

- Fully implement, as a matter of urgency, all commitments included in the Phase One Agreement, including those with respect to trade secrets, patents and undisclosed test data, 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 drugs that are new to China;

- Expand the scope of copyright protections in China to cover live sports event broadcasts;

- 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;

- Encourage consistent application of Copyrightability requirements to AI assisted works in China and provide this within the framework of international Copyright norms; and

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

The Chamber is committed to working with the U.S. government to monitor and address China's unfair practices and lack of enforcement with respect to each of these issues. In the following sections, it offers our assessment of Chinese 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.

Copyright and Related Rights

Index Stat: China ranks 27th out of 55 in the copyright-related Index indicators.

Copyright Reforms

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. Rights relating to performance, sound recording, and broadcasting have also been more clearly defined. 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:

Live Sports Event Broadcast and Non-Interactive Streaming

Despite favorable court judges recognizing the copyrightability of live sports events, the Chinese government has yet to provide clarification in any legislative documentation that live sport event broadcasts and non-interactive streaming are forms of creativity protected by the Copyright Law as "audio-visual works". In addition, the Chinese government has yet to confirm that all live television broadcasts are copyrightable works in China, which would provide the needed legal protection to prevent pirated Internet retransmissions of valuable live broadcasts.

Chamber Recommendation: We urge China to use the pending legislative process of the copyright implementation regulation draft as an opportunity to clarify that live sport event broadcasts and non-interactive streaming should be protected.

Combating Internet Piracy

Illegal downloading and streaming of foreign media content remains problematic in China. We believe the Chinese government could improve protections for digital media by promulgating 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. There is also an expectation for proactive administrative enforcement that has the capacity to close infringing websites and remove unauthorized applications. In recent years, administrative bodies in China have shown a propensity to decline the imposition of administrative penalties in situations where they are unable to engage with the parties operating these infringing platforms. This has significantly heightened the challenges faced by rightsholders in seeking administrative remedies, given the frequent occurrence of instances where these infringing parties cannot be located through conventional investigative methods. Additionally, China has yet to criminalize 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.

Chamber Recommendation: We believe the Chinese government could improve protections for digital media by promulgating 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.

Market Access Restrictions

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'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 "Over the Top" ("OTT" or "internet-delivered") audiovisual sector resulted insignificant growth in market access in the years prior to 2014, China subsequently announced new limits on the use of foreign content by OTT 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 new regulations have substantially cut back on the percentage of total content spending spent on foreign audiovisual firms. Further, these limits penalize legal service providers to the benefit of China's vast illegal online marketplace, which freely ignores the limits. Finally, China continues to prohibit foreign investment or control in online video services, even though U.S. companies are the global leaders in the space.

Chamber Recommendation: The Chamber urges China to address concerns related to market access restrictions on copyright-protected content.

Patents and Related Rights

Index Stat: In the patent-related indicators, China scores shortly behind Israel and Australia and on par with Greece.

Weak Patent Enforcement on Pharmaceutical Products

In 2020, we were 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.

To begin with, 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. Article 9(4) of the Measures simply states that if no final judgment has been received by NMPA from the relevant authorities within the prescribed 9-month waiting period and the technical review process is completed, the drug registration application will be transferred for processing and final approval in line with standard procedure. For rightsholders, there is no guarantee that relevant legal proceedings before a Chinese court or the CNIPA will be concluded within the 9-month period. Consequently, there is a real possibility that no effective resolution is reached within that time frame, and that the follow-on product is approved for market by the NMPA. It is entirely possible for rightsholders to get final approval for their pharmaceuticals prior to the expiration of those patents, even though the third paragraph of Article 76 in the Patent Law directed creation of the Measures to flesh out a patent linkage system. Additionally, the 9-month waiting period is both shorter than previous draft proposals — which had a period of 24 months — and equivalent timelines in the United States and Singapore, where the period is 30 months. Finally, the 9-month waiting period is not available for biologics.

Moreover, the Measures present formality requirements that may present challenges to pharmaceutical rightsholders. The Measures require registration of relevant patents within 30 days of receiving a drug registration certificate as well updating their registrations within 30 days of any change. The original registration for marketing approval — and any update to it — must include the drug name, dosage form and specifications, the holder of the drug marketing authorization, the relevant patent number, patent name, patentee, patent licensee, date of patent granting, date of expiry of the protection period, patent status, patent type, relationship between the drug and the relevant patent claims, mailing address, contact person, contact information.

In 2022, the first judicial proceedings were concluded relating to this early-resolution system. The case had initially been filed in late 2021 with the Beijing IP Court and was concluded following an appeal to the Supreme Court with a final judgment issued in August 2022. The case focused primarily on the validity of the underlying patent claims and not the early resolution process itself. However, the Supreme Court's judgment provided useful reference to and clarification on the mechanics of the notification process and responsibilities of follow-on applicants. The broader policy conclusion from both the initial judgment and the appeal is that rightsholders may be able to achieve a judgment within the above described 9-month waiting period. The Chamber will continue to monitor judicial proceedings and the extent to which rightsholders for all forms of biopharmaceuticals can effectively and practically seek redress prior to the marketing of a follow-on product in a process that is fair and transparent to all parties.

Finally, we are very concerned that NMPA since January 2019 has granted at least 51 marketing approvals to local drug companies to make infringing copies of innovative medicines while the reference products in each case are still subject to patent protection. These actions

have continued since the Phase One Trade Agreement was concluded and appear designed to benefit Chinese companies at the expense of innovators in the United States and elsewhere. We are further concerned that at least two of these infringing products have recently been invited to apply for inclusion on the National Reimbursement Drug List ("NRDL").

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 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 and delivered comments to the Chinese government in response to its second draft amendment to the Patent Law in August 2020 (regarding the PTA and PTR provisions), urging that the resulting mechanisms achieve their objectives of encouraging the development of innovative medicines.

PTA and PTE provisions have been added to the amended patent law – which took effect on June 1, 2021, and the revised Patent Law Implementing Rules and the Patent Examination Guidelines – which were issued in end of 2023. Both 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. This is not consistent with the best international practice.

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 regulatory review period before NMPA and is available to all patented drugs that are new to China, rather than new to the world.

Chamber Recommendation: The Chamber looks for forward to working with the U.S. government to ensure effective implementation of patent term extension.

Restrictive Patentability 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 where CNIPA continues to impose stringent requirement before 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 data was 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.

Awaiting New Patent Examination Guidelines

CNIPA released a draft revision of the Patent Examination Guidelines for public comment on October 31, 2022, which was then issued on December 21, 2023, and took effect on January 20, 2024. Among key concerns to industry are:

- That the definition of new drug for PTE is "new to the world"; and

- That the 15 days mailing grace period is cancelled for official communications issued electronically on or after January 20, 2024 — as such, preparation time for response will be shortened due to this change.

Considering time differences, translation needs, and other circumstances these changes may be a challenge for MNC companies.

Chamber Recommendation: The Chamber encourages engagement with the Chinese government on the draft revisions to the patent guidelines as it remains to be seen whether the potentially mixed bag of patent term, eligibility, and compensation specifications currently on paper lead to a net gain for rightsholders.

Elimination of Patent Filing Subsidies for Chinese Actors While IP Remains an Industrial Policy Focus

As noted in a 2021 report from the U.S. Patent and Trademark Office, non-market factors such as subsidies and government mandates on patent filings have depressed the commercial value of patents in China. However, China's National Intellectual Property Administration issued a January 2021 notice stipulating the complete cancelation of subsidies for patent applications in June of 2021 the cancelation of subsides for patent grants by 2025.

This development coincides with state ambitions to see higher-quality patents and greater monetization of Chinese IP articulated in a January 2021 speech by President Xi Jinping. While we note that this policy adjustment will improve the value of patents in China for domestic and foreign rightsholders alike, we note that the state can still actively distort the IP market in China. China's most recent Five-Year IP plan still includes numeric targets for officials to meet with regards to "high-quality" patents.

Chamber Recommendation: We encourage the U.S. government to work with their Chinese government counterparts to ensure China continues to take steps towards the issuance of high-quality patents.

Compulsory Licensing

China's Export Control Law (effective December 2020) — which includes factors such as economic development and industrial competitiveness in determining control lists — is creating uncertainty about whether technology developed by foreign companies in China-based R&D centers can be exported, thereby creating a non-market restraint on companies' ability to commercialize their technology.

One area that deserves close monitoring is the way China tries to control the determination of global FRAND royalty rate in the wireless communications or audio-video codecs area, which may rise to a level of compulsory licensing. Chinese courts have increasingly docketed the cases through controversial cause of action, including antitrust claims, to allow implementers to ask for China courts' determination of FRAND royalty rates, against the willingness of patent owners. It is expected that Chinese courts are trying to accelerate court proceedings to hand down FRAND rates ahead of other parallel proceedings that the same patent owners may file outside China. This trend is more concerning as some Chinese judges see the FRAND rate cases to counter influence of foreign courts' decisions.

Additionally, in one case of *GNPE v. Apple* (unpublished[8]) it appears that there is an inclination to apply a FRAND license requirement to patents that may have claims that happen to read on a standard but where the patent developer or owner has not made any commitment to license under FRAND terms and had not participated in the development of the standard. While in that matter, the plaintiff/patent owner apparently claimed that the defendant/infringer was infringing because it was implementing a standard that its patent covered, the reason for the decision to force a FRAND obligation on the patent owner may not extend to other patent holders who prove infringement directly and do not rely on claims by the defendant that its product implements the standard. Monitoring of developments in this area should also be undertaken.

[8] https://chinaipr.com/2017/01/08/gpne-vs-apple-the-multi-year-saga/

Chamber Recommendation: We encourage the U.S. government to continue to track compulsory licensing-related developments in China.

Trade Secrets & Regulatory Data Protection

Index Stat: China scores behind Honduras and Colombia in the Trade Secrets and Protection of Confidential Information Index indicator.

Trade Secrets

The protection of trade secrets in has been strengthened with the changing legislative landscape of the Anti-Unfair Competition Law (AUCL). The Chamber applauds China's new legislative efforts to protect trade secrets in 2020, which includes:

- The SPC Interpretation on Several Issues Concerning the Application of Law in the Trial of Civil Cases of Disputes over Infringements of Trade Secrets (issued on August 24, 2020, effective from September 12, 2020);

- The joint judicial interpretation (III) by the Supreme People's Court and Supreme Procuratorate Office on Several Issues related to Application of Law in Intellectual Property Infringement Criminal Cases (passed on August 31, 2020, effective from September 14, 2020);

- The notice of Amending Case Acceptance and Prosecution Guidelines on Trade Secret Criminal Cases by Supreme Procuratorate Office and Ministry of Public Security (issued on September 17, 2020); and

- The amendment of Criminal Law (XI) (passed on December 26, 2020, effective from March 1, 2021), with respect to IP crimes (Art. 219 dealing trade secrets).

All these legislative and law enforcement rulemaking measures supported much stronger protection of trade secrets, by providing clearer and stricter application of punitive damages, introducing strengthened procedural protections for rightsholders, including an expanded definition for "misappropriation," which will likely nudge Chinese courts toward a more nuanced approach to the adjudication of trade-secret-related civil and criminal cases.

However, we also note with concern the publication of SAMR's draft Trade Secret Rules (issued in September 2020), which contain numerous ambiguities over jurisdictional issues, and appear to limit their scope to provide protection only for Chinese trade secrets (see Article 3). The Rules also provide only a loose definition of what constitutes "disclosure" of a trade secret, and establish a massive expansion of local administrative enforcement, which could present risks of discriminatory treatment and abuse of foreign companies by local officials connected to domestic companies levying false accusations against competitors for trade secret theft.

Chamber Recommendation: The Chamber believes the U.S. government can encourage further revisions to these Rules and other trade secret regulations, as well as judicial practices.

Regulatory Data Protection (RDP)

China committed as part of its accession to the World Trade Organization ("WTO") to provide 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, some of our members report that China's data exclusivity is effectively illusory and does not preclude generic drugs from obtaining approval during the patent term. 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 drugs 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: We urge 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 drugs 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.

Innovation and Industrial Policy

Notwithstanding incremental positive steps in select areas, China's regulatory environment is increasingly emphasizing industrial policy outcomes that are raising costs, risks, and uncertainties for many U.S. companies. Over the past year, Chinese central government agencies have doubled down on efforts to advance the senior leadership's objective of creating national — and even global — champions with cutting-edge technology and IP in key industries. Specifically, in contradiction of former President Hu Jintao's promise in 2011 to "de-link" the promotion of indigenous innovation[19] from government procurement, Article 91 of China's December 2021 revision to its *Law on Progress in Science and Technology* states that the government shall prioritize procuring domestically produced "scientific and technological products and services," and shall first consider procuring products that have "entered the market for the first time" before purchasing products with commercial track records. The U.S. Chamber China Center's ICT and Data Working Group has been closely tracking related policy developments in this area which, among other things, aim to strengthen indigenous innovation, IP, and brands, at the expense of foreign-owned businesses operating in China. In the proceeding sections, our submission highlights the laws, regulations, and standards with an IP nexus that are of particular concern to American industry in China.

China's Cybersecurity Review Regime

In December 2021, the Cyberspace Administration of China ("CAC") released a finalized version of the Cybersecurity Review Measures expanding the scope of China's cybersecurity review regime from critical information infrastructure operators ("CIIOs") to all online platform operators "conducting data-handling activities that influence or may influence national security." The finalized Measures have also retained from previous drafts politicized and potentially discriminatory review criteria for products and services, such as the "reliability of supply channels" and the "risk of supply disruptions due to political, diplomatic, and trade factors." The broad scope of the "network products and services" covered by these Measures — in combination with the security and localization requirements imposed by China's MLPS 2.0 standards — threatens to force U.S. companies to submit to intrusive reviews unconstrained by the rule of law that could compromise critical IP and confidential business information during the cybersecurity review process.

Chamber Recommendation: The Chamber urges engagement with the Chinese government to ensure that cybersecurity measures do not force U.S. companies to disclose proprietary information.

Anti-Monopoly Law ("AML")

In June 2022, China enacted a new Anti-Monopoly Law. The new Law greatly expands the government's basis for action against anti-competitive behavior and substantially increases fines and penalties. While article 8 maintains large carve-outs for state entities and businesses that are "vital to the national economy," article 41 imposes a non-discrimination clause on public bodies regulation and licensing of "non-local goods" which could, potentially, apply also to foreign producers and promote fairer competition on the Chinese market.

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, including "Provisions on Prohibiting Abuse of Intellectual Property Rights to Exclude and Restrict Competition". Like the underlying legislation, this regulation considerably expands the powers of investigation, punishment, and meaning of what constitutes anti-competitive behavior within the context of the exercise of IP rights. Specifically, several articles defining anti-competitive behavior – including articles 18 and 19 which refer explicitly to SEPs – contain not only broad language on what constitutes anti-competitive behavior within an IP rights context but also vest considerable discretion with the anti-competition authorities in identifying and defining such behavior. Under these articles anticompetitive behavior is simply defined as "Other abuses of market domination identified by the State Administration for Market Regulation."

In that vein, the State Administration for Market Regulation released *Provisions on Prohibiting the Abuse of Intellectual Property Rights to Exclude and Restrict Competition,*

officially taking effect as of 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.

Chamber Recommendation: The Chamber is concerned that the new 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 its application to intellectual property closely.

The State Council Decision on TIER and the Foreign Investment Law

On March 18, 2019, the State Council of China announced a decision with immediate effect to amend several TIER provisions in an effort to deepen reforms and improve market conditions. The amendments, as enacted, to a limited extent address several controversial rules that are alleged to pressure companies to accept forced technology transfers.

One change that could potentially benefit foreign companies is broadened rights to independently negotiate contracts in technology transactions. Parties may independently agree on indemnity provisions and the ownership of improvements made by the licensees. Cross licensing, royalty-free licensing or joint ownership should be allowed. Parties may leverage their business interests to decide on these terms. Nevertheless, China retains general requirements on fairness of contract terms. "Gross unfairness" might be cited as grounds to void licensing contracts. Clarifying how the concepts of "fairness" and "gross unfairness" are evaluated, then, would help ensure that these general requirements are not imposed upon foreign companies in an arbitrary or discriminatory manner.

The FIL came into force on January 1, 2020. Although China has abolished provisions which expressly impose technology transfer requirements on foreign companies, it is also developing measures which may bring implicit restrictions to bear. The Phase One Agreement contains several provisions designed to limit the ability of Chinese regulators and business partners to force technology transfer, calling for any transfer or licensing agreements to be based on "market terms that are voluntary and reflect mutual agreement." We commend the following provisions, which promise to:

- Make administrative and licensing requirements and processes transparent, and ensure that enforcement of laws and regulations is "impartial, fair, transparent, and non-discriminatory"; and

- Prohibit pressuring or requiring the unnecessary disclosure of sensitive technical information and protect the confidentiality of any sensitive information disclosed.

At first glance, the fact that these commitments have been explicitly codified in the Phase One Agreement seems promising. Nevertheless, we fear that the text of the Agreement's technology transfer chapter contains several potential loopholes that could enable the forced transfer of technology to continue. For example, the chapter:

- Contains no commitment to establish criminal penalties for forced technology transfer, and fails to specify which agency will be tasked with enforcement;

- Fails to specify when disclosure of sensitive technical information is deemed "necessary"; and

- Contains no specific measures designed to prevent government officials from conducting whisper campaigns, indirectly incentivizing Chinese entities to acquire technology, or retaliating against foreign companies for withholding technology.

Chamber Recommendation: The Chamber believes the effectiveness of the Phase One Agreement's technology transfer provisions will depend on the institutionalization of new standards of fairness and non-discrimination within China's regulatory system. We encourage the U.S. government to closely follow the implementation of the Phase One agreements technology transfer provisions as a result.

The Standardization Law

The latest revision to the Standardization Law expands on a public disclosure requirement that is both unique to China and potentially damaging to all market participants and would add unnecessary costs and risks for all enterprises in China. Furthermore, a newly added and deeply concerning article stipulates state endorsement of incorporating indigenously innovated technology into industry and social standards. Combined with other implementation documents and public statements that allow social standards to be transposed to become national and industry standards, the inclusion by the state of a preference for indigenous innovation (i.e., domestic Chinese IP) seems to create a trade barrier that would conflict with the WTO Technical Barriers to Trade. Moreover, it may violate the principle of coherency where it is contrary to an alternative solution in an international standard, and further, it may violate the spirit of the principle of openness, where not all potential contributors can contribute their technical ideas with equal opportunity nor on an equal basis.

Chamber Recommendation: The Chamber encourages the U.S. government to work with their Chinese government counterparts to ensure revisions to the Standardization Law are consistent with China's international obligations.

Corporate Social Credit System

The Chamber is concerned that China's Corporate Social Credit System ("SCS") uses Big Data and AI-powered techniques to collect and analyze a broad spectrum of data, including:

- Self-reported data from companies, including information directly requested by specific agencies and data pulled from license applications and product certification procedures;

- Data collected during government inspections, which the State Council has said will be guided by the principle of "two random selections, one public release";

- Real-time monitoring of metrics such as product performance, emissions, and logistics;

- Data collected by third parties, such as e-commerce data from Alibaba and Tencent;

- Video surveillance data from CCTV cameras that capture visible company activities; and

- Data on business partners, which, if poorly rated, could negatively impact scores.

Chamber Recommendation: The Chamber encourages further transparency with respect to SCS ratings and requirements, algorithmic scoring mechanisms, and institutional channels for challenging undesirable SCS ratings, as well as guarantees to adopt laws and regulations that ensure the full protection of sensitive corporate data integrated into the National Credit Information Sharing Platform to ensure that the SCS does not present considerable risks to foreign IP holders.

Cloud Computing

While U.S. cloud service providers have been at the forefront of the movement to the cloud in virtually every country in the world, China has imposed onerous regulations on foreign cloud service providers — effectively barring them from operating or competing fairly in China. Chinese laws and regulations classified cloud computing services as telecom services requiring a governmental license that is only granted to Chinese companies. U.S. cloud service providers have been forced to transfer valuable IP, surrender use of their brand names, and hand over operations and control of their business to a Chinese company to sell in the Chinese market.

Chamber Recommendation: The Chamber encourages the U.S. government to work with their counterparts in China to ensure cloud computing regulations do not place undue burden on foreign cloud service providers.

Trademarks, Related Rights, and Enforcement

Index Stat: China scores 37th out of 55 in the Index Enforcement indicators, ranking behind Honduras and above Costa Rica

Latest Judicial Reform Efforts

The Chamber notes the development and application of online case filing, docketing, hearing and document service systems against the background of COVID-19 in recent years. According to SPC Report on the Judicial Reform of Chinese Courts (2013-2022), 11.439 million cases were filed online in courts nationwide, accounting for a rate of 30.9%, with 1.275 million court sessions conducted online. At the same time, people's courts across the country actively explored the application of asynchronous trial models, allowing parties to conduct litigation activities such as mediation, evidence exchange, and inquiry online in a non-synchronous manner within a certain period. The civil retrial system in China has undergone major reforms, significantly impacting retrial cases in the past two years.

From October 2021 to July 2023, Implementation Measures for the Pilot Reform of the Functional Positioning of Four-Level Courts was issued as the guidelines of a pilot program. During this pilot program, the general principle was that provincial level high courts should handle retrial applications with SPC providing guidance and supervision, except in certain circumstances. This may mean that in some occasions these provincial high courts are handling retrial of effective judgments issued by themselves. The intention is to relieve SPC from caseloads and make sure SPC can invest more on making guidelines and principles.

On July 28, 2023, as the pilot program ended, SPC released the Guiding Opinions on Strengthening and Regulating the Case Appeal Jurisdiction and Retrial Review Work, officially announcing reform of the civil retrial system. Under the Guiding Opinions, in general higher courts should still handle retrial applications cases from lower courts that meet retrial conditions, with named exceptions. In certain occasions, cases that fall within the jurisdiction of lowers courts can be escalated to SPC.

Overall, these judicial reform efforts in China demonstrate its ongoing efforts to deal with growing IP disputes and elevate its own capability to adjudicate cases of global stakes.

Chamber Recommendation: The Chamber recommends the U.S. government closely monitor progress in this area to ascertain whether the aforementioned judicial reforms and implementation mechanisms are delivering real benefits to foreign IP holders.

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, we urge continued monitoring of the IP courts cases and their outcomes.

