

**By electronic submission:**

Mr. Daniel Lee  
Assistant U.S. Trade Representative for Innovation and Intellectual Property (Acting)  
Office of the U.S. Trade Representative  
Washington, D.C.



**2021 SPECIAL 301 SUBMISSION**

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

January 28, 2021

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

Re: Docket Number USTR-2020-0041; *Request for Comments and Notice of a Public Hearing for the 2021 Special 301 Review*

Dear Mr. Lee:

The U.S. Chamber of Commerce is pleased to submit the attached comments for the Office of the U.S. Trade Representative's *Request for Comments and Notice of a Public Hearing for the 2021 Special 301 Review*.

The Special 301 Review shines a much-needed spotlight on inadequate IP protection and enforcement globally. 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



Myron Brilliant  
Head of International Affairs  
U.S. Chamber of Commerce

## Table of Contents

<b>Foreword</b>	<b>Page 1</b>
-----------------	---------------

*from the U.S. Chamber's David Hirschmann & Myron Brilliant*

<b>Section A: Measuring IP &amp; Access</b>	<b>Page 3</b>
---	---------------

- The Chamber *International IP Index*
- “Fair Value for Innovation”, The 2019 Chamber *Innovation & Creativity Access Barometer*

<b>Section B: Global Trends</b>	<b>Page 5</b>
---------------------------------	---------------

- The International IP Landscape and the U.S. Government
- The International IP Landscape across Strategic Markets
  - Bangladesh
  - Taiwan
  - Eastern Europe
  - United Arab Emirates & Israel
  - Vietnam
  - Turkey
  - China
  - Republic of Korea
- The International IP Landscape in Trade
  - U.S. FTAs
  - Non-U.S. FTAs: RCEP & AFCFTA
  - USMCA Implementation
- The International IP Landscape in Multilateral Organizations
  - Ongoing Challenges and Opportunities at UN Agencies
  - The Global Pandemic and Compulsory Licensing
  - Misuse of Competition Law in International Fora
- The International IP Landscape in Enforcement
  - Transshipment and Small Parcels
  - Counterfeit Goods Online
  - The Online Grey Market
  - Piracy Devices and Copyright Enforcement

**Section C: Developed Market Profiles**

**Page 24**

- Australia
- Canada
- Chile
- European Union
- Japan
- Republic of Korea
- Switzerland

**Section D: China**

**Page 57**

**Section E: Developing Market Profiles**

**Page 94**

- Argentina
- Brazil
- Colombia
- India
- Indonesia
- Mexico
- Russia
- Saudi Arabia
- South Africa

## Foreword

*from the U.S. Chamber's David Hirschmann & Myron Brilliant*

The American private sector plays a critical role in the unprecedented global effort to create and distribute vaccines and respond to the public health and economic fallout of the COVID-19 pandemic. As of December 2020, for example, data from the World Health Organization showed more than 50 vaccine candidates in clinical research and 163 more in the preclinical stage, with several vaccines already granted regulatory approval in various markets.<sup>i</sup> Building on decades of investment in dedicated research & development—and leveraging collaboration among transnational R&D teams across research laboratories and enterprises in different countries—the private sector proved capable of helping bring to an end the devastating impacts of this terrible disease. The global intellectual property and innovation ecosystem were put to the test—and it delivered.

The U.S. Chamber of Commerce is the world's largest business organization, representing companies of all sizes across every sector of the economy. Our members range from the small businesses and local chambers of commerce that line the Main Streets of America to leading industry associations and corporations. We have some of these very companies to thank for the innovations, creations, and discoveries that enrich our lives—from the production and delivery of creative content to biopharmaceutical products and digital services. These companies also employ our society's most brilliant and creative minds, provide stable and high-paying jobs, and enhance America's competitiveness in the global economy. The most recent data available from the U.S. Patent and Trademark Office found that IP-intensive sectors support \$6.6 trillion of the U.S. economy (32% of GDP) and some 45 million American jobs. What's more: these jobs are accessible to Americans of varying skill levels and offer a 46% earnings premium over non-IP-intensive industries. These sectors also power U.S. trade flows: accounting for nearly 52% of merchandise exports.<sup>ii</sup>

But even though the global pandemic will someday end, the widespread economic and labor disruption of 2020 may be a harbinger of even greater changes: the so-called “Fourth Industrial Revolution” and growing impact of automation on the workforce. With this in mind, we considered how IP-intensive industries—and the jobs they create and support—are so critical to the continued success of the American economy. IP-enabled jobs also have the potential to lift up historically underserved sectors of our society. It was fitting, as this year the Chamber unveiled a multi-year plan to address systemic inequalities, in areas such as education and unemployment, facing Black Americans and other minority populations.<sup>iii</sup> As part of this “Equality of Opportunity” initiative, we underscore how good jobs can help underserved communities achieve the American Dream. IP-enabled jobs, particularly those in science,

technology, engineering, and math (or STEM), will play a major role in getting us there. STEM careers are growing--registering a 79% increase between 1990 and 2018, or 9.7 million to 17.3 million jobs. And by and large, these jobs are well-paid and stable, allowing underrepresented groups to build household wealth and share this success with their children.<sup>iv</sup> The creative content and digital sectors, for their part, also account for some of the most high-paying jobs in the U.S. economy. Industry estimates show that film and television jobs provide higher salaries than the national average. This holds true for direct jobs (\$86,049), distribution-related jobs (\$77,158), and production-related jobs (\$101, 999).<sup>v</sup> What's more, creative industry jobs are spread across the U.S.—not just Los Angeles and New York, but Atlanta, Nashville, Albuquerque, and others. Most importantly, IP-intensive industries have also shown a remarkable ability to integrate technology into their work while preserving an all-important “human touch.”

The potential of IP-enabled jobs to power socioeconomic development is also attracting attention abroad. To help foreign governments in their drive to become knowledge-based economies, the Chamber releases an annual summary and scorecard of countries' IP systems called The International IP Index (“The IP Index” or “the Index”). The Index measures key indicators of strong intellectual property protections in the following disciplines: patents, design patents, copyrights, trademarks, trade secrets, commercialization of IP assets, enforcement, systemic efficiency, and membership in and ratification of international treaties. Preliminary findings from the Index inform the Chamber's comments to the Special 301 Review. This year, we have chosen to discuss the broader IP landscape as well as the IP systems of 16 markets plus the European Union. This list includes developed markets: Australia, Canada, Chile, the E.U., Japan, South Korea, and Switzerland; China; and developing markets: Argentina, Brazil, Colombia, India, Indonesia, Mexico, Russia, Saudi Arabia, and South Africa. These markets were selected due to size, geopolitical significance, and the significance of IP issues for both U.S. industry and the global economy. Issues raised in Market Reports are organized, in many cases, according to indicators used in the Index.

2020 challenged us all in series of unprecedented ways. Throughout this, we commend the work of USTR and officials across the U.S. government for their tireless efforts to promote and protect our nation's intellectual property around the world. Whether you're reading this report in an office, a basement or a bedroom, we wish to express our gratitude for your continued work on behalf of innovative U.S. industries, companies, workers, and consumers. Thank you.

## **Section A: Measuring IP and Access**

### **The 2021 Chamber International IP Index**

Now in its 9th edition, the Chamber’s International IP Index creates a template for markets large and small to leverage IP protection and become 21st century, knowledge-based economies. It does this by mapping the IP ecosystem in 53 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.<sup>vi</sup>

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.<sup>vii</sup> 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. This year’s Index will include an updated statistical annex featuring 29 positive correlations. The 9th edition of the Index is expected to be released in mid-March 2021.

### **The 2019 Chamber Innovation & Creativity Access Barometer**

To complement our suite of original research (including the IP Index), in Fall 2019 the Chamber launched the Innovation and Creativity Access Barometer (“The Barometer”).<sup>viii</sup> The Barometer is a tool that measures and compares consumers’ ability to access innovative and creative works in 20 leading economies (the G20 nations plus Algeria). It consists of 16 indicators in the following four categories:

- Licensing and technology transfer
- Localization requirements
- Biopharmaceutical products
- Creative works

The first two categories are cross-sectoral in they affect most, if not all, sectors of an economy. The second two categories are sector specific, highlighting some of the most knowledge-intensive industries.

## What the Barometer Measures

The Barometer evaluates policies that limit or prevent the availability of innovative or creative products, services, or technologies in a market. These policies range from old-fashioned protectionism (including so-called localization policies and local content requirements in public procurement) to sector-specific barriers (like price controls for biopharmaceuticals and quotas for the importation, consumption, and distribution of creative works).

For instance, tariffs on medicines and medical devices remain high in emerging markets despite the promise of the GATT and WTO in lowering overall tariffs. Beyond the tariff line, market entry for various innovative and creative sectors is increasingly conditioned on a quid pro quo basis as economies use the localization of manufacturing, research and development, and/or capital investment to power their socio-economic agendas. The Barometer indicates that developed and developing markets alike are prone to abuse their pricing and regulatory power in ways that limit their citizens' access to IP-intensive products, services, and technologies. Some key findings include:

- Scoring 93% across all four categories in the Barometer, the U.S. demonstrates the greatest openness to innovative and creative products, services, and technologies.
- In addition to scoring over 10% lower than the U.S., Germany and Japan reveal key weaknesses in biopharmaceuticals masked by overall strength in non-sectoral categories.
- Other developed economies, including the United Kingdom, Italy, Australia, France, and Canada, see their cross-sectoral strength seriously eroded by weaknesses in access to creative content and biopharmaceuticals.

Overall, there is a nearly 50% difference between the top and lower halves of sampled economies in the Barometer. Outside the U.S., developed countries perform well on localization, licensing, and tech transfer policies, but they—surprisingly—underperform in sector-specific areas. This is despite scoring well on IP protections in the Barometer's companion research product, the IP Index. Developing markets underperformed across the board on indicators that affect commercial access to innovative and creative goods and services.

Many of the policies described in the Barometer also appear to breach international treaty obligations, e.g., the General Agreement on Tariffs and Trade and the WTO Agreements on Technical Barriers to Trade, Trade-Related Aspects of Intellectual Property Rights (TRIPS), and Trade-Related Investment Measures. It is also worth noting that many of the policies identified by the Barometer also undermine the expected return on the investment made by business in these often-risky sectors—undermining the rationale for market entry in the first place.



## **Section B: Global Trends**

### **The International IP Landscape and the U.S. Government**

U.S. government leadership has been critical in promoting a global, data-driven dialogue about the importance of IP. In the global pandemic, this role has become more important than ever—particularly in holding the line on WTO TRIPS standards. The Chamber has, for many years, supported efforts to ensure that U.S. government officials have every tool at their disposal to continue this sustained engagement. We remain committed to our continued partnership and shared mission.

But as one of the world’s most innovative economies, jobs in the U.S. depend on our government’s ability to accurately measure to impact of IP-intensive industries. For many years, the U.S. Department of Commerce’s Bureau of Economic Analysis’ research methodology has been unable to study the scale of digital licensing in and between IP-intensive industries. This, therefore, underestimates their role in the U.S. economy.<sup>ix</sup> Part of this challenge is also rooted in lack of resources and staff. To address this problem, the Chamber asks our representatives in Congress to ensure that the BEA—and the critical work they do—is appropriately funded.

Similar challenges have been observed at the Patent & Trademark Office and the agency’s highly regarded IP attachés. For many years, the relatively junior diplomatic rank accorded the attachés limited their ability to meet with appropriate, senior foreign government officials. The Chamber was therefore pleased by recent news that the IP attachés in Mexico City, New Delhi, Brussels, and Beijing were appointed the diplomatic title of “counsellor.” This rank not only enables greater dialogue with foreign governments on IP, but it is also an important symbol of how IP powers the bilateral relationships with Mexico, India, the EU, and China. We are grateful to the U.S. Departments of State and Commerce for their leadership in resolving this issue.<sup>x</sup>

### **The International IP Landscape across Strategic Markets**

Broader issues of enforcement, market access, and forced localization strongly affect U.S. Chamber members’ ability to create and use their IP abroad. Below we have used market-specific examples to explain these global trends in context.

## **Illicit Trade from Bangladesh Poses a Risk to Public Health**

Bangladesh continues to be a source of counterfeit medicines in Asia—endangering patients and legitimate commerce alike. This problem has particularly affected the market in India, which has been overrun with illegally smuggled (Afanix 40 and Crizoncent) and counterfeit medicines (osimertinib, ibrutinib, and crizotinib). According to a Times of India report in November 2019, oncologists estimate that some 12% of total anti-cancer capsules and tablets prescribed in India are fake.<sup>xi</sup>

Legally, Bangladesh can produce certain patent-protected medicines for consumption in the country under a WTO “Least Developed Country” waiver (LDC). But the sale of these medicines outside Bangladesh is not allowed by the LDC waiver. Nevertheless, the grey market for illicit medicines between India and Bangladesh has grown to \$41 million in 2019 (Rs 300 crore). One major reason for this is the rugged, porous, 566-mile-long border between the country and the Indian state of West Bengal. A 2020 report in the Hindustan Times found that—alongside illicit pharmaceuticals—counterfeit currency, narcotics (such as methamphetamine-derived “Yaba tablets”), firearms, and high-value cattle are among the flood of goods smuggled across the border.<sup>xii</sup> Online, Bangladeshi counterfeiters heavily promote their fake products to patients and doctors in India through platforms like IndiaMart and WhatsApp.<sup>xiii</sup>

The challenge of counterfeit Bangladeshi pharmaceuticals can be traced to violations of law, resource challenges, and the need for greater partnership on both sides of the border. As recently as July 2020, Indian and Bangladeshi border agencies shared concerns that the other side was not doing enough to halt smuggling.<sup>xiv</sup> The Chamber urges the U.S. government to encourage intensive training, strategic deployment of resources, and greater partnership between Indian and Bangladeshi authorities. In addition, authorities should take greater action against websites selling illicit medicines and local distributors supporting their spread.

## **The Continued Challenges of Taiwan’s Piracy Ecosystem**

Taiwan continues to characterize enforcement challenges in the Asia-Pacific region. In March 2020 local authorities reported successful actions against 8maple.ru, a site that was receiving 32 million visits and earning \$140,000 per month. But despite the take-down of 8maple.ru and its seven mirror sites, the arrest of two primary operators, and the seizure of \$2 million in cash and assets, Taiwan-based servers continue to host some of Asia’s most popular websites for infringing content.<sup>xv</sup> Some of these are familiar names, including Dyt8.net and Dy2018.com and the .tw domain for Sci-Hub. Others, like Gimyvod.com,

are new entrants. Since the takedown of 8maple.ru, Gimyvod.com--offering illicit Chinese language content--has grown to log 39.8 million monthly visits (from 8 million unique visitors) according to August 2020 SimilarWeb data.<sup>xvi</sup>

Despite helpful amendments in 2019 that criminalized the manufacture and import of piracy devices, Taiwan still does not allow for no-fault injunctions to order ISPs to disable access to infringing sites nor measures against unauthorized camcording in a movie theater. Given the Asia-Pacific region's leadership in online enforcement, the Chamber is concerned that ongoing gaps in law could jeopardize anti-piracy efforts in this strategic region. We request that the U.S. government continue its sustained engagement on this persistent problem.

### **The Piracy Ecosystem of Eastern Europe and Cybersecurity Risks**

Eastern European countries like Ukraine, Russia, and others remain the venue of choice for hosting servers and sites that illegally distribute creative content. The most notorious examples might be Sci-hub.io and Libgen.rs--both hosted in Russia. For seven years, Sci-hub.io and its mirror sites have illegally downloaded and facilitated access to more than 70 million journal and academic articles. The sites' activities have not just affected 85% of toll access journals, but unsuspecting students and university personnel targeted by phishing attacks used to access the content in the first place. Given these reported incidents, the Chamber is concerned that Sci-hub.io is a growing cybersecurity risk.<sup>xvii</sup>

Other creative sectors also struggle with illegal sites operating from Russia. The audiovisual industry, for instance, reports no less than seven cyberlockers, torrents, hosting providers, and ad networks facilitating piracy from Russia. The music industry, for its part, has reported enforcement threats from nearly ten Russia-based facilitators. Together, this ecosystem supports countless illegal views per month. The Chamber also echoes rightsholder concerns about enforcement challenges in Ukraine and Poland--the latter of which accounts for nearly 1,200 piracy sites operating as if they were legitimate businesses. In their report on piracy in Poland in 2017, Deloitte found that 51 percent of Internet users on average, i.e. more than 12 million Poles, use websites offering illegal access to content.<sup>xviii</sup> Although some governments (such as Russia) have taken steps to identify and disable access to infringing sites, critical gaps have contributed to a worsening problem. The Chamber urges the U.S. government to work alongside government partners and other stakeholders to address this illegal activity.

## **Patent Enforcement and Data Protection in the Middle East**

In last year’s Special 301 comments, the Chamber underscored its concerns that the government of the United Arab Emirates was not protecting patents. Starting in 2017, industry reported that the Ministry of Health’s Decree 404 would facilitate the denial of marketing approval for copy products that infringe on UAE or Gulf Cooperation Council (GCC) patents. In September 2020, the UAE government issued Decree 321 to address this problem by providing eight years of regulatory data protection. The decree also provides mechanisms for patent holders to enforce their rights and resolve disputes. However, we note a troubling exemption to these requirements (Article 5)—creating, in effect, a compulsory license-like precedent. While the provision notes that it would apply in only “certain exceptional cases and for the overall general health of the community”, no such exception is anticipated in the TRIPS Agreement. Implementation of this provision, then, may have the unfortunate effect of bringing the UAE out of step with its international obligations. Overall, however, the Chamber welcomes the actions taken to date by the UAE government and we look forward to working with them as they implement these new measures.<sup>xix</sup>

Relatedly, Israel enacted legislation affording limited RDP to small molecule drugs, but it fails to provide such protection for biologics. Israel established an inter-governmental committee in 2018 to consider providing RDP for biologics, although the process has not yet yielded a policy recommendation for providing adequate protection. We urge Israel to complete the regulatory impact assessment process and provide a period of RDP for biologic drugs that reflects the highest international standards.

## **Digital Market Access Challenges in Vietnam**

Of all governments mandating content quotas in the digital space, none has drafted measures as extensive as that of Vietnam—a growing regional market for rightsholders. The country has long maintained burdensome screen and broadcast quotas (limits on foreign content during all broadcast time, with a blanket ban during prime time, for instance). But in August 2018, the Ministry of Information and Communications called for a 30% digital content quota and greater censorship through draft amendments to Vietnam’s Decree 06. The amendments also established a licensing scheme that would require a local presence for foreign companies and forced joint ventures with local companies. These restrictions, if implemented, could severely harm investment in Vietnam’s audiovisual sector and worsen its existing piracy issues. Although we understand the government of Vietnam redrafted the Decree 06 amendments in fall 2020 to make some concessions relating to the proposed content quota, the licensing proposal and uncertainty around censorship requirements continue to concern rightsholders. In addition, we note that

Decree 06 has been packaged alongside other policies affecting digital platforms, including a wide-reaching Cybersecurity Law. Given this challenge, we request that the U.S. government continue its consultations with the government of Vietnam to adopt a light-touch regulatory framework for digital content and service providers in line with global best practices.

### **Forced localization of manufacturing in Turkey**

Turkey is notable for the scope of its localization requirements for the pharmaceutical sector. In a public move to promote Turkish industry and manufacturing, the government removed foreign medicines from its reimbursement list (some 119 products from 2017-2018) and has used domestic manufacturing requirements to enforce a de facto ban on many imported medicines. These issues forced the European Union to file a WTO dispute in April 2019 regarding Turkey's TRIPS and national treatment obligations.<sup>xx</sup> Larger structural and transparency problems persist within the reimbursement program itself—particularly in the way the country's Health Ministry has adjusted Euro/Turkish Lira exchange rates to artificially secure discounts on innovative medicines. Under the country's Pricing Decree, foreign pharmaceuticals were only reimbursed at 70% of the sticker price in 2018. In 2019 the rate was again changed from 70% to 60%. Today, industry reports that significantly lower exchange rates have further reduced U.S. biopharmaceutical companies' chance to receive a fair value for their innovative products in Turkey. The Chamber asks the U.S. government to engage in consultations to quickly resolve the many challenges brewing in this strategic market.

### **Competition Policy in the Republic of Korea**

Broader issues related to the use of competition law to curtail IP rights strongly affect Chamber members' ability to create and use their IP abroad. In Korea, for example, the Korea Fair Trade Commission ("KFTC") has taken a dangerous approach to the regulation of patents in competition proceedings—seeking to apply its orders to patents granted by governments around the world. In doing this, KFTC has subjected several U.S. companies to unfair competition proceedings and far-reaching extraterritorial remedies. Contrary to Korea's obligations under the U.S.-Korea Free Trade Agreement ("KORUS"), KFTC has effectively shielded certain witnesses from cross-examination and refused to provide a U.S. company with needed access to information in its case file--undermining the ability of U.S. companies to defend themselves. As USTR recognized in the 2020 National Trade Estimate report, Korea's proposed amendments to the Monopoly Regulation and Fair Trade Act ("MRFTA") do not

appear to meaningfully address U.S. concerns.<sup>xxi</sup> The Chamber notes that robust procedural protections would also protect U.S. IP rights from industrial policies masquerading as antitrust investigations. In that regard, the Chamber appreciates the U.S. government’s continued efforts to raise concerns about inadequate and unfair KFTC hearing procedures—noting that USTR has recently called for formal consultations on the issue. At the end of last year, the KFTC announced additional procedural reforms, similar to those used in the European Union, to address some of these concerns. We applaud these important steps. Going forward it will be important to monitor implementation to ensure that companies are able to mount a proper defense to respond to competition complaints brought by the KFTC.

### **Data Mercantilism in China**

National policies on data localization and cross-border data transfers are--alongside standards of IP protection and enforcement--important determinants of the ability of economies to create, innovate, and generate new intellectual property. They also are important measures of the openness and fairness of those markets to non-nationals who rely on IP in their commercial operations. Likewise, data-related trade barriers also threaten other IP priorities--from protecting brands, to investigating IP infringement and conducting comprehensive prior art searches. The ability to track and trace infringing activities across IT networks and borders is particularly important as many infringing acts involve an online element, whether via the offer and sale of infringing articles online; the cross-border exfiltration of source code, trade secrets or other proprietary data; the circumvention of technological protection measures; or the unauthorized and unlicensed use of copyrighted software or trademarks in an online environment.

Innovation and market access-limiting data localization mandates and data transfer restrictions take many forms. Sometimes the policies expressly require IP, innovations, technology, or other data to stay in-country. Sometimes, these policies impose unreasonable conditions on sending IP, innovations, or other data abroad or prohibit such transfers outright. Often these measures cite legitimate public policy objectives, such as privacy, cybersecurity, or prudential oversight as their underlying purpose. But not only do such measures fail to advance these purposes, they also create market access barriers.

In China, India, and, increasingly, the European Union, data localization serves as a tool of industrial policy and for supporting local champions. Even though China has made progress in advancing basic standards of IP protection and enforcement in recent years, since 2017 the government has erected “data mercantilism” barriers embodied in a complex web of discriminatory data localization mandates and data transfer restrictions. Some of these measures were designed to implement the Cybersecurity Law (CSL) which became effective that same year, while others focus heavily on concepts of indigenous

innovation and preferences for domestically generated IP and technology. Because the CSL and other measures authorize the Chinese state to prevent U.S. innovators and IP holders from transferring their information out of China (even when it belongs to them), if the information deemed to be “important”, “sensitive”, or “critical,” these measures create significant uncertainty for innovative and creative activity in China. The restrictive approach to data flows hampers the ability for U.S. innovators and IP holders to do business across borders. No doubt, together these restrictions have the unfortunate effect of creating significant market uncertainty for foreign persons who rely on IP rights in exporting their products and services to China, if not everywhere.

## **The International IP Landscape in Trade**

### **U.S. Free Trade Agreements**

Free trade agreements with the United States continue to provide a critical mechanism to strengthen IP laws abroad and protect domestic and foreign innovators. The Index shows that countries that enjoy trade agreements with the U.S. tend to have significantly more advanced IP ecosystems than others. These IP commitments, in turn, spur enhanced innovative output and private-sector investment in R&D and creative content. Such comprehensive, high-standard U.S. trade agreements have not only elevated IP standards in global markets, but encouraged global, IP-enabled trade flows. Despite their importance, in recent talks IP chapter negotiations have been relegated to so-called “Phase II” agreements. And though the Chamber welcomed greater engagement with economies like Brazil and Ecuador, comprehensive negotiations—like those underway with the U.K. or Kenya—will be key in supporting IP-intensive industries and companies.<sup>xxii xxiii xxiv xxv</sup>

Despite these benefits, challenges remain for U.S. FTAs. Of note, the KORUS Agreement, signed in 2007, is widely regarded as having one of the most effective IP chapters of all the trade agreements signed in the last two decades. Yet, Korea still ranks behind twelve other global economies in the 2020 Index. Similarly, as noted below, the final USMCA omitted key provisions which would have enabled a 21st century regime in Canada and Mexico. The Chamber believes that future U.S. trade agreements must build upon the areas where past agreements have fallen short in order to maximize the benefits that robust IP systems create.<sup>xxvi</sup>

## **Non-U.S. FTAs: RCEP & AFCFTA**

This year also yielded progress in FTAs negotiated without the involvement of the U.S., including the Regional Comprehensive Economic Partnership (RCEP) and the African Continental Free Trade Agreement (AFCFTA). Despite their differences—be it appropriate U.S. involvement, scope, and size—these agreements are large enough to guide views on intellectual property policies in their respective regions.