Criminal Law Revision

China's draft amendment to its Criminal Law (issued for comment by the NPC in October 2020 and passed on December 26, 2020) contains strengthened IP protections, including criminal penalties for trade secret infringement and provisions mandating the destruction of infringing and counterfeit goods. The prosecution guidelines were also amended on September 2020, which reduced the numerical threshold for criminal prosecution to RMB 300,000 (around USD 50,000) and made flexibilities available on how to calculate actual losses. This revision has proven effective to close legal loopholes for infringers and reduce liability thresholds for counterfeiting and piracy.

In January 2023, SPC and SPP jointly released the Draft Interpretation of Handling IP Criminal Cases, which specifies that the threshold of the crime of selling counterfeit goods includes "illegal gains" or "sales amount" standard. The current Criminal Law poses a major challenge to change "sales amount" standard to "illegal gains", which makes it difficult to fix evidence in the crime of selling counterfeit goods. The Draft Interpretation is a positive move to provide a clear guidance on the application of law to safeguard the legitimate rights and interests of the trademark right owners.

Chamber Recommendation: We encourage continued monitoring of amendments to the Criminal Law to ensure that it effectively protects trademark rightsholders.

Trademark Law

On January 23, 2023, CNIPA released draft amendments to the Trademark Law for public comments, which proposes systemic changes to the current trademark registration and protection system with strong efforts to curb bad faith trademarks. The amendments introduced 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 Chamber applauds China's ongoing efforts and welcome continued development of IP law that benefits the interests of all rightsholders. However, some proposed provisions and mechanisms may need more caution and consideration, and the Chamber has submitted comments to address relevant concerns.

Chamber Recommendation: The Chamber encourages the U.S. government to seek clarifications may be needed on standards of trademark use reporting requirements and repeated filings, so to balance the need of controlling bad faith filings and the need of protective filings by legitimate owners. Further, under Article 42.2 of the draft amendments the court would not be allowed to take the changed status of the cited mark into account in administrative litigation unless one can demonstrate "apparent unfairness", a concept not specified. This proposed rule may have the unintended consequence of increasing the number of trademark administrative cases, further pressing the courts and CNIPA examiners.

Damages

There is a notable increase in cases granting punitive damages in the last 3 years. The Trademark Law in 2019 increased the maximum statutory compensation for trademark infringement from RMB 3 million to RMB 5 million. Punitive damages are allowed up to five times the actual loss of the trademark owners, or the illegal gains of infringers or reasonable multiples of trademark royalties.

In 2021, SPC released Interpretation on the Application of Punitive Damages in Hearing Civil Cases of Infringement upon Intellectual Property Right, clarifying the legal test for "serious circumstances of infringement" and "maliciousness". Following the Interpretation, SPC released 6 typical cases granting higher damages to right owners by applying punitive damages. Various high courts have released guidelines on calculation of punitive damages.

According to a statistical analysis over publicly available cases in 2021, there are 74 cases that granted punitive damages, and 31 cases that granted high statutory damages by considering the maliciousness and seriousness of infringement.

Chamber Recommendation: The Chamber encourages the U.S. government to continue to monitor the application of trademark damages, which have the potential to deter future infringement.

Bad-Faith Trademark Registrations

According to 2022 White Paper on China IP Protection, the number of trademark registrations in 2022 reached 6.17 million (decrease of 20.2% year-on-year), and the cumulative

number of effective registered trademarks reached 42.67 million. 372,000 counts of bad faith trademarks were denied in total.

Although filing fees and the government's average time to review trademark filings have been reduced, we are concerned that the record numbers of filings and the review timeline being suddenly reduced will make it easier for bad-faith trademarks to be registered and approved. In turn, this could increase costs for legitimate businesses to oppose these filings.

The Chamber has taken note of CNIPA recent initiatives, 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.

Phase One Agreement Counterfeiting Provisions

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.

Pharmaceutical Counterfeiting

The positive changes in the PRC Criminal Code and the establishment of a special police force dedicated to food and drug safety in local areas have resulted in a sharp increase in successful criminal prosecutions, especially before the COVID-19 time. Chinese police had reported progress in going after online sales of counterfeit medicines. The Chamber is encouraged by the special campaign initiated by the National Medical Products Administration (former China Food and Drug Administration) targeting the online sale of counterfeit medicines and is pleased that Chinese officials reported that the campaign will continue in future years.

On August 26, 2019, the revisions of the Drug Administration Law of the PRC were passed. The newly revised Drug Administration Law came into effect on December 1, 2019. The Drug Administration Law was first promulgated in 1984, and the 2019 revision constitutes the first overhaul since a 2001 revision.

The revision modifies the definition of counterfeit drugs. Drugs imported without authorization are no longer listed as counterfeit drugs. And fake drug without active ingredients is no longer treated counterfeit drug. Such changes to the definition have caused troubles to go after counterfeiting, although the revised law raises the number of fines significantly.

The fine to produce counterfeit drugs is increased from 2-5 times to 15-30 times the value of illegally produced and sold drugs. The law also expands the scope of application of punitive damages, not limited to the consequences of causing death or serious damage to health and clarifies that the amount of punitive damages is "10 times the payment price or three times the loss". China also amended its criminal code in December 2020 to further clarify the criminal liability against any manufacturing, importation, and sales of drugs without

administrative approvals. Also, provision of fraudulent proof, data, samples during the drug approval application process is also criminally liable.

The revisions to the Drug Administration Law and Criminal Code are promising, and the Chamber looks forward to the practical effect of the newly revised laws. Meanwhile, enforcement staff of major pharmaceutical companies reported that Chinese police often found it challenging to trace suppliers of raw materials used for making counterfeit medicines and to take other regulatory measures to combat illegal API problems. China's unwillingness to impose injunctive relief for patent infringements results in the proliferation of infringement, including in Bangladesh and other LDC countries. With injunctive relief, companies would be in a position to eliminate infringement at its root with the API and therefore very much limit finished goods development in LDC like Bangladesh.

Chamber Recommendation: The Chamber encourages the U.S. government to work with the Chinese government to consider implementing injunctive relief for patent infringements to stem pharmaceutical counterfeiting in China.

Design Rights

Index Stat: China receives less than 50% of the overall score in the design rights Index indicators, scoring alongside the Philippines, Nigeria, Kuwait, Jordan, and Egypt.

Design Patents and Partial Designs

In October 2020, the so-called "Fourth Amendment" to the Patent Law was approved. Under the Fourth Amendment, design protection of partial product designs will be available in China and rightsholders will be allowed to file for protection of selected portions of product designs. The term of a design patent has also been extended from 10 years to 15 years. These rules took effect on June 1, 2021.

Chamber Recommendation: The Chamber was encouraged by the increase in design patents term and encourages the U.S. government to continue to identify ways to improve design patents protection.

Section E: Developing Market Profiles

ARGENTINA

Overview

Despite its high Human Development Index score (0.842 in 2023), gaps in Argentina's IP framework have limited the ways the country can capitalize on its innovative capacity to power socio-economic growth. The country continues to be hampered by restrictive patentability

standards, localization requirements, reimbursement challenges, and others. And thanks to reluctant customs authorities and weak information sharing, large-scale infringements of IP continue to thrive. As the Argentine government strategizes on how best to encourage domestic consumption, secure foreign investment, and ultimately drive growth, the Chamber also asks the U.S. government to constructively engage with Argentine officials —providing real-life and proven examples of how clear, thoughtful rules can fuel business investment and workforce development.

Patents and related rights

Index Stat: Argentina ranks 47th out of 55 economies for the patents, related rights, and limitations Index category. Not only does Argentina rank within the bottom third overall globally, but it also falls within the bottom third for the Latin American region.

Patent Backlog

Inventors, creators, and rightsholders face excessive processing times and long delays. A substantial backlog of patent applications has existed at INPI for several years with an average time to grant for many high-tech arts (including biopharmaceuticals, chemical, and biotech patents) being close, in many cases, to approximately a decade.

Despite the difficult regulatory landscape, there are helpful signs that INPI is taking steps to streamline its operations and tackle its backlog of nearly the over 21,000 patent applications up for consideration. To help alleviate this backlog, the INPI has taken some corrective actions. The agency has: created expedited procedures for patent applications already issued elsewhere; hired more patent examiners; and has been working with WIPO to digitize its patent services. There has also been a concerted effort from INPI to engage in international patent cooperation and harmonization efforts. Resolution 56/2016 has laid the basis for Argentina's participation in PPH agreements with other economies' patent offices. Similarly, in 2019, the Argentinian government worked to implement Decree 403/2019 to expedite patent and utility model applications. The INPI also signed a Memorandum of Understanding with the European Patent Office to establish a "Reinforced Partnership" to encourage capacity building and improve productivity for processing patents related to artificial intelligence, the fourth industrial revolution, and the internet of things. The Chamber applauds these efforts.

However, and despite the strides Argentina has taken in recent years to reduce the backlog in patent approvals, including the initiatives above and the State Simplification and De-Bureaucratization process introduced in 2018, significant delays persist. On average, it takes approximately 6.5 years to obtain approval for pharmaceutical and biotechnology patents, and there are no mechanisms in place to offset these prolonged delays.

Chamber Recommendation: The Chamber encourages the U.S. government to collaborate further with the Argentinian government to ensure that its patentability standards are in-line with international best practices.

Patent Enforcement and Injunction Issues

Even for innovators that overcome the immense odds to securing patent protections in Argentina, the country's legal system leaves little room for effective enforcement. Preliminary injunctions, for instance — a basic component of any IP framework that helps but a stop to the sale of patent-infringing goods during litigation — were nominally provided for in 2003 under amendments to Law 25.859. Current remedies for patent and trademark infringement include pre-trial mediation proceedings; precautionary measures to obtain the attachment and seizure of infringing products under sections 38 and 39 of the Argentine Trademark Law; injunctions based on section 50 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 ("TRIPS"); and, if necessary, criminal sanctions and actions. Patentees can also file civil suits to obtain damages suffered due to infringement under section 81 of the Patent Law.

However, fifteen years after their implementation, the pharmaceutical industry reports that obtaining injunctive relief remains time-consuming, burdensome, and confusing. According to industry, this is one of the most frustrating barriers they face when doing business in the country.

Chamber Recommendation: The Chamber asks that the U.S. government work with the Argentine government to meaningfully streamline the process and encourages the Argentine government to become a party of the Patent Cooperation Treaty ("PCT").

Copyrights and related rights

Index Stat: Argentina ranks 48th out of 55 economies on the copyrights, related rights, and limitations Index category. As it was in the patents category (listed above), Argentina ranks in the bottom third overall globally while also ranking last within the Latin American region, falling behind Venezuela.

Enforcement

Argentina currently lacks an effective legal framework to adequately enforce copyright protection. In general, Argentinian law provides only general exclusive rights for authors and creators with limited reference to the online environment. No copyright-specific legal provisions are currently in place with respect to secondary liability related to online piracy or an injunctive-style relief mechanism. However, and as noted in the Chamber's most recent International IP Index, some important instances of judicial action exist, albeit isolated cases of courts ordering the disabling of access to infringing content and websites. This has happened in spite of the status quo that has affirmed that ISPs generally do not have secondary liability for

copyright infringement and that existing notice-and-takedown mechanisms rely on direct communication from rightsholders with ISPs, internet hosts, and online mediators.

Additionally, 2023 saw some welcomed developments with respect to the enforcement of copyright. In May, a federal court ordered not only the disabling of access to several copyright infringing websites, but the order also included a so-called dynamic element. The plaintiffs, led by a coalition of international, regional, and domestic rightsholders, specifically requested that the injunction include the ability to update and apply the disabling of access to new websites and URLs when they appear. This type of dynamic injunction effectively addresses the issue of mirror sites and disables infringing content that re-enters the public domain by simply being moved to a different access point online. These types of orders are becoming more commonplace around the world, with similar mechanisms available in, for example, the Netherlands, Greece, Singapore, India, Canada, and the UK.

Chamber Recommendation: Going forward, 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, as would undertaking routine, ex officio actions, such as raids of physical markets, to stop hard goods piracy.

Trade secrets and related rights

Index Stat: Argentina ranks 45th out of 55 economies in the trade secrets and protection of confidential information category, due in large part to extensive gaps in the country's current legal and regulatory framework. Argentina is ahead of only Venezuela in the Latin American region.

Regulatory Data Protection

Despite having participated in drafting Article 39.3 of the TRIPS agreement, Argentina has not fully implemented its obligations safeguarding regulatory test data. Currently, data exclusivity and patent term extensions for regulatory delays are not available in Argentina. Moreover, there are no clinical results available for competing generic products and no information to support efficacy claims. And under Law 24,766, Argentine officials may rely on data submitted by originators to approve requests by competitors to market similar products. The Law also does not provide for protection against reliance and does not define key terms, including what constitutes "dishonest" use.

Chamber Recommendation: The Chamber asks the U.S. government to monitor Argentina's data exclusivity practices and advocate for the full implementation of its RDP obligations.

Commercialization of IP assets and market access

Index Stat: Argentina ranks 28th out of 55 economies in the commercialization of IP assets Index category, placing it in the middle tier of global economies and in the top third for the Latin American region. The commercialization of IP assets category is Argentina's highest ranking on the nine categories measured in the Index.

Pharmaceutical Reimbursement

In 2015, Argentina's Ministry of Health and Secretary of Commerce issued joint resolutions to establish a reimbursement program favoring locally made generic and biosimilar products. In the years since, Argentina's Health Insurance Agents must favor Argentine products if they have the same active ingredient or are priced significantly lower than a foreign product. The Chamber notes that the regulations' key terms remain undefined, making it difficult for industry to know when a domestic product would be favored over a foreign product. This program seems to be out of step with global guidelines on biosimilars that prevent countries from automatically substituting biosimilars for the original biologics. It also runs afoul of Argentina's national treatment obligations, including those under the WTO General Agreement on Tariffs and Trade.

Furthermore, in 2020 the government of Argentina indicated that they would adopt international reference pricing methodologies for price controls on "high cost" medicines. Subsequently, the Fernandez government, in late 2021 and spearheaded by the Minister of Health, Carla Vizzotti, and the Secretary of Commerce, Roberto Feletti, reached an agreement with pharmaceutical companies to freeze prices of all medicines until January 7th, 2022, taking into consideration their cost by November 1st. This agreement extended the aforementioned pricing methodologies for all medicines marketed in the country to provide to the Argentine population access to "essential consumption." Additionally, in August 2023, Economy Minister Sergio Massa announced a freeze on medication prices after an economic devaluation by the International Monetary Fund amid skyrocketing hyperinflation – in which the health sector, mainly driven by the cost of pharmaceuticals, saw the second highest inflation rate of 15.1%. The freeze was agreed upon with national pharmaceutical companies and was in place until October 31.

Chamber Recommendation: The Chamber asks the U.S. government to continue its engagement with the government of Argentina on a facts-based, common-sense approach to facilitating a fair and innovative pharmaceutical reimbursement mechanism.

BRAZIL

Overview

In recent years, there have been several positive developments on IP in Brazil, which continued into 2023, including 2020's National Intellectual Property Strategy, followed by the government of Brazil's 2021 "Innovation Strategy", the goal of which was to bring about a new paradigm to government IP management that is working to increase cohesion, synergy and the effectiveness of policies related to innovation. As always, the Chamber is excited to continue its partnership with the government of Brazil on these two strategies in 2023 and forward.

Most prominently, the Chamber continues to be encouraged by the work undertaken by the National Institute of Industrial Property ("INPI") to improve Brazil's administration of IP—particularly in addressing its multi-year backlog of patent applications. 2023 has proven to be a watershed year for INPI, who committed to hiring dozens of patent and trademark examiners to reduce the backlog. While serious efforts have been made on the copyright front in 2023, there are still legal gaps in the country's patent, copyright, trademark, and enforcement measures. Given the country's positive progress, the Chamber urges the U.S. government to prioritize Brazil in its IP-focused engagements in the region and to build on its positive momentum in 2024.

Brazil's path to OECD membership, which started early in 2022, should be seen as a key motivator to strengthening IP rights in Brazil. In June 2022, OECD issued Brazil's roadmap memorandum, which included IP-related issues under the review of the Trade Committee and the Committee for Scientific and Technological Policy. The Chamber views the US government and private sector support and guidance in the process for Brazil full membership to the OECD as key to improving IP rights in Brazil.

Patents and related rights

Index Stat: While Brazil ranks 36th out of 55 economies globally, it ranks 49th out of 55 economies in the patents and related rights Index category, the second worst in the Latin American region, ahead of only Venezuela. Patents and related rights are Brazil's second-worst IP category, ahead of the membership and ratification of international treaties category.

Patentability

Rightsholders in 2023 continued to face many basic challenges in registering and protecting patent eligible subject matter in Brazil. Above all there has been no resolution with respect to the provision of a TRIPS compliant minimum term of patent protection. Given the Brazilian Patent and Trademark Office INPI has historically had a backlog of patent applications ranging from 10 to 13 years – depending on the field of technology – the Industrial Property Law had up until 2021 provided innovators in Brazil with a guaranteed minimum term of exclusivity and protection of 10 years from grant for standard patents. Article 40 of the Law stated that the term of protection shall "not be less than 10 (ten) years for an invention patent and 7 (seven) years for a utility model patent, beginning on the date of granting, unless the INPI has been prevented from examining the merits of the application by a proven pending judicial

dispute or for reasons of force majeure." For years article 40 provided rightsholders with a proverbial floor of exclusivity and insurance against INPI's endemic delays. In a series of decisions in the Spring of 2021 the Brazilian Supreme Court removed this floor. Not only did the Court declare that article 40 was unconstitutional and would no longer be available or applicable, but the Court also stated that the ruling should be retroactively applied but only to granted patents in the biopharmaceutical and health related fields.

As noted over the last few years, the ruling is a grave blow to Brazil's national IP environment with thousands of biopharmaceuticals rightsholders discriminated against and exclusivity periods cut short. Through this decision the Brazilian Supreme Court has not only further weakened Brazil's already weak standards of patent protection, but the selective retroactive application of the ruling to one field of technology and innovation is a gross violation of article 27(1) of the TRIPS treaty and established international principles of non-discrimination. Since this ruling, legislative proposals have been presented in the Brazilian Chamber of Deputies that would provide a period pf patent term restoration due to administrative delays during patent examination and prosecution. However, to date, no legislative action has been taken. In response to this situation close to 50 lawsuits have been filed across Brazil with rightsholders from the life sciences and health sector arguing for an extension of a granted patent term because of these continued delays in patent prosecution. Unfortunately, these lawsuits too have not led to any further clarity on the matter.

In a positive development, a Federal court in Rio de Janeiro in April 2023 granted an adjustment of close to one year to the term of a granted patent, finding that there had been undue delay in the granting of the patent. (At the time of research, this case had been appealed by the Brazilian Government.). In contrast, and although the facts of the case and legal issue at hand was different, a Supreme Court panel ruling in January 2023 found that rightsholders did not have the right to extend a patent term of protection beyond 20 years from filing, irrespective of time of grant. The bottom line is that rightsholders continue to face deep uncertainty on whether they will be able to effectively register and protect their innovations in Brazil.

Chamber Recommendation: The Chamber urges the Brazilian Government and lawmakers to immediately address these issues. The Chamber recognizes INPI's continued commitment to reducing processing times — as stated in the *Strategic Plan 2023-2026* — but large application backlogs and unreasonably long application processing times are not unique to Brazil or INPI and there are a variety of mechanisms that can more effectively deal with this. Such mechanisms could include, for example, the introduction of a new statutory defined variable term of adjustment — as proposed in the Chamber of Deputies — or a patent validation mechanism with other major IP offices.

Patent Backlog and Review Delays

As stated above, and more broadly, across all economic sectors and patent arts, 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 worst affected. The past few years have seen a growing level of commitment and efforts by INPI to finally address this backlog, with most recent developments in the Summer of 2023 representing the most comprehensive actions to tackle the backlog.

First, in 2019, the Brazilian government launched the Backlog Fight Plan (*Plano de Combate ao Backlog de Patentes*). Several administrative resolutions have been passed by the INPI over the last few years, all aimed at accelerating the decision-making and patent prosecution process both for applications with and without existing prior art searches and documentation. These actions have reduced the number of pending applications. Unfortunately, according to a recent analysis from Osha Bergman Watanabe & Burton LLP of the patent examination timelines for biopharmaceutical patents, the average patent examination timeline for biopharmaceutical patents granted between January 1, 2020, and March 23, 2022, remains unreasonably high at 10.25 years. Moreover, the Chamber had expressed concern that significant budget cuts to INPI in 2022 had threatened its ability to continue improving the backlog, and sent a letter to Geraldo Alckmin, the Vice-President of the Republic & Minister of State for Development, Industry and Foreign Trade, and Simone Tebet, Minister of State Planning and Budget for the Ministry of Planning and budget in June 2023, calling for:

- INPI to hire new employees to make up for attrition and departures since INPI's last round of hiring in 2017;

- INPI to have sufficient funding to meet its existing obligations and to cover needed expenditures to provide quality and timely examination, IT improvements, and other personnel needs as necessary;

- Granting INPI access to millions of reais in collections that have not yet been appropriated for its use; and

- INPI having broader autonomy when hiring new employees to streamline the process.

The Chamber was pleased to learn about the plans spearheaded by INPI and the Ministry of Development, Industry, Services and Trade to continue the initiative and to improve the deadlines for examining patents and trademarks of the Patent Prosecution Highway Brazil-U.S., among other reforms. Continued efforts to address the current backlog are essential to support innovation and creativity, as well as to drive economic growth driven by IP and through Brazil's reindustrialization plan.

Additionally, that same month, the Chamber was encouraged by an announcement by Minister Alckmin regarding a federal tendering to fill 120 vacancies in INPI, including planning

analysts, researchers and technologists, and examiners who will work to reduce the backlog of registration of trademarks and patents. Of the 120 new hires, 40 will be assigned to patent examination and 40 to trademark examination. At the same time, INPI has incorporated fast track programs to reduce the backlog in the technological space, spearheading a successful program to reduce pendency in green technology, which will serve as a blueprint for similar programs in other fields, including biotechnology. There remain roughly 800 vacancies left to be filled, and the Chamber is encouraged by INPI's public desire to fill roughly 400 in the coming year.

Chamber Recommendation: The Chamber believes that implementing the recommendations, as well as 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

Brazilian health and pharmaceutical policies have historically had a strong focus on localizing industrial production, R&D and cost controls through the overriding of IP rights. The relevant sections of Industrial Property Law 9.279 provide 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. As noted in past editions of the Special 301, these sections have been used in the past during price negotiations with foreign biopharmaceutical innovators to reduce their prices in light of the threat of approving the manufacturing of local generic versions of patented medicines.

The focus on compulsory licensing as a public policy tool in Brazil has intensified in the last few years. Several amendments to the Industrial Property Law were signed into law in late 2021 with many more under discussion. Passed amendments included 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.

More specifically, Congressional authorities in Brazil used the pretext of the ongoing COVID-19 pandemic to review provisions of the Brazilian Patent Statue to strengthen compulsory licensing of patents in cases of "national emergency or public interest."" As such, in May 2021, the Brazilian Senate approved Bill 12/2021 (now Law No.14.200/2021) to create a two-step compulsory licensing process which would then amend the provisions of the Brazilian Patent Statute. In July, the House of Representatives approved the Bill with additional amendments. However, in that September, the Bill was sanctioned with vetoes by Brazilian President Jair Bolsonaro.

Industry has expressed concerns with the incoming Lula Government, which succeeded the Bolsonaro Government on January 1, 2023, given the Lula Government's handling of compulsory licensing in the past, most notably in 2007. The Chamber will be closely monitoring any developments the second Lula Government may take on this front for 2024.

Copyrights and related rights

Index Stat: Brazil ranks 44th out of 55 economies in the copyrights and related rights Index category, ahead of only Ecuador, Argentina, and Venezuela in the Latin American region.

Copyright Law

As noted in previous editions of the Special 301, rightsholders have for years faced significant challenges in protecting their content and enforcing their copyrights in Brazil. Compared with other regional and global economies, the legal regime remains under-developed and whether it be through online access or through physical goods, piracy levels remain elevated. Nevertheless, the last few years have seen several dedicated enforcement operations against IP infringing websites, vendors, and suspected criminals, most notably the government of Brazil identifying issues to the Copyright Law — with a focus on anti-piracy — as a priority action in the National IP Strategy. The Chamber strongly supports the government of Brazil's emphasis on copyright enforcement, noting the immense challenges that rightsholders face protecting their content in the digital environment.

Online Piracy and Enforcement

The Brazilian Copyright Act provides basic exclusive rights and protection with relatively limited provisions in place addressing the issue of online infringement. Brazil does not have a formalized and comprehensive notice and takedown system in place. Historically, there has been some cooperation between ISPs and rightsholders, but this is piecemeal, ad hoc, and not systematic. Although primarily concerned with issues of data privacy and network neutrality, the 2014 *Marco Civil da Internet* (Internet Bill of Rights, Law No. 12,965) did contain some provisions relating to the protection of content and copyright online. Specifically, Section 3 and Articles 18–20 of the act provide a broad safe harbor provision for ISPs relating to third-party infringement, with ISPs required to act and make infringing content unavailable only once a court order has been issued unambiguously finding that the content is infringing. Given that the Brazilian justice system generally suffers from long processing times and high costs of litigation, 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. As a result, and as has been noted over the course of the Special 301, industry data and consumer surveys have

consistently shown that Brazil remains a central piracy hub in Latin America, with online infringement growing as broadband penetration and the use of mobile technologies all grow.

The Chamber notes the dedicated enforcement operations against IP infringing websites, vendors, and suspected criminals, including the wildly successful "Operation Copyright," an initiative by the Brazilian Federal Police to tackle copyright piracy. Reports suggest that the police took coordinated action in five Brazilian states, shutting down torrent sites and seizing equipment and suspected goods. Further, the Chamber continues to support the government of Brazil's National Council to Combat Piracy and the Secretariat of Integrated Operations and its continued leadership on the anti-piracy campaign "Operation 404." Spearheaded by a special police enforcement unit ("SEOPI"), the Ministry of Justice and with international support from the United States Embassy and UK law enforcement officials, this special enforcement effort has had direct and tangible results: hundreds of websites and applications offering copyright infringing content have been shut down and over 50 search and seizure warrants have been issued and executed across 20 Brazilian states with several high-profile arrests.

In 2023, these efforts continued in full force, with authorities in Brazil and Peru shutting down access to hundreds of infringing websites and online access points. Media reports suggest that over 500 websites and piracy applications were taken down through the efforts of Operation 404 during the summer months in the last three years. The Chamber commends the joint efforts between U.S. and Brazilian law enforcement in successfully resolving this case and hopes that it proves a model for greater bilateral cooperation.

In a separate development, the heads of Anatel (the National Telecommunications Agency) and Ancine (the national Film Agency) in August 2022 announced the signing of a cooperation agreement that has the potential to put in place a new administrative injunctive relief mechanism targeting online piracy. Under the proposed agreement the two agencies would work together and disable access to infringing content available online and streamed through set-top boxes.

The Chamber also notes that Anatel launched a dedicated campaign against illicit IPTV set-top boxes. As in many other economies in the region, Brazil has seen an explosion in the growth and use of these physical boxes and the internet-based applications that provide users with copyright infringing content. Anatel's "Action Plan to Combat the Use of Clandestine TV Boxes" was announced in February 2023 and gives the agency a dedicated enforcement function to locate and disable these illegal set-top boxes. In September, Anatel announced that it had operationalized a dedicated laboratory and testing site to assist in these efforts. The agency is reportedly targeting both the physical devices and their streaming applications online and had at the time of research seized almost 1.5 million illegal set-top boxes and disabled access to hundreds of illicit access points. Together these are positive developments and mark a potential turning point for creators and rightsholders in Brazil.

Chamber Recommendation: The Chamber recommends that the U.S. government collaborate with Brazilian government colleagues to ensure that successful initiatives, such as those from CNCP, have the resources and local government support to combat all forms of copyright piracy more effectively throughout Brazil. Bilateral collaboration can also highlight the importance of best practices for e-commerce and copyright through instruments such as the WIPO Internet Treaties.

Trademarks and related rights

Index Stat: Brazil ranks 38th out of 55 global economies in the trademarks and related rights Index category, placing it in the middle tier of Latin American economies.

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 ("DIREP"), and State Police. Although industry reports in 2020 that São Paulo — in particular the Shopping 25 de Março and Avenida Paulista — remains a major hub for the sale of counterfeit goods, the taskforce has not just seized products, but is actively pushing to close several distribution centers.

Chamber Recommendation: To support these efforts, the Chamber recommends that the National Congress approve Bill 333/1999. This Bill would bring criminal penalties and fines for trademark infringement in line with those already established for copyright infringement. Bill 333/1999 also allows for the *ex officio* seizure and destruction of infringing goods—a major advancement in Brazil's enforcement regime. The Chamber notes that this Bill only needs to be passed by the Lower Chamber's plenary session to become law.

Trade secrets and related rights

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, ahead of only Venezuela, Argentina, and Peru.

Regulatory Data Protection

Brazilian Law 10.603/2002 currently provides regulatory data protection for veterinary products, fertilizers, and agrochemicals but does not extend this protection to pharmaceuticals made for human use. Regulatory data protection protects innovative companies against the unfair, commercial use of their data by a third party during the marketing approval process. The lack of regulatory data protection for human-use innovations has created challenges for biotechnology companies operating in Brazil.

Chamber Recommendation: The Chamber encourages the U.S. government to work further with the Brazilian government, the new Lula administration, ANVISA, and ANPD to ensure equivalent and equitable regulatory data protection for human-applied innovations.

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 and Venezuela.

Local Content/Forced Localization

Brazilian law includes several local content requirements which affect several IP-intensive sectors, including creative content and the information and communications technologies ("ICT"). In the audiovisual sector, for instance, 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 quotas expired in September 2023. In response to the expiration, Bill #3.696/2023, which would reinstate the PAY-TV quotas until 2038, was recently approved by the Senate and, at the time of this review, is now being considered in the House of Representatives.

These localization policies limit the legitimate content that Brazilian consumers can access and has an unfortunate effect of increasing illegal consumption of content.

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.

Screen Quotas

The most recent Presidential Decree on Screen Quotas, released in January 2020, imposed quotas for 2020 that are like prior years, requiring varying days of screening depending on the number of screens in an exhibitor group. For example, an exhibitor group with 201 or more screens is required to meet a 57-day quota, and all the screens in the exhibitor group's complexes must individually meet this quota. These quotas expired in September 2021, but they may be renewed at any time. Over the course of the last several years, there have also been competing legislative proposals have been introduced that would either loosen or tighten the restrictions, including a draft bill (5092/2020) seeking to extinguish any deadline applied to the theatrical quotas.

Chamber Recommendation: The Chamber believes that local content quotas limit consumer choice and can push consumers toward illegitimate content sources, and as such strongly opposes these arbitrary quotas.

Enforcement

Index Stat: Brazil ranks 26th out of 55 global economies in the enforcement Index category, its third highest IP category. Despite its higher-than-average rank, it still falls within the middle tier of Latin American economies, ahead of Peru, Honduras, Costa Rica, Ecuador, Argentina, and Venezuela.

Camcording

Camcording piracy, while a persistent problem in Brazil, is trending in the right direction. The COVID-19 pandemic, which caused the widespread closure of cinemas in Brazil for much of 2020, has temporarily halted camcording activity. However, as cinemas reopen to moviegoers, rightsholders anticipate that this illicit activity will resume.

Chamber Recommendation: The Chamber urges the Brazilian government to approve Bill No. 2714/2019, which appropriately removes the requirement to prove a profit motive in the prosecution of this content theft.

COLOMBIA

Overview

As a strong regional partner of the U.S., the Colombian government is well-positioned to capitalize on greater foreign direct investment in innovative industries. The Chamber was pleased to see the government take steps to improve its IP system in recent years under the Duque Administration, from ensuring its domestic law comported with the U.S. FTA to initiating the CONPES National IP Strategy. However, the Chamber is disappointed to see that these steps are not being honored nor supported by the Petro Administration. The Chamber also notes that Colombian legislators have proposed a bill to pressure the government of Colombia in support of the WTO TRIPS waiver mentioned elsewhere in this filing.

The Colombian government must also address several outstanding challenges which IP-intensive industries face. Chief among these concerns are politically-driven declarations of public interest compulsory licenses and gaps in the implementation of copyright-related FTA commitments. Additionally, the government of Colombia approved the National Development Plan (2022-2026) which includes a policy for sanitary sovereignty to foster local production of biologics medicines and vaccines and encourage additional and troubling “flexibilities” on intellectual property. In addition, within the new National Development Plan, are provisions which include “health reform.” The Chamber believes these provisions will generate

uncertainty in the insurance model, disrupt the introduction and dissemination of innovative therapies, and raises the prospect of questionable funding mechanisms which could represent a major access barrier for patients.

As a strategic market for many Chamber members, we strongly encourage the U.S. government to engage with the Colombian government in providing guidance and best practices for thoughtful IP policy mechanisms.

Patents and related rights

Index Stat: While Colombia ranks 31st out of 55 economies globally, it ranks 30th out of 55 economies on the patents, related rights, and limitations Index category. However, Colombia ranks in the top tier of Latin American economies due to its relatively robust framework for patent protection — albeit with serious and growing issues of concern.

Pharmaceutical Patent Enforcement

The U.S.-Colombia FTA calls for a patent linkage system to be in place in both countries. Although government authorities have introduced provisions intended to implement this obligation, they are missing key elements, and problems with the underlying legal framework for enforcement undermine their effectiveness. In 2013, the National Institute of Food and Drug Monitoring ("INVIMA") introduced a mechanism for the notification of patent holders concerning potentially infringing market authorization applications; yet it is the responsibility of the patent holder to pursue prosecution, and Colombia does not provide a legal ground for litigation on the basis of drug registration or suspension of marketing authorization of disputed products. As a result, this has led to the approval and marketing of follow-on products, even though a patent for the original drug is still in force. The Chamber recommends that the U.S. government work with the Colombian Government to ensure to bring their patent enforcement framework into compliance with its FTA commitments.

Compulsory Licenses

At times, the government of Colombia has relied on the use or the threat of the use of compulsory license to achieves policy outcomes, including most recently in 2016 (when the government sought to cut the price of Gleevec), 2017 (against medicines for the treatment of hepatitis C), and, most recently, in 2023 with the declaration of public interest against medicine for the treatment of HIV. As its basis, Article 70 of the 2014-18 National Development Plan widened the basis for the issuing of compulsory licenses in a manner that goes beyond the TRIPS Agreement, Article 31, the 2001 Doha Ministerial Declaration, and the subsequent General Council decision concerning Paragraph 6. The provision allows Colombian authorities to define public health emergencies broadly and to actively seek out compulsory licenses.

Most recently, in October 2023, Colombia's Health Minister, Guillermo Alfonso Jaramillo, issued a Declaration of Public Interest ("DPI") (Resolution 1579) aimed at conducting a comprehensive assessment of the feasibility of compulsory licensing to procure generic iterations of a pharmaceutical agent for HIV treatment, namely dolutegravir, originally manufactured by ViiV Healthcare, which is an entity under GlaxoSmithKline ("GSK"). This pharmaceutical product is commercially recognized as Tivicay, or alternatively, Dovato when employed in combination with other therapeutic agents. In seeking to purchase generic versions of the drug through the Pan American Health Organization, Colombian officials have — erroneously — relied on "emergencies" provisions under the TRIPS agreement as a basis for the DPI despite 88.35 percent of Colombian patients having access to antiretroviral treatments.

After the October DPI, industry leaders were informed that the Ministry of Health would be potentially pursuing additional compulsory licenses — using the same erroneous justification under the TRIPS agreement — against more small molecules, to circumvent Colombia's existing price control mechanism and government procurement processes.

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. The Chamber encourages the U.S. government to work closely with the Colombian government to help enable access to the newest innovative treatments by promoting more competition in the marketplace, rather than undermining IP protection.

Copyright and related rights

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

Online Piracy

The U.S.-Colombia FTA provides for a notice and takedown regime that is similar to the framework under the U.S. Digital Millennium Copyright Act. Despite Colombia's treaty obligations, no law introducing such a framework has been passed to date. Similarly, Colombian law does not provide for a defined and copyright-specific infringement injunctive style relief mechanism as is being adopted in more and more economies across the world. As a result, the piracy of audiovisual content represents a major challenge to rightsholders in Colombia.

In 2021, positive efforts to combat copyright infringement continued. In what could be an important new pathway for rightsholders to enforce their rights on the Internet, the national copyright office *Dirección Nacional de Derecho de Autor* ("DNDA") ordered the disabling of

online access to copyright infringing material. To date, the DNDA had ordered the disabling of access in two separate cases: the first case concerned the unauthorized publication of a scientific journal article and the second case, the unauthorized broadcasting and dissemination of copyrighted audiovisual content through a local company IPTV Colombia Premium, in March 2021. These cases are of real significance, particularly the action taken against IPTV Colombia Premium.

Chamber Recommendation: The Chamber encourages the Colombian government to build upon this positive momentum and continue efforts to better protection copyrighted contented online and will continue to monitor these positive developments.

Trade secrets and related rights

Index Stat: Colombia ranks 23rd out of 55 economies in the trade secrets and protection of confidential information Index category and is the second highest ranked in the Latin American region.

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 exists no additional protection for subsequent modifications, label extensions, pediatric indications, new pharmaceutical forms, and, to some uncertain extent, biologics.

Chamber Recommendation: The Chamber encourages the U.S. government to highlight the importance of regulatory data protection for innovative biopharmaceutical products — as well as enforce existing decrees on interpreting new chemicals — to the government of Colombia. Resolution of these issues will better protect life sciences innovators and enhance access for Colombians to the newest, 21st century medicines.

Commercialization of IP assets and market access

Index Stat: Colombia ranks 47th out of 55 economies in the commercialization of IP assets Index category, placing it in the bottom third of all economies globally as well as the bottom third in the Latin American region.

Audiovisual Prominence Requirement

On May 21, 2020, the Ministry of Information and Communications Technology released the final decree to regulate Article 154 of the National Development Plan, which aims to increase visibility of local content on VOD platforms for users in Colombia. Helpfully, the final decree appears to provide a flexible and non-prescriptive approach (i.e. it allows each service

provider to comply using virtually any mechanism of the platform's choosing, with no quota, and with a 9-month extended timeline for implementation) (February 21, 2021). U.S. motion picture industry stakeholders are currently implementing the requirement, and the Tax Office of Colombia is the entity in charge of enforcing and auditing the producer's compliance of the Statutes and regulations the Chamber encourages the U.S. government to monitor this issue, as audiovisual prominence requirements in the digital space can potentially limit the distribution of U.S. content.

Pharmaceutical Procurement Since 2022

Colombia employs a price control mechanism for pharmaceuticals, overseen by the National Medicines and Medical Devices Prices Commission ("CNPMD"). Annually, the CNPMD assigns a reference price for all pharmaceutical products available in the national market. This reference price serves as a regulatory instrument to determine pricing for each specific commercial presentation of these medicinal products. The methodology employed for establishing prices for new medications is rooted in evaluations conducted by the Institute of Technological Assessment in Health ("IETS"). The Chamber has, in previous 301 submissions, expressed concern regarding the comparison points used to determine pricing, laid out in the statutory act 1751 of 2015, article 23, which states that the regulation of drug prices must be determined based on international comparisons. It is our opinion that Colombia should continue utilizing international standards to determine prices. Maintaining price predictability and stability through the international reference pricing framework is critical to ensuring pharmaceutical companies can continue bringing new-cutting edge medicine to Colombian patients and invest in the next-generation of medical innovation.

Additionally, there is concern by industry and stakeholders regarding the inclusion of countries in the country reference list that are known to have troubling price fixing methodologies, lack of data transparency, and less effective IP frameworks, including China and India, and most notably, Turkey due to the volatility of its currency. The Chamber notes that the Ministry of Health has published comments addressing concerns regarding Turkey's inclusion in the reference list and responded that it should be removed. However, at the time of this research, no new draft regulation has been published to do so.

Consequently, Colombia's international reference pricing methodology and other cost containment measures are being used to set the same price for both the public and private segments of the market. Such a practice does not account for different supply chain costs in the reference countries and does not reflect the realities of the Colombian market vis-à-vis other jurisdictions.

In August 2022, the Colombian Ministry of Health and Social Protection issued Circular No. 13, setting a price control regime for medicines regulated under and marketed in Colombian territory. Circular No. 13 thus established the list of drugs and products subject to the direct price control regime and set the Maximum Sale Price and the price per regulatory

unit of Non-Available Vital Medicine. Circular No. 13 is an update of an earlier regime, Circular No. 12, which was issued in early 2022 and consisted of 2,489 products under direct control. The current Circular "[applies] to manufacturers, importers, marketers, holders of registration of medicines, as well as health service providers of all regimes, including special and exception regimes." Those operating under the new regime set forth by Circular No. 13 must adhere to the following aspects:

- That medicines from "relevant markets" will be subject to monitoring by the National Commission on Prices of Medicines and Medical Devices ("CNPMDM") and must consider the difference between the international reference price ("PRI") and the national reference price ("PRN"); and

- That the maximum price of medicines integrated into the direct price control regime established under Circular 13 and other relevant laws and regulations will have already included the adjustment factors or average identified in the reference countries between the ex-factory point and the wholesale point

At the end of 2023, the Ministry of Health initiated public consultations for a new price control methodology, adjusting the current one known as Circular 03, and an additional methodology for the definition of the price of new medicines based on therapeutic value (value-based price) implementing Art. 72 of the National Development Plan of 2014. In both cases, the industry has defended the need to guarantee comparability only with products with sanitary registrations in Colombia, respect for international price methodology and the inclusion of countries in the basket that have a favorable framework for innovation.

More broadly, the Chamber is concerned that modifications to Colombia's international reference pricing framework will undermine innovators' ability to utilize their IP rights and deny Colombian patients the benefits effective innovation ecosystems create. Rather than take a step towards changing the existing methodology, the Chamber encourages the CNPMDM to draw upon the best practices and internationally agreed standards for international reference pricing. The Chamber stands ready to work with the U.S. and Colombian governments to ensure that Colombia continues to be an attractive destination for FDI from U.S.-based companies and that Colombians continue to have access to adequate and reliable health solutions.

INDIA

Overview

India offers U.S. industry tremendous opportunities to tap a fast-growing and innovative economy and massive, growing middle class which is extremely tech savvy. The country also has a massive media and entertainment sector that produces a significant amount of content and has rapidly rolled out video OTT applications over its mobile sector that counts more than one billion consumers. As part of its dramatic transformation, the Chamber expects broad-based

reforms, a rapid expansion of the country's infrastructure, and a massive and growing middle class of hundreds of millions of people. A key element of India's reform efforts will focus on economic growth in IP-intensive industries such as information technology, the creative industries, pharmaceutical manufacturing, and other advanced technologies.

Regretfully, the government of India joined the government of South Africa in proposing a waiver proposal at the WTO TRIPS Council to override nearly every aspect of the IP system in response to the ongoing COVID-19 pandemic. However, as those in industry are keenly aware, the once-respected global IP system has been critical to the fight against the disease—with distribution of multiple vaccines underway and therapeutics and diagnostics playing an active role in helping to keep people healthier and safer. This proposal was and continues to be unfortunate, as India has made strides in integrating itself into the broader international IP system throughout 2020, most notably building on its 2018 accession to the WIPO Internet Treaties. The Chamber notes, however, that key treaty provisions remain unaddressed as of December 2023. This includes a much-needed clarification that India's private use exception is compatible with the Berne three-step test and the lack of adequate measures to combat circumvention of technological protection measures. So far, such clarification has not been adjudicated. In 2019, the Indian Patent Office signed a limited Patent Prosecution Highway ("PPH") agreement with the Japan Patent Office. And, in late 2020, the government of India announced changes to the annual Form 27 reporting requirement after a multi-year consultation process.

The Chamber applauds these developments – including the Draft Patents (Amendments) Rules, 2023, as patent backlogs and burdensome reporting requirements are long-standing barriers to filing for IP rights to do business in India. The Chamber also applauds the continued and strong efforts on behalf of the Indian government to crack down on copyright piracy through the issuing of dynamic injunction orders – a welcomed step that we hope continues into 2024 and beyond and compliments India's already strong awareness-raising efforts on negative impact of piracy and counterfeiting.

Finally, the Chamber recognizes and congratulates India on being not just a regional, but global leader on championing and instituting targeted administrative and financial incentives for the creation and use of IP assets for SMEs and startups.