In November 2020, a coalition of countries, including Australia, Brunei, Cambodia, China, Indonesia, Japan, Laos, Malaysia, Myanmar, New Zealand, the Philippines, Singapore, South Korea, Thailand, and Vietnam announced a signing of the aforementioned RCEP--reducing tariff lines for some sectors. But in more complex areas of economic integration and convergence, RCEP represents a missed opportunity. This is most apparent in the IP chapter, where, instead of encouraging all signatories to take uniform IP commitments, a patchwork approach is taken. RCEP signatories may reserve the right to impose varying “TRIPS flexibilities” (Article 11.8.1(a)), while best practices for IP administration, such as a post-grant patent opposition system, are ignored. Instead, signatories may enact time-consuming and burdensome pre-grant patent opposition processes (Article 11.8.2(c)(i)). Finally, the RCEP IP chapter includes reference to copyright exceptions and limitations that do not comport with international best practice and commitments such as the Berne Convention and its three-step test (Articles 11.8.3 and 11.8.4). Despite welcomed steps to reduce market access barriers, such “shortcomings” compelled the U.S. Chamber to discourage the U.S. from engaging with RCEP. Nevertheless, this experience reinforces the importance of U.S. leadership in comprehensive free trade agreements.<sup>xxvii</sup>

Meanwhile, negotiations continued for the AFCFTA’s Phase II chapters on IP, competition, and investment. The Chamber applauds the African Union’s aim to increase economic integration among Africa’s 50+ economies and appreciates the U.S. government’s commitment to supporting this process as appropriate. Chamber members recognize the importance of foreign investment to stimulate socioeconomic growth and workforce development on the African continent. The AFCFTA can be the catalyst for this change, but the right rules must be in place. We urge the U.S. government to continue its exchange of technical advisors and IP best practices with the African Union. In addition, policymakers should consider devoting more resources to engaging with this strategic market, such as the installation of an Africa-based IP attaché.<sup>xxviii</sup>



## USMCA Implementation

The final United States-Mexico-Canada Agreement (USMCA) represented a significant missed opportunity to elevate IP standards with two of the largest U.S. trading partners. The IP Chapter of the USMCA as signed by all three parties in 2018 was a significant improvement over NAFTA, TRIPS, and the original TPP agreement. However, in December 2019, the text of Chapter 20—which provided for 10 years of regulatory data protection—was significantly revised and important components of the original USMCA had either been removed completely or fundamentally altered. The Chamber was disappointed by the removal of these critical IP provisions, as the ones included in the final agreement no longer represent 21st century-standard life sciences IP protections.<sup>xxix</sup>

However, the USMCA did result in substantive reforms for copyrights, trade secrets, and enforcement measures in Canada and Mexico. In Canada, the term of protection for some copyrighted works was extended to 75 years through the Canada–United States–Mexico Agreement Implementation Act. Additionally, Canadian law has not historically 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.”

Furthermore, 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. Despite the shortcomings of the agreement related to life sciences protections, the Chamber believes these legislative changes will improve the environment IP rightsholders in Canada and asks the U.S. government to work with their Canadian government counterparts to ensure the provisions are effectively implemented.<sup>xxx</sup>

In Mexico, significant changes were made through amendments to the Federal Law on Copyright. Overall, the amendments strengthen the level of protection for copyrighted works in Mexico, extending this protection onto the Internet and the digital environment. Specific changes include: i) a new notification system whereby ISPs are obliged to act expeditiously and remove suspected content upon receiving a notification (articles 114 and 232); ii) robust DRM and TPM provisions outlawing the use,

manufacture, sale, importation, distribution or otherwise offering to the public circumvention devices and technologies (article 232); and iii) making illegal the use, manufacture, import or other form of distribution of satellite signal decoders (article 145). However, some of the amendments 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. However, 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. The Chamber encourages the U.S. government to work with the Mexican government on further guidance to clarify the provisions on online infringement.

Additionally, Mexico’s revised Industrial Property Law implementing the USMCA introduced a mechanism to help address the sale of counterfeit goods and infringement of trademark rights online. The law includes a provision whereby injunctive style relief can be obtained directly from the national IP office (IMPI) in respect of online violations. Specifically, article 344 sub-sections VII and VIII gives IMPI the power to “order the alleged offender or third parties to suspend, block, remove content or cease acts that constitute a violation of this Law through any virtual, digital or electronic means, known or to be known.” The U.S. Chamber believes this is a positive development, which will help offer better protection against online infringement in Mexico.

A key obstacle to these copyright advancements is the fact that the National Human Rights Commission and a minority group of senators are challenging parts of the 2020 legal reforms at Mexico’s highest court. In parallel, there have been a number of amparo trials filed in district courts against the USMCA reforms, particularly against the notice and takedown process and TPMs sanctions.

These new laws will need to be properly enforced. For decades, criminal enforcement activity in Mexico has been relatively uncoordinated and weak, hampered by structural deficiencies and insufficient resources. The 2020 legal reforms did not fully address these deficiencies. Success in a criminal case still depends on proving a “direct economic benefit” to the infringer, instead of focusing on the harm caused to a rights holder by infringement. An important exception—the result of a 2020 reform—is for criminal prosecutions against the illicit camcording of motion pictures. The “direct economic benefit” for criminal cases is a difficult hurdle to overcome for a prosecutor willing to initiate a case in a system already lacking resources.

While the Chamber applauds these positive developments, we are concerned with the lack of implementation of several of the life sciences IP provisions. First, Article 20.36 of the USMCA makes clear that patents should be granted for all inventions. 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. Additionally, Article 20.50 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.” Yet Mexico’s revised Industrial Property Law, which implements the USMCA, does not contain any legal provisions relating to the existing linkage regime. While a proposal for a revised linkage regime was put forth by the Chamber of Deputies in the Fall of 2020, the proposal does not incorporate the requirements of the USMCA and would not address the deficiencies in the current system. Finally, 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.” However, 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. The Chamber is particularly concerned by the lack of implementation of these provisions given that the life sciences IP text was considerably watered-down in the final agreement. As such, we urge USTR to work with the Mexican government to ensure the existing patent-related provisions are effectively implemented and applied in Mexico.

## **The International IP Landscape in Multilateral Organizations**

### **Ongoing Challenges and Opportunities at U.N. Agencies**

Specialized agencies in the United Nations (U.N.) framework continue to play an important role in the administration of IP rights around the world. As the U.N.’s subject-matter expert, the World Intellectual Property Organization (WIPO) provides administrative and technical assistance to states who have acceded to and implemented various IP-focused treaties. The Chamber welcomes the recently confirmed Director General of WIPO, Daren Tang, and urges the U.S. Government to continue

encouraging WIPO to play a leadership role in promoting the understanding and appreciation of IPR within the U.N. system. More broadly, WIPO can also leverage this position to engage with government and non-government actors around the world.<sup>xxxix</sup>

The World Trade Organization (WTO) also plays an important role through its administration of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement. However, the Chamber remains very concerned by the actions of various special interest groups, certain countries, and other U.N. agencies grounded in the mistaken belief that IP rights are a barrier to widespread access of goods and services. For copyrights, this has manifested itself in “development agenda” goals to expand exceptions and limitations to copyright or the OECD’s Directorate for Science, Technology and Innovation position that copyright is an impediment to digital commerce. The misguided assumption that copyright protections impede development is contrary to data in the Index that found positive correlations between the strength of IP environments and important socioeconomic indicators—including the amount of creative outputs and access to online content.<sup>xxxix</sup> For patents, the Chamber notes ongoing discussions to regulate genetic resources, which could complicate efforts to develop breakthrough cell & gene therapy options. In addition, challenges continue among staff—particularly at the World Health Organization—who mistakenly assume that diminishing IP protections will lower prices for or increase access to medicines. Such actions are short-sighted and will prevent the discovery of new medicines—some of which can save money by reducing the need for the costliest health interventions (such as hospitalization). Further, the Chamber notes the important link between patient access and administrative barriers at the national level. Time-consuming patent examination or opposition processes can make it more difficult for companies to efficiently distribute their product, but many WIPO member states staunchly oppose efforts to streamline their patent examination processes in the name of national sovereignty. And where WIPO can spearhead these programs—such as through the WIPO Match program or helping member states implement existing treaty obligations—they are often thwarted by countries that could most benefit.<sup>xxxix</sup>

The most recent high-profile example of such anti-IP efforts relates to a proposal to waive WTO members’ obligations to provide for IP rights as they relate to the global pandemic. This is even though there is no evidence that IP has been a barrier to the development of therapies, vaccines and other solutions. In fact, IP and other incentives have been a prerequisite for today’s unprecedented collaboration and long-term investments made by business, upon which recently developed vaccines and therapies are based. We have provided more information on this issue in the section below, on “The Global Pandemic and Compulsory Licensing.”<sup>xxxix</sup>

The Chamber will continue to engage on these emerging issues within international organizations. In the coming weeks and months, future discussions on the promotion of innovation,

development, and access to medicines at WIPO, UNCTAD, WHO, WTO, and OECD will only find success if our U.S. delegation is appropriately staffed and prepared. It is essential that American leadership in multilateral organizations creates—and in many cases, maintains—a global environment which supports creativity, innovation, and access to new technologies through strong IP rights.

### **The Global Pandemic and Compulsory Licensing**

The global pandemic has raised concerns among policymakers that patients will be unable to access needed vaccines, treatments, and diagnostics. Already, legislative bodies in Chile, Canada, Germany, and Thailand have tabled compulsory license proposals. This is even though other options—such as working alongside industry to ensure broad access—exist. Meanwhile, other countries have also introduced emergency regulations that call for the indiscriminate use of compulsory licenses for COVID-19 products or those implemented under vague national security grounds. For instance, the Hungarian government used its compulsory licensing mechanism for remdesivir, a treatment for COVID-19, following a request by a local company. This is despite the fact that Hungary had already been procuring and using the medicine through a Joint Procurement Agreement negotiated between the European Union and the patentee. The Hungarian government did not engage with the patent holder nor indicated that this supply did not meet national needs. This action runs counter to Hungary’s commitments, as well as the European Commission’s position, to use compulsory licenses as a means of last resort and a safety net, when all other efforts to make IP available have failed.<sup>xxxv</sup> The Chamber and its members are also concerned about the Russian government’s decision to grant a compulsory license for remdesivir. Meanwhile, countries like Indonesia have also issued emergency decrees such as the Presidential Regulation No. 77/2020, to be considered for various medicines already available locally, reversing some of the positive steps (discussed later) taken by the Indonesian government to protect intellectual property.<sup>xxxvi</sup>

The Chamber also notes the introduction the aforementioned “waiver” in the WTO TRIPS Council. The proposal, first tabled by South Africa (and later supported by India and other countries) this summer, contemplates the revocation of many types of IP, including patents, copyrights, trademarks, and trade secrets, for virtually any COVID-19-related products.<sup>xxxvii</sup> In the Chamber’s view, this waiver is unnecessary and could undermine the progress made thus far in fighting the global pandemic. The private sector was able to develop, test, and manufacture multiple viable vaccines for COVID-19 in less than a year—and IP protections were key to getting us here, supporting research and development pipelines decades in the making. Vaccinating billions of people will, no doubt, be a challenge. But our society will

only be able to fight the global pandemic if we are working together. Without a system of rights, an important foundation of which is represented by the WTO TRIPS Agreement, we can have little confidence that the pipeline will be there to support an effective response to the next crisis. Further detail is set out in our Open Letter to Government leaders alongside global business associations released in summer 2020. The private sector, with its R&D capability, manufacturing scale, and logistical know-how is already partnering with governments and NGOs to ensure widespread access to needed solutions for the global pandemic. Disruptions to the legal environment now—when it’s most needed—would jeopardize efforts to stop COVID-19 and fail to address the challenges of a global response to the pandemic.<sup>xxxviii</sup>

Another international institution of relevance is the World Health Organization (WHO). The WHO’s draft 2020-2022 implementation plan for the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) proposes that the WHO engage in activities far outside its mandate that, if carried out, would harm global health and undermine intellectual property (IP) rights that the United States has long championed. Considering the important, positive decision of the U.S. administration to rejoin the WHO, we believe the U.S. should work with other international governments to reform the WHO, ensuring it avoids mission creep and that on IP matters it defers to WIPO and the WTO, which have the appropriate expertise and policy-making capacities.

### **Misuse of Competition Law in Multilateral Fora**

The Chamber also notes ongoing efforts in multilateral fora to use competition policies to inappropriately curb IP rights. For example, recent discussions and publications from the UNDP and WIPO have identified competition policies as potential leverage in promoting access to medicines.<sup>xxxix</sup>

<sup>xl</sup>Evidence of this trend is also visible at the WTO. Despite some welcome moderation by the government of Brazil, we have seen China, India, and South Africa—through submissions and statements at WTO TRIPS Council meetings—continue to advocate that the TRIPS Agreement provides broad discretion “in how they (member states) apply competition law in respect of the acquisition and exercise of IP rights.” These countries have also suggested an exchange of information on how competition policy and law could be used to curtail IP rights.<sup>xli</sup> They have also called for greater capacity building in how competition law, IP rights, and technology transfer interface in developing countries.<sup>xlii</sup>

Such a misreading of TRIPS would not only distort trade and undermine innovation, but also create an uneven playing field for innovative U.S. businesses and workers. In the face of such proposals, U.S. government interventions have been key—forcefully warning that “the misapplication of competition law is particularly concerning in IP disciplines because it runs the risk of forestalling future

innovation.” U.S. leadership in the TRIPS Council will remain crucial in holding the line on TRIPS standards and promoting an evidence-based dialogue about the importance of IP. It is important that the administration remain vigilant against efforts to impose exceptions and limitations to patent protections under inappropriately broadened competition policies. Allowing such approaches would only result in the stifling of new technologies and life-saving medicines that contribute to global well-being and economic growth.

### **The International IP Landscape in Enforcement**

The ever-changing enforcement environment strongly affects U.S. Chamber members’ ability to create, use and protect their IP both at home and abroad. The global scope of physical counterfeiting is the largest it has ever been—measured at \$509 billion dollars by the OECD in its 2019 report, “Trends in Trade in Counterfeit and Pirated Goods.”<sup>xliii</sup> Similarly, in a June 2019 report, “Impacts of Digital Piracy on the U.S. Economy”, the Chamber found that global online piracy costs the U.S. economy at least \$29.2 billion in lost revenue each year.<sup>xliv</sup> Below we have highlighted examples of priority challenges for global IP enforcement.

### **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. These shipments arrive at a U.S. Postal Service (USPS) sorting facility, are inspected and assessed for duties by U.S. Customs and Border Protection (CBP), and then enter the U.S. postal stream for delivery to U.S. consumers. To avoid detection of counterfeit goods by 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. Remote sellers may even offer refunds for seized products to attract U.S. consumers. The issue of counterfeits in express and mail shipments has continued to grow, as noted by the CBP, the World Customs Organization, and the U.S. IP Enforcement Coordinator.<sup>xlv xlvii</sup> According to CBP, 11 million maritime containers arrive at U.S. seaports each year. At land borders, another 11 million arrive by truck and 2.7 million by rail. Today, mail parcel shipments, including through express consignments, account for more than 500 million packages each year. Seizures in the small package environment made up 93% of all seizures in 2018, a 6% increase over 2017. The sheer

volume of such small shipments makes it impossible for CBP agents to vigorously screen and detect suspect shipments, and the USPS may not inspect materials shipped domestically by first-class, priority, or express mail without probable cause.<sup>xlvi</sup>

In early 2020, the Chamber was pleased to see the release of a detailed action plan for DHS and CBP to address this problem, including commitments to release an in-depth study, draft updated shipping guidelines, and undertake necessary fee adjustments. The Chamber supports the continued implementation of this plan.<sup>xlvii</sup>

Finally, we wish to note a positive global development in transshipment enforcement. In August 2020, the government of Vietnam published a new Decree (98/2020/ND-CP) to address the definition of “quality counterfeit” under Article 192 of Criminal Code. This change, which became effective on October 15, 2020, will allow for full and appropriate criminal prosecution of counterfeiters. The Chamber hopes that this positive development will be complemented by necessary capacity building and trainings for Vietnamese law enforcement and prosecutors. In addition, we hope that the government will take up deliberations on clear protections for partial designs and trademarks alongside its drive to raise IP standards in the country.

### **Counterfeit Goods Online**

As the online ecosystem continues to expand and evolve, combating IP theft has become an increased challenge. Combined with a shift in consumer purchasing habits and the explosion of e-commerce, criminals and transnational criminal organizations have adopted sophisticated strategies to peddle illegal and illicit products directly to consumers shopping online. This continues despite considerable investments of legitimate businesses in product integrity, chemical safety standards, and the trust of consumers. As a result, it has become extremely difficult for consumers to differentiate legal, authentic, safe, and trustworthy products from fake counterparts illegally manufactured by criminals. 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 have the resources and tools to combat criminals operating in the online environment.

Still, determining identities and tracking criminals is especially difficult online, as they can be highly skilled at hiding their identities and locations. The WHOIS database for website registrants—the publicly available information on who has registered an internet domain name—had long been used as a resource by law enforcement and IP rightsholders to help identify and combat criminals operating in the



online environment. Registrars and registries have shut down public access to this information to comply with the EU’s General Data Protection Regulation (GDPR) and avoid substantial fines from the EU’s data protection authorities. Unfortunately, the European Data Protection Board--the EU’s caucus of privacy regulators--has proven unwilling to provide the Internet Corporation for Assigned Names and Numbers (ICANN) and its accredited registries and registrars with pragmatic guidance that maintains access to the WHOIS database into a GDPR compliant manner. Even in the cases where criminals can be identified accurately, they may be in (or flee to) countries with inadequate enforcement systems, including jurisdictions that do not cooperate with U.S. authorities. Some countries—even developed countries such as Switzerland—lack or have inadequate laws, while others might impose impractical standards, such as numerical thresholds, that stifle enforcement efforts. Also, some countries simply lack the will to bring cases to court, sometimes for political or even questionable motivations.<sup>xlix</sup>

Industry has made significant investments to combat online crime, with rightsholders spending hundreds of millions of dollars annually on these efforts. For its part, the U.S. government has proven to be an effective and willing partner in these efforts. This year, for instance, marked the launch of “Operation Stolen Promise” by U.S. Immigration & Customs Enforcement. The timing of this initiative was also fitting, as bad actors found the global pandemic an ideal chance to peddle counterfeit goods. Homeland Security Investigations and CBP have seized nearly 1,800 shipments of mislabeled, fraudulent, unauthorized or prohibited COVID-19 test kits, treatment kits, homeopathic remedies, purported anti-viral products and personal protective equipment (PPE) and seized \$30.7 million in illicit profits. The operation also focused on COVID-19-related financial fraud and cybersecurity schemes.<sup>1</sup>

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. Another example of this collaborative approach: The U.S. Immigration and Customs Enforcement (ICE) and the National IPR Coordination Center, together with Interpol, working

together to establish the Illicit Goods and Global Health program designed to emphasize enforcement against trafficking of counterfeit and illicit goods. Similarly, an OECD taskforce continues its workstream to study and counter illicit trade--creating a strong commitment to understanding the threats illicit trade poses to our global economy and examining, through quantitative metrics, new solutions to combating the production and sale of counterfeit goods. While enforcement and prosecution remain a top priority, the deterrence and disruption of criminal enterprises also have significant value.

### **The Online Grey Market**

The greatest source of illegally diverted drugs is the internet. 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 such as a counterfeit version of the cancer drug Avastin which made its way to U.S. patients—without any active ingredient—by a Canadian company operating illegal online pharmacies.<sup>li</sup> 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.

### **Piracy Devices & Copyright Enforcement**

Online copyright enforcement remains a challenge despite greater availability, affordability, and diversity of content via legal services than ever before. And as the global pandemic has accelerated digital distribution, bad actors have become ever more adept at making “near-perfect” copies for instant and illegal distribution.<sup>lii</sup> In prior filings, the Chamber has noted its concerns regarding the growth of piracy devices (also known as Illicit Streaming Devices, or ISDs) to locate and stream or download unauthorized content from the internet. These concerns remain top of mind, as piracy devices and apps continue to facilitate unauthorized access to motion pictures and television programming (including encrypted

content), music, music videos, video games, published materials, and even karaoke. Given the ease of access to unauthorized or unlicensed content, piracy devices are frequently marketed as an alternative to the many legal content delivery options available to consumers.

Worse still, piracy devices and apps are part of an integrated and sophisticated online ecosystem--making enforcement especially challenging. And because piracy devices are also capable of other uses, retailers and distributors can only be held liable under certain fact patterns. Enforcement often requires that the app developer or distribution sites be identified and located. But unless coordinated and aggressive government actions are taken against the criminals who have invaded the online ecosystem—often generating significant illicit proceeds from their activities--the threat of piracy devices on the legitimate market for digital delivery of copyrighted content will become ever more severe. The Chamber notes developments in how the U.S. government will address the damage of unchecked piracy on American workers and exports. Earlier this year, the U.S. Copyright Office concluded a multi-year study on Section 512 of the Digital Millennium Copyright Act, with an emphasis on whether the statute was fulfilling Congressional intent.<sup>liii</sup>

We also applaud recent law on small claims, criminal measures, and other issues of importance to copyright enforcement. At the end of 2020, Congress passed important intellectual property measures, including the Protect Lawful Streaming Act, the CASE Act, and the Trademark Modernization Act of 2020. This legislation closed the “felony streaming loophole” by providing law enforcement with necessary tools to combat the large-scale theft of streamed content, allowing individual creators and small businesses a fair and efficient alternative to expensive federal litigation to resolve infringement disputes, and curbing the abuse of our trademark system by those who file fraudulent trademark applications.<sup>liv</sup>

## **Section C: Developed Market Profiles**

### **AUSTRALIA**

#### **Overview**

The Chamber is a committed stakeholder in the U.S.-Australia relationship, and we believe that securing strong IP protection will be critical to further strengthening ties between our two countries. The Chamber applauds the steps taken over the past year to strengthen its IP ecosystem through proposed measures to establish an early notification framework and benchmark the economic contributions of IP-intensive industries. While these are positive steps forward, and we hope they will become law in the coming months, innovative and creative companies continue to face challenges to adequately protecting their IP in-country. A more effective IP framework will incentivize innovation and creativity, attract foreign investment, and stimulate 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**

##### **Patentability Requirements**

Historically, there has been uncertainty around the patentability of biotechnology innovations, given the conflicting case law and rulings on the matter. While the Australian Federal Court confirmed the patentability of isolated genetic material in *D'Arcy v. Myriad Genetics* in 2014, the ruling was reversed by the Australian High Court in 2015. In the decision, the High Court found that the isolation of genetic material did not constitute an inventive step since it considered that the protected substance – the genetic material – was essentially the same information as in its natural form. This decision weakened the patentability of biotechnology and diagnostic-related inventions in a manner similar to what has taken place in the United States since the mid-2010s.

Following a period of uncertainty, the past few years has seen several important decisions taken both through new case law as well as administrative rulings by IP Australia on what constitutes patentable subject matter for biotechnology. Most notably, *Cargill Incorporated v. Dow AgroSciences LLC and Arrowhead Research Corporation* [2016], which confirmed that isolated nucleic acids are patentable as long as they have been modified. Equally important are two decisions rendered by the Australia Federal Court in the last two years. The first case, *Meat & Livestock Australia Limited v Cargill, Inc* [2018], involved a determination as to the patentability, not of isolated naturally occurring gene sequences, but of

their actual practical application and use in a given invention. The second case, *Sequenom, Inc. v Ariosa Diagnostics, Inc.* [2019], involved a similar claim as to whether the disputed patent involved an inventive step and, specifically, a ‘human action’ with economic utility as opposed to simply being a naturally occurring phenomenon. In both cases, Justice Beach ruled in favor of the patent holder and clarified the grounds for patentability of biotechnology innovations.

Following these rulings, IP Australia’s Patent Manual of Practice & Procedure, section 2.9.2.6 Nucleic Acids and Genetic Information, was updated in June 2020 to now also include reference to this new body of case law. The U.S. Chamber was encouraged by these court decisions, which should help restore predictability and certainty around the patentability of biotechnology innovations in Australia.

### **Patent Linkage and Market-Sized Damages**

Since the 2004 U.S.-Australia Free-Trade Agreement (AUSFTA) was passed, the patent linkage system derived from AUSFTA has contained several notable deficiencies. First, the system lacks an automatic stay (as provided by the Hatch-Waxman in the U.S.) and instead requires patent holders to apply for an interlocutory injunction (which is not always granted) through a court of competent jurisdiction. Further, in an attempt to balance the interests of innovators and generic producers, the Australian system added both a certification from the generic producer (Section 26B) of invalidity and/or non-infringement, and a certification from the patent holder (Section 26C) that the infringement proceedings are in good faith, have reasonable prospects of success and will be conducted without unreasonable delay. However, the potential maximum penalties for providing false or misleading information are disproportionately higher for a 26C Certificate (patent holder) than for a 26B Certificate (generic producer). Finally, patent holders are not made aware consistently and on a timely basis of potentially infringing follow-on products in advance of their approval by Australian drug regulators in the Therapeutic Goods Administration (TGA) and listing on the Pharmaceutical Benefits Scheme (PBS). The most effective patent linkage mechanisms include a window of notice prior to the generic’s entry into the market. Over the last two years, the Australian government took steps to identify opportunities to address the issues around patent notification.

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 exposure draft of this legislation is yet to be released, however it is projected 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. Additionally, beginning in January 2021, the TGA will publish a description of major innovative medicines applications that are under evaluation by the TGA. The U.S. Chamber applauds these 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. The U.S. Chamber recommends that the U.S. government work closely with their Australian government counterparts to ensure the early notification system is effectively implemented in order to better protect IP rightsholders.

Finally, in addition to the uneven penalty structure and the lack of automatic stay, commercial pressures further undermine legal certainty. Specifically, because the PBS imposes automatic and irreversible price cuts on medicines as soon as competing versions enter the market, there seems to be a strong incentive for generic companies to launch at risk, and innovator companies must pursue preliminary injunctions in order to resolve patent disputes. At the same time, since 2012, Australia's Department of Health has pursued market-sized damages (on top of those sought by the generic company) aimed at compensating for a delay in the PBS price reduction that would have been applied to a patented medicine during the period of a provisional enforcement measure. However, there is no corresponding mechanism for the government to compensate innovators for the aforementioned losses if an infringing product is launched prematurely.

The continued application of market-sized damages appears to be inconsistent with the Australia-U.S. Free Trade Agreement (AUSFTA). Article 17.10.4(a) of the AUSFTA states that Australia is obligated to "provide for the patent owner to be notified" of the identity of a third person requesting marketing approval during the term of a patent and to "provide measures in its marketing approval process to prevent" third persons from marketing a product during the term of the patent without consent of the patent owner. The policy sends a troubling signal that IP protection can be undermined in an effort to drive down domestic prescription drug prices.<sup>lv</sup>

However, in 2020, there was a potential precedent-setting decision in the long-running case *Commonwealth of Australia v Sanofi (No 5)* [2020] FCA 543. The case revolves around the actual ability of the Australian Government to claim damages and is the first time a court has made a judgment as opposed to the relevant parties reaching an agreement through a private settlement. In the April 2020 verdict, the court ruled against the Government, dismissing its claims for damages. Local legal analysis suggests that the judgment sets a high bar for future claims as although the court recognized the legitimacy of the claim, a successful claim will have to prove a direct link between the granted

preliminary injunction and listing on the PBS. The Chamber appreciates USTR's ongoing engagement on market-sized damages issues with the Australian government since the onset of the policy in 2012. We encourage the U.S. government to continue to work with its Australian government counterparts to ensure that biopharmaceutical innovators are not subject to future market-sized damages claims in light of this precedent-setting court decision.