But there is much more work to be done. The Chamber supports easing barriers to licensing and technology transfer, including reforming or, at the very least, modifying strict registration requirements. Additionally, the Chamber calls attention to the 2021 dissolution of the Intellectual Property Appellate Board ("IPAB"). While the IPAB filled in the need for expeditious disposal of appeals against Registry actions/orders, however, the shortage of judges and members, especially in the last 10 years, was leading to a huge backlog in disposal rates. There is, currently an under-resourced and over-stretched judiciary, but with specialist IP Divisions being set up as part of the new Commercial Courts system, introduced through the Commercial Courts Act, 2016, the rightsholders' ability to enforce their IP rights in India and

resolve IP-related disputes is likely to get a fillip. While some regional circuits, most notably in New Delhi, have reconstituted some IPR expertise and have made progress in the speedy adjudication of IP disputes, many other courts lack the specialized knowledge or capacity to replace the IPAB. The alternative structure to the specialist IPAB in the form of having a Commercial Court within each of the High Courts as also at the District Court level has resulted, especially in Delhi which, on and from July 7, 2021, has dedicated IP judges, in a quicker timeline for conducting an infringement action and resolution of IP Division with at least 2 single judges hearing original cases and appeals against orders of the Patent, Trademark, Copyright and Designs office and a dedicated Division Bench that hears appeals against such orders.

Close on the heels of this achievement, the Madras High Court has also set up an IP Division with effect from April 5, 2023. Such developments demonstrate India's commitment to enforcement of IP rights in the country and to create an ecosystem of IP awareness and effective compliance. This is bound to lead to growth of IP owner confidence in enforcement of their rights. The need of the hour is to have an IP Division at least in Mumbai as well since it is an important jurisdiction housing India's burgeoning media and entertainment industry. The Chamber also remains concerned about limited framework for the protection of biopharmaceutical IP rights as well as the lack of RDP available or patent term restoration for biopharmaceuticals.

The Chamber also notes the importance of U.S. government engagement in India — and 2020 proved to be a watershed year. Nine years after it had expired, the Chamber was pleased to see the renewal of a bilateral MOU on IP cooperation in December 2020. U.S. industry also continues to express a strong desire to see a positive and near-term conclusion to the ongoing U.S.-India trade negotiations. The Chamber welcomes discussions on an impending trade agreement between the two countries and look forward to a solutions-driven working relationship on IP.

Patents and related rights

Index Stat: Although India ranks 42nd out of 55 economies globally**,** it ranks 46th out of 55 economies in the patents, related rights, and limitations Index category**,** placing it in the bottom tier of Asian economies.

Patentability

Over the last few years, the Government of India has taken steps to improve its national IP environment that includes processing of patent applications in a more-timely manner. India had come a long way in the Global Innovation Index ("GII") from the 81st spot in 2015 to the 40th spot in 2022 today. In 2016, the Ministry of Commerce and Industry and the Department of Industrial Policy and Promotion released the *National Intellectual Property Rights Policy*. This document outlines the strategic direction and policy goals of the Indian government with

respect to the protection of IP. As noted at the time, the *Policy* addressed several important gaps in India's national IP environment, including the need for strengthening administrative capacities at India's IP offices and reducing processing times for patent and trademark applications.

Since then, considerable energy has been put into decreasing pendency rates for patent and trademark applications. More staff have been hired and resources invested into modernizing and improving the administrative capacities of the Office of the Controller General of Patents, Designs and Trademarks. While these efforts have resulted in some improvement, rightsholders still face substantial delays and processing times for patent and trademark applications.

Recognizing this, the Prime Minister's Economic Advisory Council ("EAC-PM"), in the summer of 2022, issued the report *Why India Needs to Urgently Invest in its Patent Ecosystem*. The report rightly recognizes the centrality of IP rights to modern economic development, noting:

> An evolved Intellectual Property Rights regime is the basic requirement for a knowledge-based economy. Technological innovation and scientific research require a robust patenting system. India is seeing a surge in start-ups and unicorns, and an efficient IPR system is an essential prerequisite for a healthy startup ecosystem.

This view echoes the sentiments expressed in 2022 by the Parliamentary Standing Committee on Commerce in its report *Review of the Intellectual Property Rights Regime in India*. In what marks a welcome shift in Indian policymakers' views of the purpose of IP rights, both these reports acknowledge the strong link between economic activity, innovation and the protection of IP rights, and the centrality of this nexus to the Indian economy. The EAC-PM report focuses on the administration of the IP system and long pendency times. The report rightly acknowledges that there have been improvements in decreased processing time and pendency rates, but, overall, the Office of the Controller General of Patents, Designs & Trade Marks's performance is behind other major economies. Specifically, the EAC-PM report points to the need for additional examiners, investments and, critically, a clear delineation of processing timeframes and deadlines. The EAC-PM also recommended limiting the timeline for filing pre-grant opposition to 6 months to fast-track the process of granting patents.

However, despite these positive developments, the Chamber continues to stress the repercussions from India's patent law establishing requirements to patentability that go beyond the internationally recognized requirements of novelty, inventive step, and industrial applicability. Under Section 3(D) of the Indian Patent Act, 1970, an additional "fourth hurdle" for inventive step and enhanced efficacy limits patentability for certain types of pharmaceutical inventions and chemical compounds. This approach to patentability requirements is inconsistent with the TRIPS Agreement, which specifies three basic patentability requirements, and importantly deters investment in developing new applications for existing pharmaceutical

molecules — especially the hundreds of thousands of such molecules that are already off-patent.

Specifically, as per the Supreme Court of India's ruling on April 1, 2013, in the *Novartis Glivec* case, Section 3(D) can only be fulfilled if the patent applicant can show that the subject matter of the patent application has a better therapeutic efficacy compared with the structurally closest compound as published before the patent application had been filed (regardless of whether or not a patent application on the earlier compound was filed in India). The Supreme Court also found in that same case that it was not in the interest of India to provide patentees with protection that goes substantially beyond what was specifically disclosed in the patent application; compounds that fall within a chemical formula of a claimed group of compounds in a patent application but that are not specifically disclosed in the patent could be regarded as not protected.

The 2015 Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals do not address these challenges of interpreting Section 3(D) adequately. The Chamber urges the USTR to work with the GOI in ways that can help India clearly identify "patentable" incremental innovation by first recognizing that there are valid incremental innovations, and that Indian entrepreneurs and the general public clearly stand to benefit from such incremental innovations. This could possibly serve as the basis for clarifying and interpreting Section 3(d) of the Patents Act.

The Indian Patents Act also imposes unique disclosure requirements for inventions using biological materials. Applicants are required to identify the source and geographical origin of biological materials and provide evidence that they have received permission from the National Biodiversity Authority ("NBA") to file for IP protection on an invention using biological materials from India. This often places an undue burden on the applicant as it may not be possible to ascertain the source and geographical origin of a material, especially if it has been procured from a commercial institution or depository or obtained from a public collection. Obtaining NBA approval has proved problematic and has resulted in the delay in the grant of patents and, ultimately, the commercial potential of useful inventions. Again, the Chamber and industry would encourage the GOI to examine this issue and work towards a solution, which will clarify an applicant's obligation under the law and reduce delays in granting patents.

The introduction of Patents (Amendment) Rules, 2021 had brought the following multiple changes particularly the process and manner of regulating the patent registration journey and rights involved regarding the patent owner:

- The individuals working in an educational institution – students, teachers, or professors, who discovered any patentable product during the course of their employment, shall enjoy a benefit of an 80% reduction on the patent fee. However, to enjoy such a benefit, the patent has to be applied in the name of the institution;

- The number of categories of the patent is increased – Small and Medium Enterprises, Government Departments, Female applicants, Institutions established by a Central, Provisional or State Act, Government companies, Government aided company and applicants under the Patents Prosecution Highway;

- The time for patent examination was around 72 months, which has been significantly reduced to 5-23 months;

- In the financial year 2021-22, the IP office granted 30,074 patents, which was previously 5978 in the financial year 2014-15; and

- In the fiscal year 2023 – 2024, the Indian Patent Office, awarded a staggering 41,010 patents, making it the highest number of patents ever awarded by the IP office.

The Chamber recognizes and applauds these important and much needed reforms and will continue to monitor progress made by the GOI in 2024 and beyond.

Updates to Patent-Related Case Law

The Delhi High Court recently laid down the test for examining divisional applications for the grant of patents. Referring to section 16 of the Patents Act 1970, the DHC stated that a divisional application may be filed:

i. in respect of an invention disclosed in the specification of an earlier parent patent application; and
ii. the event there is no duplication of claims in the two specifications (i.e., the parent specification and the divisional specification)

Accordingly, as per Section 16 of the Indian Patents Act, the claims of the divisional application cannot be outside the scope of the claims of the parent specification and at the same time there cannot be any duplication of claims. Essentially, the High Court upheld the maintainability of a divisional application, and further held that therapeutic efficacy is not a requirement in a divisional application vis-à-vis the compounds disclosed/claimed in the patent application.

Separately, in the matter of Avery Dennison Corporation v. Controller of Patents & Designs (C.A. (COMM.IPD-PAT) 29/2021), the Delhi High Court issued an important ruling the scope of inventions and patent protection. The court held that mere simplicity in the invention will not deter it from patent protection. The court discussed different tests to determine the existence of the inventive step and lack of obviousness and held that these tests cannot be applied in a straitjacket manner. However, the court held that “one of the sure tests in analyzing the existence of inventive step would also be the time gap between the prior art

document and the invention under consideration. If a long time has passed since the prior art was published and a simple change resulted in unpredictable advantages which no one had thought of for a long time, the Court would tilt in favor of holding that the invention is not obvious."

The Patent Office recently issued a notice allowing the applicant or a party to an application proceeding to file a request for adjournment of the hearing if they have reasonable cause. However, industry has noticed that while filing the request for adjournment is now permissible, a "reasonable cause" is not mentioned nor defined. The Chamber supports continued efforts from the GOI to better define what constitutes a "reasonable cause" to limit confusion and administrative uncertainty for parties involved.

In a recent judgement, in the case of *Novozymes v. the Assistant Controller of Patents and Designs* (*Novozymes* case), the Madras High Court in September 2023 was required to determine whether the provision of Section 3(d) applied to biochemical substances like "Phytase" or not, and in doing so, observed that, while it was held (by the Supreme Court) in the 2013 *Novartis Glivec* case (referred to above) that the amendment of Section 3(d) by the Patents (Amendment) Act, 2005 was primarily and especially intended to deal with pharmaceutical products and agrochemical products, it did not, however, follow from that it [Section 3(d)] only applies to pharmaceutical and agrochemical substances, and not to biochemical substances.

The Supreme Court had also held that the test of efficacy under Section 3(d) would vary depending on the product under consideration, and that, in the context of pharmaceutical products, it meant therapeutic efficacy. In this judgment, the Madras High Court also opined on the quantum of efficacy and answered questions relating to marginal improvement of efficacy by stating that "The substantive provision, by contrast, only requires enhancement of the known efficacy with no indication as regards margin of enhancement. Given that Section 3(d) applies to new forms of a range of known substances, even by way of guidelines, it may not be possible to fix a numerical value or percentage of enhancement that applies across the board, and this appears to be the position taken by the Patent Office in its guidelines." Accordingly, the patent applicant must "establish that there is reasonable enhancement of efficacy to the satisfaction of the Controller of Patents, and reasonable enhancement may be defined as enhancement that is material from an improvement of efficacy perspective."

Updates to Standard Essential Patent (SEP) Related Case Law

As the world's second largest mobile market, and an emerging destination for design and manufacture of smartphones and telecommunications equipment, India has seen disputes related to SEPs over the past decade.

In the recent proceedings between Ericsson and Intex (FAO(OS) (COMM) 296/2018, and FAO(OS) (COMM) 297/2018), in March 2023, the High Court of Delhi held that a SEP owner has

a right to be granted an interim injunctive relief, with the payment of royalties in full, irrespective of the pendency of suits for deciding if a SEP is valid and essential or not. Intex was directed to pay the entire royalty amount to Ericsson.

Further, the Delhi High Court, through multiple judgements, recognized that there are two particular potential behaviors that must be avoided - known as “hold up” and “hold out”. The court stated that the FRAND obligations have been interpreted to impose a burden not just on SEP holders, but on implementers as well. The SEP regime incorporates mutual reciprocal obligations on both the SEP holder and the implementer. It is not a ‘one way street’ where obligations are cast on the SEP holder alone. Consequently, the SEP regime balances the equities between the patentee and the implementer and ensures a level playing field.

Because of the above balanced approach taken up by the Indian courts, almost all the concluded SEP related court cases have been settled out of court by the parties with the exception of one case. These judgments over last few years have strengthened the patent rights enforcement in India and have played a significant role in developing jurisprudence related to SEPs that is aligned with established global practices.

Computer-Related (Software) Inventions

Article 27 of the TRIPS states that patent protection applies to all inventions regardless of the field of technology and clearly defines the necessary requirements for the issuing of a patent. This includes for novelty, inventive step, and industrial use. Based on these qualifications and criteria, “source code” and “object code” of a program may be protected as “Literary Work” under the Berne Convention of 1971 – this is according to Article 10 of the TRIPS.

The Chamber was encouraged by a December 2019 ruling in the Delhi High Court providing more clarity on the patentability of computer-related inventions in India. In her ruling, Judge Prathiba M. Singh noted that the Section 3(k) of the Patents Act was worded “so as to ensure that genuine inventions which are developed, based on computer programs are not refused patents.” This follows up on the re-issued guidelines on computer-related inventions (“CRIs”) in 2017 as an important step towards recognizing the principle of comprehensive patentability with non-discrimination across technology sector, including patentability of all forms of software technology in an emerging, digital age. While the guidelines deleted the novel hardware requirement of the prior guidelines, the business community hopes to receive further guidance on what will be considered patentable under the new rules.

However, as of December 2022, and despite Judge Singh’s ruling, Indian courts have yet to recognize any lawful extent towards the protection of licensing agreements exclusively for software components, their fair use standards, and the authors’ and rightsholder’s rights. Further clarity around the patentability of CRIs that recognizes the importance of CRIs to India’s

future will be critical to fostering technological innovation across India and ensuring India can unleash the benefits provided by a more effective IP regime.

2023, however, saw a change in the position of law when the Delhi High Court, in the case of Microsoft Technology Licensing LLC v. Assistant Controller of Patents and Designs [C.A.(COMM.IPD-PAT) 29/2022] set aside a patent refusal based on Section 3(k) of the Patents Act, 1970, which is the section barring the registration of "computer programmes per se." The Delhi High Court clarified that "If a computer-based invention provides a technical effect or contribution, it may still be patentable. The technical effect or contribution can be demonstrated by showing that the invention solves a technical problem, enhances a technical process, or has some other technical benefit." However, despite this clarification, the Delhi High Court also acknowledged that there is a pressing need to clarify the concepts of technical effect and contributions "in order to strike a balance between protecting the rights of inventors and promoting public interest and social welfare". Further developments in this regard are keenly awaited.

Notification Procedures on Foreign Patents

Patent applicants in India are required to provide detailed information on counterpart and possibly related patent applications abroad, with strict penalties levied on rightsholders (including patent invalidation) for mistakes. This rule was codified in 1970 under Section 8 of the Indian Patent Act.

In Summer 2020, the government of India announced changes to the Form 27 reporting requirement, which would ease the burden for rightsholders doing business in India. This was, overall, a positive change. The new Form 27 removed questions pertaining to licenses and made it possible to file one form for several patents relating to the same invention. Still, the new Form 27 did retain questions about the approximate value of the patented technology as either manufactured or imported into India. In a positive move, the 2023 changes not only propose to remove any questions relating to the approximate value of the patented technology, but also clarifies that the importation of an invention does not, in itself, mean that it is "not worked" in India. These proposed reforms are important and have the potential to improve India's national IP environment.

It should also be noted that the changes made to Form 27 address several major concerns raised by industry experts and rightsholders, including: issues related to maintaining confidentiality and integrity, as well as the problem of the multiplicity of filings, due in large part to the requirement to make separate filings for related patents. The Chamber looks forward to working with the U.S. government and their Indian government counterparts to ensure that India maintains the confidentiality of the working statement disclosures included in Form 27.

Since India is a growth market for the world, innovators are encouraged to protect their IP rights in India. In March 2022, the Delhi High Court applied the "doctrine of equivalence"

concept in *Sotefin SA* v. *Indraprastha Cancer Society And Research Center & Ors,* to arrive at the finding of a prima facie case of infringement and dismissed the exemption of parallel import under section 107A(b) of the Patents Act 1970. The Court held that patents are territorial in nature and therefore, unless otherwise mandated by law, a patent protected outside India will not be recognized and protected in India. Further, the import of any product that violates an Indian patent will not be allowed even if it is patented in another jurisdiction.

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 drugs and patented drugs 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 drugs after the five-year mark. Worse still, just one month later, the NPPA kicked off a pilot program to cap trade margins on 42 oncology drugs — 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.

No doubt, 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.

Patent Term Restoration

Patent term restoration provides additional patent life to compensate for the time lost during clinical trials and the regulatory approval process. Indian law does not provide patent term restoration for pharmaceutical products.

Chamber Recommendation: The Chamber recommends that the U.S. government work with GOI to implement a PTR term to spur innovation in India.

Patent Opposition

As noted in last year's Special 301, it is especially welcome news that the 2022 report by the Prime Minister's Economic Advisory Council ("EAC-PM"), entitled *Why India Needs to Urgently Invest in the Patent Ecosystem*, acknowledged the detrimental impact the current opposition system has on patent processing times. Section 25 of the Patents Act outlines the procedures and requirements for initiating opposition proceedings. The law provides for both pre- and post-grant oppositions. The procedures are similar; the key difference is that pre-grant

opposition can be initiated by "any person" whereas post-grant opposition must be initiated by an interested party. The pre-grant opposition mechanism in India has long been criticized for adding significantly to the already lengthy patent prosecution timelines. In 2023 the EAC-PM report's suggestion to clearly define timelines during patent prosecution — including for opposition proceedings — has been followed up with action by the Controller General.

In August 2023, the "Draft Patents (Amendment), Rules, 2023" were published. The proposed changes include some improvements to the existing opposition mechanisms, including introducing more defined timelines as well as vesting more discretion with the Controller General as to the "maintainability of the representation" of the opposition.

In 2020, a new Form 27 was introduced, which removed questions pertaining to licenses and it made it possible to file one form for several patents relating to the same invention. The Form did retain questions about the approximate value as either manufactured or imported into India. Taking feedback from stakeholders the suggested 2023 changes to Form 27 not only propose to remove any questions relating to the approximate value of the patented technology, but also clarifies that the importation of an invention does not mean that it is "not worked" in India. These proposed reforms are important and have the potential to improve India's national IP environment.

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 case concerned a writ petition filed against the order declining the Patentee's request for linkage of the VAHAN e-Module for registration of electric vehicles by the Secretary, Ministry of Road Transport & Highways. 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.

It is expected that appeals will be made, and the Chamber will be watching these developments in 2024.

Copyrights and related rights

Index Stat: India ranks 34th out of 55 economies in the copyrights, related rights, and limitations Index category.

Copyright Rules

In fall 2020, the government of India notified stakeholders of its intent to examine the country's copyright rules — particularly as they relate to the "ease of doing business." In its comments, the Chamber noted the strength of India's world-famous creative industries, and its high score for copyright indicators on the IP Index. However, domestic industries and foreign direct investment in film, television, music, and other sectors can only flourish under clear, established rules. For that reason, the Chamber urged the government of India to faithfully implement its obligations under the WIPO Internet Treaties — re-affirming the country's commitment to narrow exceptions and limitations that comply with the Berne Convention and three-step test. Parts of India's Copyright Act can also be streamlined to better support new creative sector business models. An example of this would be removing the second provision to Section 17 which provides that in case of any literary, musical, or artistic work incorporated in a cinematograph work, the producer's first ownership in the cinematograph work shall not affect the right of the author of such literary, musical or artistic work. This creates and leaves room for confusion with respect to what "right" of the author of such literary, musical, or artistic work and is contrary to laws in other jurisdictions where the author of a literary, musical, or artistic work in a cinematograph work is presumed to have transferred his rental right--provided that equitable remuneration is provided to them.

Other countries also allow the assignment (or option to waive their rights) conditionally or unconditionally. None of these aforementioned actions were taken up in a legislative or case law capacity since the fall of 2020.

In August 2023, the office of the Controller General of Patents, Designs and Trade Marks issued a public notice requesting stakeholders to submit their suggestions/comments for the issuance of fresh manuals for Patents, Trademarks, Copyrights and Geographical Indications, whereafter the said suggestions/comments would be reviewed by an expert committee. The deadline to submit suggestions/comments lapsed on November 15, 2023. The Chamber will be watching these developments, especially since permitting all stakeholders to submit suggestions may result in players from the industry reverting with innovative solutions to practical problems faced by the industry in the ordinary course of business.

Piracy

As broadband connectivity and mobile phone use has exploded in India, so has a marked increase in the availability of infringing content. Despite this shifting landscape, Indian law remains unclear about the availability and requirements of a notice and takedown system to combat online piracy.

However, in what is otherwise a challenging copyright environment in India, a positive trend has emerged over the past few years as rightsholders are increasingly able to defend and enforce their copyrights through injunctive relief. Since 2012, there have been several cases whereby access to websites offering pirated and infringing content has been disabled through

court orders including notorious international sites like The Pirate Bay. This positive trend continued in April 2019, when the Delhi High Court issued a so-called "dynamic" injunction to address the issue of "mirror sites." These sites, which mimic infringing content on a main mother site, are a recurring headache for rightsholders— a fact echoed in the Court's decision: "It is desirable that the Court is freed from constantly monitoring and adjudicating the issue of mirror/redirect/alphanumeric websites and also that the plaintiffs are not burdened with filing fresh suits."

Dynamic injunctions, further, are becoming a global best practice for enforcement, with orders becoming more commonplace in countries like Singapore and the UK. These positive efforts continued in 2023. In January the Delhi High Court ordered the disabling of access to so-called "stream-ripping" websites and access points. This marked the first time in India an order had been issued targeting this type of infringement. And, in August the same court issued a dynamic injunction against the infringement of audiovisual content that also includes future creation and copyrighted work. The August injunction also marks the first time such an injunction has been issued in India. This judicial route of injunctive style-relief now offers rightsholders an effective and meaningful way of combating copyright infringement in India.

Another step undertaken by the government of India is the introduction of the Cinematograph (Amendment) Bill, 2023, which, apart from prescribing new, age-based certification categories, and making film certificates perpetually valid, also aims to curb the menace of 'film piracy' by way of prescribing stringent penalties and punishments, which, it is hoped, would act a deterrent.

The Chamber notes that CIPAM collaborated with industry to launch anti-piracy video campaigns, with leading Bollywood stars to raise awareness on the menace of piracy. CIPAM launched an Anti-Piracy Video Campaign in collaboration with Viacom 18 Media Pvt. Limited using popular cartoon characters to raise awareness with children on piracy. In collaboration with the Internet and Mobile Association of India ("IAMAI"), CIPAM also organized a workshop on the Copyright Policy Framework in Digital Age.

Although not specific to copyright and the creative industries, the Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Rules, 2021, do include reference to IP rights and copyright specifically. Under 3(b) of the Rules, intermediaries are obliged to not only inform users of each intermediaries' rules and conditions of use – including the illegality of any illicit activity conducted over or through the platform, such as the infringement of IP rights – but also to "ensure compliance" with those terms of use (in accordance with 3(a) of the Rules). With respect to copyright infringement specifically, it is unclear how these proposed Rules would interact with the underlying legislation (the Information Technology Act), the current Copyright Act, and existing case law. The notice-and-takedown mechanism under the 2000 Information Technology Act and subsequent 2008 amendments relate only to expeditious removal of infringing material upon notification.

In the Copyright Act the burden on intermediaries is even less pronounced with any removal being only for an initial period of 21 days, with a court order required for any further action. Equally, existing case law on the matter has explicitly stated that there is no burden or requirement under either law for intermediaries to take proactive action against potentially illicit and IP rights infringing activity. That was the unmistakable conclusion from the 2015 Supreme Court decision *Shreya Singal v. Union of India*. In a case primarily centering on the constitutionality of section 66A of the Information Technology Act and its potential limitations on free speech, the Court also outlined a detailed interpretation of the meaning of section 79 of the Information Technology Act which sets the framework for exemptions from liability of internet intermediaries including the requirements for expeditious removal of infringing material. The Court held that it was not up to the intermediary to make a judgment as to the potential infringing nature of a piece of information referred to in a notice. Rather, the Court stated that this determination needed to be made through the judiciary and specifically that a court order needed to have been "passed asking it [the intermediary] to expeditiously remove or disable access to certain material."

Chamber Recommendation: The Chamber recommends that industry, along with USG and GOI, work more closely together to find meaningful ways to address copyright-infringing content online.

Updates to Copyright-Related Case Law

The Chamber notes with interest several updates to copyright-related case law in India. First, the Supreme Court recently held that the offence of copyright infringement under Section 63 of the Copyright Act is a cognizable and non bailable offence. If the offence is punishable with imprisonment for three years and onwards but not more than seven years the offence is a cognizable offence, the bench comprising Justices MR Shah and BV Nagarathna observed.

Second, the Chamber also applauds two recent Delhi High Court orders blocking approximately 30 websites that were illegally streaming and hosting pirated content to the public. The first case, in the May 2022 decision, *Universal City Studios v. Vegamovies.run & Ors*, blocked 12 websites that were disseminating pirated content belonging to Universal City Studios LLC without its authorization. In the second case, decided January 2023, the Court issued an ex-parte interim order while hearing a suit by worldwide music industry group IFPI — representing Sony Music, Universal, and Warner — stating that 18 websites were used to download copyrighted audio and visual content from platforms including YouTube. In that case, *Sony Music Entertainment India Private Limited & Ors. vs. YT1S.COM, YT1S.PRO, YT1S.DE & ORS*, Justice C Hari Shankar ordered ISPs to block the domains in question, plus any new domains that may appear as a "mirror/redirect/alphanumeric avatar of the websites which already stand injuncted." Perhaps most notably, Justice Shankar labeled the infringing sites as "rogue sites," expanding on the definition established in a previous decision, in which a site is considered "rogue" if the primary purpose of a site is "to infringe, the owner fails to respond to takedown notices, and has a general disregard for copyright." The most recent development in the realm

of illegal streaming and hosting of pirated content is the Delhi High Court's judgement dated August 9, 2023, in *Universal City Studios LLC and Ors. v. DotMovies.Baby and Ors.*, wherein the court issued a "Dynamic+ injunction," which protects both current and future works of the rightsholder. This trend was carried into the end of the year as well, with another such Dynamic+ injunction being passed in *Universal City Studios Llc. & Ors. vs Fztvseries.Mobi & Ors.*, in November 2023.

In the case of *Neetu Singh & Anr v Telegram FZ LLC & Ors*, the Delhi High Court ruled that copyright infringers cannot be permitted to seek shelter under mobile messaging platform Telegram's policies, pointing to the fact that its physical servers are in Singapore. The Court held that Telegram must adhere to Indian law and disclose details including IP addresses, mobile numbers, and devices used in operating channels involved in copyright infringement if ordered to do so by Indian courts.

Other noteworthy decisions in 2023 include the Delhi High Court's judgment, dated May 23, 2023, in the case of *RDB and Co. HUF v. HarperCollins Publishers India Private Limited*, wherein the court determined that while the producer of a cinematograph film would have copyright over the film, the script and screenplay of the film constitute original literary works, which are distinct from the film, and the copyright in them would be owned by the writer of the film since there was no separate contractual agreement between the writer and the producer for the assignment of copyright in the script and screenplay (from the writer to the producer). Accordingly, the Delhi High Court opined that the right to novelize the script and screenplay would vest with the writer and not the producer of the film.

Furthermore, the Delhi High Court has, in separate judgements in 2022 and 2023, recognized and protected the celebrity, personality and publicity rights of Mr. Amitabh Bachchan and Mr. Anil Kapoor (both of whom are actors in the film industry and celebrities in India) and granted injunctions, restraining third parties from using their names, likeness, images, voices, mannerisms, catchphrases, and employing technological tools such as AI, face morphing, and GIFs for financial gain or commercial purposes.

Trade secrets and related rights

Index Stat: India ranks 32nd out of 55 economies in the trade secrets, related rights, and limitations Index category.

Regulatory Data Protection

Regulatory data protection safeguards an innovator's safety and efficacy data from generic competitors' marketing generic versions during a pre-determined period. TRIPS Article 39.3 requires parties to provide legal protections for certain pharmaceutical test and other data, but India has not yet done so. This type of data protection would provide an economic incentive for innovative companies to test drugs, seek marketing approval, and introduce new

drugs to the Indian market. In tandem, the commercial benefits for generic manufacturers after this short period are significant — it permits them to market their similar products at a fraction of the cost and none of the risk that an innovator must face to gain approval. By preventing the authorization of third-party products that rely on an innovator's data for a defined period, data protection ensures that an innovator's data is not subject to unfair commercial use. The Chamber encourages GOI to take steps to implement its TRIPS Article 39.3 regulatory data protection commitment and prevent authorization of third-party products that rely on an innovator's data for a defined period.

Commercialization of IP assets and market access

Index Stat: India ranks 39th out of 55 economies in the commercialization of IP assets and market access Index category.

Statutory License for Broadcasting

In 2012, India's Copyright Act was amended (in Section 31D) to define "remuneration rights" for music rightsholders and create a statutory license scheme for the use of musical works and sound recordings by broadcasters. This means that any radio or television station can apply for license under India's Copyright Board to use a musical work for a set price. The Chamber notes, however, that Section 31D contradicts "rights of communication" granted to rightsholders in Sections 13 and 14 of the same law. This issue has become more important since 2016, when DPIIT reportedly has been considering the expansion of the statutory licensing scheme to all internet transmissions to any service provider—not just terrestrial radio and television stations—for the use of literary or musical works. This change has the potential to affect a broader cross-section of creative industries. The current law, however, is that no statutory licenses can be granted to online streaming services, in consonance with a judgment dated October 20, 2022, passed by a Division Bench of Bombay High Court, in the case of *Wynk Limited v. Tips Industries Limited.*

We echo concerns from across the creative industries that this expansion of the 2012 Copyright Act amendments would directly conflict with India's international treaty obligations — in particular, the WIPO Internet Treaties — as well as the actual wording of Section 31D in the Copyright Act. Ten years later, industry points to the statutory licensing scheme as the main reason for lower broadcasting revenues for producers and performers — despite the country's overall strength in the broadcasting and music sectors.

Chamber Recommendation: To fix this problem, the Chamber recommends that the Indian government appropriately limit the relevant Copyright authority's role to collective administration instead of the current system of granting and pricing of licenses. Furthermore, the government of India should reject any attempts to expand the scope of Section 31D and should discourage legislative proposals in the same vein, and instead look to achieve compliance with India's international obligations.

In addition, the Chamber notes that in 2017, with the passing of the Finance Bill, the Copyright Board was dissolved, and its functions were transferred to the Intellectual Property Appellate Board ("IPAB"), which has also now been dissolved.

Dilution of Broadcast IP

It has been observed that MIB has been mulling changes to the legislative framework governing sports broadcast in India. Though most of these legislative changes do not seem to be directly impacting IP acquired/created, they have a damaging impact on monetization of media IP rights.

In October 2018, India's MIB proposed the Draft Sports Broadcasting Signals (Mandatory Sharing with Prasar Bharati) (Amendment) Bill, 2018. The Bill requires private sports broadcasters to share their live feeds of sporting events that are of national importance with the public broadcaster Prasar Bharati, which runs the television network DoorDarshan ("DD") and All India Radio ("AIR"), who can then retransmit the broadcast signals on its terrestrial network and its own direct-to-home ("DTH") platform, DD Free Dish. This Bill, if passed, will substantially widen the scope of the Sports Broadcasting Signals (Mandatory Sharing with Prasar Bharati) Act, 2007 ("Mandatory Sharing Act"). Most recently, in February 2022, it was announced by the Ministry of Information and Broadcasting that the bill had been placed on hold for further consideration until at least after general elections — effectively placing it on a "back burner."

The proposed amendment effectively gives DD the right to broadcast sporting events of "national importance" not only on its own terrestrial and DTH network but also on other private distribution platforms. Thus, the Bill is an additional prescription to expand the scope of the Mandatory Sharing Act and make available DD's feed of sporting events of national importance on all other distribution platforms in the garb of providing access to the largest number of viewers.

The Chamber remains concerned that such an amendment would seriously undermine the incentives of private broadcasters — who invest significant financial resources to acquire broadcasting rights for sporting events and built a platform for advertisers and distribution of channels — if they were forced to offer their rights or licenses up for free to the public broadcaster. Furthermore, the amendment lacks clarity on what constitutes a game or sporting event of "national importance," leaving private broadcasters with growing uncertainty over the commercial viability of their enterprise. The MIB made this movie despite a Supreme Court ruling in 2017 in *Prasar Bharati v. BCCI and Ors.* that the Mandatory Sharing Act adequately serves public interest by making available sports events of national importance on Prasar Bharati's terrestrial and Free Dish DTH network and not on private broadcast distribution platforms.

Findings from a 2018 GIPC study, "Leveraging Intellectual Property in the Global Sports Economy" show that broadcasting rights are the foundation for investment in transmitting tournaments to fans and sports enthusiasts. The study shows that revenues from licensing agreements and media rights are often the main source of funds for sports organizations to build stadiums, host sporting events, and carry out community outreach to maintain high levels of interest. Major sporting events can now be streamed or broadcast anywhere in the world, giving millions of fans the opportunity to participate in the excitement of an event. The sports economy is an instructive case study of how an IP asset becomes a platform for economic activity and related industries. To add perspective, most countries have, either through specific legislation or through case law, established that the broadcasting of a sporting event is copyrightable. For example, U.S. companies have invested billions of dollars in Indian sports and regional coverage of Indian sports. The biggest of these investments is close to $2.55 billion spent on the acquisition of global broadcast and digital rights of the Indian Premier League ("IPL") over a five-year period. The call for mandatory sharing of these rights to cable TV operators through the current Bill and its retroactive nature would obviously undermine the value of this investment.

The Chamber believes that the proposed amendment raises important concerns about contract sanctity, ease of doing business, and retroactive policymaking. We strongly request that the MIB does not implement the proposed changes. Further, we encourage the MIB and the USG to take a proactive approach to the U.S. ICT Working Group by identifying ways to remain engaged through the sub-working group process. Currently, the critical sectors of media, entertainment, sports, and culture are not significant elements of this bilateral dialogue, but the U.S. industry would like to see these aspects of business and diplomacy included. This platform offers a clear opportunity to improve engagement on important topics, such as the business of sports, entertainment, and culture.

Furthermore, several U.S. companies have invested millions of dollars in India's creative sector and local economy to either develop their own proprietary content or acquire content for television broadcasting, particularly in the general entertainment channel ("GEC") category comprising of reality shows, soap operas and films. The returns on these investments depend solely on the broadcaster's ability to monetize such content through a combination of subscription revenues and advertisement revenues. However, beginning 2004 when TRAI was notified as the regulator for broadcasting services, it has issued a series of Tariff Orders and Interconnection Regulations that limited the right to price and manner of offering of TV channels by broadcasters. As content in TV channels are subject matter of copyright, this approach on part of TRAI has curtailed their ability to monetize their IP through broadcasting. Moreover, on the advertising front, TRAI has placed restrictions both in the form of time cap on advertising over TV channels restricting the broadcaster and copyright holder's ability to commercialize from such content.

It should be noted that the matter relating to advertisement-cap in television is sub-judice. However, the trend emerging from judicial pronouncements doesn't bode well for

copyright holders and publishers based in India as recently the Supreme Court in October 2018 while adjudicating on an appeal challenging TRAI's jurisdiction over content broadcasted on television ruled that TRAI, if in exercise of its regulatory power under the TRAI Act, were to impinge upon compensation payable for copyright, the best way in which both statutes can be harmonized is to state that, the TRAI Act, being a statute conceived in public interest, which is to serve the interest of both broadcasters and consumers, must prevail, to the extent of any inconsistency, over the Copyright Act which is an Act which protects the property rights of broadcasters. It is surprising that the Supreme Court held the telecommunications law to supersede the Copyright Act to protect public interest. Rather, India could look at harmonizing the telecommunications law regime with Copyright Act in the manner that U.S. Congress has achieved.

Chamber Recommendation: The Chamber strongly recommends that the GOI to make efforts to protect the integrity of the copyright regime in the country and respect the rights available under international copyright regime, including the Berne Convention and Rome Convention. We also urge TRAI to base its regulations on sound, balanced and sustainable economic principles. Lastly, the Indian government should eliminate "must provide" rules in the PAY-TV sector and price caps for PAY-TV channels.

Broadcast Developments in 2023

There have, however, been noteworthy developments in the Indian media, entertainment, and broadcasting space, with the government of India taking several measures to create a fertile climate for both global and national broadcasters to thrive in India. These developments include the introduction of laws which aim to cater to the needs of the broadcasting sector while balancing the needs of the consumers/the public at large.

In early 2023, the government of India notified the Digital Personal Data Protection Act, 2023, which governs the processing of digital personal data (such as a person's name, phone number, Aadhar, PAN, as well as profiling/usage data, such as user preferences and choices), within the geographical boundaries of India. The Data Protection Act, while introducing obligations on data fiduciaries (i.e., person/s that define the purpose and means of processing – akin to 'data controllers' under the GDPR), also prescribes penalties, thereby compelling data fiduciaries to enhance their data handling approaches. The passage of the data protection law in India is important from a compliance perspective given the changing technological landscape in the broadcasting space, which works on subscription models, and therefore makes stakeholders liable to properly store and protect their subscribers' personal data.

In addition to the above, in November 2023, the MIB also invited suggestions/feedback/comments from the general public and stakeholders on the draft Broadcasting Services (Regulation) Bill, 2023 (Bill), which is aimed at bringing regulation to the evolving landscape in the broadcasting industry, particularly in the context of new and emerging technologies. This Bill is set to replace the Cable Television Networks (Regulation) Act,

1995, and also extends to over-the-top ("OTT") content and digital news, while streamlining regulatory processes. The deadline to submit comments/feedback lapsed on January 15, 2024, whereafter provisions of the Bill will be modified and the amended bill will be placed for consideration before the houses of parliament.

Another piece of legislation slated to have an overarching effect on the broadcasting regulatory landscape in India is the Telecommunications Act, 2023, which came into effect on December 24, 2023, and has now repealed the Indian Telegraph Act, 1885, the Indian Wireless Telegraphy Act, 1933 and the Telegraph Wires (Unlawful Possession) Act, 1950. Under this Act, telecom companies would be required to seek authorization to establish, operate, maintain, or expand telecommunication networks. Since telecommunication and broadcasting are inextricably linked (with telecommunication services being pivotal in any effective broadcasting activities), any efforts to invest in expanding telecommunications technologies would attract regulatory compliances.

Enforcement

Index Stat: India ranks 44th out of 55 economies in the enforcement Index category, ahead of only the Philippines, Pakistan, and Indonesia.

Effective Border Measures and Remedies

Furthermore, the Chamber encourage the establishment of positions for cybercrime law enforcement officers in State police stations, and a centralized IP crime unit under CBI Cyber Crime Detective Unit to focus on IP crimes, as a means to enhance India's institutional enforcement capacity.

Under current Indian law, the Central Board of Excise and Customs, which falls under the jurisdiction of the country's Department of Revenue, is responsible for directly dealing with IP rights enforcement issues. India's customs authorities have the statutory power to confiscate and prohibit the import or export of counterfeit or pirated goods that infringe IP owners' rights. Similarly, the government has enabled IP owners to enforce their IP rights at Indian borders under the Intellectual Property Rights (Imported Goods) Enforcement Rules 2007.

Despite these laws on the books, India's Customs authorities lack the necessary training and resources to enforce IP rights at the border. Customs should substantially simplify the process of and reduce the cost necessary for rightsholders to register copyrights and trademarks with Customs and to confirm that a shipment contains infringing products. Currently, a rightsholder must file a civil action to complete the seizure process if the importer does not voluntarily abandon the infringing goods. Because of this, counterfeit goods can be "tied up" at a port for years on end. Rightsholders must also secure "bank guarantees" of 25% to 110% of a seized shipment's value. And though the government claims that this is to

compensate for future damages or mistaken seizures, the guarantees represent a particularly burdensome requirement for U.S. companies doing business in India.

Chamber Recommendation: To remedy these problems, customs officials should keep records of cases, expedite procedures, and create standard processes to communicate and collaborate with rightsholders. Customs officers at all levels should be empowered to combat infringing trade through use of risk-management targeting. Finally, they should be given the power to seize and destroy old and new seizures alike.

Camcording

As mentioned in last year's Special 301, the pirating of film and audio-visual content through illicit camcording has historically been a major challenge to both domestic and international rightsholders in India. To provide a greater level of deterrence to this type of behavior a Cinematograph (Amendment) Bill was introduced by the Indian Government in 2019. In 2023 a final bill was enacted. The Cinematograph (Amendment) Bill 2023 includes new language and criminal sanctions on film piracy including potential imprisonment of up to three years and a substantial fine of up to 5% of the production costs of the infringed motion picture. This is a positive development and the passing of this bill into law should help address a long-standing issue in India. 2023 also saw the enactment of the *Jan Vishwas* (Amendment of Provisions) Bill, 2023. The legislation introduces changes to criminal sanctions in over 40 different pieces of legislation, including the Copyright Act. Specifically, section 68 of the Act — relating to the making of false statements to law enforcement — has been eliminated. It is unclear why the Indian Government saw the need to decriminalize this activity.

Systemic efficiency

Index Stat: India ranks 24th out of 55 economies in the systemic efficiency Index category, one of its strongest IP categories measured.

Targeted Incentives for SMEs

India, along with Brazil, are identified by The Index as the world's leading economies in targeted incentives to SMEs, and India remains as such. Expedited review for patent filings, reduced filing fees and technical assistance are all available to Indian SMEs and start-ups. Of particular note, is a new program for startups under GOI's "Startup Standup India" initiative. Part of this program is the Scheme for facilitating Start-Ups Intellectual Property Protection ("SIPP") run by the Office of the CGPDTM. This has resulted in a remarkable rise of filing of patents by startups rising from 511 in the year 2017-18 to 1482 in 2021-22. Startup patent applications are also provided expedited examination, a reduction in the filing fees, and access to IP facilitators.

INDONESIA

Overview

The U.S. Chamber is one of the leading advocates for the importance of comprehensive U.S.-Indonesia bilateral relationship. As the world's fourth most populous nation with the 10th largest economy, IP-driven innovation and creativity can strengthen Indonesia's vibrant economy and send a signal to countries across the region about the rule-of-law system needed to foster ingenuity. The Chamber appreciates the Indonesia's government's willingness to engage with industry to reform its domestic legislation and make them more consistent with international standards. Notwithstanding this positive engagement, the Chamber encourages the U.S. government to engage with the Indonesia government to resolve the outstanding issues described below.

As part of the government's import substitution policy, the Indonesian Government through the Ministry of Industry and Ministry of Health applies a stronger preference for medicines with high local content for public procurement. The so-called TKDN (Local Content Requirement) includes use of raw material content (50%), research and development process (30%), production process (15%), and packaging process (5%). The international pharmaceutical industry has requested for exemption of the TKDN regulations and hope that a revised regulation will be issued that 1) distinguishes originators from local generics 2) recognizes the industry's contribution to healthcare resilience, and 3) underscores US companies' commitment to continuing their investment, facilitating capability building/people development, contribution to export, and good ESG ("Environmental, Social, and Governance) practices.

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

In 2016, the Indonesian Parliament ("People's Representative Council") passed a new wide-ranging patent law (Law 13/2016). Industry had several concerns with the 2016 legislation, including:

- Article 20 made the granting of a patent conditional on localizing manufacturing and/or R&D in Indonesia;
- Article 4 denies patent protection for new uses and new forms of existing products;
- Article 167 allows the parallel importation of follow-on products under patent protection in Indonesia but approved for consumption in other markets; and

- The interpretation of Article 4d of the patent law allows a limited form of patenting of computer-implemented inventions.

In February 2020, the Indonesian Government proposed new Amendments to the Patent Act. In a reversal from its previous stance the proposed amendments – as part of a sprawling legislative package, the Omnibus Job Creation Bill – simply revised article 20 of the 2016 Patent Act, allowing importation as part of patent implementation (Article 107(2) in the Job Creation Bill). While the Omnibus Job Creation Bill was passed into law in October 2020, the Indonesian Constitutional Court subsequently ruled that the Omnibus Bill was unconstitutional.

In early 2023 the Indonesian Parliament approved a new version of the Omnibus package. Article 107(2) relating to the working of a patent in Indonesia remains unchanged in this version of the law, which is positive. However, following the enactment of this second version of the Omnibus Law several new petitions were filed with the Constitutional Court arguing the law's enactment did not follow due process and was unconstitutional. It is unclear whether any of these challenges would be successful, but the Court has recently ruled the new version of the Bill as constitutional while still reviewing some petitions regarding the bill substance.