Taken together, addressing the shortcomings of Australia's early notification and resolution framework will help bolster Australia's innovative industry, attract greater biopharmaceutical foreign direct investment, and support Australia's economic and global competitiveness. An appropriate location for the resolution of the above matters is the Medicines Working Group, which was created by the Australia – U.S. FTA but has not met since 2008. The Medicines Working Group is a forum for representatives of both governments' health agencies for the discussion of medicines-related issues that may intersect with the intent of the FTA. The Chamber believes the importance of the above issues, and the unique position of medicine innovation during a global pandemic creates opportune timing for the reformation of the Medicines Working Group and the addition of industry participation to ensure resolutions achieve their intended outcomes.

### **Intellectual Property Laws Amendment Bill**

On February 26, 2020, the Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill received Royal Assent. The Bill contains provisions that are of concern to IP-intensive industries operating in Australia. The Bill currently replaces the 'reasonable requirements of the public' test with a 'public interest' test when the Federal Court considers the application for a compulsory license. As part of the justification for the replacing the 'reasonable requirements of the public' test, the Explanatory Memorandum to the Bill notes that the test "is not used elsewhere in Australian legislation, and there is limited case law to provide guidance on its interpretation, causing uncertainty." The Bill subsequently sets out three factors for the court to consider regarding the new 'public interest' test. However, the Bill states that it can take into account "any other matters the court considers relevant." The open-ended criteria for meeting the test of public interest stands contrary to described objective of limiting uncertainty and will, in effect, create greater ambiguity about circumstances that may meet the 'public interest' test.<sup>lvi</sup>

Additionally, Schedule 2 on the Crown use of patents will amend the Patent Act under Section 160A to expand the definition of Crown purposes to include services funded by the Commonwealth, State, and/or Territory governments. The expansion of Crown purposes may further expand the grounds

on which a compulsory license can be issued. This undermines the certainty that effective patent systems provide and upon which every innovator in the market depends. By introducing an undue element of political discretion into the patent system, both the Schedule 4 and Schedule 2 provisions may suppress Australia’s innovative potential and weaken the IP incentive that enables high-risk research and development into new, innovative technologies and medicines.<sup>lvii</sup> For these reasons, the Chamber encourages the U.S. government to work with their Australian government counterparts to amend the provisions on compulsory licensing and Crown purpose in order to preserve Australia’s existing robust and effective IP framework.

## **Copyrights and related rights**

### **Copyright Amendment (Online Infringement) Act**

In 2018, the government continued to use Section 115a of the Copyright Amendment (Online Infringement) Act 2015, which allows courts to require Internet Service Providers (ISPs) to disable access to foreign-hosted sites (or “online locations”) whose primary purpose is to infringe copyright. In a landmark ruling in *Roadshow Films Pty Limited v Telstra Corporation Limited*, the federal court granted an injunction to disable access to online locations that, unlike websites containing illegal content, provided access to illegal streaming of hundreds of paid TV channels accessible through set-top boxes. Yet there is still room for improvement. Evidence submitted by the Australian Film and TV Bodies in 2019 in response to a government-initiated public consultation process on the overall effectiveness of Section 115a shows that the average timeframe between filing date and judgement is 225 days, significantly longer compared to the timeframe of the United Kingdom (77 days) and Portugal (27 days). The Chamber hopes the U.S. government will continue to work with its Australian counterparts to ensure that Australia continues to strengthen and streamline the copyright framework in order to become a global leader in protecting copyrighted content online.

## **Trade secrets and related rights**

### **Regulatory Data Protection**

Current Australian law allows only five years of regulatory data protection for biologic medicines—drugs made up of living matter that are incredibly expensive and risky to produce. The current five-year standard represents an exclusivity level far below the U.S. standard of 12 years and is a significant roadblock for innovative companies that are stimulating research and development (R&D) in



treatments for some of the riskiest and most complex issues facing human health. Additionally, 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. As such, the Chamber suggests that enhanced data exclusivity protection for all medicines would be in Australia's interest and 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**

### **Reimbursement and Listing Uncertainty**

Historically, innovative companies have encountered a complex regulatory framework for marketing authorization in Australia. As a result, the Chamber welcomed the October 2020 announcement to create a New Medicines Funding Guarantee allocating \$2.8 billion over the next four years to fund new and amended listings. This funding guarantee should help facilitate more timely listing of medicines recommended by the Pharmaceutical Benefits Advisory Committee (PBAC). Additionally, the Australian Government committed to eliminating the equal "offset" policy that mandated every dollar spent on new medicines must be counterbalanced by an equivalent offset saving, determined in advance, from within the health budget. The Chamber believes that pricing and reimbursement systems that focus strongly on cost containment come at the expense of access to the newest 21st century medicines. The Chamber encourages the U.S. government to collaborate with the Australian government to ensure that these positive changes to the Australian listing system are effectively implemented in order to ensure faster access to medicines in Australia.

### **Local Content Quotas**

Under the Broadcasting Services Bill 1992 and derived regulations (Australian Content Standard), a majority of programming on broadcast television must be Australian in origin. Specifically, 55% of all content broadcast between the hours of 6 a.m. and midnight must be local. There are also detailed specifications and requirements on local programming for different types of content, including children's television. Radio broadcasting is also subject to quotas. The Commercial Radio Broadcast Code of Practice stipulates minimum broadcasting quotas of Australian content. These quotas range from 5% to 25% depending on the format of service and style of broadcast. There are also certain local content requirements focusing on local news broadcasting, community service announcements, and local weather.

At the onset of the global pandemic, the Australian Communications Minister announced that the government would suspend local content quotas for documentary, drama, and children’s programming. The Minister suspended the local content obligations in an attempt to alleviate the economic implications of the COVID-19 crisis. However, the government did not waive the requirement that 55% of all content be Australian. Additionally, in November, the Communications Minister proposed that the government should create new legislation requiring that streaming services invest a percentage of their revenue from the market on local content. As consumers increasingly rely on entertainment as a welcome distraction from the ongoing pandemic, the Chamber believes it is all the more important that the Australian government limit the use of local content requirements for creative works from around the world in order for content to be more readily, legally available to Australian consumers.

## **Enforcement**

### **Ex officio authority**

The Australian Border Force (ABF) does not have the authority to take ex officio action against goods suspected of infringing a copyright or a trademark—despite provisions in the AUSFTA (Art. 17.11.22) and the Comprehensive and Progressive Amendment of Trans-Pacific Partnership (CPTPP) which clearly require that Australian border officials take ex officio action against suspected infringing goods, including goods in-transit. CPTPP Article 18.76(5) states: “Each Party shall provide that its competent authorities may initiate border measures ex officio with respect to goods under customs control that are: (a) imported; (b) destined for export; or (c) In-transit.” In late 2018, Australia introduced and passed implementing legislation amending its customs law, the Customs Amendment (Comprehensive and Progressive Agreement for Trans-Pacific Partnership Implementation) Bill 2018. This law does not include any provisions relating to ex officio powers or goods in transit. At the time of research, neither the ABF nor Australia’s IP office, IP Australia, had provided any public indication that the Australian customs regime had changed. In the current iteration of the fact sheet “Protecting Intellectual Property” available on its website, the ABF states that it “can only seize goods suspected of infringing intellectual property rights if there is a valid Notice [of Objection] in place.” The Chamber encourages the U.S. government to highlight the importance of ex officio authority in its ongoing dialogue with the Australian government.

## **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 as a result of CETA.<sup>lviii</sup>

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.<sup>lix</sup>

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)**

Canada's IP environment could also improve significantly with the proper implementation of 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 has now 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 US 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. 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. In order to fulfill the fundamental purpose of restoring patent term lost due to marketing approval delays, the PTR term must confer the full extent or rights contained in the underlying 20-year patent term. Moreover, there is not even 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. The Chamber encourages the U.S. government to work with the Canadian government to implement a PTR system that is consistent with other frameworks implemented by developed economies.

## **Copyrights and related rights**

### **Copyright Term**

As a result of the Canada-United States-Mexican Agreement Implementation Act, the term of protection for sound recordings has been extended to 75 years. However, Canada has not yet extended term of protection for all copyrighted works, contrary to its obligations under USMCA Art 20.62 (a). The Copyright Act should be amended posthaste to extend term of protection beyond the current 50 years for Canada to meet its USMCA obligations and to provide protection for all forms of creative works in line with global norms. Further, the implementation legislation did not amend the term of protection for all copyrighted works. Instead, Canada relied on a 30-month delay to implement this obligation from the date of entry into force of the USMCA. The Chamber notes our concern with this transition period, as well as the threat of registration requirements on the additional 20-year period, introducing amendments related to reversion and/or termination rights, and other measures. We strongly believe that the passage of such rules would weaken the benefits of USMCA to the creative economy in North America.

### **Piracy**

Long known for its threadbare copyright enforcement framework, Canada remains home to a cottage industry of intermediaries, servers, and know-how servicing large-scale infringers. For copyright-infringing goods, too, rightsholders face hurdles. Industry has reported that—after a rightsholder has asked for assistance—Canadian customs authorities burden them with the costs for storage, handling, and destruction of detained goods. The situation is just as bleak online. Zippyshare, for instance, one of the world’s most popular cyberlockers for infringing music—with a global Alexa ranking of 491 and 634.4 million visits in the past year—uses reverse proxy and privacy services based in Canada to cover its tracks. Other pirate sites, such as the pay-for-download site Mp3va (hawking nearly 7 million artists’ songs for just 0.15 each) and stream ripper Mp3juices locate their servers or proxies in Canada. Although the Chamber welcomes positive anti-piracy developments in recent years, 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. The U.S. government should commit to greater engagement with the government of Canada to discourage digital copyright infringement, including implementing recommended reforms of the Copyright Act, namely: (1) providing rightsholders with the ability to obtain broad and effective injunctive relief, including site-blocking and

de-indexing orders, against all intermediaries whose services are used by third-parties to infringe copyright; and (2) narrow the scope of the safe harbor provisions so that they only apply where the service provider is acting in a passive or neutral manner and ensure that broad exceptions do not shield intermediaries that have knowledge that their systems are used for infringing purposes but take no steps to stop it. In addition, 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.

### **Copyright Act Review**

Enforcement issues aside, the Chamber remains concerned about the legislative framework for copyright in Canada—especially regarding the parliamentary review of the country’s Copyright Act and the removal of critical IP provisions from the USMCA. One issue that remains top of mind is 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.<sup>lx</sup>

With this in mind, 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.<sup>lxi</sup> 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.

Given the different recommendations from two Standing Committees and the ongoing legal action over fair dealing issues, the Chamber encourages the U.S. government to continue to work with its Canadian government counterparts to raise the bar for copyright protection in Canada in order to adequately protect 21st century creative content, including implementing the recommendations noted above.

### **Trade secrets and related rights**

#### **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. We 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.

### **Disclosure of Confidential Business Information**

In 2014, Canada amended its Food and Drugs Act, enacting Bill-C17 (“Vanessa’s Law”) to include broad provisions that would allow the Health Minister to disclose confidential business information (CBI), including trade secrets, submitted to Health Canada as part of the regulatory approval process for pharmaceutical and medical device products. In 2015, the government released the guidelines to this law. These guidelines maintained the broad and sweeping powers of the legislation. Specifically, Section 21.1.2 includes the power to disclose CBI (including data submitted as part of an application for market and regulatory approval of medicines and medical technologies) to any person without notifying the owner of that information in cases where the Health Minister believes there’s a “serious risk of injury to human health.” While the guidelines included reference to Canada’s international treaty obligations (specifically TRIPS and NAFTA) and stated that “any disclosure of CBI ... in relation to new chemical entities needs to be compliant” with Canada’s commitments under both these treaties, questions have remained as to what type of information would be disclosed and under what circumstances.

Using its authority under Vanessa’s Law, Health Canada proposed new regulations in late 2017 on the release of submitted clinical test data: “Regulations Amending the Food and Drug Regulations and Medical Devices Regulations—Public Release of Clinical Information in Drug Submissions and Medical Device Applications.” The stated purpose of this initiative and the release of this information is to “enable independent analysis that will have widespread benefits throughout the health system, and lead to greater accountability for Health Canada and product sponsors.” Under its Regulatory Impact Analysis Statement, Health Canada issued a proposal to model the release of clinical information on the process followed by the European Medicines Agency (EMA), including the use of redactions for information deemed to be CBI. The Chamber recommends that the U.S. government work with the Canadian government to ensure that Health Canada puts in place adequate safeguards to limit and control the release of CBI.

## **Commercialization of IP Assets and Market Access**

### **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, which forces American companies to negotiate province by province and often obtain even lower prices. For many years, the PMPRB’s decisions have diminished the value of American IP and innovation. In August 2019, the Canadian government published proposed regulations to amend Canada’s Patented Medicines Regulations that will greatly exacerbate this problem and discriminate against U.S. innovators in an attempt to reduce the cost of innovative medicines in Canada at the expense of U.S. health care consumers and future innovation. Notably, the proposal removes the U.S. and Switzerland from the basket of comparator countries that the PMPRB uses to set drug prices, adding instead seven new countries, including Australia, Belgium, Japan, the Netherlands, Norway, Korea, and Spain. Additionally, the proposal would require patentees to report price and revenues, net of all price adjustments (e.g., confidential rebates). Finally, the proposal includes additional excessive price regulatory factors wherein the PMPRB will consider a medicine’s value and financial impact on consumers and the health care system.

The PMPRB regulations will exacerbate what is already a challenging market entry environment and make it less likely that Canadian patients can access new, innovative biopharmaceutical treatments and products. A 2018 report for the Fraser Institute notes “Health Canada estimates that these changes will generate savings of CA\$12.6 billion over the next 10 years through reduced prices for patented medicines. While the new regulations may ensure Canada doesn’t pay ‘excessive prices,’ there is reason to worry that they may also reduce the availability of new therapies for Canadian patients. If biopharmaceutical innovators believe that the new regulatory framework prevents them from profitably marketing their drugs in Canada, they may elect not to launch new products in Canada. Instead of improving access, the new regulations may essentially become a further barrier to access to new medicines.” Further, the report states that “Canada estimates that the innovative biopharmaceutical sector will lose CA\$8.6 billion in revenues over the next 10 years. The proposed changes will reduce the financial capacity of patentees to invest in the Canadian life sciences sector ... The proposed changes clearly disincentivize innovative drug launches in Canada, potentially de-prioritizing Canada in the global launch sequences for new drugs.”

In December 2020, the government announced the PMPRB guidelines implementation would be delayed from January 1, 2021 to July 2021. The date for full compliance was also pushed back two filing periods from January 1, 2022 to July 2022. However, on January 14, 2021, the government shortened the

timeline for compliance to one filing period, and companies now must comply with the new guidelines by January 1, 2022. While industry will file comments as part of the Canadian government’s consultation process, we 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.<sup>lxii</sup>

## **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. We encourage 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 its OECD membership and “very high” human development index score (0.851 in 2020—the highest in Latin America) Chile ranks in the bottom half of markets surveyed by the 2020 IP Index.<sup>lxiii</sup> China, Russia, Colombia, Mexico, and the Dominican Republic all have considerably higher scores. Like Chile, the Dominican Republic and Mexico also have free trade agreements with the United States, but these countries score nearly 8.5 points higher (53.96 and 54.38, respectively) than the country’s current 45.64.<sup>lxiv</sup> This gap can be attributed to the Chilean government’s continued resistance to implementing provisions of the U.S. FTA buffeted by a generalized anti-IP sentiment.

The most recent example of this was in October 2020, when the country’s Lower Chamber passed a non-binding resolution in support of the waiver overriding IP protections to address the global pandemic.<sup>lxv</sup> Although the resolution recognizes the need for an “all-of-society” approach to fighting this terrible disease, the legislators use public R&D funding as justification for overriding IP rights. Unfortunately, the necessity of private R&D activities, manufacturing and logistical know-how in fighting COVID-19 are ignored. We will overcome this pandemic only by working together, and channels exist for governments to respect the principles of IP while engaging in dialogue with rightsholders. In the Chilean context, however, the resolution has proven to be another disappointing development in a country bursting with innovative potential. While we have 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.

### **Patents and related rights**

#### **Compulsory Licensing**

Alongside the nonbinding resolution mentioned earlier, the Chilean government has continued its deliberation on multiple pieces of domestic legislation to expand the basis for compulsory license applications. These proposals have only gained traction in the global pandemic. In March 2020, for instance, the Lower Chamber passed a resolution calling for compulsory licenses on any medicines, vaccines, or diagnostics for combating the pandemic.<sup>lxvi</sup> At the same time, over the last few years, other politically-driven resolutions continue to be debated, calling for the compulsory licensing of innovative therapies for patients suffering from hepatitis C. This includes 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 continues to discuss Bill 12.135-03, which includes several troubling amendments to Chile’s Industrial Property law. The bill includes patent working provisions that mandate that patent holders reasonably supply the Chilean market. Moreover, the bill includes provisions on compulsory licensing for non-commercial public use and broadens the procedural discretion for compulsory licensing petitions.

Additionally, Chilean Congress continues its discussions on the Drug Act II (Ley de Farmacos II) 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. In 2020, a joint committee of Congress continued its examination of the Bill, though many problematic provisions remain. 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.

### **Pharmaceutical-related FTA Commitments**

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. Since 2012, the Chilean Congress has considered an amendment to the Industrial Property Law No. 19.039 that would introduce a fairly promising patent linkage system, including a public registry of known patents relevant to new market approvals and proof in new applications that such patents are not infringed. However, there has been no movement on the measure in recent years. <sup>lxvii</sup> <sup>lxviii</sup>

Additionally, the FTA requires that Chile make patents available for inventions that are new, involve an inventive step (are non-obvious), and are capable of industrial application (are useful). However, the inventive step criteria are interpreted somewhat narrowly, especially for inventions dealing with chemical compounds. The existence of major structural differences between a new claimed

compound and previously existing compound is required, despite the fact that the technical solution provided by the new compound does not form part of the prior art. Furthermore, there are significant patent delays in the Chilean patent office for pharmaceuticals, with waiting periods of up to five years.

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

### **Patent Prosecution Highway (PPH)**

In July 2020, Chile became the 27th member of the Global Patent Prosecution Highway. This is a significant step to support innovators and inventors in Chile.<sup>lxix</sup> PPH initiatives and increased cooperation between IP offices is one of the most tangible ways the administration and functioning of the international IP system can be improved and harmonized to help inventors and rights-holders. Chile’s membership in the GPPH builds on its membership in other international PPHs, including the South American PROSUR PPH initiative and bilateral agreements with the Japan Patent Office and the State Intellectual Property Office of the People’s Republic of China.

### **Copyrights and related rights**

#### **Online Piracy**

Despite its high level of economic development, copyright infringement remains a major challenge in Chile. The Alliance Against Pay-TV Piracy (ALIANZA) found in 2020 that Chile (along with Uruguay) exhibited the highest demand for infringing content per internet user.<sup>lxx</sup> Because of this, large-scale piracy sites, such as Cinecalidad.to and Pelisplus.me remain popular in Chile. These sites, respectively, accounted for over 12 million and 60.74 million visits in September 2020, according to SimilarWeb data. It has also been reported that internet users in Chilean cities are the highest in the region

for illegal downloads of the nearly 70 million articles available on Sci-Hub—one of the largest sites facilitating unauthorized access to academic works protected by copyright.<sup>lxxi</sup> Meanwhile, the most recent data available (2017) shows that Chile has a 55% usage rate of unlicensed software, or \$238 million worth. This is high when compared to that of Brazil (46%) and Mexico (49%). Chile is also not immune from both longstanding and growing piracy threats in the region, such as the unauthorized retransmission of encrypted satellite signals (also known as signal piracy) and the explosive growth of piracy devices. The effect of piracy on Chile’s market for legitimate content, as well as the business of international and local rightsholders, is significant. The Alliance Against Pay-TV Piracy estimated in 2019 that Chilean rightsholders lose some \$93 million from signal theft alone.<sup>lxxii</sup> The Chamber encourages the U.S. government to highlight the detrimental effects of piracy on both domestic and foreign creativity-intensive industries in the ongoing dialogue with the Chilean government.

### **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 expeditiously and efficiently remove infringing content online (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. ISPs are also not incentivized to remove infringing material in a timely manner, there are 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.

The country 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. Another example is NeoGames.cl/Neotronics.cl, which deceptively bills itself as an “authorized reseller” in Chile for handheld video game consoles and offers bundle packs, or consoles pre-loaded with video games. Industry reports that traffic to this site increased during the global pandemic: 20% over the last six months, or over 25,000 monthly visits. 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.

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.

## **Commercialization of IP Assets and Market Access**

### **Screen Quota Bill**

Chile’s National Congress has continued its push to establish a series of restrictive screen quotas by amending law N° 19.981 on Audiovisual Promotion. Bill 8620-24 would obligate movie theaters to ensure that nationally produced or co-produced audiovisual works make up at least a fifth of total works exhibited when ticket sales for a Chilean or co-production film, taken as an average from Thursday to Sunday, constitute at least 10% of overall cinema hall capacity in peak season and 6% in off-peak season. In free-to-air television, 40% of content must be of Chilean origin and at least 15% must correspond to Chilean cinematographic works, such as feature films, series, mini-series among others, in prime time. Since it was re-introduced in summer 2018, the bill has faced numerous constitutional challenges in the legislature as well as concerns that it violates key provisions of the U.S. FTA. Despite industry’s



engagement on this issue, the Lower Chamber approved the bill in January 2020 and it is currently under discussion in the Senate Committee for Education and Culture.<sup>lxxiii</sup>

## **EUROPEAN UNION**

### **Overview**

The U.S. and European Union (EU) have traditionally been the global leaders in protecting and promoting IP rights (IPR). And the Chamber, for its part, is proud to have been a co-host of the Transatlantic IPR Working Group Stakeholder Consultation for over 10 years. This fruitful collaboration has shown itself in many ways, from the EU’s introduction of its own Counterfeit and Piracy Watch List to recent mentions in its 2020 Third Country Report, highlighting that: “The U.S. was removed from the priority list in light of the good cooperation in international fora such as the TRIPS Council and the OECD as well as its engagement in bilateral discussions in the context of the Trans-Atlantic Working Group on IPR.”<sup>lxxiv</sup> The Chamber wishes to thank the U.S. and EU delegations for their hard work and supports continued—indeed more frequent and continuous—intersessional bilateral engagement on IPR issues. This includes first rate bilateral cooperation in third countries and at MLOs. At the same time, we note a concerted push within the EU to erect barriers and diminish IPR in specific areas, as evidenced by the passage of an “export and stockpiling waiver” to Supplementary Protection Certificates (SPCs) during 2019. This and further anticipated developments on IP Incentives, the forthcoming IP Action Plan and the EU Pharmaceutical Strategy will present challenges for U.S. businesses. We encourage the U.S. government to highlight how such reforms will undermine the rationale for business investment in the EU and its member states, and have a correspondingly negative effect on the ability of European Governments to raise tax revenues, and support their citizens ability to access goods and services as well as secure employment in these advanced industries.

### **Patents and related rights**

#### **EU Pharmaceutical Strategy**

While the EU generally maintains intellectual property (IP) protections and other incentives that enable such research and development, the Chamber is concerned by the potential future direction of a new European Commission (EC) Pharmaceutical Strategy for Europe and associated ongoing review of IP and other incentives for pediatric medicines and orphan products. This could result in the weakening of IP rights in one of the world’s largest markets. As currently framed, the EU Pharmaceutical Strategy

neither appropriately recognizes the significant contribution of innovative medicines to the patients and economies of Europe, nor does it properly address the EU's role in this innovative sector. There is a clear need for the EU to strengthen, rather than undermine, key conditions that promote and enable tomorrow's innovations. The Chamber and our member companies and associations welcome the opportunity to work with the EU in determining the best way to address these issues.

## **EU Intellectual Property Incentives Review & IP Roadmap**

The EU is conducting an analysis of the current EU legislative instruments and related incentives that aim to facilitate and support the investment in the development of medicinal products. The Chamber is concerned that this review can result in the weakening of existing incentive mechanisms for biopharmaceutical innovation and create an unlevel playing field for transatlantic medicines trade and investment.

Recently, the EU introduced changes to its legislation amending Regulation EC 469/2009 concerning the supplementary protection certificate (SPC) for medicinal products, to introduce an SPC export and stockpiling waiver (in force as of July 1, 2019). The waiver allows companies to manufacture generic and biosimilar products in Europe during the effective SPC period for export purposes to third (non-EU) countries and to stockpile during the last six months of the validity of the SPC for the domestic market. The SPC manufacturing waiver weakens the scope of the exclusive rights conferred by an SPC and sends a negative signal to the world that the EU is weakening its commitment to IP incentives and innovation.

In addition to the SPC manufacturing waiver, the Chamber is also concerned with the ongoing review of IP incentives in Europe where proposals are being considered to weaken existing incentives. This includes the now-communicated intention of the Commission to narrow and weaken Regulations concerning orphan and pediatric medicinal products, as part of a broader Pharmaceutical Strategy that, contrary to a previously declared intention to make Europe a leader in innovation, is likely to weaken the investment rationale for life science innovators doing business in and with Europe. For example, the European Commission recently published its Inception Impact Assessment on Medicines for Rare Diseases and Children, identifying 4 concrete options under consideration that appear to reduce these critical IP incentives in Europe.<sup>lxv</sup> On the contrary, reforms should introduce targeted incentives to complete the existing incentives and specifically address unmet needs, such as in the areas of rare diseases.

The EU also noted consideration of plans announced in the Pharmaceutical Strategy to condition incentives “to support broader access for patients”. While we support goals to enhance access for patients to innovative therapies, any such “conditionality” would be a counterproductive precedent, as it appears to envision that a company may only enjoy its intellectual property if its product is available in most or all EU markets. This approach, however, fails to consider factors that determine market access within individual European markets outside the control of companies, e.g., distinct national regulatory requirements, differences in medical practices, the speed of pricing and reimbursement negotiations, the ability to achieve an adequate price acceptable for both payers and industry, the level of health expenditures (and general wealth) in the market, external reference pricing, and/or requirements to see a product reimbursed in other markets (as is mandated by law in some markets). The Chamber has similar concerns regarding the recently announced IP Roadmap, which includes some particularly troubling language on compulsory licensing as well as potentially challenging proposals on Standard Essential Patents (SEPs).

We welcome the EC’s “IP Action Plan” to unleash the EU’s innovation potential and support resilience as a step in the right direction. However, we remain extremely concerned that proposals for compulsory licensing coordination in the Plan could undermine the EU’s innovation and IP framework. Furthermore, certain Member States’ compulsory licensing policies run counter to the EC’s position of using such policies as “means of last resort.” For these reasons, the Chamber requests that the U.S. Government continues to engage with its European Union and Member State counterparts to seek assurances that the problems described herein are quickly and effectively resolved.