Chamber Recommendation: The Chamber appreciates the Indonesian government's ongoing work to amend the 2016 patent law, and encourages the U.S. government to work with their Indonesia government counterparts to make the following changes to the upcoming revised patent law:

- Ensure the Article 107(2) requirements of importation and the licensing of the relevant invention are now included in future versions of the law;

- Provide greater clarity for innovators on the scope of patentable inventions;

- Clarify the scope of the parallel importation policy to ensure the provisions do not undermine innovative biopharmaceutical companies' IP in Indonesia or increase the risk of counterfeits entering the market; and

- Ensure the wording of the upcoming revised patent law expressly allows for the patentability of computer related inventions in the body of the law (and not in the interpretation section).

Compulsory Licensing

The 2016 amendments to the Patent Act also included changes to Indonesia's compulsory licensing framework, with the latest implementing regulation for a CL being ministerial regulation No. 30/2019.

Additionally, a new Presidential Regulation, Number 77 2020, allows for the government to override any granted patent exclusivity in the event of a public emergency (including, but not limited to, a public health crisis) and for purposes of defense and national security. The regulation explicitly states that this can be justified not only during a public health crisis, such as the COVID-19 pandemic, but based on cost and specifically if a given "pharmaceutical products and / or biotechnology that are priced expensive" [sic].

In November 2021, the Government issued a government use license for patents related to a COVID-19 treatment. While the license cites the urgent need to access the medicine, the treatment has already been made available in Indonesia through the patentee's voluntary licensing program. This development further weakens what was already a highly challenging national IP environment for biopharmaceutical rightsholders.

Finally, in August 2023, the Government enacted the Health Omnibus Law (Law No. 17). Articles 314 and 326 of the Law reiterate the Government's responsibility, and right, to override patent protection 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.

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

Copyrights and related rights

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 positive performance, online piracy continues to present a challenge for rightsholders.

Injunctive 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 Bioskoperen continuing to pervasively promote pirated content online.

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.

MEXICO

Overview

A harmonized IP framework across North America is critical to fostering greater economic and global competitiveness across the region and globally. While the IP chapter of the U.S.-Mexico-Canada Agreement ("USMCA") omitted many of the key life sciences IP provisions, the final text did include meaningful changes to Mexico's copyright, trademark, and IP licensing framework, albeit with longstanding issues of enforcement.

Additionally, the Chamber appreciates the Mexican government's efforts to foster an evidence-based discussion in Geneva on the expansion of the TRIPS waiver to therapeutics and diagnostics. Notably, the joint communication from the Mexican and Swiss delegations effectively delineated many of the reasons why a waiver expansion is unnecessary. The Chamber appreciates Mexico's position, which underscores the government's appreciation for IP-driven innovation.

Notwithstanding these positive developments, challenges remain to securing effective IP protection in Mexico, as detailed below. The Chamber encourages the U.S. government to work closely with its Mexican government counterparts to address the outstanding IP challenges outlined below to improve the environment for innovative and creative industries in the market and honor commitments made as part of the USMCA.

Patents and related rights

Index Stat: Mexico ranks 23rd out of 55 economies globally, it ranks 31st out of 55 economies in the patents, related rights, and limitations Index category, due in large part to significant gaps in securing and enforcing commitments under the USMCA and for partial and ambiguous protections for life sciences.

Patentability Requirements

Historically, it has been difficult for rights-holders to obtain protection for computer programs, software, and computer-implemented inventions ("CIIs") in Mexico. Article 19 section 3.4 of the old Industrial Property Law excluded computer programs as patentable subject matter. While there have been examples of patents being granted for CIIs in Mexico, these are few and far between and claims often needed to involve a hardware component. Legal practice and available patent statistics suggest that both the number of applications and patents granted for software and computer related patents by the IMPI have been low. Local

legal analysis suggests that while the situation has evolved over the years and the IMPI does not out of hand reject CII applications, the success of a given application is largely dependent on showing how a given piece of software interacts and acts in concert with computer hardware.

On July 1, 2020, the USMCA formally took effect in the United States, Canada, and Mexico. Relevant provisions of the USMCA are clear that patents should be granted for all inventions. Article 20.36 states that "each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application." Neither computer programs nor software are excluded per se under sub-sections 2 and 3. However, Mexico's implementing law, the revised Industrial Property Law, does not offer the same level of clarity. Instead, like the old IP Law, article 47(5), explicitly excludes "computer programs" as patentable subject matter. To date, no implementing regulations or revised patent guidelines had been issued. The USMCA's language on patentable subject matter is quite clear.

In addition, IMPI's policies regarding patent prosecution appear to be inconsistent with the Mexican patent statue. The Federal Law for the Protection of Industrial Property (FLPIP), effective November 05, 2020, prohibits applicants from filing voluntary cascade divisionals, i.e., IMPI must issue a lack of unity objection. However, applications filed under the former 1991 law should still be prosecuted under the former law, which had no restrictions on cascade divisionals. Since May 2023 IMPI has abruptly changed its practice by not accepting any voluntary cascade divisionals if the first parent case has issued or been abandoned. Our members have identified several impacted cases filed before Nov 05, 2020, and no lack of unity objection.

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

While a 2003 Presidential Decree introduced a basic system of patent linkage, the framework has several key deficiencies – and, according to industry, the decree has not been implemented in a comprehensive and consistent manner, failing to comply with the terms laid out in the USMCA. First, process and use patents are excluded from the linkage in the Official Gazette. This greatly limits the type of patents eligible for listing — while leaving process and use patents without effective protection. With restrictions as to the type of patents that can be registered, patent holders cannot enforce their right prior to market authorization and, in parallel, the listings cannot provide the certainty that generic and follow-on manufacturers need to foresee which versions of their product will not be at risk of potential infringement proceedings. In effect, this means that both generic manufacturers and innovators face more uncertainty and higher potential costs, as any disputes would have to take place after market

authorization through litigation. This would incur legal costs and, potentially, higher damages, as a potentially infringing product would be on the market. Additionally, resolution of patent disputes through administrative or judicial routes tends to be delayed and is often ineffective.

The USMCA includes a requirement to introduce a more comprehensive and practical system of biopharmaceutical patent enforcement. Article 20.50 of the USMCA provides a clear requirement that the contracting parties provide "a system to provide notice to a patent holder or to allow for a patent holder to be notified prior to the marketing of such a pharmaceutical product, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use…[and] adequate time and sufficient opportunity for such a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies." Mexico's revised Industrial Property Law, which implements the USMCA, does not contain any legal provisions relating to the existing linkage regime. Additionally, for pharmaceutical patent enforcement mechanisms to operate effectively, innovators must be able to enforce all relevant patents, including those concerning compounds, formulations, and medical uses. While the Mexican Institute of Industrial Property publishes certain patents that could be implicated in a patent linkage dispute in the Official Gazette, its most recent update in August 2022 does not include all relevant patents on medicines, namely medical use patents. Further, the Mexican government has not stated how it will provide notice to interested parties that a third party is seeking marketing approval for a patented product, which creates an opportunity to dispute that approval either judicially or administratively.

Even though Mexico passed the new Federal Law for the Protection of Industrial Property (LFPPI) in July 2020 as part of a package of five bills to implement United States-Mexico-Canada Agreement provisions, to date the Mexican Institute of Industrial Property (IMPI) has not issued the follow-up regulations that would provide critical detail on the implementation of key LFPPI provisions in areas such as patent term adjustment, patent linkage and other areas. As a result, manufacturers are now experiencing IP violations in Mexico. Over the last year, marketing authorizations have been granted to copycat generic manufacturers without regard to the existence of a valid patent on the product. The granting of marketing approval to such generics violates Mexico's patent linkage obligations in Article 20.50 and Annex 20-A in the USMCA, which establish standards and obligations for the parties regarding effective patent linkage systems. In some cases, the Mexican Government has even proceeded to international tenders of medicines for products with valid patents.

U.S. companies have provided direct evidence to the Mexican authorities, but yet the infringing companies are still able to participate in government tenders and IMPI is not enforcing its laws or issuing injunctive relief. Over the last twelve months, for one company, COFEPRIS has granted 7 marketing authorizations to 3 patented products in Mexico.

Chamber Recommendation: The Chamber would support the formulation of clear regulations that require the publication of compound, formulation, and medical-use patents in the Official

Gazette. Such provisions would allow effective notice and opportunity for industry stakeholders to engage before follow-on applications are approved by Mexico's health regulator ("COFEPRIS"). More broadly, the Chamber encourages the U.S. government to collaborate with their Mexican Government counterparts to ensure the full implementation and application of the patent enforcement requirements of USMCA in Mexico.

Patent Term Restoration ("PTR")

Mexican law has historically not provided any restoration of patent term lost due to regulatory review periods for biopharmaceutical products. Article 20.46 of the USMCA requires that contracting parties make "available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process." The term of restoration is dependent on the type of mechanism used. Footnote 40 of the Agreement describes that this can be a two-year additional sui generis protection or up to a five-year period of adjustment. Mexico's revised Industrial Property Law does not contain reference to a period of restoration or additional sui generis protection for delays caused by the drug registration and marketing approval process. Article 126 of the law only provides the possibility of obtaining an adjustment to the term of protection in the case of unreasonable delays at the IMPI as part of patent prosecution. Any adjustment period is only available if the processing of a patent application takes longer than five years and the delay is directly attributable to the IMPI.

The USMCA is clear on the requirement that contracting parties should make available a period of restoration due to delays caused by the market review process for biopharmaceuticals.

Chamber Recommendation: The Chamber encourages the U.S. government to work with the Mexican government to ensure the patent term restoration requirements of USMCA are effectively implemented and applied.

Copyrights and related rights

Index Stat: Mexico ranks 20th out of 55 economies in the copyrights, related rights, and limitations Index category, making it the highest ranked economy in the Latin American region and just outside of the top third economies globally.

USMCA Implementation

Mexico has historically had one of the more challenging copyright environments in the OECD, lacking in both substantive IP rights and enforcement against online and hard goods copyright piracy. The Federal Law on Copyright sets out standard exclusive rights of reproduction, public transmission, use, distribution, and sale, but has not included provisions or mechanisms that are more specific to addressing Internet or online infringement.

The USMCA contains several provisions that would strengthen standards of copyright protection in Mexico including with regards to digital rights management and technological protection measures, cable, and satellite piracy, camcording piracy, and the introduction of a notice and takedown regime. On July 1, 2020, amendments to the Federal Law on Copyright were published incorporating many of the most important copyright provisions of the USMCA. Overall, the amendments strengthen the level of protection for copyrighted works in Mexico, extending this protection onto the Internet and the digital environment. The Chamber welcomes these positive developments which will help better protect Mexican creators and IP-intensive industries operating in Mexico.

While the addition of these amendments implements critical aspects of Mexico's copyright commitments under the USMCA, they have been challenged in the Mexican constitutional court. If the constitutional challenges or the legislative initiatives were to succeed, it would create a significant setback for IP rightsholders and make Mexico less globally competitive. However, while these constitutional challenges were first launched in July 2020, the Chamber nor industry have seen any movement within Mexico's court system pertaining to any challenges regarding copyright provisions. The Chamber will continue to monitor any developments in 2024.

Despite these positive developments, however, there are some parts of the amendments that remain unclear. For example, with respect to potential ISP liability for infringing content, article 114(8) is quite clear that ISPs will not be responsible for any damages caused by potential copyright infringement as long as they act expeditiously and in good faith to remove infringing content and take measures to prevent the same infringing content from reappearing. In the same article, subsection V, the law states that the "inability of an Internet Service Provider to meet the requirements set forth in this article by itself does not generate liability for damages for violations of copyright and related rights protected by this Law." 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 these ongoing challenges, in a positive step, national and international rightsholders signed several partnership agreements in 2022. In a series of meetings held throughout the summer and fall, collaboration agreements were signed with the Mexican Audiovisual Producers Rights Management Entity ("EGEDA"), the Entertainment Software Association ("ESA"), the Business Software Alliance ("BSA") and Mercado Libre. These agreements are aimed at facilitating stronger enforcement against online piracy and the circulation of counterfeit goods in Mexico. The Chamber notes the importance of these agreements, which should help strengthen protection against copyright-infringing content.

Chamber Recommendation: The Chamber encourages the U.S. government to collaborate with the Mexican government to implement similar collaborations to combat online piracy while also clarifying the provisions on copyright-infringing content online.

Trade secrets and related rights

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

Regulatory Data Protection and USMCA Compliance

In June 2012, Mexico's Federal Commission for the Protection against Sanitary Risk ("COFEPRIS") published guidelines that provide a maximum of five years' protection against the use of undisclosed test data by any person for the purpose of marketing approval. However, the effective application of the guidelines remains an ongoing concern. One specific issue is the extent to which RDP will be granted to both large and small molecules. While Mexico agreed to a 10-year term of regulatory data protection in the original USMCA agreement, the provision was removed from the final deal, which undermines the environment for life sciences innovators in Mexico.

To date, and despite the newest Mexican Federal Law for Protection of Industrial Property, there does not exist an appropriate term of regulatory data protection for biologics or chemical compounds, contrary to Mexico's commitments under Articles 20.48 and 20.49 of the USMCA.

Chamber Recommendation: The Chamber encourages the U.S. government to work with its Mexican government colleagues to press for more effective RDP in Mexico to support the growth of domestic innovation and creative a stronger environment for biopharmaceutical foreign direct investment.

Commercialization of IP assets and market access

Index Stat: Mexico ranks 22nd out of 55 economies in the commercialization of IP assets Index category, the highest of any Latin American economy, due in large part to efforts to ease ability to commercialize IP assets and develop public-private partnerships, particularly for public research organizations and universities.

Patented Medicines Procurement

Innovative industry continues to face a series of challenges with Mexico's public procurement practices, due to its comparatively lengthy, non-transparent and uncertain public procurement system. Additionally, changes made to this system — often sweeping and consequential for industry — are made without proper or meaningful stakeholder consultation.

To start, in 2019, the Mexican Government consolidated the process for medicines procurement and transferred the authority to the Ministry of Finance ("SHCP"). The SHCP-led

procurement of medicines, again, lacks transparency in decision-making process and appears to be inconsistent with Mexico's domestic public procurement rules and international obligations. Chief among the Chamber's concerns is how the SHCP has centralized the entire procurement process of medicines for all public health institutions (IMSS, ISSSTE, PEMEX, SEMAR, SEDENA and Ministry of Health/Seguro Popular/State Health Ministries)—a decision inconsistent with Mexico's own public procurement rules as well as Mexico's obligations under several free trade agreements (notably including those with the U.S., EU, Canada, and Japan). These actions also have the potential to limit competition, increase the risk of product supply issues and generate legal uncertainty for pharmaceutical manufacturers.

In addition to these challenges, Mexico outsourced the purchase of medicines for its public sector to the United Nations Office of Procurement Services ("UNOPS"). UNOPS acquires medicines through an international open invitation to bid ("ITB"). However, the UNOPS procurement manual establishes an exception to this general rule for sole source products. UNOPS must acquire sole source, patented products through direct contracting negotiation with the patent rightsholders or their licensees. This process is equivalent to the limited tendering processes outlined in the USMCA or direct adjudication processes in Mexican legislation.

On August 25, 2020, UNOPS published the list of the products it planned to acquire on behalf of the Mexican public sector (represented by INSABI). The Chamber understands that UNOPS then negotiated with patent rightsholders for the sole source products on the list and finalized those negotiations on or around December 4, 2020, and UNOPS launched the ITB for the remaining pharmaceutical products. According to UNOPS procurement manual, the ITB is open for offers from every company that considers itself to be in a position to provide the goods in question.

The Chamber's member companies were alarmed to learn that the ITB included more than 20 patented products. Under the ITB, there is no mechanism to ensure that patented products are sold only by the rightsholders, creating the possibility of patent infringements in violation of Mexico's international obligations under the Trade-Related Aspects of Intellectual Property Rights ("TRIPS") Agreement, the U.S.-Mexico-Canada Agreement ("USMCA"), and other free trade agreements.

While UNOPS subsequently announced an amendment to the ITB to remove some, but not all, of the patented products, it is critical that the U.S. government engage at the highest possible levels of both the Mexican government and UNOPS to urge them to align UNOPS purchasing methods and exclude all patented pharmaceutical products from the ITB, acquiring them through negotiations with the rightsholders.

Additionally, there is a great deal of uncertainty around the process. For example, it is not clear when the negotiations will be held for the patented products that have now been taken off the list, nor are there clear guidelines as to when the products that were negotiated

with the manufacturers will actually be purchased. Industry also noted that the UNOPS agreement proved to be resoundingly unsuccessful and led to significant shortages of procurement of medicines not approved by the Federal Commission for Protection against Sanitary Risk ("COFEPRIS") and amended the Federal Procurement Law in the public sector. Among the reasons for this include mismanagement, logistical barriers within the supply chain, gaps in interoperability, and a lack of consultation with relevant stakeholders.

Furthermore, the Chamber would like to highlight its concern with the new burdensome packaging requirements that UNOPS process requires. To participate, manufacturers are required to include on the primary, secondary, and tertiary packages of pharmaceutical products an indication that products are for the use of the public sector and purchase is prohibited. To comply with such a requirement is extremely complicated for imported medicines since the primary packages couldn't be manipulated or modified once they leave the production plants. Therefore, the foreign producers may be de facto excluded from the UNOPS purchases. Such a requirement is inconsistent with USMCA and creates an unjustifiable barrier to trade.

Finally, the Chamber is also concerned with the secondary regulations on the Federal Procurement Law, which the Executive Branch amended in June 2021. The amendments permit the simultaneous supply in the purchase method through a direct reward, which is similar to the limited tendering provided under USMCA. Industry believes that, in practice, the new amendments will circumvent public tendering, which would be out of step with Mexico's commitments under Chapter 13 of USMCA. The Chamber encourages the U.S. government to ensure that medicines procurement process in Mexico is consistent with the provisions of USMCA.

In January 2023, Mexican regulatory authorities blatantly violated the IP rights of a major U.S. manufacturer by issuing two marketing authorizations to two companies even though active patents exist. The INPI notified Comisión Federal para la Protección contra Riesgos Sanitarios ("COFEPRIS") of the existence of the patents. Furthermore, Instituto de Salud para el Bienestar ("INSABI") allowed those two companies to participate in an open tender for the therapeutic area in direct violation of Mexico's IP obligations.

Specifically, the National Institute of Welfare launched a public tendering of medicines. That invitation included AXIPABAN, a patented pharmaceutical product normally purchased through a limited tendering method. The rightsholder of the patent is Pfizer. Once INSABI received the offers from the bidders, Pfizer realized that two of the foreign companies' submissions offered that the generic of AXIPABAN be manufactured out of Mexico - even though they do not have marketing authorization in the country to commercialize that product. Subsequently, INSABI denied the request from Pfizer and Asociación Mexicana de Industrias de Investigación Farmacéutica ("AMIIF") to disregard the proposals coming from these potential infringers. For days, they remained on the list of potential suppliers that the entity evaluated for purchase.

Beyond the infringement already committed by the bidders (offering to sell without the consent of the patent owner), the Chamber considered that in the aforementioned case, there were violations to the USMCA, including: (i) that INSABI is permitting the participation of pharmaceutical products in its bids in a scenario in which the COFEPRIS has not applied the linkage mechanism to ensure that the pharmaceutical products commercialized in Mexico do not infringe patents, and (ii) INSABI did not apply the limited tendering to purchase AXIPABAN, the appropriate public purchase method to avoid the acquisition of infringing products.

However, after internal and external pressures, INSABI requested that Pfizer meet with regulatory officials in late January, just days before a decision was to be reached. Based on the meeting, INSABI made the decision to either award the tender to Pfizer and disqualify the other two companies or withdraw the tender entirely and come back to Pfizer for direct purchase. According to Pfizer, officials claimed to have been unaware of the three active patents.

The Chamber was extremely concerned over these developments and believes that the proper authorities in Mexico must reassess their public tendering scheme as not to violate America's IP rights under USMCA and other IP obligations. Further, the Chamber stresses that the aforementioned scenario could only have happened due, in large part, because of the lack of a meaningful patent linkage system in Mexico. As noted above, USMCA requires parties to have a patent linkage system in which the patent holder is given notice of a generic application and is provided adequate time and sufficient opportunity to seek procedures and expeditious remedies for the timely resolution of any infringement or validity dispute. Despite having gone into effect in July 2020, Mexico currently has no relevant regulation proposals to establish new or updated linkage system rules that comply with current USMCA obligations.

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.

Enforcement

Index Stat: Mexico ranks 22nd out of 55 economies in the enforcement Index category, the second highest in the Latin American region, behind only Colombia.

Effective Border Measures and Remedies

Historically, Mexico has struggled to stem the flood of illicit trade and counterfeit goods. Existing provisions in Mexico's Customs Law only give authorities *ex officio* powers to initiate board measures —not decide nor seize and destroy IP-infringing goods. Instead, every shipment suspected of infringement must obtain a corresponding order from the Attorney General's Office for inspection and detainment. Administrative procedures can be helpful when

pursuing well-established infringers with a known address, but these are expensive and time-consuming stop-gap measures. For that reason, rightsholders are increasingly opting to pursue criminal actions through AGO's Specialized Unit. But even though this team is solely focused on copyright and industrial property infringement, budget cuts have reduced its effectiveness and ability to perform raids and seizures as before. The Chamber urges the U.S. government to work with the Mexican government in improving its enforcement framework despite these budget cuts and in accordance with Chapter 20 of the USMCA. The Chamber also encourages Mexican legislators to introduce meaningful anti-counterfeiting legislation —empowering Customs to seize and destroy counterfeit goods independently from IMPI administrative orders and adding mechanisms to address the growing threat of small parcels and counterfeit goods sold online. Some specific recommendations include:

- Implementing registration requirements for third-party sellers that allow the authentication of both seller and product;
- Actively blocking offers that offer suspicious counterfeit products;
- Banning repeat offenders; and
- Preventing banned offenders from re-registering on the platform.

Chamber Recommendation: the government of Mexico should quickly adopt other legal reforms to fully implement the USMCA. For example, Mexico should remove the proof-of-profit ("direct economic benefit") requirement as a prerequisite to criminal liability, including for satellite and cable decryption. Mexico should also add aiding and abetting criminal provisions for both physical and online piracy, remove the for-profit limitation on the making available right, and clearly include a violation of making available in the Criminal Code.

RUSSIA

Overview

Over the course of 2023, the Russian Government has continued implementing an import substitution strategy, strongly focusing on local manufacturing to support various economic sectors, and introducing changes to its national IP environment, affecting IP rights, and thus impacting creators, innovators, rightsholders, and industry overall. Since the Russian invasion of Ukraine, and in response to economic sanctions, brain drain, and diplomatic exodus, Russia's government has taken drastic steps in instituting new laws and regulations that target IP rights in an arguably punitive way. Specifically, and as noted in last year's Special 301, various laws and decrees have specifically targeted the IP rights of rightsholders, entities or organizations "associated with foreign states who commit "unfriendly actions against Russian legal entities and individuals."

The Chamber is concerned how the revocation of IP rights has severely limited access to innovative and creative goods and services in Russia, which will only serve to compound the negative effects of the ongoing war and continue economic destabilization not just regionally but also globally. The Chamber recommends the U.S. government closely monitor the following IP-related issues in Russia.

Russia's Response to Government Sanctions

The Chamber is deeply concerned about the Russian government's decision to revoke IP rights for foreign rightsholders in response to foreign government sanctions. The new provisions, under Federal Laws 46 and 213, Government Decrees 79, 81, 95, 299, 322, and Decree Order 430 target the IP rights of rightsholders, and entities or organizations "associated with foreign states who commit unfriendly actions against Russian legal entities and individuals." This includes either the suspension or severe restriction of the payment of licensing fees, royalties, and any other associated payments in relation to the use of a patented technology, utility model, or industrial design and the other measures to support various economic sectors that generally weaken IP rights protection.

Specifically, Decree 322 restricts rightsholders' ability to receive and remit funds abroad and outlines how pre-existing licensing payments should be made. While exempting certain industries, including food products, medicines and medical equipment, the Decree limits the ability to remit funds outside of Russia and denominates all transactions to be in Russian rubles.

Compulsory licensing ("CL") enforcement

In 2021, the State Duma passed, and President Putin signed into Law, amendments to the Civil Code Part IV. These changes amended article 1360 inserting a further justification for the overriding of any granted rights relating to patents, utility models, and industrial designs. The Russian Government now has exceptionally broad powers of justification to issue a compulsory license and override duly granted IP protections. Further proposals were presented in the State Duma in 2023 for introducing a compulsory licensing regime specifically targeting copyrighted and audiovisual content.

In October 2021, the Russian Government adopted a resolution on calculating the compensation for use of an invention, utility model, or industrial design in the interest of national security. The compensation amounts to 0.5% of the revenue received by the company for manufacturing and selling products or rendering services using the invention, utility model, or industrial design without the patent holder's consent. This level of compensation is not sufficient to provide the protection that innovators need to support their research and development.

In March 2022, the level of compensation was decreased to 0% if the patent holder has the citizenship of or place of registration/primary business/ primary profit in an "unfriendly state" (Decree No. 299 dated March 6, 2022).

In May 2023, "[t]he concept of technological development until 2030" (Technology 2030) was approved by Prime Minister Mishustin. One of the central features of the strategic cross-cutting industrial-economic policy document is the use of involuntary tools to access innovative technologies and IP assets. The document, which lays out a long-term plan for achieving "technological sovereignty" and parity with the West, specifically identifies the use of involuntary licensing mechanisms of "unused results of intellectual activity, the exclusive rights to which belong to rightsholders from unfriendly countries" as one of the pillars upon which Russian future technological development can be achieved.

As noted above, the Chamber is deeply concerned with the Russian Government's overly broad justifications for issuing compulsory licenses and its punitive measures against innovators deemed "unfriendly" to the state. The Chamber notes that, especially in recent years — at the legislative, executive and, more extensively, at the judicial level, the Russian Government has worked in tandem to facilitate compulsory licensing.

The Chamber notes that repeated compulsory licensing and legal uncertainty will only erode the Russian IP environment and reduce incentives for future innovation, biopharmaceutical and otherwise.

Parallel import legalization

In March 2022, Russia adopted Federal Law No. 46-FZ "On amendments to certain legislative acts of the Russian Federation." It represents a set of measures to support sustainable economic development in the face of sanctions pressure from foreign states and support for various sectors of the economy, including the pharmaceutical and medical devices industries. Article 18, subsection 13 of the Law states that "a list of goods (groups of goods) in respect of which certain provisions of the Civil Code of the Russian Federation on the protection of exclusive rights to the results of intellectual activity expressed in such goods, and the means of individualization with which such goods are marked, cannot be applied".

In June 2022, President Putin signed the additional amendments to article 18 of the Law No. 46-FZ (213-FZ). These amendments appear to further broaden the suspension of IP rights under the Civil Code Part IV by stating that: "It is not a violation of the exclusive right to the results of intellectual activity or means of individualization, the use of the results of intellectual activity, expressed in goods (groups of goods), the list of which is established in accordance with clause 13 of part 1 of this article, as well as the means of individualization with which such goods are marked."

As a next step, at the end of March 2022, the Russian Government issued Resolution 506 "On goods (groups of goods) in respect of which certain provisions of the Civil Code of the RF (on the protection of exclusive rights to the results of intellectual activity, expressed in such goods, and the means of individualization by which such goods are marked) cannot be applied" (signed by Prime Minister Mishustin). This Resolution appears to limit the suspension of protection under the Civil Code Part IV to articles 1359(6) and 1487 – both of which relate specifically to parallel imports and Russia's preexisting legal regime with respect to the national exhaustion of IP rights. However, Government resolutions are subordinate regulatory and administrative legal mechanisms and do not carry the force of statutory Russian federal law and can be revoked or altered at any time. Subsequent Government announcements throughout 2022 have clarified the goods that are subject to the parallel importation regime.

While these lists are subject to change and changes have taken place over the course of 2022 and 2023, they have consistently included a broad range of consumer goods products, medical goods, automotive parts, electronics, and other staple goods. Press reports suggest that the list has expanded in 2023 with both luxury goods added and an increasing number of automotive manufacturers. However, medicines are excluded from the list. The estimated value of parallel imports for 2022 was over USD 20 billion and growing. The net result is that there continues to be deep and abiding uncertainty over the extent to which rightsholders will, in practice, be able to use and enforce their IP rights in Russia.

Chamber Recommendation: The Chamber recommends that the U.S. government continue to closely track the Russian government's efforts to further deteriorate the country's IP framework.

Patents and related rights

Index Stat: Russia ranks 54th out of 55 economies in the patents and related rights Index category, ahead of only Venezuela.

Pharmaceutical Patent Enforcement

The Chamber is concerned that the Russian regulatory system does not protect and enforce IP rights — particularly in the biopharmaceutical sector. For instance, there are no provisions in Federal Law #61-FZ "On the Circulation of Medicines" (the Law #61-FZ) to cross-check an innovator patent's status (so-called patent linkage mechanism) within the state registration procedure framework for generics and biosimilars. Because of this, any manufacturer can apply for and receive marketing authorization for a generic or biosimilar product and, in turn, participate in state tenders--even though a patent for the original innovative drug is still in force. As a result, in the last several years, many innovative companies (patent-holders) were required to bring and engage in extended patent litigation proceedings. These proceedings have shown a general reluctance of the Russian courts to protect innovator's patent rights. Moreover, the Russian courts constantly refuse to grant preliminary

injunctive relief, which has been successfully implemented in other parts of Europe to prevent the launch of counterfeit products on the market. The Russian judicial system's refusal to use this instrument has put innovative companies at a significant disadvantage.

In 2019, the Ministry of Economic Development and the Federal Service for Intellectual Property ("ROSPATENT") proposed to create a "Unified Register of Pharmacologically Active Substances Protected by a Patent for an Invention" and link it with the date of entry into force of a generic marketing authorization certificate. Because this mechanism had an impact on the state-level registration process, the Ministry of Health did not support the introduction of its patent linkage mechanism into the registration framework In accordance with the Rules for Registration and Examination of Medicines for Human Use, approved by the Decision of the Board of the Eurasian Economic Commission dated 3 November 2016 № 78 (the EAEU Rules on Drug Registration and Examination), when applying for the registration of medicines (bringing the registration dossier in compliance with the EAEU requirements), confirmation of registration (re-registration) of medicines and amending the registration dossier of medicines, the applicant is obliged to indicate information on the protection of intellectual property rights to the medicine by patents or trademark registration certificates valid in the territory of the EAEU member (indicating number and date of the patent / certificate, term and territory application, the right holder). Copies of patents, trademark registration certificates or relevant license agreements in force on the territory of the EAEU member states in relation to the registered medicines must be attached to the corresponding application. Additionally, applicants submit a letter certifying that the intellectual property rights of third parties, protected by a patent or transferred under a license, are not violated in connection with the registration of the relevant medicine. This procedure became obligatory as of January 1, 2025, for the registration of the new medicines in Russia and in the other countries, members of the Eurasian Economic Union.

In 2021, an outline of what this register was to look like was published by the Ministry of Economic Development. ROSPATENT also announced the development of a pilot program whereby rightsholders could on a test basis register their existing rights. Despite the broader suspension of IP rights across Russia over the last year, as noted above, ROSPATENT reiterated its commitment to the development of a registry in 2022. Although a positive development, there was still no primary or secondary legislation outlining what the pre-marketing patent enforcement mechanism would look like. In 2023, the work on Russian Register of Pharmacologically Active Substances Protected by Patent (so-called API Patent Register) was put on hold at the Russian Federation level as this was restricted to compound patents only, with no patent linkage mechanism prohibiting generics and biosimilars to get marketing authorization, price registration or participating in tenders while the original patent is in force. The API Patent Register would not facilitate either for innovators to rely on a preliminary injunction ("PI") in case the asserted patent is included in this Register.

The Eurasian Patent Organization ("EAPO") announced that from March 1, 2021, a new information and retrieval resource — the Pharmaceutical Register of the Eurasian Patent Office

(hereinafter referred to as the "EAPO Pharmaceutical Register") — has been publicly available on the EAPO web portal. This Pharmaceutical Register contains information about Eurasian and national patents based on which the protection of pharmacologically active substances (chemical compounds, including those described by a general structural formula, biotechnological products, compositions, and combinations containing pharmacologically active substances), methods for obtaining pharmacologically active substances and their medical applications. Patent data from the registry could be recognized by national courts in the event of patent infringement proceedings, if the information about the corresponding valid Eurasian or national patent is indicated in the registry, this possibility is legally absent.

On December 7, the Eurasian Patent Organization ("EAPO") approved the Statute on the Eurasian Pharmaceutical Register. EAPO Member States will decide within national legislation on whether to use patent data from the Register as official information. The adoption of the EAPO Statute potentially can provide the opportunity to leverage the patent data from EAPO Pharmaceutical Register in Russia.

Copyrights and related rights

Index Stat: Russia ranks 55th out of 55 economies in the copyrights, related rights, and limitations Index category, with an absolute score of 0.0, signaling the worst and most egregious violations of copyright protections.

Online Piracy and Enforcement

Despite some progress having been made since 2013's changes to the Civil Code Part IV, piracy challenges continue in Russia, and have only been exacerbated since the invasion of Ukraine. Industry reports that the market's rate of illegal software use has remained unchanged and Russia hosts some of the world's most high-profile pirate sites, including: *seasonvar.ru* (a St. Petersburg-based streaming website of television programs), Mp3juices (a site hosted in Moscow that allows users to download mp3 audio files from songs posted on YouTube), and even the social network VK.com (a one-stop shop for over 50 million Russians to obtain pirated movies, television shows, and eBooks), and these troubling trends continue to persist. The notorious pirate site for copyright-protected journals and academic articles, Sci-Hub, was founded in Russia and continues to operate on Russian servers.

It should be noted that while Russia remains the host to illicit sites that cater to English-speaking audiences, many pirate sites have moved to foreign hosting locations after several legal reforms allowed rightsholders to seek injunctions through the Moscow City Court, but as has been pointed out, Russian courts have traditionally been slow to respond and adjudicate the onslaught of infringing content.

Finally, and despite the previous tightening of Russian legislation and the increasing "bans" of pirated content, online piracy will continue to be a significant challenge in the near-

and long-term future in Russia. According to Russian news agency TASS, industry experts — including the state-sponsored Russian Association for Electronic Communications ("RAEC") — forecast that by the end of FY 2023, the market volume of online piracy may reach $60 billion or more. Industry experts point to, among other issues, declining incomes of the Russian population and lack of access to "new Western films and other content" as a key reason for the severe uptick in piracy online and beyond — a direct result of the Russian Government's hostility in Europe and beyond post-Ukraine invasion.

Chamber Recommendation: The Chamber recommends that the U.S. government continue to work with the Russian government to more effectively address online piracy and to work with regional partners to collaboratively stem the hosting of infringing sites in other jurisdictions.

Trade secrets and related rights

Index Stat: Russia ranks 36th out of 55 economies in the trade secrets and the protection of confidential information Index category, its best IP Index category.

Regulatory Data Protection

Under its WTO commitments and the 2010 Law of Medicines, Russia has committed to implementing a regulatory data protection term of six years. However, progress has yet to be made to develop a fully functioning form of regulatory data protection. This has been compounded by the uncertainty generated by the Russian courts' interpretation of the existing legal framework. Furthermore, legislative amendments to the Law of Medicines that regulate the period for the submission of follow-on product applications took effect in 2016. These amendments allow applicants to submit their applications for market approval four years after market approval for small-molecule products and three years for biologic (large-molecule) products. On December 14, the State Duma adopted in the 2nd reading amendments to Federal Law #61-FZ "On the Circulation of Medicines", including provisions on the protection of data from preclinical and clinical trials:

- An application for registration of a medicinal product can be submitted to MoH:
    - For generics - after 4 years from the date of state registration/registration of the reference medicine in the RF;
    - For biosimilars - after 3 years from the date of state registration/registration of the reference medicine in the RF; and
    - It is not permitted to use for commercial purposes information on the results of preclinical and clinical trials of drugs for 6 years from the date of state registration/registration of the reference medicine.

The 3rd reading is planned in January 2024. This approach shall provide the possibility to apply the data and market exclusivity regime to medicinal products registered in accordance with EAEU legislation.

Personal Data Protection

More broadly, despite the ongoing threat to IP rights post-Ukrainian invasion, the Russian government has implemented new regulatory schemes to further protect personal data. Russia's Federal Service for Supervision of Communications, Information Technology and Mass Media (the "Roskomnadzor") recently adopted and implemented, as of September 2022, new regulations under Russia's Federal Law on Personal Data, including required data breach notification; new language to prohibit contractual data processing that includes conditions to restrict data subject rights; and proposals to further stiffen penalties and liabilities around data breaches.

Chamber Recommendation: The Chamber will continue to advocate for the introduction and application of full coverage of protection for regulatory data in Russia and recommends that the U.S. government continue to monitor the Russian government's regulatory efforts to protect data.

Commercialization of IP assets and market access

Index Stat: Russia ranks 49th out of 55 economies in the commercialization of IP assets and market access Index category.

Forced Localization Policies

Russian industrial and economic policy has increasingly resorted to mandating local industrial production and R&D through the multiple state-sponsored initiatives. Some of the most affected sectors include aerospace and nuclear energy, nanotechnology, medical technologies, and alternative fuels. The effects on the biopharmaceutical and information and communications technologies ("ICT") sectors, through data localization requirements are severe. A law passed in July 2021, "On the Activities of Foreign Persons in the Information and Telecommunication Network 'Internet' on the Territory of the Russian Federation," requires certain large tech companies adopt a wide-reaching localization protocol. Companies that fail to adhere to the localization protocols will face significant and severe penalties, including partial or full restriction of the company's resources in Russia, Together, these localization policies create significant market-access barriers for rights-holders.

Specifically, to establish "medicines sovereignty" by 2030, the Russian government has put forth several initiatives and measures, so-called "2nd man out" along with "Patents on the Shelf" and further development of state program as Pharma 2030. Thus, the Government is planning to adopt a Decree on "2nd man out" mechanism implementation which provides

absolute priority in public procurement for 215 INNs "strategically important medicines" produced locally in full cycle including API synthesis. It has been announced earlier in 2023 that the mechanism implementation will start from January 2025.

On April 3, 2023, the Government approved Decree 529 on subsidizing R&D of domestic drugs, analogues of which are currently under patents protection (so called "Patents on the Shelf" initiative). As the Ministry of Industry and Trade ("MoIT") states the mechanism is aimed at reducing the risk of shortages and ensuring drug security in the Russian healthcare system. Key points touching IP issues that have been elaborated and addressed by the industry:

- The purpose of regulation is to provide subsidies to local manufacturers to help them quickly start their own production after the expiration of a foreign patent;

- The subsidy agreement provides for the manufacturer's obligations to respect IP rights of patent owners of foreign drugs;

- The infringement of IP rights can only be confirmed by a court decision that has entered into force; and

- A special Commission upon instructions from the Government will form and update the List of Substituting Medicines designed to replace drugs protected by patents in Russia.

As a next step, in December 2023 the Ministry of Industry and Trade ("MoIT") published the first list of 25 INNs, analogues of which are planned to be developed as part of the "patents on the shelf" program. Russian companies will receive subsidies on a competitive basis for the development and registration of medicines protected by patents in the RF.

On June 19, 2023, the Government by its Resolution No. 1495 officially approved the Strategy for the development of the pharma industry until 2030 ("Pharma-2030") with the goal to achieve self-sustainable industry development with full cycle manufacturing of a wide range of strategically important drugs, to create attractiveness of pharma industry for investors, to ensure a stable and predictable environment for R&D, manufacturing, and sales of products, develop export potential. The Ministry of Industry & Trade must present an Action Plan "Road Map" for the implementation of the strategy.

Chamber Recommendation: The Chamber recommends that the Russian government abandon its misguided and innovation-killing forced localization policies, which will only continue to hinder Russia's economic and industrial wellbeing.

Enforcement

Index Stat: Russia ranks 40th out of 55 economies in the enforcement Index category,

Online Enforcement

Russia continues to struggle with hard goods piracy and the sale of counterfeit goods online, with online piracy alone swelled significantly in 2023 and may continue to do so in 2024. Under normal circumstances, the Chamber would suggest best-practice measures to combat the epidemic of online piracy and counterfeit goods, including consistent and effective notice and take down procedures for listings of infringing goods, better information sharing with rightsholders on true seller IDs and the volume of infringing sales, and policies to deter repeat infringers. However, owing to the invasion of Ukraine, the socio-economic fallout domestically, and along with the Russian government's admission that it expects online piracy to rapidly expand, the Chamber does not anticipate that the Russian government will take meaningful steps to curb and combat the rapidly expanding use and dissemination of pirated materials online.

SAUDI ARABIA ("KSA")

Overview

The Saudi government has recently taken major steps to improve the framework for IP-driven innovation. In 2019, Saudi Arabia established a new authority responsible for intellectual property ("IP") protection and enforcement (Saudi Authority for Intellectual Property – "SAIP") to create and develop IP strategy, regulations, guidelines and mechanisms for IP protection and enforcement in coordination with other relevant agencies, including the Saudi Food and Drug Authority ("SFDA"). The Ministry of Justice established a commercial court dedicated to resolving commercial law disputes including IP cases.

In April 2023, SAIP released a draft version of what is an overarching Intellectual Property Law. The draft Law covers all major IP rights in the Kingdom. It does not provide new legal definitions or requirements to existing specialized statute, but, rather, the draft Law aims to complement the existing legal framework and achieve "consistency and harmony between specialized systems…enhancing clarity and transparency in procedures related to intellectual property."

Of note is the strong emphasis on promoting the identification, development, and use of IP assets by public sector entities and supported organizations. Chapter Four of the Law requires such entities to identify and use IP policies in their day-to-day operations. The Law also includes reference to the role that AI will play in the development of new technologies and products; the draft Law states that ownership of a patent right can only be granted to a "natural person". At the time of research, no final version had been published or any further action taken. The Chamber will monitor these developments in 2024.

However, continued actions by SFDA are undermining these positive developments and the investment climate in Saudi Arabia. SAIP has issued proposed regulations on compulsory

licensing and regulatory data protection ("RDP") that further weaken IP protections in the Kingdom. Finally, while industry reports indicate the Kingdom's customs authorities are actively engaged in addressing the sale of counterfeit goods, the growing availability of trademark-infringing goods in the market speaks to the need for even-greater partnership between industry and the government. The Chamber encourages the U.S. government to work with their counterparts in KSA to ensure that its IP laws are appropriately calibrated and enforced, to protect inventors and creators as well as encourage further investment by U.S. businesses in KSA in alignment with the objectives of Vision 2030

Patents and related rights

Index Stat: Although Saudi Arabia ranks 34th out of 55 economies globally overall, it ranks 28th out of 55 economies on the patents, related rights, and limitations Index category, ahead of the UAE, Kuwait, Egypt, Pakistan,

Pharmaceutical Patent Enforcement

While Saudi Arabia introduced a patent linkage system in 2013, the Saudi Food and Drug Authority ("SFDA") effectively overrode it by approving a follow-on product to daclatasvir, a medicine under a registered patent held by BMS. In mid-2017, the SFDA started granting marketing approval to generic versions of innovative medicines during the term of the patent(s) protecting those treatments or the period of RDP. SFDA's repeated approval and related price listings of generic copies of innovative medicines is contrary to Saudi Arabia's own patent enforcement and data protection rules. These actions also contradict the country's World Trade Organization ("WTO") commitments.

As noted in last year's Special 301, in 2022 the Saudi FDA in cooperation with SAIP published "The Procedure to Deal with Patents When Registering Generic Products in Saudi Food and Drug Authority (SFDA)". This document outlines a new procedure to be followed by the Saudi FDA when registering a follow-on drug application. The Procedure states that follow-on applicants must submit a statement (Annex 1) stating that the follow-on application does not infringe any existing IP rights. This declaration is to be accompanied by a "freedom to operate" analysis and certification that no outstanding patent exclusivity is in place by an IP agent licensed by the SAIP. The publication of this Procedure is a positive move by the Saudi FDA.

However, the new Procedure does not, strictly speaking, introduce a "linkage" regime, whereby a drug regulatory authority conditions the approval of a follow-on biopharmaceutical product on their being no relevant period of market exclusivity in place for the underlying reference product. The Procedure does not contain a notification mechanism to the relevant rightsholders or an automatic stay period ensuring a period in which any dispute can be resolved prior to the approval and launch of the follow-on product. The linking of the approval of follow-on biopharmaceutical products to the exclusivity status of a reference product is an

effective way of achieving a balance between the protection of pharmaceutical exclusivity (usually but not always through patent protection) and stimulating early market entry of follow-on generic products. Linkage ensures that any disputes are resolved prior to the marketing of a follow-on product. This grants innovators a fair opportunity to secure return on their long-term, high-risk R&D investment by ensuring they can effectively use their legally granted exclusivity. It also limits potential damages for generic manufacturers as no potentially infringing product is ever launched or approved for market.