## **JAPAN**

### **Overview**

The Chamber recognizes the excellent work that the government of Japan does to encourage other governments to value IP in their domestic regulatory environments, as well as its overall strong performance on The Index. That said, the Chamber notes that Japanese government policy on the pricing of medicines risks undermining its broader pro-innovation regulatory regime and recent steps taken by the Japanese government with respect to patent protection suggest a retreat from its traditionally strong record of IP enforcement. Over the last decade, Japan made important reforms in the areas of drug pricing, drug evaluation and approval, and vaccine policy that made its health care procurement system more transparent, more pro-innovation, and more conducive to innovative biomedical research and development. However, since December 2017, the Japanese government has begun to move in a more negative direction, pursuing changes to the way it prices medicines (see below). In our view, now that they have been implemented, these reforms significantly undermine Japan's pro-innovation environment and signal Japan's increasing unwillingness to shoulder its fair share of global R&D costs. Such developments are compounded by the Japanese government's decision to move from the current biennial price revision system to an annual revision system in 2021. Finally, we are also concerned about recent actions which appear to undermine the predictability of Japan's patent enforcement regime.

### **Revisions to the Price Maintenance Premium (PMP) System**

Several new policy proposals were announced as part of a drug-pricing policy package in December 2017. They run counter to the government's pledge to fuel Japanese innovation and provide a fair return on businesses' investment in innovation. The Chamber is concerned that the number of innovative products that qualify for the PMP have been reduced considerably, and that under the new requirements fewer U.S. biopharmaceutical companies will qualify for the full benefit of the PMP. Furthermore, the new eligibility criteria appear to favor domestic Japanese companies at the expense of U.S.-headquartered firms, which also calls into question Japan's commitment to fair and nondiscriminatory policies.

However, these changes to the PMP system are not isolated to that program. Another issue of serious concern is that the Japanese government decided to move from biennial price revision system to an annual revision system. In December 2020, the government announced a new rule that will apply annual price cuts (effective April 1, 2021), to medicines with more than a 5 percent difference (yakkasa)

between the government reimbursement price and the surveyed market price, which includes 69 percent of all medicines and 59 percent of patented medicines. In 2021, the average price cut on covered products will be 5.2 percent (before application of the PMP) and is expected to be similar or worse in future years. This decision not only deviates from the 2016 four-Ministers agreement which stated that only the minority of products with a large yakkasa would be subject to the off-year price revision, it ignores the discussions at Chuikyo, the health care policy advisory board to Minister of Health (MHLW). With this non-transparent process, we also understand that there were extremely limited opportunities for meaningful engagement with relevant business stakeholders, underscoring the overall concerns we have regarding the transparency and predictability of the Japanese market for innovative medicines.

Such reforms would significantly penalize and undervalue breakthrough therapies in an attempt to manage budget impact. Reforms of this kind reduce the predictability and transparency of the drug pricing system in Japan, and create significant additional, cumulative headwinds for future investment in innovation.

### **Health Technology Assessment Changes**

In addition to the pricing changes outlined above, the Japanese government implemented a new Health Technology Assessment (HTA) system in April 2019. In 2018, the Japanese government cut the prices of several leading innovative products that were subject to an ongoing cost-effectiveness assessment pilot program. For these products, the price premium granted at launch was reduced based on an inadequately justified cost-effectiveness threshold of JPY 5 million yen per quality-adjusted life year (QALY). Given the challenges experienced during the pilot program, the Japanese government decided to re-review the outcome of the pilot program for several products. In January 2019, the Japanese government announced that it would implement the new HTA system, which is broader in scope than originally proposed (although still limited to revising the price premium granted at launch), and inconsistent with international norms. In particular, the HTA criteria ignore many aspects of a product's value. So far, a total of 13 products are under consideration by the HTA as of November 2020, including 2 products not covered by HTA criteria and many of the products are innovative medicines.

As with PMP, the new system has been developed without meaningful opportunities for interested stakeholders to provide comments on the practical effect of the proposals for future investment in Japan, and access to medicines for Japanese consumers. The Chamber therefore remains very concerned about the current direction of the new HTA system in Japan, because it appears the Japanese

government increasingly does not provide a reasonable return of fair value for innovation. The Chamber encourages the U.S. government to engage its Japanese counterparts at the earliest opportunity to bring about a greater appreciation by the government of Japan to increase its support of global R&D on innovative medicines and to ensure, at a minimum, that U.S. business has an opportunity to contribute its views on any new policy reforms in this area.

## **Patent Enforcement**

Generally, Chamber members and associations value the highly predictable and reliable intellectual property protections provided in Japan. However, recent actions by the MHLW cast doubt on the future predictability of Japanese IP protections. Specifically, while MHLW appropriately takes the position that it should not arbitrate patent disputes, this past summer it unilaterally determined that it was appropriate to approve multiple generic versions of an innovative product, even though the Japan Patent Office (JPO) had upheld two of the four claims on the underlying method of use patent. In other words, MHLW independently decided to interpret whether the upheld patent claims covered the innovative product.

The innovative manufacturer in this specific instance has initiated patent infringement suits against each of the approved generics. That, however, has served to highlight another shortcoming in Japan's patent enforcement system. Specifically, now that the MHLW has approved these generic versions, those products will be able to enter the market as soon as the MHLW adds these products to the NHI price standard list. Those products were added to the National Health Insurance price list in December 2020, thereby enabling potentially infringing products to enter the market. While injunctive relief is typically available in Japan, such relief can take months to secure, thereby frustrating the ability of the innovator to seek an injunction before potentially infringing products are allowed to enter the market. As a result, the manufacturers of each of the approved generics may be put in the position of having to decide whether they will introduce their products into the market despite the risks associated with the ongoing litigation.

In short, this situation creates significant uncertainty for innovators and generic manufacturers alike and could ultimately result in products being prescribed to Japanese patients that ultimately have to be withdrawn from the market based on the outcome of the pending litigation. It is exactly this uncertainty that well-functioning and effective patent enforcement systems are designed to avoid.

## **Trademark enforcement**

We congratulate the Japanese government’s initiative to review the definition of a trademark under Trademark Law Article 2 (ii). Currently, this provision defines the use of trademarks as limited to business “in connection with the services of a person who provides or certifies the services as a business (on a regular basis) (except those provided for in the preceding item)”. This has affected customs’ ability to address small parcels, as it is interpreted to not apply to so-called “imports by an individual for personal use.” Because of this, the number of cases claiming personal use—and ultimately circumventing custom injunctions--has been increasing significantly. As of December 2020, related amendments to the Trademark Law were approved by the Trademark System Subcommittee at the Japan Patent Office, and the government subsequently opened a public consultation. The Chamber encourages further engagement on this issue, so that regulations will not be hollowed out in cases where overseas companies disguise themselves as individuals to ship counterfeit products.

## **REPUBLIC OF KOREA (ROK)**

### **Overview**

While the Republic of Korea (ROK) does well in terms of respecting intellectual property rights, the Chamber has concerns about several IP and market access issues. As with Japan, Korea’s drug pricing policies severely 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, as well as in the Chamber’s Innovation and Creativity Access Barometer.

Furthermore, there are concerns that Korea’s pricing practices are inconsistent with its commitments under the U.S.-Korea Free Trade Agreement (KORUS FTA)—and continued focus on implementation of the agreement in the pharmaceutical sector is needed. To this end, the Chamber welcomed the U.S. government’s ability to secure a commitment from Korea to amend its premium pricing policy for global innovative drugs, to ensure non-discriminatory and fair treatment for U.S. pharmaceutical exports. Unfortunately, the ROK has implemented this commitment in a manner that eviscerates the ability of any company to qualify for premium pricing. This allows the Korean government to continue to value innovative medicines according to the prices of older medicines.

## Pricing Issues

Following reforms implemented in December 2006—known as the Drug Expenditure Rationalization Plan (DERP)—drug prices in the ROK are determined by a two-step process based primarily on cost reduction, rather than a holistic assessment of a drug’s value. First, the Health Insurance Review and Assessment Service (HIRA), through its Drug Reimbursement Evaluation Committee (DREC), recommends drugs for listing based on a “pharmaco-economic” (PE) analysis, which takes into account clinical usefulness and cost-effectiveness. Second, the National Health Insurance Service (NHIS) makes pricing recommendations following negotiations with pharmaceutical manufacturers, using HIRA’s price as a ceiling. The Ministry of Health and Welfare (MOHW) has the ultimate authority for approving all pricing and reimbursement decisions.

This two-step process inappropriately depresses the price of innovative medicines in several significant ways. HIRA’s PE analysis recommends reimbursement prices for patented drugs by referencing other drugs in the same therapeutic class, including off-patent and generic drugs. Off-patent and generic drugs are already subject to drastic price-reduction measures in the ROK. However, linking prices of newly patented drugs—which reflect investment in R&D, as well as the very high overall risk and costs of bringing a new drug to market—to already heavily discounted prices of off-patent and generic drugs results in innovative medicines being priced at unsustainably low levels.

Repetitive and excessive price cut mechanisms after reimbursement listing continue to be problematic in the market. These include 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.

Separately, the Chamber suggests the Risk Sharing Agreement (RSA) system should be expanded to provide an alternative pathway for reimbursement listing to enhance patient access to innovative medicines regardless of disease area and alternatives. Although the system was expanded with the revision of the RSA guideline in August 2019, to include severe diseases as well as rare diseases and cancers, the qualifications are difficult to satisfy, and non-first-in-class drugs are still ineligible for RSAs. Other issues with the system include an unpredictable contract renewal process and overly strict pharmacoeconomic requirements.



## **Transparency and Due Process Concerns with KORUS Implementation**

Since 2010, MOHW has repeatedly changed its pharmaceutical pricing and reimbursement policies without considering the long-term implications for innovation and market predictability. The continued uncertainty has impacted the ability of innovative pharmaceutical companies to operate in the market and raises concerns that Korea's transparency and due process obligations under KORUS are not being met.

Under Article 5.3(5)(e) of the U.S.-Korea Free Trade Agreement and the side letter thereto, Korea agreed to "make available an independent review process that may be invoked at the request of an applicant directly affected by a [pricing/reimbursement] recommendation or determination." Korea has taken the position, however, that reimbursed prices negotiated with pharmaceutical companies should not be subject to the IRM because the National Health Insurance Service (NHIS) does not make "determinations" and merely negotiates the final price at which a company will be reimbursed. However, this interpretation completely negates the original purpose of the IRM, which should apply to the negotiation process for prices of all reimbursed drugs, particularly patented medicines.

In short, 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. The Chamber encourages the U.S. government to work with its counterparts in the ROK to help update its domestic biopharmaceutical pricing regime, to reflect fair value for the investment of industry in innovation, and for ROK policy to become consistent with its KORUS obligations.

In addition, as referenced in the earlier "Misuse of Competition Policy" section of this submission, competition authorities in ROK have followed China's example, misusing competition enforcement to extraterritorially obtain deep price cuts from U.S. patent holders. For instance, a 2017 decision by the Korean Fair Trade Commission (KFTC) took an unprecedented and dangerous step to the regulation of patents in the context of competition proceedings, seeking to apply its orders to patents granted by governments around the world.

## **Patent Term Restoration**

While patent term restoration does exist in Korea, there are two significant issues that undermine its effectiveness. First, 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. Failure to do so has a discriminatory effect on companies outside Korea that conduct necessary trials—on which the Korean Ministry of Health relies in approving the drug—outside of Korea.

Second, in cases where the Patent Office determines a certain duration of PTR that is less than the full amount originally requested by the patentee, and the patentee challenges that determination and subsequently loses the challenge, no PTR is granted. Even the duration that the Patent Office previously determined itself is lost. 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.

### **OTT Regulation**

In May 2020, Korea’s National Assembly passed the Telecommunications Business Act Amendments (Articles 22-7), which require content providers to take responsibility for “network stability and consumer demand.” The Chamber notes that the Enforcement Decree of the Telecommunications Business Act, which entered into force in December 2020, does not stipulate a network usage fee. It instead requires content providers to work with ISPs to ensure network stability. The Chamber reiterates that the stipulation of network usage fees represents an unnecessary intervention into the commercial relationship between content providers and ISPs. Worse still, it may hamper foreign investment flows in the country’s sophisticated digital media sector. We continue to urge the Government to apply KORUS-compliant, light-touch regulations for OTT services.

### **Trademark Enforcement**

Enforcement in the Republic of Korea can be improved by allowing officers to seize imported counterfeit goods when provided clear evidence that the goods are infringing. Today, Korean customs authorities defer this decision-making process to the courts, where the process is lengthy and costly. Additionally, the Chamber supports greater collaboration between rightsholders and authorities on product authentication. Customs authorities should also be provided more resources to address the growing threat of small parcels.

## **SWITZERLAND**

### **Overview**

Despite Switzerland’s strong overall score on the Index, it remains a base for registered companies, computer servers, torrents, and cyberlockers distributing infringing content. Industry reported that this concentration of sheltered, illegal activity continued in 2020: cyberlockers like Uploaded.net (owned by Swiss company Cyando AG) and Uptobox.com (owned by Swiss company Upworld Genius) continue to profit from the sale of “subscriptions” and advertising to view copyright-infringing content while hosting providers with servers in Switzerland, such as Private Layer and Network Dedicated SAS, continue to ignore infringement notices from rightsholders. The Chamber also notes its disappointment at recent enforcement developments in the Swiss judiciary: that the former operators of Rapidshare, one of the largest pirate sites in the world, were acquitted of copyright infringement by a Swiss judge in January 2021. At one point in 2009, the couple operating the sites reported gross dividends of nearly \$53 million dollars. They were fined \$790,000.<sup>lxxvi</sup>

In addition, the Chamber notes continued gaps in Swiss copyright law—despite recently-concluded amendments. By spurning a growing global best practice for ISPs to block access to infringing websites, the Swiss government will continue to drift further afield of its international obligations explained in detail below. This record is especially concerning given that Switzerland is the host of the U.N. agency with oversight of international IP treaties. As the U.S. Government continues to engage with its counterparts in Switzerland, we strongly urge that these issues be raised and where possible resolved expeditiously.

### **Copyrights and related rights**

#### **Copyright Amendments**

The Swiss framework for copyright—both as a practical and a legislative matter—has been a long-standing concern to the Chamber, and 2020 was no exception. This past year brought further troubling developments for the country’s copyright and licensing framework.

A new provision in Swiss Copyright Law for instance (effective since April 2020) interferes with VOD licensing by imposing a mandatory, inalienable collective author and performance rights remuneration on VOD services available in Switzerland for films produced in Switzerland or in countries practicing similar remuneration schemes. Films from other countries are not affected; however, the provision lacks clarity, as to qualifying countries or remuneration schemes and co-productions.

Another legislative reform, in effect since April 2020, ultimately introduced two enforcement instruments into the Swiss copyright framework: a staydown duty imposed on hosting providers “creating particular infringement risks” (targeting Swiss-based sharehosters); and a specific legal justification for processing personal data, such as IP addresses, for purposes of criminal prosecution of copyright infringements. Both provisions contain vague legal concepts, lack clarity, and may therefore require court decisions to become effective. This is on top of 2016 amendments (and a 2017 redraft) that undervalued the sanctity of exclusive rights and contractual freedom, which have been in marked contrast to Swiss policy on other mechanisms to protect IP, such as patents and trademarks. The Swiss government’s failure to protect rightsholders included broad exceptions which failed to pass the widely recognized Berne Convention’s three-step test. Some of the most glaring examples for the audiovisual sector included:

- A private copy exception which extends to copies made from illegal sources<sup>lxxvii</sup>
- Inclusion of catch-up services, which implicate the exclusive right of making available, within the scope of the private copy exception, which, of course, is only relevant to the reproduction right
- Extensive application of mandatory collective licensing to the detriment of individual exercise of exclusive rights and contractual freedoms
- Weak protection for technological measures (digital rights management)
- Bans on contract overrides, including as regards exceptions and mandatory collective licensing of statutory remuneration rights

Despite ultimate improvements, the absence of a meaningful reform bill indicates a reluctance on the part of Swiss leadership to live up to the country’s obligations under international agreements to provide remedies that prevent and deter infringements. The enforcement deficit remains deeply problematic, particularly within the context of our otherwise strong bilateral trade relationship. Given this, data processing for purposes of out-of-court or civil law enforcement, such as cease-and-desist letters and injunctions, remains in legal uncertainty. Swiss law also still allows circumvention of technological protection measures for purposes of uses permitted by law, including the inappropriately wide scope of the private use exception. In combination, these deficits leave the Swiss marketplace largely unprotected against cross-border piracy services.

Nonetheless, 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. It is critical that the Swiss government adopt changes 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.

## **Section D: China**

### **Overview**

The U.S. Chamber and its member companies have long been and remain committed to balanced and mutually beneficial U.S.-China economic and commercial engagement. We continue 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. In January 2020, the U.S. and China concluded their Phase One Economic and Trade Agreement (the “Phase One Agreement”)—a significant achievement in ongoing efforts to advance fairness and reciprocity in the bilateral economic and commercial relationship. The Chamber continues to support the full and timely implementation of the Phase One Agreement, and is encouraged by the steps China has taken to date to follow through on the IPR-related commitments enumerated in the agreement’s text. As specified by its Intellectual Property Action Plan—which included commitments to prohibit certain forms of forced technology transfer; improve the legal environment for protecting trade secrets; combat piracy and counterfeiting; enhance trademark and copyright enforcement; provide effective and time-bound resolution of patent disputes; create a patent linkage system; and strengthen judicial procedures and administrative enforcement—China enacted several important reforms to its IPR protection system in 2020, including:

- The passage of a Civil Code that establishes tort liability for IP infringement (May 2020);
- A draft amendment to China’s Criminal Law that strengthens IP protections, including criminal penalties for trade secret infringement and provisions mandating the destruction of infringing and counterfeit goods (Oct. 2020);
- Supreme People’s Court (SPC) judicial interpretations and provisions that strengthen legal protections for trade secrets and trademarks (Aug.-Sep. 2020);
- An amended Patent Law that provides for patent term extension and early patent dispute resolution (Oct. 2020); and
- An amended Copyright Law that recognizes copyrightability of audio-visual works and significantly raises penalties for copyright infringement (Nov. 2020).

- Although the key details of numerous forthcoming implementing regulations and regulatory guidelines—as well as the extent to which Chinese regulators and courts respect the word and spirit of these reforms—remain to be seen, the Chamber views these developments as a positive sign for the continued strengthening of IPR protections in China:

We look forward to the implementation of the Phase One provisions in the abovementioned areas—with respect to partial designs, post-grant supplemental data, early resolution of patent disputes, and patent term extension—in a manner that results in the meaningful improvement in IP protection for innovative medicines in China. Most importantly, this includes the grant of preliminary injunctions for patent infringement lawsuits. We also welcome China’s commitment to provide “effective protection and enforcement of pharmaceutical-related intellectual property rights, including patents and undisclosed test or other data submitted as a condition of marketing approval”, and stand ready to work with both governments to ensure the full implementation of these critical IP protections in China. Nevertheless, as China appears to be taking positive steps to strengthen intellectual property (IP) protections and enforcement in the aforementioned areas, the Chamber remains concerned about a lack of progress and even notable backsliding in several key areas, including:

- Ineffective 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),
- The encouragement of active challenges and anti-suit injunctions that interfere with decisions rendered on standard-essential patents (SEPs) in global jurisdictions;
- Recognizing 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; and
- Continued use of market access restrictions, administrative practices, and cyber-espionage to forcibly acquire sensitive IP and valuable proprietary information from foreign companies.
- Ability to use copyright to protect 3D designs;
- Limited developments on the efforts to use new regulations/legislation to contain Bad Faith Trademark filers as they continue to flood the Trademark Office and tie up significant time and resources to combat.

- Need for clearer, more consistently applied, and more achievable exam standards that make trade dress protection/registration and enforcement (2D and 3D) more realistic and achievable.

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

- Fully implements, 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, copyrights, piracy and counterfeiting, trademarks, and judicial enforcement and penalties;
- Provides effective protection against the unfair commercial use of test data;
- Expands the scope of copyright protections in China to cover live sports event broadcasts;
- Eliminates unnecessarily burdensome legal provisions and other onerous requirements in the patent and trademark enforcement system; and
- Carries 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, we offer our assessment of Chinese IPR protections and practices across a wide range of areas, which we look forward to engaging further with the U.S. and Chinese governments on in the year ahead.

## **Patents and related rights**

### **Patent Enforcement**

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 these mechanisms were still ambiguous, leading to uncertainty about their scope, implementation and value for biopharmaceutical innovators in China and abroad. The draft measures for the Implementation of the Early Drug Patent Dispute Resolution System

(September 2020) provide some necessary clarity on key issues, but some provisions in the draft are confusing and potentially problematic.

Furthermore, 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). The Chamber urges the U.S. Government to encourage China to move swiftly to implement the proposed reforms in a manner that enables 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 second draft amendment to the Patent Law in August 2020 (regarding the PTA and PTR provisions) that would ensure that the resulting mechanisms achieve their objectives of encouraging the development of innovative medicines. However we note that further efforts are necessary to ensure effective implementation.

### **Restrictive patentability criteria**

In April 2017, the China National Intellectual Property Administration (CNIPA) amended its Patent Examination Guidelines that would require examiners to take into account post-filing experimental data submitted by an applicant. In December 2020 CNIPA issued the amendment to the Patent Examination Guidelines which states that post-filing experimental data could be conditionally accepted to prove both sufficient disclosure and inventive step. Furthermore, in September 2020, the Supreme People's Court issued 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.



## **Protection for the Invention Containing Algorithmic, Business Rules or Methods**

On December 31, 2019 the Guidelines for Patent Examination were revised again, and some special rules on the review of invention patent applications that contain algorithms, business rules, or methods have been introduced in the Guidelines. Patents involving artificial intelligence, big data or blockchain generally include the features of algorithms, business rules or methods. The revised Guidelines provide a much clearer guidance to the patent applications in these new areas.

## **Data Supplementation for Patent Applications in China**

SIPO (now CNIPA) had been criticized for years for not accepting post-filing data after patent applications are filed. In 2013, both during Vice President Joe Biden's trip to China and at the U.S.-China Joint Commission on Commerce and Trade (JCCT), China agreed to consider post-filing data and explicitly agreed that any of its newer versions of the patent examination guidelines will not have retroactive effects. On April 1, 2017, SIPO released the amendment of the Patent Examination Guidelines. A paragraph related to data supplementation was included in the new Guidelines: "The experimental data submitted after the application date shall be examined by the examiners. The technical effects to be evidenced by the supplementary experimental data shall be those that a person skilled in the art can get from the disclosed content of the patent application."

The amendments provide that an applicant can supplement data to further strengthen the technical effects that have already been proved by the data in the specification, while for asserted technical effects in the application, post-filing supplemental data may still not be accepted. In June 2018, a new draft judicial interpretation on patent validity litigation released by the SPC seemed to further narrow the scope for acceptance of data supplementation by suggesting that post-filing experimental data will be accepted when there is a different technical effect for review that is "directly and unambiguously" disclosed in the application.

In a provision that seems to address these areas of uncertainty, Article 1.10 of the recently signed Phase One Agreement stipulates: "China shall permit pharmaceutical patent applicants to rely on supplemental data to satisfy relevant requirements for patentability, including sufficiency of disclosure and inventive step, during patent examination proceedings, patent review proceedings, and judicial proceedings." In December 2020 CNIPA issued the amendment to the Patent Examination Guidelines, which will come into effect as of January 15, 2021. In this amendment supplementary data could be conditionally accepted to prove both sufficient disclosure and inventive step, but it's not clear whether

these amendments will make a substantial difference in practice. The Chamber encourages the U.S. government to push China to revise relevant guidelines and judicial interpretations to ensure that China follows through on this commitment to allow for more data supplementation.

### **Patent Quality and Utility Model Patents**

There are signs that CNIPA is putting its focus back on the growth of patent filings at the cost of quality. It is therefore essential that the U.S. government continue to engage with China in this particular area to encourage the filing of high-quality patents and to mitigate the damage caused by the abuse of the utility model patent system in China.

In the Patent Examination Guidelines of March 2013, SIPO officially permitted patent examiners to conduct patent searches to examine novelty of utility model application and design patent applications.<sup>lxxviii</sup> The change of practice reportedly has led to numerous rejections issued by SIPO against utility model filings. However, China seems to keep emphasizing the number of filings in its recent work plan to implement the national IP strategy for 2015-2020. One of the new quantitative measures is invention patents per 10,000 people, which is aimed to increase from four in 2013 to 14 by 2020; another measure is Patent Cooperation Treaty (PCT) filings, increasing from 22,000 applications in 2013 to 75,000 in 2020.<sup>lxxix</sup> All these measures tie to filings without accounting for the quality of the patents. This raises a strong concern that the national or local governments may continue using subsidies to incentivize large numbers of, but not necessarily quality, patent filings. Again, the Chamber urges the Chinese government to reduce or eliminate government subsidies for design patent filings and mandate substantive examination of utility model and design patents prior to initiating litigation.<sup>lxxx</sup> The Chamber also recommends that the inventiveness criteria for utility model patents be raised to the same level as invention patents. Currently, utility model patents have no substantial examination, and they are difficult to be invalidated due to the low inventiveness criteria. Because of the low inventiveness threshold for utility model patents, there remain a significant number of utility model patent applications and patents. In addition to requiring substantive examination, China's patent system should further allow recourse to civil litigation for patent infringement to the exclusion of any administrative enforcement remedies, which can be subject to local protectionism and discriminate against foreign rights-holders. Doing this would help rights-holders who can actually demonstrate the innovative nature of their patent or other rights to address, inter alia, the problem of low- or no-quality patents before competent (and less political) adjudicators and courts. Finally, China's patent system should be reformed to ensure that infringement

litigation that is based on unexamined rights cannot proceed until the validity of the utility model and design involved is finally determined through the PRB's examination and judicial review.

### **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 of products containing a new chemical ingredient. In practice, however, China does not have a mechanism to grant RDP and the criteria are inconsistent with China's commitments. 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. This draft measure represented a strong first step toward reform in this area, however, it appears reform efforts in this area have stalled. We urge 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.

### **Protection of Human Genetic Resources**

As one of the important targets of IP protection in China, human genetic resources and the management thereof have attracted much attention in recent years. The Regulations on the Management of Human Genetic Resources came into effect on July 1, 2019. The Regulations clearly provide for the use and external supply of human genetic resources. According to the Regulations, if the achievements are made by using China's human genetic resources for international "exploratory" cooperative scientific research, the patent application of which must be jointly filed by the participating parties and the eventual patent rights shall be shared by them. The Regulations separates management of human genetic resources into four categories, including increasing protection, promoting rational use, strengthening regulation, and optimizing service supervision after reviewing the experiences from the implementation of the Interim Measures for the Management of Human Genetic Resources (1998).

## **Copyright and related rights**

### **Copyright reforms**

China's amendment to its Copyright Law (November 2020) is broadly aligned with the development of China's cultural industry over the past few years, and is geared towards strengthening digital copyright protections while simultaneously strengthening/increasing penalties for copyright infringement. The new law includes discussion of protections for audio-visual works that are common in today's digital environment, including webcasts and short videos.

In particular, we note the following changes to the Copyright Law as indicative of China's desire to strengthen copyright protections in the digital era:

- It both empowers and regulates the role of collective copyright management organizations;
- It introduces the Three-Step Test to define where the "limitation of rights" end;
- It eliminates the loopholes of licensing in re-transmission of signals by broadcasting organizations;
- It significantly raises the statutory damages for infringement from RMB 500,000 to RMB 5,000,000, thus significantly increasing the cost of copyright violations, and shifts the burden of proof for incurred damages from the plaintiff to the defendant; and
- Promises to enable stronger administrative enforcement.

Despite these positive inclusions in the newly revised Copyright Law, we are disappointed and concerned with the Chinese government's continued lack of progress in the following areas:

### **Live Sports Event Broadcast and Non-Interactive Streaming**

In spite of favorable court judges recognizing copyrightability of live sports event, 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. We urge China uses the pending legislative process of the copyright implementation regulation draft as opportunity to make clarification.

## **Unauthorized Camcording**

China's government has shown only limited progress in combatting the unlawful to use—or attempted use—of audiovisual recording devices to make or transmit copies of cinematographic works or other audiovisual works, or any part thereof, from performances of such work in an exhibition facility. To address this issue, the Chinese government could implement watermarking in theatrical prints and ensure that regulators and those involved in the value chain for theatrical distribution step up efforts to deter illegal camcording, which is responsible for over 90% of all piracy during the theatrical window. A more comprehensive solution requires enactment of a specific criminal law against using, or attempting to use, an audiovisual recording device to make or transmit a copy of an audiovisual work from a performance in an exhibition facility. Furthermore, to address livestreaming, the Copyright Law should be revised to prohibit the unauthorized retransmission of content online.

## **Online Piracy**

With respect to online piracy, there has been some progress in recent years in government enforcement against distribution of infringing content. Chinese enforcement authorities have begun to crack down on illegal distribution of content, and rights-holders have successfully sued websites engaged in brazen infringement, in some cases supported by the NCAC.<sup>lxxxix</sup> Not surprisingly, the legitimate market has responded positively to this crackdown on illegal activity. However, China still lacks effective tools to encourage cooperation of internet intermediaries, ensure rapid takedown of infringing content, take action against repeat infringers, and provide proactive measures to address piracy. The NCAC national campaign, pushing ahead the third amendment of the Copyright Law, and the new NCAC guidelines for cloud services have been good steps in the right direction, but much more still needs to be done. Increased criminal actions against online infringers and additional measures against Internet Service Providers (ISPs) and online platforms that host or otherwise facilitate access to infringing content that is widely distributed, e.g., through links distributed through social media, should be a priority in the coming year.

There is an additional type of piracy that has become rampant throughout Asia—piracy devices such as media boxes, set-top boxes, or other devices that allow users, through piracy apps, to stream, download, or otherwise access unauthorized content from the internet. Piracy devices are part of a sophisticated and integrated online ecosystem facilitating access to pirated audiovisual materials. These devices have emerged as a significant means through which pirated motion picture and television content is accessed on televisions in homes in China. China is a hub for the manufacture of these devices. The devices may be promoted and/or advertised to enable infringement of copyright or other illegal activities.

Chief among these activities are: (1) enabling users to access unauthorized decrypted motion pictures or television programming; (2) facilitating easy access, through apps, to remote online sources of unauthorized entertainment content, including music, music videos, karaoke, motion pictures and television programming, video games, and published materials; and (3) preloading the devices with infringing apps that provide access to hundreds of high-definition (HD) motion pictures prior to shipment or allowing vendors to load content upon import and prior to sale, or as an “after sale” service. The Chamber notes that the Beijing IP Court held a set-top box manufacturer liable for streaming unauthorized content under secondary liability theory in 2015. The Chamber is hopeful that China will take a firm stand against this type of infringing activity and take enforcement efforts to eradicate the problem, including against exports.

The issue of online journal piracy continues in China and appears to be worsening. Unauthorized services sell online access to, or copies of, journal articles without the authorization of—or payment of compensation to—publishers. These unauthorized services undermine the investment that international (and Chinese) publishers make in journal publishing, which helps to deliver high-quality journals that are critical to the advancement of science, technology, and medicine within China and globally. Timely enforcement and effective deterrence is critically important. China’s failure to conclude the investigation of the case against KJ Med illustrates the remaining enforcement challenges that allow such an entity to continue its operations.

Publishers also continue to be concerned about “sharing services,” which are open online platforms where users can upload and share documents. These services, such as Baidu Wenku, Sina, and Docin, employ “digital coin” systems, whereby coins earned through uploading documents may be used to “purchase” English-language and Chinese translations of trade books, textbooks, and journals for download. These sharing services have ineffective notice and takedown processes for reporting and addressing infringements. Other online entities sell login credentials that are used to gain unauthorized access to proprietary online journal databases.

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. Additionally, China has yet to criminalize violations of the Anti-Circumvention Provisions for Technological Protection Measures (TPMs) and Information Rights Management (IRM) and internet offenses that may lack a demonstrable profit motive but that impact rights holders on a commercial scale.

## **Criminal Law Revision**

China's most recent 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 also made flexibilities available on how to calculate actual losses. We hope this revision, once the new law takes effect on March 1, 2021, will close legal loopholes for infringers and reduce liability thresholds for counterfeiting and piracy.

## **Innovation and Industrial Policy**

Notwithstanding incremental positive steps in select areas, China's regulatory environment is increasingly emphasizing industrial policy outcomes that are raising the costs, risks, and uncertainties for many U.S. companies in China. Over the past year, Chinese central government agencies have made a concerted effort to erect a legal and regulatory framework to advance the senior leadership's objective to create national—and even global—champions with cutting-edge technology and IP in key industries. The Chamber's China Center has comprehensively documented many of these efforts in two recent reports—"Preventing Deglobalization: An Economic and Security Argument for the Free Trade and Investment in ICT" and "Made in China 2025: Global Ambitions Built on Local Protections." Moreover, the China Center's ICT and Data Working Group has been closely tracking discrete policy developments and advocating on behalf of its membership.

## **China's Cybersecurity Review Regime**

The Cybersecurity Law (CSL), adopted on June 1, 2017, creates a legal framework that may weaken companies' ability to protect IP and other confidential business information (CBI). In addition to broad data residency requirements, the CSL also establishes a framework for security reviews that has potentially intrusive aspects—including the possible required disclosure of source code, algorithms, and other sensitive IP—that may result in U.S. companies being either marginalized from the market or forced to disclose valuable, proprietary information.

## **MLPS 2.0 Standards Series (Baseline, Technical Requirements, and Evaluation Requirements)**

On May 13, 2019, SAMR released three standards to specify implementation details for the Cybersecurity Classification Protection Regulations (MLPS 2.0), the draft of which was released in July 2018. These standards, which became effective on December 1, 2019, significantly expanded the scope of MLPS coverage, which will now include not only “information systems,” but also network infrastructure, cloud computing platforms/systems, mobile application platforms, connected devices, and industrial control systems. Applying to all network operators (defined as all entities using a network, including the internet, to operate or provide services) regardless of system classification level, the MLPS 2.0 Standards will impose security, network, and risk-management requirements, including localized infrastructure, storage, and maintenance requirements for cloud computing. In practice, this means that if the Ministry of Public Security (MPS) deems a network to be at-or-above Level 2 on MLPS’s 1-5 point “security classification” scale, the company operating that network will be required to undergo an “expert review,” the protocol for which remains unspecified. This “black box” review—along with data localization requirements—could result in disclosure of sensitive IP and corporate data.

## **Cybersecurity Review Measures**

Effective June 1, 2020, the Cybersecurity Review Measures subject companies deemed “critical information infrastructure (CII) network operators” to cybersecurity reviews carried out by Chinese regulatory authorities. Although Article 16 of the Measures includes stronger language on confidentiality than had been contained in previous drafts—ordering regulatory authorities to “strictly protect” IPR and trade secrets—the definition of “network products and services” in the Measures is excessively broad, with the regulation describing this term as “primarily” referring to: “Core network equipment, high-performance computers and servers, high-capacity storage devices, large databases and applications, network security equipment, cloud computing services, and other network products and services that have a significant impact on the security of critical information infrastructure” (Art. 20). The broad scope of “network products and services” covered by the Measures threatens to qualify many U.S. companies operating in China as “CII network operators,” potentially forcing them 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.



## **Cryptography Law**

China's first Cryptography Law was passed on October 26, 2019. The Law aims to promote the steady and sound development of cryptography, as well as ensure the effectiveness of China's cybersecurity systems from January 1, 2020.

The Law classifies cryptography into core, common and commercial categories, stipulating that core and common cryptography are used to protect national secrets and should be governed by the strict and united administration of cryptography authorities. The Law limits participation by foreign companies to the commercial category of encryption and only under strict regulation, which will include import and export controls and national security reviews that could directly or indirectly force companies to hand over sensitive or confidential data (see Articles 25-28).

## **Anti-Monopoly Law (AML)**

On January 2, 2020, SAMR released draft amendments to the AML for public consultation. Overall, the AML draft amendments contained a number of positive changes, including significant increases in the level of fines for various offenses, the adoption of a "rule of reason" approach for assessing vertical agreements (including resale price maintenance), a definition for the term "control," and efficiency improvements to merger review procedures. The AML draft amendments also call for increased scrutiny of internet companies, outlining various concepts of what constitutes harm necessary to address when an internet company holds a dominant position.

The Chamber has a long history of robust engagement with Chinese authorities on all aspects of the implementation of China's AML. In September 2014, the Chamber commissioned a report providing detailed analysis on China's application of its AML.<sup>lxxxii</sup>

China, for example, has an established record of launching or threatening investigations against foreign patent holders under its AML in order to enhance the competitive position and leverage held by Chinese companies seeking to license foreign technology. Such actions often employ intimidating and non-transparent procedural mechanisms to pressure U.S. rights-holders to license technology to Chinese parties at below-market rates, thereby depriving U.S. companies of the fees they would otherwise be able to charge. China's discriminatory enforcement of antitrust laws to advance its ambitions to overtake U.S. technology leadership is integral to China's industrial development model and has been employed across a number of sectors, including telecommunications, medical devices, and auto parts, among others. In this

sense, while the 2020 AML draft amendments proposed necessary reforms to China’s antitrust regulatory framework, whether these changes will deliver any benefit to foreign patent holders remains to be seen.

In 2019, The State Administration for Market Regulation (SAMR) made public The Interim Regulation Prohibiting Conduct Abusing Dominant Market Positions together with two other sets of regulations to implement the AML. The Regulation calls for an effects-based analysis for new types of anti-competitive agreements and abuse of dominance under the Anti-Monopoly Law’s “catch-all clauses”. The regulation also contains specific points for the internet sector and intellectual property rights (IPRs). For internet companies and similar businesses, the dominance assessment can take into account industry specificity, business models, user numbers, network effects, foreclosure effects, technological characteristics, market innovation, data control and processing, and any associated market power. In the IPR space, countervailing power (likely to mean the licensee's bargaining position in a cross-licensing context) is a relevant factor.

It is critical that competition law authorities view IPR as complementary to the end goal of promoting consumer welfare, not a threat to it, requiring special treatment under the AML. The Chamber hopes that the anti-monopoly enforcement agencies will agree with this universally held view among leading competition enforcement agencies and abandon plans to incorporate an “essential facilities doctrine” for IPR, as well as agree with other concerns from members of the Chamber, and we urge USTR to track this process closely.

## **Technology Transfer**

Since the 1980s, China has regulated cross border technology transfers with a view of protecting domestic companies. What has long been controversial are the restrictions imposed by the Joint Venture Law and the Regulations on Administration of Technology Import and Export (TIER) in technology import contracts.

In its Joint Venture Law, China stipulated that in a joint venture involving foreign parties, the Chinese parties should have the right to continue using licensed technology after the initial 10-year term expires. In addition, TIER stipulates restrictions on the contract terms of inbound technology transfer.

- TIER makes it compulsory that a foreign licensor has the obligation to indemnify Chinese licensees for any loss arising from the use of the licensed technology under the contract (Art. 24). One key provision that has come under much criticism is that such compulsory rules prevail over

the Contract Law of the PRC, under which two Chinese parties are allowed to freely negotiate indemnification terms.

- TIER requires that any improvements made by the Chinese licensee to the imported technology shall per se belong to the licensee (Art. 27). Similarly, the Contract Law does not contain such rules. Parties are free to use contracts to allocate the ownership of improvements made by the licensee. However, the judicial interpretations issued by the top court authority further clarify that there must be a reasonable consideration for any grant-back of the improvement by the licensee.
- TIER also requires that anti-competitive restrictions imposed by a foreign licensor shall be invalid. Such anti-competitive restrictions include (a) bundled sales of unnecessary technology, raw materials, products, equipment or services; (b) payment for expired or invalid patents; (c) restraining licensees from improving the technology; (d) restraining licensees from obtaining licenses from competing sources; (e) imposing restrictions on sourcing of the raw materials, parts, products or equipment; (f) imposing restrictions on quantity, types, and sales price of products; and (g) restricting export channels. Notably, similar anti-competitive restrictions are prohibited under the PRC Contract Law and relevant judicial interpretations for any and all licensors.

It has been a longstanding concern of the business community that any contract terms not compliant with these mandatory rules might be considered void or not enforceable. Foreign parties often choose a foreign law and venue to govern the contract, which can sometimes help circumvent these rules. However, enforceability in China can still be a question mark, and the legal cost of international arbitration tends to be very high.

The Phase One Agreement contains a number of 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:

- Forbid requiring or pressuring persons to transfer technology in relation to acquisitions, joint ventures, or other investment transactions;
- Prohibit administrative and licensing requirements requiring or pressuring persons to transfer technology;
- Prohibit requiring or pressuring persons to “use or favor” technologies owned or licensed by domestic persons as a condition for licensing, market access, or receiving benefits;
- 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 a number of 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.

Overall, 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. As China continues to implement its Phase One commitments, this will be an area worth following 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 a number of TIER provisions in an effort to deepen reforms and improve market conditions.<sup>lxxxiii</sup> The amendments, as enacted, to a limited extent address a number of 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 abolishment of controversial provisions that formerly inhibited the independent negotiation of contracts aligns with the newly-promulgated PRC Foreign Investment Law (FIL), which explicitly states that forced technology transfer is not allowed in China. Art. 22 (2) of the FIL sets forth that government agencies and their officials are forbidden to take administrative measures to force any technology transfer. 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. Since 2015, China has been switching its foreign investment management regime to a security-based review system. As a result, the newly-promulgated FIL stipulates that foreign investments shall be subject to national security reviews, the content of which—despite the release of the Foreign Investment Review Measures (December 2020)—remain ill-defined. Any licensing or assignment of sensitive technology to overseas parties may be deemed as threatening national security, and thus prohibited.

### **Compulsory Licensing**

Compulsory licensing is not a new concept within China’s legal and regulatory frameworks. A provision in the former SAIC’s IP enforcement rule promulgated under the AML could be used in some cases to force U.S. companies to license their essential technologies to Chinese companies. Furthermore, China’s Patent Law includes a provision on compulsory licensing that may, if applied broadly, impose an unreasonable obligation for patentees to provide their technology to Chinese competitors.

China is also exploring tying compulsory licensing to state funding. In July 2017, the State Council issued a Guiding Opinion that discusses compulsory licensing of patents that are obtained with funding from the state.<sup>lxxxiv</sup> This approach raises significant concerns for companies that would choose to accept public money to conduct R&D in China, including under industrial plans such as Made in China 2025 and within Strategic Emerging Industries, as they could be forced to license their IP to the Chinese government.<sup>lxxxv</sup> This policy, if implemented, would undermine innovation and diverge from the spirit of comments made by Minister Miao Wei that Made in China 2025 would not compel technology transfer.

Moreover, China’s new 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 area, which may rise to a level of compulsory licensing. Chinese courts have increasingly docketed the cases through controversial cause of action 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 as a way to counter influence of foreign courts' decisions.<sup>lxxxvi</sup>

### **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.<sup>lxxxvii</sup> Furthermore, a newly added and deeply concerning article stipulates state endorsement of incorporating indigenously innovated technology into industry and social standards.<sup>lxxxviii</sup> 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.

### **Made in China 2025**

The Made in China 2025 plan provides clear evidence of China's efforts to use state resources to support indigenous innovation, domestic production, and Chinese IP. In "Made in China 2025: Global Ambitions Built on Local Protections," the Chamber comprehensively documented the legal and regulatory environment as well as the specific implementing measures of the Made in China 2025 plan that are adversely impacting American industry. Since the publication of the report, Chinese government ministries have continued to implement near-term plans, including the Additive Manufacturing Development Action Plan (2017-2020) and the Three-Year Action Plan (2018-2020) on Strengthening the Manufacturing Industries' Core Competitiveness, that, among other things, aim to strengthen indigenous innovation, IP, and brands, at the expense of foreign-owned businesses operating in China.

## **Foreign Investment Law**

Following the groundbreaking PRC Foreign Investment Law (the "FIL") being voted into law on March 15, 2019 to unify and replace the main existing rules governing foreign invested enterprises ("FIEs") and their activities—namely the Sino-Foreign Equity Joint Venture Law (the "EJV Law"), the Sino-Foreign Cooperative Joint Venture Law (the "CJV Law"), and the Wholly Foreign-Owned Enterprise Law (the "WFOE Law")(collectively the "FIE Laws")—the Ministry of Justice released the long-awaited draft PRC Foreign Investment Law Implementation Regulations (the "Implementation Regulations") to seek public comments. The Implementation Regulations came into effect on Jan 1, 2020. The "Implementation Regulations" stipulate that the state is to establish a number of intellectual property rights protections, including a punitive compensation system, a rapid collaborative protection mechanism, a dispute resolution mechanism, and channels of assistance in protecting the intellectual property rights of foreign investors and FIEs.

At the same time, the Implementation Regulations impose limitations on the powers of administrative organs. Administrative organs and their staff, in theory, no longer have the administrative authority to compel or covertly compel foreign investors or FIEs to transfer technology. Additionally, administrative organs are now required to establish and improve internal management systems, and to implement effective measures to protect the commercial secrets of foreign investors and FIEs learned of during the lawful performance of duties.

## **Corporate Social Credit System**

On January 1, 2020, China's Corporate Social Credit System (SCS) was officially slated to come online, although many parts of the system remain under construction. While this system will in all likelihood require more time until it becomes fully operational, it promises to subject all companies operating within China to a series of algorithmic scoring systems based on government-determined criteria, with distinct rating mechanisms and blacklists managed by each of China's regulatory line agencies. Foreign companies found to be non-compliant with these criteria—some of which remain opaque and vaguely worded—will face the threat of being blacklisted, exposing them to sanctions, intensified inspections, public shaming, and even debarment from markets. With respect to IPR and the protection of confidential business information, the SCS will use 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”,<sup>lxxxix</sup>
- 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.

Without 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, the SCS could present considerable risks to foreign IP holders.

### **China Standards 2035**

China is currently in the process of drafting the content of its “China Standards 2035” initiative, a strategic drive to increase Chinese involvement in the creation of standards at both the national and international levels to embed Chinese IP in global infrastructure and technology. Announced by the Chinese Academy of Engineering in 2018 and supported by the Standardization Administration of China (SAC), the foundational text for China Standards 2035 is still being formulated, with its release expected in 2021. However, key priorities in China’s standards initiative can be found in the Main Points of National Standardization Work in 2020, which indicates the critical technology areas in which China’s standardization efforts will be focused.

### **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.<sup>xc</sup> 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 in order to sell in the Chinese market.

## **Remuneration**

China's position on service invention remuneration is unclear. The latest Patent Law amendment has eliminated the most controversial provisions in this area. But it is worth monitoring if the National Intellectual Property Administration (CNIPA) or the legislature may come up with new regulations as a successor to the earlier SIPO's draft service invention regulations (SIRs). The draft regulations include provisions on the ownership of inventions, the employment relationship, and the companies' commercialization of inventions. In partnership with the American Chamber of Commerce in China (Beijing), the Chamber provided detailed comments to SIPO on the measures in December 2012, August 2014, and May 2015.<sup>xci</sup>

## **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.

In September 2018, the National Radio and Television Administration (the replacement of the State Administration of Press, Publication, Radio, Film and Television since March 2018) published a draft of new rules that will limit foreign content to 30% of a channel's full schedule, broken down by genre, and ban it completely between the hours of 7 p.m. and 10 p.m. Curiously, China also prohibits foreign companies from producing films or TV shows in China—other than on a project-by-project co-production basis. This restriction, which is blatantly protectionist, further reserves China's large and fast-growing market for its own companies.

Collectively, these policies make China one of the most closed markets in the world for foreign content. One bright spot had been the "Over the Top" (OTT, or internet-delivered) audiovisual sector,

which had seen significant growth in market access in the years prior to 2014, when China 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—most recently through the Administrative Provisions on the Internet Information Content Environment released in December 2019—despite the fact that U.S. companies are the global leaders in the space.<sup>xcii</sup> The Chamber urges China to address concerns that have been raised.

### **Latest judicial reform efforts**

China held the Third Plenum of the 19th CCP Central Committee in March 2018, with a focus on the reorganization of Party and governmental agencies, including IP agencies and courts, to reduce redundancies. But issues still remain, such as the fact that the copyright authority (under the National Copyright Administration of China, or NCAC) is still separated from trademark and patent authorities (now under SAMR). There is also an overlap of legacy authority over international IP between CNIPA and the Ministry of Commerce (MOFCOM).

On Feb. 27, 2018, China’s top policymaking bodies, the General Office of the Party and General Office of the State Council, issued the Opinions on Several Issues regarding Strengthening Reform and Innovation in IP Trials (“Opinions”), setting forth basic guidelines, principles, reform targets, and critical measures for reforms and innovations in IP cases. A couple of positive reforms were highlighted, such as measures to reduce the burden of proof to be borne by IP owners, determining damages mainly based on compensation and with punitive damages, establishing a national IP appellate hearing mechanism, and strengthening capacity building of technology investigation officers and making rules for the admission of technology investigation comments. Many related reforms were also included in the Phase One Agreement concluded in January 2020, such as:

- Providing for deterrent-level penalties in civil and criminal cases to deter future IP theft or infringements, and strengthening existing remedies and penalties by imposing punishments “at or near the statutory maximum permitted under its laws”;
- Shifting the burden of proof to accused parties following the provision of prima facie evidence in civil proceedings for trade secret misappropriation cases;

- Identifying the “use or attempted use” of claimed trade secret information as an “urgent situation,” thereby allowing judicial authorities to issue preliminary injunctions;
- Promising to substantially lower thresholds for initiating criminal enforcement;
- No longer requiring trade secret holders to demonstrate “actual losses” as a prerequisite for initiating a criminal investigation; and
- Providing for “expeditious remedies” —including preliminary injunctions—to resolve patent disputes in a timely manner.

Additionally, prior to the conclusion of the Phase One Agreement, in 2019 the CCP began rolling out a number of provisions similar to commitments made in Phase One when it released the Implementation Opinions on Strengthening the Reform and Innovation of Intellectual Property Trials, aiming to further improve Beijing’s IP judicial protection system.<sup>xciii</sup> The Implementation Opinions identify four major tasks: First, to improve the IP litigation system; second, to strengthen the structure of the intellectual property trial system in Beijing courts; third, to build up a professional pool of IP judges; and fourth, to enhance the application of information technology during IP litigation procedures. Some highlights include:

- Encouraging and guiding parties to preserve evidence through notary offices or other qualified commercial organizations. Electronic evidence created via the use of modern technology should be lawfully examined, and all kinds of legal evidence should be treated equally;
- Actively enhancing the role of social organizations and professional agents in the evaluation of intellectual property values, and guiding parties to confirm the value of intellectual property by providing third-party evaluation reports. Also, encouraging parties to apply for expert witnesses to appear in court, and using expert witness’ professional knowledge to resolve compensation issues, which are usually difficult to quantify;
- Promoting the implementation of the centralized jurisdiction of the Beijing Intellectual Property Court on technical IP cases in the Beijing-Tianjin-Hebei region;
- Expanding the scope of selection for IP judges, promoting the system of publicly selecting IP judges from lawyers and law professors; and trying to select professionals from the government as IP judges; and
- Strengthening exchanges among IP judges and promoting international judicial cooperation.

The Chamber intends to closely monitor progress in this area, and to ascertain whether the aforementioned judicial reforms and implementation mechanisms are delivering real benefits to foreign IP holders.

## Intellectual property courts

The establishment of three specialized IP courts in Beijing, Shanghai, and Guangzhou, and over 20 IP tribunals around China, has been encouraging to the Chamber and its members. We have identified various improvements and reform measures established through these IP courts. For example, the Beijing IP Court has been developing new mechanisms to publish guiding cases and has been citing precedents from the corresponding judgments. It has started using en banc trials in trademark administrative cases, which helps in establishing standing precedents. Also, the Beijing IP Court sought outside opinions from several research institutes on a trademark issue in January 2016, which could be seen as a Chinese version of an “amicus brief”. Regrettably, none of such practice continued or endorsed by other courts. Similar practice was seen in another case related to the copyrightability of live sports broadcasts. We also note that hiring technical assessors by the Beijing IP Court may help in adjudicating complex patent cases, although more time will be needed to evaluate the efficacy of the technical assessors and whether litigants have opportunities to cross-examine the technical assessors’ opinion. The SPC recently issued an opinion to further improve the judicial transparency through the disclosure of the trial details of important cases to the public. The Chamber also welcomes the IP courts’ efforts to increase transparency through the disclosure of the courts’ decision-making process and trial details of all cases to the public.

The Chamber also notes that the court has a 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. On November 6, 2019, the Beijing IP Court released a summary of IP cases adjudicated over the last 5 years.<sup>xciv</sup> According to the summary, the Beijing IP court has accepted 72,681 IP cases since Nov 6, 2014, with a 26% average annual increase. 70% of the cases were administrative patent and trademark cases, and 30% were civil cases. Among them, 58% of cases were trademark disputes, 25% were copyright disputes, 13% were patent disputes, and others included unfair competition disputes and franchising and technology contracts. In administrative cases involving foreigners, the success rate for foreign parties was 49% (excluding cases where both the plaintiff and third parties were foreign parties); in civil cases, the success rate of foreign parties was 68% (excluding cases where both the plaintiff and the defendant were foreign parties). On June 2020, the Beijing IP Court was proud to claim that it has concluded a total of 71,131 cases and has successfully turned around its caseload situation by an 41% annual growth rate of closing cases.<sup>xcv</sup>

China’s Supreme Court established an IP Court within the SPC in December 2018 with a national jurisdiction over appeals of technical civil and administrative IP cases (patent, new varieties of plants,

mask work, trade secret, computer software, and antitrust cases). The specialized IP courts' decisions will be appealed to the new SPC's IP Court instead of high courts. The mission of the SPC's IP Court is to formulate judicial standards and trial rules based on its investigation and research of relevant practices, and such standards and rules shall be followed by the lower courts. This may suggest that the SPC's IP Court will take over the responsibility of formulating certain judicial interpretations and selecting guiding cases. Thus, we could expect a more consistent guidance, both procedural and substantive, from the SPC over IP cases, especially when involving technical matters.