Indeed, linkage also provides both innovators and generic companies with an opportunity of lower-risk challenges of validity or non-infringement, by largely taking the issue of damages out of the equation. Patients also benefit from the increased certainty, as they avoid the risk of having to change treatments depending on the outcome of a patent lawsuit. In sum, a well-balanced linkage system recognizes the crucial role of patent protection in promoting innovation, and the role of generic entry in providing patients access to lower cost biopharmaceuticals. Having in place a functioning linkage regime that provides rights-holders with a meaningful and real ability to stop follow-on products from being launched when a granted term of exclusivity is in place would be a substantial improvement to the biopharmaceutical IP environment in Saudi Arabia.

Draft Patent Law

The Saudi Authority for Intellectual Property (SAIP), in April 2023, issued a draft intellectual property ("IP") legislation (the "Draft IP Legislation") in line with the National Intellectual Property Strategy to revitalize the Kingdom's IP System, hoping to further support and expand the Kingdom's knowledge-based economy.

The Draft IP Legislation, among other outcomes, seeks to harmonize and provide consistency between the various existing IP provisions of law, including those pertaining to patents, industrial designs, copyright, and trade secrets. It also aims to encourage research, development, innovation, and entrepreneurship in IP. The Chamber welcomed the introduction of the Draft Patent Law, which it sees as an opportunity to capitalize upon SAIP's ongoing efforts to enhance the ecosystem for innovation in the Kingdom.

And while the Chamber and industry leaders have been proud to work with the Kingdom to help increase its overall quality of healthcare and transform the biopharmaceutical sector into a leading driver of an innovative economy, there do exist concerns with some of the provisions included in the Draft Patent Law which will undermine the legal certainty and predictability provided by patent protection and weaken the ecosystem for biopharmaceutical innovation.

First, the Chamber and various industry leaders have expressed concerns regarding the patentability provisions of the Draft Patent Law. The Chamber believes that the current provisions will discourage investment in research to improve existing medicines. Life sciences

innovators are required to file initial patent claims at early stages of research and development, years before an intended product reaches the market and its applications and treatments have been clinically tested. Extensive investments in clinical trials and ongoing research and development are required to discover subsequent health conditions that may be treated by the initial product, which can deliver invaluable benefits to patients and consumers. To facilitate continued investment in innovation, it is critical that the Draft Patent Law allow for patentability of new uses and avoid broad exceptions to patentability.

Second, there are concerns regarding the disclosure requirements for the source of genetic resources and associated traditional knowledge. The Chamber supports access and benefit sharing agreements, however, the disclosure requirements included in the Draft Patent Law could negatively impact the future of biopharmaceutical innovation in the Kingdom. As a result, the Chamber recommends removing Article 12.3(f) from the Draft Patent Law.

Third, the Chamber recommends that SAIP focus on a post-grant opposition system as opposed to a pre-grant mechanism. Historically, pre-grant opposition systems can create lengthy timelines for patent prosecution and undermine the system of predictability traditionally created by a patent. Alternatively, post-grant systems enhance legal certainty for the patent applicant by allowing the innovator to retain the rights to the patent during opposition proceedings. The Chamber recommends that SAIP amend the provisions to the draft Patent Law in favor of a post-grant opposition system.

Finally, the absence of provisions to provide for patent term adjustment and restoration are disappointing. Patent term adjustment mechanisms are utilized globally to account for undue patent office delays. Patent term restoration provides additional patent life to compensate for time lost during clinical trials and the regulatory approval process. The availability of patent term adjustment and restoration provisions contribute to a thriving life sciences innovation ecosystem.

Chamber Recommendation: As SAIP considers revisions to the Draft Patent Law, the Chamber urges the government to consider including such provisions mentioned above.

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 and related rights

Index Stat: Saudi Arabia ranks 30th out of 55 economies in the copyrights, related rights, and limitations Index category.

Online Piracy and Piracy Devices

Rightsholders have historically faced significant challenges in protecting their copyrighted content and trademarks in Saudi Arabia. Relevant laws and regulations are not well-developed, and the illicit use of IP-infringing material has remained high. With respect to copyright, current Saudi law provides for only basic exclusive rights and protection of creative works. While article 9 of the Copyright Law Royal Decree No. M/41 includes a reference to the exclusive right to communication of a given work to the public "via any possible means," the Kingdom appears to have, rather than comprehensive, an overarching framework for a notification and takedown mechanism for infringing online content. The SAIP does mandate, through the appropriate departments in respective ministries:

- Receiving complaints of copyright violations on the Internet. Implementing proactive and periodic online inspection visits to detect violations;

- Implementing several partnerships with rightsholders and digital platforms to ensure compliance and enforcement of regulations;

- Coordination, through the Permanent Enforcement Committee, to enhance the enforcement of intellectual property rights on the Internet; and

- Coordinating, communicating, and finding effective business models with intermediaries to prevent infringing practices and content piracy.

Historically, the Ministry of Culture and Information has sporadically disabled access to web content, including copyright-infringing content, but this has been on an ad hoc basis. Consequently, estimated rates of physical and online piracy have remained high. With respect to the protection of brands and trademarks, enforcement has historically been a challenge. However, SAIP has worked diligently to improve the national IP environment and the ability of rightsholders to enforce their rights more effectively. The SAIP has also made the disabling of access to infringing content (copyright and trademark related) part of its enforcement remit.

Additionally, the Authority created a portal through which rightsholders can directly communicate any suspected online infringement to the SAIP which will then take enforcement

action. In May 2022, the Authority released its annual enforcement report for 2021. For the calendar year SAIP received just over 1,200 complaints from rightsholders (1,023 for potential copyright infringement and 194 for alleged trademark infringement) and disabled access to over 2,000 websites from which infringing content was being disseminated. The Authority also carried out over 6,000 in-person visits to physical stores investigating the dissemination and sale of IP-infringing goods. This activity has continued in 2023. Over the last year, SAIP had disabled access to over 3,000 websites from which infringing content was being disseminated and conducted over 5,000 physical in-person visits.

Chamber Recommendation: The Chamber commends SAIP and the Saudi Government. This is yet another positive step taken by the SAIP to offer rightsholders an effective and practical route of IP enforcement in Saudi Arabia.

Trade secrets & market access

Index Stat: Saudi Arabia ranks 27th out of 55 economies on the trade secrets and the protection of confidential information Index category, second only to the UAE.

Regulatory Data Protection

In 2020, the SAIP released new draft implementing regulations on how confidential commercial information will be protected in Saudi Arabia. While the SAIP should be applauded for publishing these draft regulations, holding a public consultation, and inviting stakeholder feedback on the matter, as noted in the Index at the time, the regulations themselves were deeply flawed and stood outside established international standards of RDP.

Specifically, article 4(1) of the regulations stated that any term of protection offered in Saudi Arabia would begin on "the date of the first registration of the preparation in another country." If applied in practice, this would dramatically re-write existing regulations and significantly curtail rightsholders effective RDP term. The introduction of such a definition and the linking of the exclusivity period in Saudi Arabia to a product's first global launch would severely limit the availability of RDP in Saudi Arabia and undermine the incentives for innovation and investment such exclusivity provides. Moreover, the draft regulations did not allow a period of RDP for new indications. However, the Chamber notes the 2022 U.S. State Department *Investment Climate Statement,* report which stated that the SAIP and the Saudi Food and Drug Authority have reaffirmed their support for the availability of regulatory data protection in the Kingdom. As the Kingdom continues to seek new investment by innovative companies, it is critical that regulatory data protection must apply to all biopharmaceutical innovation including both small-molecule chemical and biological pharmaceuticals. The Chamber stands ready to work with the Saudi government to resolve these concerns as soon as is practicable.

Among the Chamber's top priorities related to intellectual property are fostering an environment where rightsholders can receive fair value for their innovation and creativity, but are concerned that pricing guidelines fail to appropriately recognize benefit to patients and the system from innovative medicines. Specifically, Saudi Arabia nominally sets prices based on a basket of reference countries, while in effect defaulting to the lowest price. This method of artificially establishing prices does not reflect the spirit of Saudi Arabia's professed interest in stimulating domestic innovation and implementing a disciplined value-based approach to health care, in general. To that point, Saudi Arabia's new health technology assessment ("HTA") system, outlined in the Saudi Health Sector Transformation Strategy, is an opportunity to enhance access to innovative medicines. It should not be implemented principally as a cost-containment tool.

Already, U.S. biopharmaceutical innovators are at a disadvantage from a government procurement system with onerous local sourcing rules (the mandatory Local Content and Government Procurement Authority ("LCGPA") list of products) and preferred price incentives for local manufacturers. Moreover, eligibility to participate in government procurement tenders has been limited to companies establishing regional headquarters in Saudi Arabia. Such local manufacturing infrastructure investments and other local partnerships required by the government to participate in government tenders have recently become even more difficult to meet, since the Council of Health Insurance produced a new policy for private sector health plans that increases the co-payment applicable to off-patent branded medicines relative to competing generic products. As a result of this new policy, co-payments for generic medicines are capped at eight dollars, while those for branded medicines are set at 50 percent of the product price, with no maximum co-payment.

SOUTH AFRICA

Overview

As Africa's largest and most-advanced economy, South Africa has the potential to attract immense investments in IP-intensive industries—benefiting the entire continent. Unfortunately, the country has taken an ever more public stance questioning the benefits of IP rights. This position is most apparent in the WTO TRIPS Council and African Union, where the South African delegation presented proposals that would override every form of IP, including patents, copyrights, and trade secrets. This first proposal would almost waive the entirety of the TRIPS Agreement for an undefined period.

The Chamber members believe in the potential of South Africa to become Africa's innovation and creativity, and applaud President Ramaphosa's stated goal to attract IP-intensive foreign investment to the country. But the country's public skepticism of IP rights and domestic legal norms have brewed widespread uncertainty about the reliability of the country's intellectual property system. The Chamber encourages the U.S. government to continue its

consultations with the government of South Africa, highlighting how legal certainty is critical to an innovative economy.

Patents and related rights

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

Patent Term Extension

As the South African government evaluates the efficacy of the Bolar exception under the 2002 Patents Act, the Chamber encourages the government to include a mechanism similar to patent term extension to support the entry of generics into the marketplace while also creating a system which supports the innovator's patent rights.

Chamber Recommendation: Fundamentally, The Chamber views patent term extension as a rule-of-law mechanism that protects the base IP incentive represented by the 20-year patent term from inappropriate erosion caused by bureaucratic or political delay and stress the importance of the South Africa government to adopt these best practices.

Patentability

The Patent Act currently provides a 20-year term of patent protection from date of filing, with annual renewal fees payable from the 3rd anniversary of the filing date. The South African government looks to international best practices to strengthen its patentability criteria — as in Section 4.1.4 of the framework — and implement a more comprehensive examination process, the Chamber recommends taking a broad approach to patentability that recognizes both the development of new technologies and the refinement of existing discoveries — the latter being a ripe area for developing country activity.

The final IP Policy proposes to introduce new standards of patentability; changes the existing framework for the issuing and use of compulsory licenses; introduces the use of parallel importation for medicines; and introduces a pre- and post-grant patent opposition mechanism. There remains a great deal of uncertainty as to what, specifically, these policy changes will mean. For example, on the issue of patentability criteria, the IP Policy states that TRIPS Article 27.1 (and related articles) "gives a country such as 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. Amongst other things, this would include the adoption of patentability criteria that address the country's public health and environmental concerns, as well as industrial policy objectives [emphasis added]." But the IP Policy is silent on 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 U.S.

By seeking to redefine these criteria in favor of a more restrictive standard, the policy unduly limits the scope of innovation that can take place in South Africa, curbing future growth prospects of any biopharmaceutical investment in South Africa. The Chamber welcomes stakeholder consultation in this area before the IP Policy becomes a binding law.

Compulsory Licensing

Section 55 and 56 of the Patents Act, Act (no. 57 of 1978) establishes the grounds for issuing compulsory licenses. Under the Patents Act, compulsory licenses in South Africa can be obtained in one of two ways:

- In the event a patent cannot be practiced because of a prior patent (referred to as dependent patent); or

- In the event of abuse of patent rights.

With respect to the issue of compulsory licensing, it is unclear what purpose the IP Policy is intended to perform. The policy states that "in order to promote the sustainability of supply, it is important to ensure that a workable compulsory licensing system is in place to achieve affordability of essential goods, and restrain anti-competitive practices, as the need arises. One such instrument recognized by international law is compulsory licensing." TRIPS Article 31, including the amendments introduced in the 2001 Doha Ministerial Declaration, and subsequent General Council decision allowing the export of medicines produced under a compulsory license (outlined in Paragraph 6), form the international legal grounds for compulsory licensing for medicines.

The chairman's statement accompanying the General Council decision (concerning Paragraph 6 of the Doha Declaration) underscores that these provisions are not in any way intended for industrial or commercial objectives, and if used, it is expected that they would be aimed solely at protecting public health. Article 31 and the Doha Declaration suggest that compulsory licensing represents a measure of last resort, intended primarily for public health and humanitarian emergencies such as pandemics, and to be used only after all other options for negotiating pricing and supply have been exhausted. It is unclear how the policy would actually achieve both "sustainability of [a safe and effective] supply" and "affordability" in relation to a public health or national emergency.

Chamber Recommendation: Overall, it is difficult to see how the IP Policy provides real-world incentives or will make it easier to invest, innovate, and create new products and technologies in South Africa, and the Chamber encourages the South African government to only utilize its flexibilities only as a measure of absolute last resort.

Substantive Search and Examination

The Chamber welcomes the IP Policy's proposal to move toward a Substantive Search and Examination ("SSE") system and believes the introduction of an SSE system will help increase the quality of patents granted and create greater certainty for the patentee and third parties alike. Additionally, the Chamber supports the Companies and IP Commission's ("CIPC") interest in working with "highly efficient" global patent offices, such as the U.K. and Singapore. The Chamber believes that through coordination, work sharing, and the adoption of best practices with these offices, South Africa will move toward a high-quality, robust patent system under the SSE framework.

However, while broadly supporting the introduction of SSE, the Chamber re-emphasizes that the use of SSE in lieu of a depository system could result in an examination backlog. South Africa should consider the lessons learned from the Brazilian government's move to an SSE system. Technological and resource restraints in Brazil created an estimated 10-year patent examination backlog since the government implemented the SSE framework. As such, the Chamber recommends that the South African government introduce mechanisms to protect against undue delays in examination, including patent term restoration provisions to account for the time lost during the patent examination process. The Chamber stands ready to work with the South African government to offer support, as needed, toward implementing an efficient and robust patent examination process through the SSE model.

Patent Opposition

Section 7.1.3 of the IP Policy sets out a high-level desire to allow for third-party opposition procedures as a cheaper alternative to revocation hearings. It provides for multiple layers of administrative patent opposition, both pre- and post-grant. In the proposed system, at no time from the grant of a patent through its expiration would either an innovative or a generic producer have a reasonable degree of legal certainty regarding the likely patent life applicable to any given product. It is difficult to ascertain whether introducing third-party opposition will be beneficial to the South African patent system without further details on how such a proposal would be implemented.

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

<u>Copyrights and related rights</u>

Index Stat: South Africa 36th out of 55 economies on the copyrights, related rights, and limitations Index category.

Scope and Limitations; Copyright Act Amendments

As discussed in previous editions of the Chamber's Special 301 and in the Index, South Africa has over the past decade been engaged in reforming its copyright framework with draft amendments considered for both the Copyright Act and Performers' Protection Act. In 2019, a final bill was approved by both the National Assembly and the National Council of Provinces and sent to President Ramaphosa for his assent. However, the President refused to sign the draft law, citing its potential unconstitutionality, and sent it back to the National Assembly for further review.

In 2021 this draft bill was formally rescinded by the National Assembly and the legislative process started anew. A fresh set of stakeholder consultations were held in 2021 and 2022 by the Department of Trade, Industry and Competition ("DTI") and a new draft law was passed by the National Assembly in 2022. In 2023 there were continued public consultations and hearings at both the provincial level and in the National Assembly with the DTI publishing a "Responses to public submissions to the Select Committee on Trade and Industry Economic Development, Small Business Development, Tourism, Employment and Labour: On the Remitted Bills" in April 2023. At the time of research, no finalized piece of legislation had been signed into law by the President.

As the Chamber's Special 301 has detailed since the first draft amendments were published, the proposed legislation has always suffered from several serious deficiencies. On the one hand, South African policymakers correctly identified the need for modernizing the existing copyright laws; this remains as true today as in 2015 when the efforts began. Just as for the rest of the world the ICT and internet revolutions are fundamentally changing how South Africans interact socially and economically. In virtually all sectors and industries and businesses economic interaction is today shaped by digital and mobile technologies. Platforms and business models that did not exist a generation ago have been enabled by the advent of digital technologies. These technologies have transformed traditional retailing and bricks and mortars stores through the ability to use ICT and internet-based platforms and technologies to better understand markets, consumers, and the world in which they operate.

Having an effective, modern copyright regime that encourages innovation and creativity is critical to make the most of the socio-economic opportunities that these deep structural changes to human behavior offer. Given the size and breadth of the creative sector in South Africa, with the right IP-based incentives in place the copyright-industries could become an even more powerful source of economic growth and development. Unfortunately, the draft amendments do not fundamentally address the current shortcomings in South Africa's copyright regime. Instead, they add more uncertainty and potential difficulties for rightsholders.

Most notably, the draft amendments have been consistent in their aim to introduce a new, more expansive system of exceptions and limitations to copyright. For many years, there has been a lack of clarity in South Africa on what constitutes infringement of copyright and

what is fair reproduction and use, with no relevant full definition in the current Copyright Act and only limited case law. All the draft copyright amendments have expanded the current exceptions regime.

The latest drafts have introduced a new general doctrine of "fair use" exceptions to all copyrighted work as well as several remarkably broad statutory exceptions and limitations, particularly for educational use. Exceptions and limitations to copyright should be considered against the three-step test embodied in the Berne Convention and the WTO TRIPS Agreement. Yet as noted by the Chamber's Special 301 and its Index throughout the review of the draft law, it was always unclear how the new exceptions and proposed system of fair use would work in practice without negating the exclusive rights of copyright owners and imperil the legitimate markets for creative works.

Similarly, although the proposed amendments would introduce protection for DRM and TPMs into the Copyright Act (currently legal provisions only exist in the Electronic Communications and Transactions Act), these provisions are undermined by the broad limitations and exceptions regime. Overall, it remains the case today that the proposed amendments do little in the way of fundamentally strengthening rightsholders' ability to more effectively enforce their rights or address the growing issue of online piracy.

Of note is that the draft legislation still does not include additional enforcement measures such as the disabling of access through an injunctive style relief program. The last decade has seen a sharp increase in the number of economies that are using judicial or administrative mechanisms to effectively disable access to infringing content. Today EU Member States, the UK, India, Singapore, Canada, and a host of other economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing so-called 'dynamic' injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that re-enters the public domain by simply being moved to a different access point online.

Commercialization of IP assets and market access

Performers' Protection Amendment Bill

Packaged alongside the Copyright Reform Act is the Performers' Protection Amendment Bill ("PPAB"), which would fundamentally change the way the creative industries can negotiate contracts in South Africa. Unfortunately, the PPAB misses the mark by fixing terms of assignment for music and literary works at 25 years (from the current 50 years) as well as giving the government the power to set royalty rates, approve language on the transfer or use of rights, and mandate the forms of payment to performers. The creative industries, however, are by their nature unpredictable —one-off projects between any number of people are common, and revenues for such projects are never guaranteed.

Take, for example, a hit song and music video made in South Africa. A record label invests money to convene a famous singer, an instrumental band, and background singers—not to mention hundreds of dancers to make the music video. Under South Africa's current contracting laws, a copyright holder (in this case the record label) has permission from these participants to distribute the finished song and video for 50 years. But where major artists have a long-term contract with a record label and are paid in royalties over time, many bands or backup dancers do not. Instead, these other parts of the talent pool are paid in lump sums, not royalties. This arrangement not only enables the project-based ethos of the creative industries, but it also often supports these workers' economic interests and creative freedom. Under the proposed PPAB, however, a record label's "permission period" would be slashed by half to 25 years — forcing the sign-off of every participant that was in the studio or on set for any new exploitation of a work. Worse still, the PPAB removes the ability for lump sum payments, establishing long-term royalty schemes for every participant in the project. Royalty schemes, however, are dependent on revenues and earnings. Projects that are not commercially successful would crimp the earning power of South African workers in the creative industries. These changes would severely hinder the creative industries' ability to convene — and fairly pay — the talented workers it supports every day. The Chamber asks the U.S. government to continue its consultations with the government of South Africa — ensuring that the final PPA bill respects global best practices for contracting norms.

Market Access & Localization

For many years, the South African government has focused on developing its domestic economy through a range of general and sector-specific localization policies. Since 2011, for instance, the government has enforced local content rules for the public procurement of goods as varied as buses, set-top boxes, clothing, and even furniture. Such requirements can range from 10% to 100%, depending on the industry.

For years, there has been growing emphasis on localization and local content requirements in South Africa's economic and industrial policy. South African policy heavily emphasized requiring foreign companies to manufacture goods in-country or transfer its technology to local companies. One recent example of this would be a government white paper released in fall 2020 on the "Audiovisual Industry Strategy." To fulfill its goal of facilitating "access to a wide range of entertainment, information and educational services", the government has called for the establishment of income thresholds to exempt local broadcasters from seeking a license for select audiovisual content. The Strategy also sketches out the enforcement of the government's "Cultural Toolkit," which would mandate local content, language, and must-carry requirements for sports broadcasts deemed "in the national interest." The Strategy also seems to contemplate the expansion of "public interest" declarations for other types of content, as well as the use of competition authorities to fight "market concentration and media plurality." Finally, the paper notes enforcement challenges in South Africa — particularly signal piracy and the circumvention of technological protection

measures (“TPMs”) — and recommends convening inter-ministerial task force to study the issue. The Chamber looks forward to engaging with the government of South Africa on these critical issues.

In the past twenty years, the creative industries have — by harnessing digital tools — leveraged their IP to make content more diverse, cheap, and accessible than ever. In that vein, the Chamber believes that the Audiovisual Strategy as outlined may adversely affect the creative industries alongside ongoing legal uncertainty in South Africa’s copyright environment. More broadly, conditioning market access or public procurement on local partnering requirements — and the sharing or divulging of proprietary technologies with local partners — presents a significant barrier to trade and an impediment to investment.

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