The SPC's IP Court is also empowered to hear major and complicated cases of first instance on a national scale. This implies that some plaintiffs may bring high-profile lawsuits to the SPC directly. This kind of arrangement is very rare in China's judicial system, and could be good news for patentees facing difficult issues involving local protectionism. However, it is not clear where one would take an appeal of first-instance decisions made by the new division.

The SPC's IP Court apparently has very high caseloads since its opening. According to the white paper released by this court, it accepted 962 appeal of civil cases (presumably mostly patent and trade secret cases) and concluded 586 cases. The court accepted 241 appeal cases on patent validity or reexamination related and concluded 142 cases.<sup>xcvii</sup> It is said to have average 72 days to complete one case.

Now as the IP Court has passed two years and it is worthwhile to see how China is going to further enhance the court in terms of staffing, given the rapid growth of caseloads. In addition to the SPC's IP Court, the first Internet Court in Hangzhou was established in 2017, followed by two more Internet Courts in Beijing and Guangzhou in 2018 to hear the first instance of internet-related cases, such as online copyright infringement cases, domain name disputes, and online tort liability disputes. It has been helping to reduce the rising number of online disputes thanks to the admissibility of blockchain-backed online data as evidence. We expect their jurisdiction to soon extend to trademark infringement cases as well. Case filing, evidence exchange, and hearings will be conducted online. First observations indicate that the Beijing Internet Court seems to be aggressive on copyrightability issues, with its first case recognizing the copyrightability of short video lasting for 13 seconds.

At the end of April 2019, SPC released the White Paper on China's Judicial Protection on Intellectual Property in 2018, stating that the courts accepted a total of 334,951 intellectual property cases, including first instance and second instance cases and applications for extraordinary legal remedy to reopen cases, and concluded 319,651 cases (including carried forward cases), representing a respective

year-on-year increase of 41.19% and 41.64%. First instance cases involving competitors (including antimonopoly civil cases) increased the most significantly by 63.04% to 4,146 cases.

## **Trademarks and related rights**

### **Trademark Law**

The Amended Trademark Law became effective on November 1, 2019. The amendments mainly address bad-faith trademark registrations, punitive and statutory damages for trademark infringers, and the disposition of infringing goods by the people's courts. The amendments to the law also codify recent practice of the courts and administrative authorities in dealing with malicious filings, thereby helping to ensure more consistent application of the law against piracy. The Chamber has submitted comments to address outstanding challenges and issues in relation to trademark registry and trademark enforcement. These remaining challenges include bad-faith trademark registrations; well-known marks; elimination of opposition appeals; lack of default decisions; deadlines that are particularly onerous on foreign rights-holders; non-use cancellations; coverage for retail service marks; and assignment and licensing procedures.

### **Damages**

Another significant feature of the amendments to the Trademark Law in 2019 is increasing the maximum statutory compensation for trademark infringement from RMB 3 million to RMB 5 million. Punitive damages will be allowed up to five times the actual loss of the trademark owners, or the illegal gains of infringers or reasonable multiples of trademark royalties. Under the last Trademark Law, punitive damages were only allowed to amount to up to three times the above calculations, and its application in civil cases was uncommon. While the increased cap of statutory damages in the amended Trademark Law gives some hope of better enforcement, the actual outcome is likely to be mixed. The courts have been handing down a higher amount of damages in anti-counterfeiting cases. The Supreme People's Court is also encouraging local courts to be more progressive in awarding damages. For instance, the Guangdong High People's Court awarded a record-breaking 1.4 billion RMB (around \$200 million) in damages in a trademark case in July 2018. The Beijing IP Court and an intermediate court in Wuhu have also awarded over 10 million RMB (around \$1.44 million) in damages in three trademark cases, respectively, in the past three years. In December 2018, the SPC included a case on its "typical cases list" where it awarded 10 million RMB in damages. As of the end of 2019, Chinese courts had issued a couple of judgments

with particularly remarkable damages. On December 31, 2019, the Jiangsu High People's Court awarded 50 million RMB (around \$7 million) to Xiaomi, which was imposed the damage of 12 million RMB (around \$1.7 million) in another trademark infringement case by Hangzhou Intermediate People's Court a day before. However, the average damage award for IP cases remains low. The Chamber will keep monitoring developments in this area.

### **Bad-faith Trademark Registrations**

According to CNIPA, over a 9-month period in 2019, the number of trademark applications in China reached 5.7 million, and the cumulative number of effective registered trademarks reached 24.16 million. Meanwhile, the number of trademark applications from foreign enterprises in China reached 193,000, an increase of 12.5% year-on-year. 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 2019 amendments to the Trademark Law require that bad faith trademark applications filed without intent to use be rejected. This provision will also be used as a legal basis for opposition and invalidation applications. The amendments also increase the obligations of trademark agents. Trademark agents shall not accept client assignments to file the applications which they know or should know are filed without intent to use or in bad faith. Violations may subject the agents/lawyers to administrative penalties. This special rule reflects the problem that some trademark agents have intentionally filed large numbers of bad faith trademark applications. The government has now decided it will not tolerate this anymore. The above misconduct by the trademark agents will also be the legal basis of opposition and invalidation applications. CNIPA has the authority to impose penalties specifically over bad faith trademark applications under the amendments. If a trademark lawsuit is filed on a malicious basis, the people's court will impose a penalty accordingly.

As a response to the new amendments, SAMR issued the Regulations on Trademark Application and Registration, effective as of December 1, 2019, focusing on bad faith registration. The Regulation emphasizes the CNIPA's role in combating bad faith registrations in invalidation proceedings. It provides that CNIPA could proactively declare the invalidation of a registered trademark for instances in which the registered trademark is found to be in violation of the Regulation as provided by Art. 44 of the amended Trademark Law. It could effectively reduce the cost for rights holders and increase efficiency for invalidation proceedings. However, this is very rare/not common in practice, and it remains to be seen

how it will be implemented if it becomes effective. The Regulation specifies factors to be considered when deciding whether there is bad faith, as stipulated in Art. 4 of the amended Trademark Law. Such factors include the number and designated classes applied by an applicant (and/or its affiliates), the applicant's business and operating conditions, prior effective decisions or judgments confirming the applicant's bad faith in trademark application and actual use, circumstances where the applicant's trademarks are identical or similar to others' prior trademarks and tradename with a certain degree of fame, etc. This gives trademark regulating authorities clearer guidance in identifying bad-faith applications and taking effective measures accordingly. One of the highlights of the Regulation is that it specifies the penalty for bad-faith applicants and for trademark agencies processing application they know are in bad faith, pursuant to Art. 11 and 12 of the amendment Trademark Law. If the circumstances are serious, CNIPA may decide to stop suspend the license of the trademark agency and publish the administrative penalty decision.

On April 24th, 2019, the Beijing High People's Court issued Guidelines for the Trial of Administrative Cases Granting and Affirming Trademark Rights, which aims to improve efficiency in reviewing trademarks and gives more protection to legitimate trademarks by preventing people who register trademarks with "malicious intent". Article 7.1 of the Guidelines provides that a trademark applicant must have a bona fide intention to use, and that such an intention should be supported by "demonstrable evidence".

The Chamber has taken note of the recent initiatives of the China Trademark Office (CTMO), which include having a centralized review at the early stage of trademark registration and opposition, putting together a white list of prominent trademarks for special protection as well as building a black list of notorious trademark squatters. A Chinese media outlet reported that such black lists have been sent to the examiners but not disclosed to the public. The Chamber and its members are looking forward to seeing tangible results of these measures. The Chamber also encourages the CTMO to explore additional tools to deter bad-faith trademark filers; for example, the CTMO could consider instituting a similar rule to the European Union trademark regulation (Section 2, Article 85), which requires a losing party to bear the opposition's cost if a trademark is found invalid.

### **Quality Examination Practices**

China's Trademark Office is the busiest in the world, and the rate of increased applications combined with strict timelines for review have put pressure on the resources of the office. While a new division was created and contract workers have been hired to deal with the demand, China is still working



on expediting review speed rather than quality. A three-year plan was issued aimed at shortening the timeline for review to four months. In December 2018, the timeline was reduced to six months from eight months. CTMO's target is to further reduce it to four months in 2020. The quality of the examination is at risk with this expansive growth. Efforts are underway to improve the training and management of these workers, as this will directly affect the quality of the trademarks issued in China.

### **OEM-related Trademark Infringement**

On September 23, 2019, the SPC gave its decision in an OEM manufacturing trademark case brought by Honda against a Chinese OEM manufacturer. Hongda registered three relevant trademarks in China. Entrusted by a Burmese company who owns "HONDAKIT" trademark in Burma, the Chinese OEM manufacturer used the mark on the vehicle parts and exported all the products to Burma. The SPC held that Heng Sheng had infringed Honda's trademark rights. The SPC particularly pointed out that it is inappropriate to simply classify OEM as an exception to the trademark infringement, which is very different from previous decisions. The SPC has to some extent given Honda implied protection against the possible infringement of its Chinese trademark outside of China. The SPC added that, the Court, when adjudicating foreign-related OEM trademark infringement cases, shall fully consider the domestic and international economic development situations and make specific analyses. Chinese courts' opinions on OEM-related trademark infringement have changed during the past few years. The last OEM case ruled by SPC supported the Chinese OEM manufacturer as non-infringement if the goods are only for export.

### **Remedies**

A notable change in the 2019 amendments of Trademark Law is the way counterfeit goods will be handled during the trademark infringement lawsuit. Under the amendments, counterfeit goods shall be destroyed at the request of trademark owners in civil proceedings, which was previously only allowed as remedy in administrative proceedings. Counterfeit goods shall not be allowed to enter into the commercial distribution channel after counterfeit labels are removed. Materials and tooling that are mainly used for manufacturing counterfeit goods shall be destroyed without any compensation, or in special circumstances shall be excluded to enter into commercial channels without any compensation.

## Online Counterfeiting

Online counterfeiting remains a significant challenge. The explosive growth of online transactions in China has fueled online sales of counterfeit goods as well as the upstream manufacturing and distribution of these goods. In 2015, a report to Chinese lawmakers found that more than 40% of goods sold online in China were either counterfeits or of bad quality.<sup>xcvii</sup> A survey by China Consumer Association in 2018 revealed that over 70% of customers have purchased counterfeit goods online. Respondents believe counterfeit goods are the most serious problem on online platforms.<sup>xcviii</sup> Over half of customers have purchased counterfeits from cross-border online platforms.

SAIC issued Measures for Online Trading and Related Services (“Online Trading Measures”) in 2014, which seemed to give high priority to consumer protection and intend to address unfair competition. But the Online Trading Measures lack sufficient deterrence against both individual vendors involving counterfeit transactions and online trading platforms. Reportedly, some online platforms have taken a very cooperative approach with courts nationwide, including collaborating on court orders for evidence preservation and providing vendors’ mailing addresses to the courts. All such measures are welcomed by the Chamber.

However, massive amounts of counterfeit goods continue to be distributed online, indicating the need to do significantly more. China must deal aggressively with repeat offenders by closely monitoring them and referring a greater number of these cases to Chinese authorities for investigation. The new division set up under China’s Ministry of Public Security – Division of Food Drug and Environmental Crime Investigation, needs to be launched nationwide at faster pace and is asked to launch investigation at early stage in those counterfeit hotspots. We urge USTR to press for effective policy changes.

The online sale of counterfeits remains a significant challenge. Massive amounts of counterfeit goods continue to be distributed online, indicating the need to do much more. The explosive growth of online transactions in China has fueled the sale of counterfeit goods online and the upstream manufacturing and distribution of these goods. Online platforms can take stronger steps to respond to this epidemic, including simplifying processes for rights-holders to register and request enforcement action, taking effective measures to identify sellers and products, giving rights-holders access to information about sellers accused of infringement, implementing policies that prevent sellers from hiding behind multiple accounts, reducing timelines for takedowns, adopting rating systems allowing the public to assess whether a seller has a history of IP violations, removing listings and stores, and issuing penalties for sellers of counterfeit goods. The popularity of counterfeit goods on social media sites has also become a new and distinct challenge for rightsholders in China.

Concerning IPR enforcement online, the long-awaited E-Commerce Law was published in 2018 and came into effect starting Jan. 1, 2019. The Chamber welcomes some changes made in the new law, such as the prompt takedown action, which requires the platforms to take down infringing products upon receipt of takedown notice. However, the law also requires that if the platforms do not receive notice of a filed lawsuit or complaint within 15 days after the takedown, they shall cease the takedown measures against the claimed infringers—a timeframe since extended to 20 working days by Article 1.13 of the Phase One Agreement. The “20-day” clause has caused concerns for rights-holders, as they have to file lawsuits within 20 working days, otherwise the infringer can come back online. This may limit the effect of “Notice-Takedown,” impose higher requirements on rights-holders, and increase the amount of infringement lawsuits filed to the courts. Also, some key concerns remain unresolved. For example, the law must be able to address the ability of counterfeiters to escape prosecution by maintaining anonymity. The Chamber hopes such significant problems will be addressed through implementation regulation, judicial interpretation, or judicial cases.

## **Design rights and related rights**

### **Design Patents and Partial Designs**

The Chamber has previously noted that the amendments to the 2016 Patent Examination Guidelines did not address the patentability of partial designs, a critical subject matter to many of our members. The latest proposed amendment to the Patent Law deleted the adoption of the idea of partial designs in the former draft and expanded patent term of design patent to 15 years. On Oct 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 take effect on June 1, 2021.

## **Trade secrets and related rights**

### **Trade Secret Protections**

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)
- 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 rule-making measures supported much stronger protection of trade secret, by providing clearer and stricter application of punitive damages, introduced strengthened procedural protections for rights holders, contained an expanded definition for “misappropriation,” and 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. The Chamber believes that further revisions to these Rules and other trade secret regulations, as well as judicial practices, merit close scrutiny from USTR in the year ahead.

## **Enforcement**

### **Restructuring the Counterfeit Economy in China**

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.

It is our hope that these commitments, prominently featured in China’s April 2020 IPR Action Plan, could help turn the tide on the flood of counterfeits that emanate from China, and we believe that China’s leadership could further crack down on counterfeits by calling for further restructuring in China’s upcoming 14th Five-Year Plan. Setting long-term restructuring goals will motivate and empower central- and local-level officials, as well as important market players, to end economic dependence on illicit trade. In creating and protecting a legitimate marketplace in China, positive benefits will come to small and medium-sized Chinese businesses and the economy and will protect consumers around the world. The Chamber has launched a research project to analyze the benefits to brand owners of this restructuring and explore methods to accomplish it in consultation with experts in China and around the world.

### **Pharmaceutical Counterfeiting**

The Chamber applauds the achievements made by the Ministry of Public Security (MPS) and local PSBs in cracking down on drug counterfeits over the years. 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. Chinese police have 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.

The Chamber was also encouraged by the agreement that China and the U.S. government have made through the Sixth Meeting of the Strategic and Economic Dialogue with respect to counterfeit

active pharmaceutical ingredients (API), but possible reforms of the Criminal Code to deal with illegal bulk chemical factories have not been implemented.

On Aug 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. Aimed at addressing prominent problems in the pharmaceutical industry, such as counterfeit and substandard drugs and high drug prices, the revised law stipulates the strictest standards and toughest measures in supervision over the whole process of the industry chain, including the research and development, manufacturing, sales, use and management of drugs.

The revision modifies the definition of counterfeit drugs. Drugs imported without authorization are no longer listed as counterfeit drugs. The revised law raises the amount of fines significantly. The fine for the production of 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 criminal 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. The Chamber hopes that the U.S. government will closely engage China on this particular area.

## **Camcording**

Illegal camcording of feature films is a significant problem in China. Given the explosive growth of China’s movie theaters, it is a problem that is likely to grow. The State Administration of Press,

Publication, Radio, Film, and Television (SAPPRFT) acknowledged the problem through notices in 2015 recognizing the threat that camcording poses to the film industry, calling for Chinese movie theaters to be aware of and take steps to address the problem, and requiring availability of digital watermarking. While these are positive developments, experience has shown that a critical step is enacting an effective criminal law against the act of camcording. An effective law does not require a showing of intent to distribute; such a requirement significantly complicates enforcement and is unnecessary since there is no legitimate reason to camcord a film.

### **Enforcement Efforts**

There are three categories of enforcement: online enforcement, in-country enforcement and cross-border enforcement. Countries around the world are struggling to address such an onslaught of counterfeit goods, to protect legitimate marketplaces, and to keep consumers safe. The Chamber's International IP Index, which maps the IP environment in economies around the world, found the vast majority failed to reach one-third of the maximum available score on enforcement against IP theft and forgery.

China appears to have maintained a similar level of active enforcement efforts against counterfeiters in the past few years. The "Jianwang 2019" campaign by NCAC has focused on theatrical movies, photos and social media. NCAC claimed the crackdown of 418 pirate movie websites and removal of 11 million infringing links.<sup>xcix</sup> In 2018, the General Administration of Customs claimed seizure of 5.86 million infringing goods valued at 35.86 million RMB (around \$5.1 million).<sup>c</sup> It is notable that criminal IP cases have increased a bit. New criminal IP cases received by the courts have slightly increased to 4,000, after the sharp decline from 8,352 in 2016 to 3,621 in 2017.<sup>ci</sup> Below are some procedural concerns and changes that could be made to improve China's enforcement system.

### **In-country Enforcement**

The Chamber is concerned that Article 60 of the new Trademark Law, dealing with reseller's infringement liability, may suppress enforcement efforts. Article 60 Paragraph 2 has been interpreted by the State Administration of Industry and Commerce (SAIC, now under SAMR) nationwide as preventing authorities from seizing counterfeits from or penalizing resellers who claim no knowledge about the sold items and prove the legitimacy of transactions with details about the sources. This provision has dramatically blocked the brand owners and SAIC authorities from going after counterfeit resellers. The

Chamber strongly recommends that USTR urge China to amend this particular provision or otherwise interpret the provisions differently.

The Chamber suggests that national and local police keep investing in more dedicated, expert-level police officers in the IP crime unit. Raising awareness could be helpful too, as knowledge of IPR infringement still varies between provinces or cities. Also, there is opportunity to improve cross-territory enforcement. Apart from the food and drug field, the police need to deliver more deterrence in the areas of consumer goods, high-tech, auto parts, and machinery.

The number of criminal transfers seems to remain low.<sup>cii</sup> The Chamber highly encourages USTR to underscore to China the need for more innovative measures to promote cooperation between administrative authorities and the public security bureaus (PSBs) in the course of investigations. Brand owners report that low rates of transfers result in part from a lack of a special budget for warehousing counterfeits and investigations and a reluctance of SAIC to transfer if it can collect large amount of fines from counterfeiters. Governments around the world must deal aggressively with repeat offenders by closely monitoring them and referring a greater number of these cases to authorities for investigation.

Local protectionism is still a concern, even if some improvements have been made: Brand owners are facing many challenges in Guangdong, Zhejiang and Fujian Province. The Chamber is particularly eager to see a substantial increase in the number of referrals of cases—large and small—to authorities in Guangzhou, one of the primary locations where online traders and manufacturers of fakes are located. Court orders to seal funds in counterfeiters' accounts at online payment service providers should be explored, as well as ways to hold parties responsible for aiding and abetting the sale of counterfeit and pirated goods, whether through advertisement or sale of these items or otherwise. The Chamber urges USTR to increase attention and focus on improving the online environment and press for effective policy changes.

Brand owners have also raised concerns about the increasing costs for warehousing and destruction of their brands seized by the Chinese enforcement authorities, especially in view of environmental concerns that are being raised over the traditional destruction methods of burning or burying the counterfeit goods. The Chamber recommends the development of national standards on the storage and destruction of counterfeit goods. In parallel, the Chinese government should explore ways to reduce the financial burden on brand owners.



## **Border Enforcement**

Cross-border anti-counterfeiting efforts and collaboration between the U.S. and Chinese customs should be a priority for both countries. As mentioned earlier, funding of the OECD phase-two study on counterfeiting that intends to map out illicit trade flows will provide the necessary data for countries to enforce at the borders and therefore should be supported by both the U.S. and China. In particular, we commend the Phase One Agreement for its provisions aiming to strengthen border enforcement by calling for an increase in the number of personnel trained to “inspect, detain, seize, effect administrative forfeiture, and otherwise execute customs’ enforcement authority against counterfeit and pirated goods” within nine months of the Agreement taking effect. The Chamber highly anticipates China’s forthcoming quarterly updates on enforcement actions, as stipulated in the Phase One text.

Dealing with counterfeits in small-parcel packages has increasingly become a focus of anti-counterfeiting enforcement campaigns. This is particularly true as global e-commerce activities are growing substantially. China’s General Administration of Customs (GAC) has taken some initiatives to stop counterfeits in transit at airports and other international express deliveries. As part of the national IPR campaign that began in September 2017, local State Post Bureaus (SPB) have been asked to launch campaigns and put in place safety check mechanisms targeting infringing goods, which require pickup checks, real name mailing, and scanner safety checks.<sup>ciii</sup> But success has been inconsistent, and practical difficulties remain significant. On the other hand, the regulator of the China Post’s express mail delivery service (EMS) and other EMS service providers—the SPB—have been trying to regulate the entire sector for years through industry standards and new ministerial rules, some of which touch on the legal duty of inspection for counterfeits. However, most of the SPB’s efforts are related to market access, and the SPB has not prioritized this issue, rarely holding EMS providers liable for assisting counterfeiters. The current regulations related to export declaration, small parcel inspection, and liability to the trade forwarder by Customs make it difficult or impossible to trace back to the real owners when export counterfeits are seized. We recommend a review of such regulation in order to positively affect the ability to protect and enforce on small parcels coming from China.

China’s General Administration of Customs (GAC) still reported growth of seizure of counterfeit goods, which apparently is higher than the prior years. On January 25, 2021, the General Administration of Customs released a summary of the seized goods and the detained goods which were suspected infringing last year. According to the summary, the number of the seized goods was 61,900 and the number of the detained goods was 56,181,900, both were an increase of 20% compared to that in 2019. Meanwhile, according to the white paper published by the Customs in 2019, the corresponding numbers were 5,1600 and 46,789,400, which were an increase of 9.32% and an increase of 86.41% than in 2018. A

noticeable point of the white paper was that the types of goods detained by the customs in 2019 were mainly light industrial products, food, and beverage, while the numbers of traditional luggage, shoes and hats decreased.<sup>civ</sup>

## **Section E: Developing Market Profiles**

### **ARGENTINA**

#### **Overview**

Despite its high Human Development Index score (0.845), gaps in Argentina’s IP framework have limited the ways the country can capitalize on its innovative capacity to power socio-economic growth.<sup>cv</sup> 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. The most recent data available from the Cámara Argentina de Comercio, for instance, found that the number of street stalls selling counterfeit goods increased by 47.5% (1,244 stalls) from January 2019 to January 2020.<sup>cvi</sup> The Chamber believes that business—and society as a whole—succeed when given the freedom to thrive. As the Argentine government strategizes on how best to encourage domestic consumption, secure foreign investment, and ultimately drive growth, we ask 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**

##### **Patentability**

Argentina does not grant patents for formulations, salts, polymorphs, combination products, active metabolites and pro-drugs, enantiomers, species selection of a genus of compounds and others—nearly 80% of all pharmaceutical innovations. The process to discover the methods is not only labor and capital intensive—it can mean the difference between success or failure in treating a patient. Although differences in the type (whether a treatment is ingested or injected) and frequency (twice-daily or once-daily, for instance) of treatments may seem slight, it is—in fact—significant. Industry research has estimated a 30% difference in treatment adherence rates for patients that took a pill once a day versus four times a day. The Chamber notes that the imposition of additional patentability criteria for pharmaceutical

patents beyond those of demonstrating novelty, inventive step and industrial application is inconsistent with Articles 1 and 27.1 of TRIPS. Moreover, by imposing additional patentability criteria that does not apply to other sectors, the guidelines discriminate against innovative pharmaceuticals.

The Argentine government has also taken steps to restrict patent protections for nucleotide or amino acid sequences, as well as biotech processes and biological components such as genetically modified seeds. Guidelines released in 2016, for instance, also added complex requirements for the disclosure of gene sequences in applications, requesting the full sequence of all genes claimed, and demonstration of their function. Since the introduction of the guidelines, there has been a sharp increase in the refusal rate for pharmaceutical patents, with less than 5% accepted by Argentina's IP regulator, the Instituto Nacional de La Propiedad Industrial (INPI). Most egregiously, in 2016 INPI rejected two ag-bio patents that had already been approved in other Latin American countries and with claims structured similarly to previously approved patents.

### **Patent Backlog**

Despite the difficult regulatory landscape, there are helpful signs that INPI is taking steps to streamline its operations and tackle its backlog of nearly 21,000 patent applications. In 2019, the Argentinian government worked to implement Decree 403/2019 to expedite patent and utility model applications. 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. Lastly, INPI built on its 2017 Patent Prosecution Highway (PPH) agreements with USPTO and JPO by signing a new agreement with the Chinese IP office, the State Intellectual Property Office of the People's Republic of China.

Though the Chamber is pleased that the Argentine government is working on capacity building and addressing the nearly 10-year patent backlog, we note that the country's increasingly narrow approach to patentability—a global outlier—has only compounded problems in an already difficult patenting environment. As such, the Chamber encourages the U.S. government to collaborate 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 to stop the sale of patent-infringing goods during litigation—were nominally provided for in 2003 under amendments to Law 25.859. Fifteen years after their implementation, however, 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. To that end, we ask that the U.S. government work with the Argentine government to meaningfully streamline the process.

## **Compulsory licensing**

The Chamber notes ongoing concerns of domestic compulsory licenses proposals in Argentina—particularly in the global pandemic. Even before COVID-19 was top-of-mind, the Argentine Congress passed a health emergency law in December 2019 that empowers the Ministry of Health to establish a compulsory or mandatory licensing mechanism in the event of potential problems of availability or unjustified/unreasonable increases that affect the population's access to medicines in a way that could put their health at risk. Such a mechanism appears to encourage a first step towards compulsory licensing in a manner that will not only undermine patient access to new medicines but bring Argentina out of step with its international obligations.

## **Copyrights and related rights**

### **Enforcement**

Argentina currently lacks an effective legal framework to adequately enforce copyright protection. Making matters worse, rightsholders have highlighted their concern with S-942/16, a bill for the “Regulation of Internet Service Providers and Internet Content Search Engines,” that would have significantly restricted industry's online enforcement capabilities. Although bill S-942/16 has lost parliamentary status, it is likely that similar initiatives will resurface in some form in 2021, as the Supreme Court has asked for legislative action in the face of its own conflicting decisions. The Chamber asks that the U.S. government closely monitor such legislation, as its passage would have broad-reaching effects on regional and national enforcement.

Going forward, the U.S. Chamber urges Argentina to increase resources and political backing for a coordinated, long-term antipiracy agenda at the federal and local level to address 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.

### **Penal Code Reform**

The Macri Administration's Penal Code Reform Bill (PE-52/19) was sent to the Senate's Justice and Criminal Matters Commission in March 2019. Although debate had started by June, it stalled after the Macri Administration lost the 2019 Presidential elections. Due to COVID-19, Congress was forced to session remotely as of May 2020, prioritizing pandemic-related issues; the bill will lose parliamentary status on February 28, 2021. If implemented, the bill would improve the enforcement landscape for copyrighted works in Argentina. Some of the copyright issues covered by the legislation include: 1) reproduction of copyrighted material and programs from the Internet without proper authorization, 2) manufacturing, storing or selling copyrighted programs without authorization, and 3) circumvention of technological protection measures (TPMs). In addition, the proposal would make theft of IP equivalent to theft of physical objects and would make the incorrect reporting of Pay-TV subscriber numbers a penalty under the law.

### **Trade secrets and related rights**

#### **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. 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, such as what happened with an innovative Hepatitis C product. 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**

### **Audiovisual Content Quotas**

In July 2018, INCAA published Resolution 1050/2018 regulating content quotas for movie theatres. Domestically produced films must represent 30% of the volume of content shown, for the entirety of one week per quarter where there is a dedicated screen. While that 30% content quota was in effect previously, under the prior regulatory regime, the screen could be shared with another film. Under the new regulation, should the exhibitor share the screen with another movie, it will be considered a partial fulfillment, and the local production must be shown for two weeks (a minimum of one screening per day for at least one additional week) or until the full quota is fulfilled. Pressure for content quotas increased in 2020 as authorities lacking resources to supervise have been slow to enforce these existing quotas. Argentina's COVID-19 lockdown that paralyzed the audiovisual industry has also motivated demands from local filmmakers that the Argentina government start enforcing the law -- and modify Media Law 26.522 to extend the quotas to streaming services.

Content quotas are expected to remain an issue in 2021, and the Chamber encourages the U.S. government to closely monitor this issue, as such quotas can reduce consumer access to content and fuel piracy.

### **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.

Furthermore, in 2020 the government of Argentina indicated that they would adopt international reference pricing methodologies for price controls on "high cost" medicines. As a general matter, such an approach assumes similarity across all countries in the reference basket and implicitly imports the pricing policies of those countries without accounting for circumstances that justify price differentiation. The

Chamber asks the U.S. government to continue its engagement with the government of Argentina on a facts-based dialogue for IP best practices.

## **BRAZIL**

### **Overview**

This past year saw sustained positive developments on IP in Brazil as the country initiated a public comment process for its first-ever National Intellectual Property Strategy, followed by a detailed series of recommendations in December 2020. This document—developed under the auspices of the Interministerial Group on Intellectual Property, GIPI (Grupo Interministerial de Propriedade Intelectual)—will guide the government’s approach to IP policies for the next 10 years. This summer, the Chamber also had the opportunity to comment on the government of Brazil’s “Innovation Strategy”, where we again highlighted the importance of IP protections to foreign investment and domestic innovation. We are excited to continue our partnership with the government of Brazil on these initiatives in 2021.<sup>civii cviii</sup>

The Chamber also notes important changes to the bilateral trading relationship. On October 2020, after 10 months of intense negotiations amid the COVID-19 pandemic, Brazil and the U.S. signed an amendment to the 2011 Agreement on Trade and Economic Cooperation referred to as the Protocol on Trade Rules and Transparency. The Trade Protocol has three annexes: trade facilitation (TF), good regulatory practices (GRP), and anti-corruption. The Protocol does not include provisions on tariff reductions nor intellectual property rights, but two of its three annexes contain state-of-the-art provisions on trade facilitation and good regulatory practices. Brazil’s commitments expressed in the agreement represent welcoming progress on rule of law principles, and should be used as a foundation for further talks. Approval of the Brazilian Congress is needed so we encourage the U.S. government to join private sector stakeholders in pushing for a speedy approval in 2021.<sup>cix</sup> The Chamber also notes bilateral cooperation in multilateral organizations. Earlier in this report, the Chamber noted its concerns regarding a waiver proposed to the WTO TRIPS that would override nearly every aspect of IP to respond to the global pandemic. We note that the government of Brazil has refrained from supporting this proposal—joining the U.S. and other countries to ensure that IP principles are not hastily overridden in the midst of such a crisis.

In addition, we continue 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. By leveraging the technology neutral Patent Prosecution Highway

(PPH), prioritizing an application’s technical merit, and increasing resources for the agency, the Chamber is confident that the environment for stakeholders will continue to improve. However, the government of Brazil must stay the course if it is to become a truly innovative economy. Legal gaps remain 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.

## **Patents and related rights**

### **Patentability and Dual Examination**

Brazil has been long-known for enforcing patentability standards far afield of international norms. One example of this is how Article 229-C of Brazil’s Industrial Property Law 9.279 allows the Brazilian National Health Surveillance Agency (ANVISA) to provide “prior consent” for biopharmaceutical patents examined by INPI. In effect, this means that patent applications must be examined twice—violating the TRIPS Agreement’s obligations on non-discrimination.<sup>cx cxi</sup> Further, it is likely that much of Brazil’s 10-year backlog of patent applications can be traced to this law—of which ANVISA does not have the staff, resources, nor technical expertise to quickly review patent applications.

In 2017, the Chamber was hopeful that an Interagency Ordinance would correct this by limiting ANVISA’s role in patent examinations to products of “strategic importance” to the country’s public healthcare system. After INPI approved a patent for a Hepatitis C drug in 2018—over the objections of ANVISA—a case challenging the Ordinance was filed in Brazil’s Federal Court. Although patent protection for the drug was eventually granted by the Court, the Chamber notes that Brazil’s independent Federal Prosecutor’s office also issued a formal challenge to the 2017 Ordinance and is pending review. The resulting legal uncertainty has hampered Brazil’s ability to secure both foreign biopharmaceutical investment and patient access to the most innovative treatments.

In 2020, however, the government of Brazil made a concerted effort to further clarify the prior consent process through a series of publicly-available manuals. This development will bring more transparency to the process as well as aid stakeholders seeking a patent in Brazil. We also note recent, structural changes to ANVISA’s review of INPI patents under Portaria 2466/2020, released in September 2020.<sup>cxii</sup> Under this administrative action, ANVISA’s ability to provide “prior consent” was limited to the following situations only:

- A request for priority examination by the Ministry of Health to INPI



- The technology related to a patent application is the subject of a lawsuit to obtain access to the drug, upon request from the Ministry of Health to ANVISA;
- Being related, based on technological prospects, to an area relevant to the actions of the Ministry of Health; and,
- Being selected by ANVISA, according to therapeutic use, from among the following groups: (a) infectious and parasitic diseases; (b) diseases of the respiratory system; (c) diseases of the nervous system; (d) rare diseases; (e) diseases of the digestive system; (f) diseases of the blood or blood-producing organs; (g) diseases of the immune system; (h) diseases of the circulatory system; (i) neoplasms; and (j) vaccines and serums.

The administrative action also established a new ANVISA advisory body under the Science, Technology, Innovation and Strategic Health Supplies Secretariat (SCTIE) entitled the “Commission on Intellectual Property in Healthcare” (COMPIS). This group--staffed by representatives from science and health agencies—will have the following responsibilities:

- Providing technical assistance to ANVISA’s “Health and IP” policies as well as assisting in ANVISA’s review of priority patent applications
- Proposing priority areas for diagnostics, assessments, and actions regarding “Health and IP”
- Support ANVISA’s role in the government of Brazil’s Joint Interministerial Group on Intellectual Property.
- Propose studies, events, and public consultations on policies related to “Health and IP” as well as assisting ANVISA in national and international fora.

At the time of this writing, it is understood that Portaria 2466/2020 has not been implemented. However, the Chamber is concerned that some of the measure’s provisions—while further limiting ANVISA’s role in the patent examination process—may serve to further entrench a policy already out of step with international patenting norms. As subject matter expert, INPI should be the sole government body in Brazil that examines and approves patents according to patentability standards recognized by Brazilian law. We encourage the U.S. government to constructively engage with the government of Brazil in bringing its patent protection and approval process in line with global standards.

### **Patent Backlog and Review Delays**

As noted in previous submissions, the Brazilian Patent Office (INPI) has a backlog of 100,000 patent applications—a nearly 10-year wait. In 2019, INPI pledged to aggressively reduce the average wait

time to two years by 2021 through the “Backlog Fight Plan” (Plano de Combate ao Backlog de Patentes). This initiative has already begun to bear fruit, with January 2021 data showing that the number of outstanding patent applications had dropped to around 72,000 from 147,000 in 2019—a 50% drop.<sup>cxiii</sup>

But while the government addresses this backlog, Article 40 of the Brazilian Patents Act has been key to establishing legal certainty for innovators and restoring partial terms of protection lost from interminable wait times.<sup>cxiv</sup> In 2020, however, a long-standing legal challenge to Article 40 by was heard in federal court. Although the case is still under review, we understand that the National Congress is also discussing a Bill to strike Article 40. With utmost respect for the independent judiciary and its critical role in Brazil’s democratic system, we note that the abolition of Article 40 would, in effect, retroactively reduce—even void outright—patent protections for some 35,000 products (in all sectors). Furthermore, we return to the reason why Article 40 was passed in the first place: to serve as a “safety valve” as the Brazilian government addressed the patent backlog and wait times. Removing this protection before the problem is resolved, then, would frustrate the efforts of local and foreign patent owners to commercialize their innovative products in Brazil. Whatever the result, the Chamber supports recent INPI initiatives and looks forward to collaborating with the U.S. government and INPI on further programs to address the patent backlog.

### **Productive Development Partnerships (PDPs)**

The Chamber continues to underscore the importance of transparency, predictability, and due process in the PDP approvals process as well as clarity on the interaction between an approved PDP and existing patent rights in Brazil.

One specific example of PDP transparency concerns took place in March 2018, when Brazil’s Ministry of Health (MoH) approved two administrative appeals for PDP proposals for lenalidomide. These appeals were filed by state-owned enterprises FUNED (Fundação Ezequiel Dias) and TECPAR (Instituto de Tecnologia do Paraná), along with Indian company Natco. It is important to note that INPI had already granted a patent in December 2017 (until 2027) for innovative lenalidomide, also known as Revlimid. We also respectfully note that the MoH’s Technical Evaluation Committee and Deliberative Committee rejected similar PDP proposals in December 2017, recognizing the existence of the Revlimid patent. We would appreciate additional clarity on the interaction between research-focused PDP approvals and existing patent rights as well as an assurance that patent rights would not be violated in the process.

Furthermore, according to Article 39 of MoH Ordinance 2531/2014, administrative appeals for PDP project proposals will be sent to the Science, Technology and Strategic Inputs Secretary (SCTIE) for a technical evaluation. That same article requires that the Technical Evaluation Committee and its validating body, the Deliberative Committee, re-evaluate the proposal during an appeal. However, we have been informed that the MoH process for the March 2018 approvals did not follow its usual internal process, as the PDP appeals were not analyzed by the Technical Evaluation Committee and/or the Deliberative Committee.

The Chamber and its members are pleased to note that toward the end of the year, on Dec. 28, 2018, the MoH published the final result of the 2017 PDP project proposals. Both FUNED and TECPAR's PDP proposals for lenalidomide were rejected, respecting the innovator patent and rightly putting an end to this particular PDP issue. The Chamber notes that approving generic-company PDPs without proven specialized expertise and technical expertise in managing the risks offered by innovative drugs could endanger the necessary balance between the benefits and risks of these products to the population. We appreciate the spirit of the PDP system in Brazil to facilitate R&D initiatives and recognize the importance of each country striving to build its own innovative capabilities. On the same note, we encourage the MoH and all relevant stakeholders in the Brazilian government to conduct and process PDP decisions and appeals in the spirit of transparency and predictability to boost IP-led innovation and scale up access to top-notch health care.

## **Copyrights and related rights**

### **Copyright Law**

In December 2020, the government of Brazil identified updates to the Copyright Law—with a focus on anti-piracy—as a priority action in the National IP Strategy. This emphasis builds on an earlier public consultation in 2019 to reaffirm its commitment to global best practices in the country's now 18-year old copyright framework. 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. Targeted changes to the Copyright Law would also give Brazil the chance to ratify and implement the WIPO Internet Treaties into its domestic law.

## Online Piracy and Enforcement

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.” After a successful action in 2019 resulted in the blocking of 210 websites distributing infringing content, a complementary action in fall 2020 disabled nearly 252 illegal websites.<sup>cxv cxvi</sup> The coordinated raids also uncovered guns, luxury cars and goods acquired from the operators’ profits, which are estimated in the millions of dollars. 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.

We also encourage the U.S. government to urge its Brazilian counterparts to institute effective and timely mechanisms to combat online copyright infringement, most notably expanding the availability of injunctive relief to prevent access to infringing materials, and ensuring that implementation of the Marco Civil Internet law and related decrees and legislation does not interfere with voluntary notice and takedown efforts or other constructive and cooperative agreements to combat online piracy. We also recommend the approval of pending legislation to criminalize signal theft in the home entertainment sector. Under the 2014 Internet Act (12.965/14, Marco Civil da Internet), any infringing content online requires a court order for removal—hobbling authorities’ ability to respond to illicit activity on the internet. In 2016, however, the Parliamentary Committee of Inquiry on Cybercrimes approved in its final report a bill on the disabling of infringing websites, now bill No. 5204/2016.<sup>cxvii</sup> The bill is still under consideration by the Committee on Science and Technology of the Lower House along with a similar bill, No. 169/17. Applauded by rights holders, these initiatives would expressly authorize Brazilian courts to issue orders requiring ISPs to block access to websites hosted outside Brazil that are dedicated to copyright infringement. Such initiatives would enable Brazil to utilize enforcement tools that are emerging as best practices in Europe and the Asia-Pacific region.

The Chamber also 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 more effectively combat all forms of copyright piracy 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.<sup>cxviii</sup>

## **Unlicensed software use**

According to the most recent data available, the rate of software piracy in Brazil slowly decreased from 53% in 2011 to 46% in 2017.<sup>cxix</sup> This places Brazil below the mean for Latin American countries. The Chamber would like to underscore the importance of raising awareness on this critical issue, highlighting several initiatives by the Brazilian Association of Software Companies (ABES) to combat the use of pirated software. The Chamber also recommends that the U.S. government collaborate with the Brazilian government to introduce additional mechanisms to combat software piracy in Brazil.

## **Trademarks and related rights**

### **Trademark Registrations and Industrial Designs**

The Chamber applauds INPI's efforts to facilitate design patent and trademark registrations by acceding to the Madrid Protocol in 2019, hiring more examiners, and making investments in the agency's IT infrastructure. Despite these efforts however, the process in Brazil remains far too slow and cumbersome. Brazilian government needs to remain diligent in providing adequate resources to address the still-lengthy delays and backlogs in the processing of trademark registrations, design patents, and utility patents. This is critical for footwear companies, in particular, that rely on trademarks and design patents to protect their innovative products. At the same time, INPI's new initiatives to restructure and address trademark application backlogs are steps in the right direction. The number of trademark applications pending examination was reduced from 358,776 at the end of 2017 to 189,122 at the end of 2018.<sup>89</sup> At the same time, the period from January 2018 to December 2018 witnessed growth in trademark registrations (9.8%) and industrial designs (1.8%) in relation to the same period in the previous year.<sup>90</sup>

### **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. 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**

### **Protection of Trade Secrets**

Confidential information and trade secrets in Brazil are primarily protected through the Industrial Property Law 9.279 (Lei da Propriedade Industrial) and Labor Code (Consolidação das Leis do Trabalho). Article 195 of Law 9.279 defines what constitutes “crimes of unfair competition,” including the obtaining, divulging, exploitation, or utilization of confidential knowledge and/or information and data that can be considered a trade secret. The law provides for both criminal sanctions and civil remedies. Article 482 of the Labor Code defines “breach of company secrecy” as grounds for employment termination and dismissal. Importantly, and unlike other jurisdictions, including many high-income OECD economies, the Industrial Property Law provides and explicitly defines the need and use of private court proceedings with regards to trade secret and confidential information litigation. Article 206 of the law states that “in the event that information disclosed in court (...) is characterized as confidential, whether industrial or trade secret, the judge shall order that the proceedings be held in camera, and the other party shall be prohibited from using such information for other purposes.”

As with other forms of IP rights, rights-holders in Brazil face significant challenges in practically enforcing their rights. The new Civil Procedure Code (Código de Processo Civil), enacted in 2015 and in force since mid-2016, has alleviated some of the pressure points within the judicial process, but rights-holders continue to face long wait times for court action. And while available, criminal sanctions are relatively weak, with Article 195 of the Industrial Property Law providing a maximum penalty of between three months to one year of imprisonment or a fine.

### **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—which protects innovative companies against the unfair, commercial use of their data by a third party during the marketing approval process—allows a biopharmaceutical company

to recoup the significant investment needed to generate the data required for the marketing approval of a new drug. The lack of regulatory data protection for human-use innovations has created challenges for biotechnology companies operating in Brazil. The Chamber encourages the U.S. government to work with the Brazilian government and ANVISA to ensure equivalent and equitable regulatory data protection for human-applied innovations.

## **Commercialization of IP Assets and Market Access**

### **Local Content/Forced Localization**

Brazilian law includes several local content requirements which affect a number of 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.<sup>xxx</sup> Although these quotas are set to expire in 2023—and they are currently being challenged in a federal court—such localization policies limit the legitimate content that Brazilian consumers can access. This resulting lack of choices has the unfortunate effect of increasing illegal consumption of content. 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.

### **Technology Transfer and Commercialization of IP Assets**

Brazil has several policies and regulations to promote the transfer of technology and commercialization of IP. For instance, one of the key tenets of the 2004 Innovation Law was to encourage the transfer and commercialization of technologies through incubation services for public researchers and greater encouragement of startup activities. The law provides incentives, including royalty guarantees, to inventors. There are also special research and development (R&D) tax incentives in place that reward the commercialization and protection of IP. These include a potential 60% deduction on corporation tax liability and social contributions, which can also increase if there is a year-on-year cumulative increase in R&D spending. An additional 20% deduction becomes available once an invention has been patented.

However, these initiatives are in many respects undermined by an administrative and regulatory framework that can be both burdensome and inefficient. For example, the practical availability of the additional 20% R&D deduction for patented inventions is very limited given patent backlogs at INPI. Despite these positive incentives, regulatory and formal requirements can limit the attractiveness of licensing IP assets in Brazil. Technology transfer agreements must be registered with INPI. During the registration process, INPI has sought to modify the terms of these freely negotiated contracts. Typical modifications include limits on confidentiality clauses and royalties. INPI's interference can also put trade secrets at risk by generally refusing to require the return of confidential information at the close of a contract's term and by limiting the time period for these agreements. These policies discourage collaboration, ultimately slowing down technology transfer rather than encouraging it.

Traditionally, significant regulatory and formal requirements were in place, limiting the attractiveness of licensing and widespread technology transfer. For example, to become effective and binding on third parties, licensing agreements were required to be published in the INPI's Official Gazette. Agreements were also required to be approved by INPI with limitations on fees and payments between the contracting parties. Exclusive licensing agreements were subject to more onerous publication requirements than non-exclusive licenses, making this process more time-consuming.

The Chamber welcomed a positive step in this space in 2017 with INPI announcing through Rule 70 that it will no longer take an active role in the framing and approval of licensing agreements. Instead, the new rule suggests that the agency will merely operate as an agency for recording those registrations. By clarifying the role of ANVISA in the patent review process and restricting the scope of review by the Brazilian Patent Office of technology transfer contracts, the government has taken positive action to remove bureaucratic barriers to innovators in Brazil. If this is implemented and, in fact, the net effect of the rule is positive, it would represent a significant improvement in the technology transfer environment in Brazil. Brazil enjoys a high score of 0.75 out of 1 on The Index's indicator on barriers to market access.

Furthermore, INPI has a suite of programs and incentives dedicated to helping SMEs register and use IP assets. Since 2016, the agency has had in place the MPE Patents Pilot Project (Projeto Piloto Patente MPE). The program provides priority review for microenterprises (MEs) and small businesses (EPP) and was reauthorized in February 2018 through INPI Resolution No. 211. Furthermore, INPI also provides technical assistance and advice through its academy program and educational programs. Finally, SMEs and MEs are eligible for an up to 60% reduction in filing and processing fees for patents. Brazil is a world leader with India on its performance on the indicator that accounts for IP incentives for SMEs, as shown in the seventh edition of the Index.



## **Cross-Ownership Restrictions and Linear OTT Regulation**

Brazil's regulators and legislators continue to examine the following questions:

- Should the 2011 Pay-TV Law be interpreted to prohibit cross-ownership between programmers/producers and distributors of pay-TV content?
- Should direct-to-consumer offers by Over-the-Top (OTT) platforms of live and/or linear audiovisual content be regulated under the Pay-TV Law?

Lifting the current Pay-TV Law's restriction on media cross-ownership would enable market verticalization, which would boost investment, competition, and innovation. On the other hand, if a programming company that distributes linear or live content on the internet (OTT) is considered to be a telecom service—and therefore subjected to the Pay-TV Law—those OTT direct-to-consumer services would face severe regulatory burdens, including: local content quotas, oversight by ANATEL, and additional costs (tax) that would be passed on to programmers. This fall, ANATEL and ANCINE both ruled that OTT platforms are “value-add services” and not subject to the Pay-TV Law. The Supreme Court, for its part, is also examining the question, and is expected to release a decision soon. In the meantime, Brazil's National Congress continues to debate legislative proposals addressing both media cross- ownership and OTT distribution.

## **VOD Regulatory Discussions**

For many years, Brazilian leaders have contemplated how to capture tax revenues from the fast-growing video-on-demand (VOD) marketplace. Brazil's existing tax model for audiovisual works is the CONDECINE tax, which is levied per title every five years on theatrical, Pay-TV and home entertainment releases, and levied annually on audiovisual ads. ANCINE sought to extend CONDECINE taxes to VOD through a 2012 normative ruling, which ANCINE intends to enforce. A CONDECINE tax would be burdensome if levied over VOD services—especially when charged on a per-title basis—as prescribed in the current ANCINE regulation and would limit the choices available to Brazilian consumers in the online content market. Currently stakeholders are not required to fulfill any regulatory burden, though a coalition of industry representatives continues to advocate for the annulment of the 2012 Normative Ruling and warned against protectionist regulatory/fiscal models that would impede local market development and investment. The regulator has yet to reach a decision and has recently issued a public consultation.

## **Screen Quotas**

The most recent Presidential Decree on Screen Quotas, released in January 2020, imposed quotas for 2020 that are similar to prior years, requiring varying days of screening depending on the number of screens in an exhibitor group. These quotas are set to expire in September 2021 and may be renewed. Brazil's screen quota is facing a constitutional challenge at the Supreme Court and competing legislative proposals have been introduced that would either loosen or tighten the restrictions. Local content quotas limit consumer choice and can push consumers toward illegitimate content sources.

## **Enforcement**

### **Anti-Counterfeiting Operations**

As mentioned earlier in this section, counterfeit and copyright-infringing goods are easily available in many Brazilian cities. Alongside notorious markets in Sao Paulo, Rua Uruguaiana in Rio de Janeiro and Oiapoque Outlet in Belo Horizonte are well-known for selling counterfeit video games and circumvention devices. To address continued enforcement challenges, the Chamber supports continued coordination between the National Council to Combat Piracy (CNCP) and local authorities to address IP infringement. Housed under the Ministry of Justice, CNCP has made a noticeable impact on these efforts since its reactivation in 2017. It has since spearheaded many impactful programs, including the "City Free of Piracy Initiative", an anti-piracy working group between brands and platforms, and a best practices document outlining measures to fight piracy on e-commerce platforms.

### **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, rights holders anticipate that this illicit activity will resume. The U.S. Chamber urges the Brazilian government to approve bill 2714/2019, which appropriately removes the requirement to prove a profit motive in the prosecution of this content theft.

## **Systemic Efficiency**

### **National Economic Impact Analysis of IP-intensive Industries**

Several departments and agencies of the Brazilian government study—on an ad hoc basis—the impact that IP rights have on the country’s economic development and output. Last year, however, marked a turning point for the government of Brazil in this area, thanks to the compilation and publication of the country’s National IP Strategy in December 2020. This aforementioned initiative will chart a 10-year plan for the government’s IP policies, with a strategic focus on targeted objectives, including: (1) The use of IP information as a strategic tool to guide research, development, and the generation of IP assets; (2) Strengthening the IP strategies of companies; (3) Including IP in development, investment and credit programs for companies and/or modernize existing instruments; (4) Promoting regional development through the generation and exploitation of IP; (5) Leveraging business opportunities and the creation of new companies based on technology transfer from Public ICTs. (6) Promoting rapprochement with users. The Chamber strongly supports the government of Brazil’s strategic focus on IP-intensive industries, and recommend the government connect it with ongoing research initiatives in government. We look forward to continued engagement with the government as it implements its National IP Strategy.

## **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. This year, the Chamber was pleased to see that the government took steps to improve its IP system, from ensuring its domestic law comported with the U.S. FTA to initiating the CONPES National IP Strategy. The Chamber notes, however, 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.<sup>cxxi</sup>

The Colombian government must also address several outstanding challenges which IP-intensive industries face. Chief among these concerns are declarations of public interest compulsory licenses, gaps in the implementation of copyright-related FTA commitments, and troubling provisions in the 2019 National Development Plan. 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**

### **Patentability**

Colombia does not grant patents for second uses. The Chamber understands that this is due to the government's interpretation of Andean Community Decision 486, Article 21, which prohibits them outright. This contrasts with Colombia's TRIPS obligations under Article 31, which allows for second use patents in certain situations.<sup>cxxii cxxiii</sup>

### **Patent Disputes**

Colombia also has not provided a mechanism for patent holders to resolve patent disputes prior to the launch of a follow-on product. This has led to the approval and marketing of follow-on products, despite the fact that a patent for the original drug is still in force.

### **Compulsory Licenses**

At times, the government of Colombia has relied on the inappropriate use of compulsory license to achieve policy outcomes—a trend that became more pronounced in the global pandemic. In summer 2020, a coalition of Colombian legislators passed a non-binding resolution asking their government to support the passage of a WTO waiver that would override much of the global IP system.<sup>cxxiv</sup> In the Chamber's view, such a move would undermine much of the progress made in developing multiple viable vaccine candidates. It would furthermore jeopardize the ability for the private sector to fund research in preparation for the next global health crisis. On a parallel track, another group of legislators proposed a wide-reaching Senate Bill in December 2020 that would drastically modify Colombia's Pharmaceutical Policy. Our chief concern is the creation of so-called "automatic" compulsory licenses by the Colombian Commerce Ministry, Food & Drug regulatory agency, and Justice Ministry. The Chamber also notes a troubling provision (Article 57, Paragraph 3) calling for the removal of governmental officials that do not grant a compulsory license with speed. Finally, the Bill contains numerous unfortunate references to the belief that IP rights are a barrier to public access of IP-intensive goods as well as the driver of greater innovation. No doubt, these exceptional mechanisms may undermine bilateral norms for IP as established in the U.S.-Colombia FTA.

In addition, the Chamber continues to monitor developments on a compulsory license for the innovative oncology medicine, Glivec. Guided by other countries active in this space, in June 2016, the

Colombian government issued a Declaration of Public Interest (DPI) via Resolution 2475 to unilaterally reduce the price of Gilevec by about 45%. On November 22, 2016, the National Commission of Prices of Medicines and Medical Devices (Comisión Nacional de Precios de Medicamentos y Dispositivos Médicos) issued Circular No. 3 of 2016, which defines the general pricing methodology applicable to all drugs under a public interest declaration. In contrast to the existing price-setting methodology—whereby the average price is calculated from a group of 17 economies—public interest medicines are subjected to the lowest price available, including prices of follow-on products. In effect, this practice all but nullifies any existing IP protection and is highly questionable in light of Colombia’s obligations under TRIPS and the U.S.-Colombia Trade Promotion Agreement. Subsequently, in April 2017, the Colombian government issued Decree No. 670, which regulates the use of the public interest measure. The decree requires any declaration of public interest to be issued by an interinstitutional technical committee composed of representatives from the Ministry of Commerce, Industry, and Tourism; the National Planning Department; and the Ministry of Health. However, later in 2017, the Ministry of Health agreed to review a Declaration of Public Interest petition that could lead to the compulsory licensing of the entire class of innovative treatments for hepatitis C. Therefore, the environment for life sciences IP protection in Colombia remains highly uncertain. The issuance of compulsory license-like mechanisms, which are discretionary in nature, creates tremendous uncertainty for innovators operating in Latin America. Compulsory licenses also 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**

#### **Pay-TV Piracy**

Similar to other countries in Latin America and the Caribbean, Pay-TV piracy remains a major challenge in Colombia and manifests itself in many ways, including:

- Shared signals or “hook-ups.”
- Retransmission of signals.

- Sale of free-to-air devices.
- Non-compliance with local laws and regulations (such as the Criminal Code, regulations from Colombia’s television regulator, or subscription contracts).
- Online piracy.

Due to the scope of piracy in Colombia, it ranks fifth out of 19 Central and South American countries for audiovisual piracy, according to the Alliance to Combat Pay-TV Piracy (ALIANZA). The estimated losses to the content industry from Pay-TV piracy are significant, with \$247.5 million in losses to operators and \$114.32 million in losses to programmers.<sup>xxxv</sup> No doubt, Colombia’s extensive piracy problem prevents it from developing a competitive and healthy audiovisual market. Therefore, the Chamber encourages the Colombian government to, as a first step, seriously study the effects of piracy in the country and consider policies to combat Pay-TV piracy. Farther afield, the Chamber notes ongoing challenges in the government of Colombia’s roll-out of a national anti-piracy plan, though the 2020 ratification of the Convention on Cybercrime was a welcome step.

### **Copyright Damages**

On July 31, 2019 the Colombian Constitutional Court issued a ruling (C-345-19) that recognizes the constitutionality of statutory damages for copyright infringement introduced by 2018 amendments to the Copyright Law. The Court confirmed that rightsholders can choose to be subject to the system of pre-established compensation or to the general rules on proof of compensation. The Court also set a new 12-month deadline for the government to promulgate implementing regulations. This development helped raise the country’s Index score, and the Chamber awaits further implementation of statutory damage mechanisms in the country.

### **NDP Article on Patrimonial Rights**

Colombia’s 2019 National Development Plan contains an article on patrimonial rights (Article 181) which seems to limit the ability of the audiovisual industry to enter into private contracts with local parties. The Chamber is concerned that this article could establish an overly rigid regime in the following ways:

- Regulating agreements and contracts relating to future works.
- Granting rights for unknown types of exploitation.

It is crucial for the functioning of the audiovisual sector that all exploitation rights be effectively consolidated in the producer. In doing so, industry is better able to secure financing for the creation of movies and television shows, commercialize new distribution methods, and meet the needs of consumers. The Chamber notes that the implementation of Article 181 could put Colombia's audiovisual production sector at a competitive disadvantage and hamper international investment in its creative industries. We ask that the U.S. and Colombian governments work together to resolve these concerns. On August 13, 2020, the Colombian Supreme Court agreed to hear a lawsuit filed by Pro Música Colombia challenging both the substance and the approval procedure of this obstacle to the free assignment of copyright rights and neighboring rights.

### **Collective Management Organizations (CMOs)**

As in other countries, the market for creative works in Colombia has become more complex in the face of technological change and new market entrants. At the same time, the Colombian government has identified the development of creative industries in the country as a key economic policy objective in the 2019-2022 National Development Plan. The Chamber notes that a major component of doing business in Colombia is the presence of Collective Management Organizations (CMOs) that collect and distribute royalties on behalf of rightsholders. We note that industry has growing concerns about Colombian CMOs' transparency and pricing structure.<sup>cxvii</sup> The absence of clear rules on CMO operations introduces uncertainty into Colombia's audiovisual market. As such, we urge the U.S. government to encourage Colombia's government to clarify the operations and fee structure of CMOs in the country.

### **Trade secrets and related rights**

#### **Regulatory Data Protection**

Decree 2085/2002 provides for a five-year period of regulatory data protection for both pharmaceuticals and agrochemicals in Colombia. However, industry reports in 2018 suggested that RDP has not been granted to some products despite the existence of this legislation. Additionally, a degree of uncertainty exists about the application of RDP to biologics. While Decree 1782 (from September 2014) modifies the registration process for biological medicines, it did not discuss regulatory data protection for biologics. Moreover, Colombian health agency INVIMA recently modified its interpretation of the conditions to recognize a new chemical entity. Specifically, INVIMA considers that new molecules that

have some “structural similarity” or “analogy” with other active ingredients in their chemical composition with medicines already approved in Colombia are not new chemical entities, because they are analogues of molecules already known and marketed in Colombia. INVIMA, without following the rules of Decree 2085/2002, is denying innovative products the category of a new chemical entity, which implies that they cannot count on the protection of clinical study data in the country. Such a narrow interpretation violates the provisions of Decree 2085/2002 since the structural similarity of a molecule with another already approved is not a cause to determine that such molecule is not a new chemical entity. 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**

#### **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. 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**

Government measures to improve the sustainability of the Colombian health system have focused solely on the pharmaceutical industry and have not addressed issues within the pharmaceutical supply chain or other health sectors. Moreover, measures have been developed in an arbitrary, hasty, and non-transparent way that leaves undermines industry confidence. As a consequence, 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 2020, the government of Colombia continued its drive to adopt more restrictive International Reference Price methodologies for national health system procurement. The final methodology is expected to be issued by the end of 2020 for implementation by March 2021.

### **Biologics Regulation**

On September 18, 2014, Colombia issued Decree 1782, which establishes marketing approval evaluation requirements for all biologic medicines. As part of the Decree, Colombia has established an unprecedented “abbreviated” pathway for the registration of non-comparable products, which is inconsistent with WHO standards and sanitary practices in the United States and other countries. Furthermore, this pathway could result in the approval of medicines that are not safe and/or effective. Industry urged the Colombian government to remove this third pathway from the Decree, to no avail. The Chamber asks that the U.S. government engage with the government of Colombia to resolve this issue.

### **Increased Regulatory Barriers under the NDP**

Colombia’s recently-passed NDP undermines recent gains Colombia has made to encourage innovation, delays access for Colombians to cutting edge technologies, and is inconsistent with Colombia’s international commitments on IP and trade. Particular concerns include Article 72, which inserts price and health technology assessment (HTA) criteria into the regulatory approval process. The Chamber encourages the U.S. government to engage with the Colombian government on the myriad pharmaceutical market access barriers affecting this industry.

## **INDIA**

### **Overview**

India offers U.S. industry tremendous opportunities to tap a fast-growing and innovative economy. 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.

This summer, however, the government of India joined the government of South Africa in supporting a waiver proposal at the WTO TRIPS Council to override nearly every aspect of the IP system. However, the IP system has been critical to bringing us thus far—with distribution of multiple vaccines already underway. This is unfortunate, as India continued to integrate itself into the international IP system throughout 2020—building on its 2018 accession to the WIPO Internet Treaties. (We note, however, that key treaty provisions remain unaddressed, including 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). The Chamber was also pleased to hear in July 2020, for instance, that the government acceded to the Budapest Treaty on the Deposit of Microorganisms. This treaty will allow for the mutual recognition of biological deposits across global patent offices. In the Chamber’s view, this development complements the country’s recent initiatives to improve its patent administration process. Since 2015, the Office of the Controller General of Patents, Designs and Trademarks (CGPDTM) has increased staff and resources invested into modernizing and improving its administrative capacities. 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, as patent backlogs and burdensome reporting requirements are long-standing barriers to filing for IP rights to do business in India. But there is much more work to be done. The Chamber supports expansion of the PPH to include more products and partner patent offices. We also support changes to the SUGAM portal and the country’s patent opposition guidelines, which will further reduce delays in getting innovative biopharmaceutical products to Indian patients. The Chamber also supports modernizing other requirements, such as hard-copy signatures on *each page* of pleadings/briefs/evidentiary statements. These documents then must be mailed for submission—taking an extensive amount of time. Finally, domestic and foreign innovators alike would also benefit from a coordinated and sustained focus on IP enforcement.

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.<sup>cxxvii</sup> At the same time, the Chamber encourages both sides to build on this progress by reconvening a government-to-government IP Dialogue. 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. We welcome discussions on an impending trade agreement between the two countries and look forward to a solutions-driven working relationship on IP.

To complement this work, the Chamber's Global Innovation Policy Center (GIPC) and the Federation of Indian Chambers of Commerce and Industry (FICCI), in partnership with the Chamber's U.S.-India Business Council (USIBC), virtually convened our third-annual U.S.-India IP Dialogue in December 2020. This Track 1.5 dialogue, which examines a solutions-driven approach to IP policy, innovation, and inclusive growth, enjoyed the participation of both U.S. and Indian government policymakers as well as private sector and academic experts. Discussions touched on the full spectrum of IP, including patent administration, the regulatory landscape, copyright infringement, commercialization, and enforcement. The Chamber looks forward to continued successes in this fruitful partnership in 2021, and looks forward to working with India on the effective implementation of its IP laws as well as building capacity for IP specialists across government.

## **Patents and related rights**

### **Patentability**

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, 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 be 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, we 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.

### **Computer-Related (Software) Inventions**

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.<sup>cxviii</sup> 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. Further clarity around the guidelines 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.

## **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. Fifty years later, Indian patent examiners and rightsholders continue to spend an immense amount of time compiling, translating, and verifying information that is publicly available online from counterpart patent offices around the world. 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.

## **State-level Patent Enforcement**

State drug regulatory authorities in India are permitted to grant marketing approval to generic versions of medicines four years after the innovator product is approved and without considering the remaining term of the patent granted by the Indian Patent Office. Lack of transparency around these decisions forces companies to enforce their patents through India's court system, oftentimes resulting in decisions after the infringing product is already on the market.

We encourage the GOI to consider an administrative fix to the Drugs and Cosmetics Rules, 1945 that would help align their framework with TRIPS Article 39.3 and provide the full term of patent to the holder - preventing both infringement and unnecessary litigation. Although improvements to SUGAM portal registration and the uploading of licenses granted for the manufacture for sale or distribution of drugs would help increase business certainty, this backend procedure could be simplified into a two-fold mechanism: First, licensees should upload information when an application is made at any State or Union Territory (UT) Food Safety and Drug Administration (FSDA) or Central licensing authority. Second, licensees should upload information regarding a granted license—that the GSR 629(E) notification rightly reflects—but within a timeline of seven working days from the license grant. This two-fold mechanism would improve the business environment in India in the following ways:

- Ensuring that any new drug approval sought under state-level drug regulators is first checked against existing patents granted by the government of India; and where a conflict arises, the patent holder is notified. This will ensure transparency and streamline the innovative-generic transition.
- Enable companies to rethink premature investments by allowing them to obtain information regarding existing patents and await patent expiration.

- Eliminate confusion in the marketplace caused by infringing products marketed and then withdrawn from the market following an infringement ruling, which can adversely affect patients.
- Avoid unnecessary or complex litigation over damages, in cost or uncertainty, for marketing an infringing product.
- Monitor the quality and safety of drugs by keeping out bad faith manufactures.

Simultaneously, the Central Drugs Standard Control Organization (CDSCO) could make non-commercial data from such applications and grants publicly available on a monthly, real time basis to send a positive signal to international investors and domestic innovators. Furthermore, to reduce the burden on licensees, the government of India could also consider empowering the State or UT FSDAs to upload information on filed or pending license applications by incorporating guidelines on “duty” of the State or UT FSDAs under the Drugs and Cosmetics Rules. Overall, the system would seamlessly fit into the workstream of several flagship initiatives of the GOI, including the “Ease of Doing Business in India”, “Digital India” as well as its SUGAM initiative. We understand that the government of India is examining changes to the SUGAM portal, so we encourage the U.S. government to offer assistance as appropriate on this issue.

### **Compulsory Licensing and Price Controls**

Alongside India’s support of the WTO TRIPS waiver, the Chamber remains concerned about the threat of compulsory licenses in India. For many years, Indian companies have sought compulsory licenses under Section 84 of India’s Patent Act and the GOI continues to consider compulsory licenses under Section 92. This has also been supported by the country’ 2017 Draft Pharmaceutical Policy, in where the government of India reserved the right to issue compulsory licenses. Section 146, which requires the disclosure of commercial-level activity in India on a patent, also remains a concern—especially in how this valuable information has been used to assist local manufacturers seeking compulsory licenses. It is the Chamber’s view that compulsory licenses, by undermining IP protections and issuing manufacturing mandates, actually lessen patients’ ability to access needed medicines and treatments. We continue to urge the GOI to repudiate the use of compulsory license as a commercial tool and deepen engagement with innovators to address public health challenges.

The Chamber also 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. 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**

Indian law does not provide patent term restoration for pharmaceutical products.

### **Patent Prosecution Highways (PPHs)**

Since 2019, the government of India has supported a limited PPH program with the Japan Patent Office. Until this announcement, India did not have a functioning PPH with any major IP office—making it a significant step to support innovators and inventors in both economies. Technology neutral PPH agreements are an emerging best practice seen in other BRIC countries such as Brazil, China, and others. In time, the Chamber hopes that the IPO-JPO PPH can be expanded to include not just more patents themselves, but for diverse sectors like the biopharmaceutical industry. The Chamber also supports the expansion of India’s PPH to include other patent offices as partners.

### **Patent Opposition**

Section 25 of India’s Patents Act outlines the procedures and requirements to initiate pre- and post-grant opposition proceedings. For many years, pre-grant oppositions from “any interested party” caused undue delays in the granting of patents in India. This has allowed parties with political, ideological, and other non-technical opposition to patent applications to unduly delay the process by raising a series of pre-grant challenges. This has the unfortunate effect of entirely “running out the clock” on a patent term before the patent is even able to be used. In the past year, the Chamber notes the entry-into-force of the Patent (Amendment) Rules 2018, which establish a two-member bench to jointly dispose of the prosecution as well as opposition proceedings. When two members disagree on an issue, a third

member will be nominated by the Controller to the bench and a majority decision treated as final. We hope that this initiative would help adjudicate cases effectively and address lengthy delays in pre-grant opposition proceedings. The Chamber is also encouraged by Justice Pratibha Singh's recent decision in *Pharmacyclics LLC v. Union of India*, where she rightly acknowledges the adverse effects of lengthy opposition procedures on the life of a patent. As countries like Turkey and Thailand consider reforms to the pre-grant opposition system, we urge the USG to also encourage DPIIT to consider emerging global best practices on patent opposition proceedings as the Indian government thinks through its own system.

## **Copyrights and related rights**

### **Copyright Rules and the Copyright Board**

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 the 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 first owner of copyright shall not be the producer of the cinematograph work. This 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.

In 2017, India merged the Copyright Board with the Intellectual Property Appellate Board (IPAB) under the Finance Act, 2017, and moved the Board under DPIIT. However, the merger process has not been fully complete, and leadership of the Board has not been finalized. The Copyright Board has also merged with the Intellectual Property Appellate Board (IPAB). Now that the Chairman and five additional members of IPAB have been appointed, the Board has begun to address a significant backlog of activity. The Chamber encourages the U.S. government to provide technical assistance and training



once the Board is fully operational, perhaps leveraging the U.S.-India MOU on IP cooperation signed in December 2020.

## **Piracy**

As broadband connectivity and mobile phone use has exploded in India, so has a marked increase in the availability of infringing content. This trend accelerated during the global pandemic, with major Indian torrent sites seeing some 62% more traffic in April 2020 than the prior year. Content protection analysts also note that, despite India’s rather advanced copyright enforcement regime, high-profile piracy sites remain popular, including *Tamilrockers.ws* and *Indoxxi* and its interrelated domains (e.g. *Indo 21*, *dunia21.app*, and *idtube.me*).<sup>cxxxix</sup>

Despite this shifting landscape, Indian law remains unclear about the availability and requirements of a notice and takedown system to combat online piracy. According to the most recent data available (2016), some 60% of software in India is pirated, creating an enormous cyber-security risk for Indian businesses and consumers. Worse still, piracy kneecaps the competitiveness of one of India’s strongest and most productive sectors. In September 2019, the Indian Music Industry (IMI) and Deloitte estimated that piracy results in USD250 million a year in losses for the local music industry—concluding that the growth of infringement in the country is nothing short of an “epidemic.”<sup>cxxx</sup>

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 a number of 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, the UK, and Russia.

We note 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. We also welcome the MIB's proposals through the Draft Cinematographic Act (Amendment) Bill to combat and criminalize movie camcording and look forward to the early enactment of the proposals. The Bill sits with the Indian Parliament Standing Committee on IT, which has taken public comment on the issue, and is listed as an item for action on its docket.

### **Digital Rights Management Legislation**

While the 2012 Copyright Act includes DRM measures, the measures allow for broad exceptions that do not cover the import and distribution of circumvention equipment. We look forward to engagement with the government of India to close these loopholes, particularly now that India has ratified the WIPO Internet Treaties.

### **Trademarks and related rights**

#### **Protection of Well-Known Marks**

In 2018 the Indian e-commerce market was estimated to be valued at just under \$50 billion and is expected to more than quadruple by 2026. Market research by local firm Velocity MR (and published in Quartz India in 2018), however, estimates that one in three Indians had received a counterfeit product when shopping online. Historically, online retailers and platforms have been subject to the requirements of the Information Technology Act 2000, subsequent 2008 amendments and Information Technology (Intermediaries guidelines) Rules, 2011. Under these rules there is a fairly clear process whereby internet intermediaries are required to take action against any illicit activity upon obtaining knowledge of the activity. Until November 2018, trademark rightsholders had little guidance on how these rules were applied, but this began to change. That month, Justice Singh of the Delhi High Court handed down a potential precedent-setting verdict in the case *Christian Louboutin SAS v Nakul Bajaj and Ors*, ruling that: "While Section 79 of the IT Act is to protect genuine intermediaries, it cannot be abused by extending such protection to those persons who are not intermediaries and are active participants in the unlawful act." While only an interim judgment, further guidance on the meaning of section 79 was provided in *Amway and Ors. v. IMG Technologies and Ors*, which clearly stated: "if any content on the marketplace violates trademark or other proprietary rights, the same would have to be taken down upon receiving notice." Both of these cases provide much needed clarity on the application and interpretation of

existing statute for trademarks online. In a further development the Ministry of Information Technology in 2019 released several drafts of new Intermediary Guidelines Rules. Similarly, the DPIIT released a draft National e-Commerce Policy that included proposals on anti-counterfeiting and IP protection. At the time of writing, neither the Intermediary Guidelines Rules nor the e-Commerce Policy had been finalized, but the Chamber hopes that the government of India will act quickly to implement them.

Rightsholders in India have long struggled with the lack of clarity on the protection for well-known marks with case law offering sometimes conflicting judgments. Recognizing this the Controller in May 2017 issued a new set of Trade Mark Rules. Rule 124 allows individual and entities to apply directly to the Registrar to receive official recognition for their marks as being ‘well-known’. These are positive steps but the associated guidelines would benefit from further clarity on what constitutes supporting evidence.

Specifically, a determining factor for the Registrar would be the availability of court judgments in India recognizing the applying mark as well-known. This would be a rather narrow basis on which a determination could be made as most well-known marks globally have yet to be determined as being well-known in an Indian court of law. It is hoped that during 2018 and the actual application of this Rule that it will be clarified that an Indian court judgment is not a prerequisite or determining factor for receiving recognition as a well-known mark.

In addition, during 2016, the DPIIT proposed a further ban on FDI the tobacco sector—“in technology collaboration, licensing for franchise, trademark, brand name and management contracts”. Such a proposal is inconsistent with India’s WTO TRIPS obligations (Article 3) and should be formally withdrawn.

The TMO has also indicated the existence of a “Famous Mark Registry”. However, it is still just a pilot program. We recommend establishing rules, standards, and timelines to allow for brands to in fact be able to participate.

## **Trade Secrets and related rights**

### **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 of time, 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 of time.

## **Commercialization of IP Assets and Market Access**

### **Procurement Preference for Local IP**

In December 2019, India's Ministry of Electronics and Information Technology (MeitY) India notified the public of its final rule-making on "Public Procurement (Preference to Make-in-India) Order 2019 for Cyber Security Products," which was broadly defined to include software and other IT products. The order provides clear advantages to products with Indian-registered IP, which offer clear advantages to domestic companies.<sup>cxxxix</sup>

### **Standard Essential Patents**

In 2019, MeitY officially released its National Electronics Policy (NEP 2019) with government promotion of the following principles: unique and specific national standards, requirements for Indian-owned standard essential patents (SEPs), and Fair, Reasonable And Non-Discriminatory (FRAND) caps.<sup>cxxxix</sup> In addition, the National Digital Communications Policy (NDCP) finalized in 2018 has provisions to "Provide financial incentives for the development of Standard Essential Patents (SEPs) in the field of digital communications technologies." The Chamber believes that such an approach would distort a non-discriminatory standards-setting process by adding a preference for domestic technology. It would also affect India's ability to obtain best-in-class technology from other countries by offering preferential incentives to domestic players. The NDCP also calls for government intervention in setting FRAND rates to "Ensure the availability of essential background IPR in FRAND terms required for promoting local manufacturing." If fully implemented, this would reduce competitiveness and supersede the judicial review of FRAND cases to adjudicate disputes. At the time of this writing, the government

has not implemented these policies. Nonetheless, industry remains concerned that NDCP and NEP would establish a dangerous precedent for standard essential patents in India.

### **Government Access to Non-Personal Data**

With its surprise inclusion in the draft Personal Data Protection Bill (PDPB), India is charting worrying new territory with provisions for government access, use, and community licensing of “non-personal” data. This topic is not well understood and may result in unforeseen problems around intellectual property rights, market access, and will likely have an adverse effect on privacy--the ostensible aim of the Bill. The Chamber is particularly concerned at this Bill’s effects on trade secret and copyright protection, the former of which have no true legal protections in the country. Having already been reviewed by a Joint Parliamentary Committee, the PDPB awaits a summary report outlining proposed changes. Indian media reports that an updated PDPB will be resubmitted during Parliament’s Budget Session at the end of January 2021.

On a parallel track, MeitY convened a committee in 2020 (and chaired by Indian privacy expert Kris Gopalakrishnan) to study and suggest measures for a robust non-personal data governance framework. An initial report released by the committee in August 2020 recommended the government of India introduce a legal regime for expropriating “non-personal” data from any foreign company that qualifies as a “data business.” A subsequent draft of the report was released in December 2020, with stakeholder comments due in late January 2021. While the Chamber continues to analyze this new version, an initial analysis indicates that our core concerns—that the government of India may pioneer a new data governance framework geared at expropriating the assets of U.S. firms—remain unassuaged.

### **Telecommunications Network Security**

The issue of security testing requirements for ICT equipment took on greater urgency in late 2020, when the government of India published a detailed implementation plan. These requirements, managed by India's Department of Telecommunications (DoT), appear to deviate from global best practices, and the government has currently not issued details, compliance requirements, or a specific timeline. Should the DoT move forward, industry requires a significant lead-time to adjust complex global supply chains to meet these types of requirements.

Of most concern are potential requirements for U.S. ICT companies to provide source code, IP and other sensitive design elements, to private or Indian government labs. The original 2011 Telecom

License Amendments, which created the in-country security testing requirement, mandated the transfer of technology from foreign equipment manufacturers to domestic ones and the escrow source code and other sensitive design elements as a condition of market entry. This extremely sensitive and proprietary information is at the core of U.S. ICT companies' products and the compromise of such information would severely harm their continued commercial viability.

Not only do India's new telecommunications security requirements raise potential WTO compliance concerns, but if they remain unchallenged, other governments may use them to justify their own elaborate information security regimes. In other words, India's approach is establishing a dangerous precedent for governments that may be inclined to use national security in a way that is detrimental to global ICT trade. USTR should urge the GOI to continue to work closely with all stakeholders, including global telecommunications service providers and equipment vendors to ensure that implementation of the telecommunications security provisions do not undermine basic IP protection, nor create obligations outside of global norms that inhibit market access.

## **Licensing**

Registration of patent licenses is mandatory under the Indian Patent Act, with Articles 68 and 69 outlining the basis and requirements of registration. As part of these requirements rights-holders need to submit all details of a given licensing agreement, including the fully executed contract. Contract details and commercially sensitive information will only be kept confidential upon request from the registering parties. The failure to register a license may result in the agreement being made null and void. Specifically, Indian case law suggests that licenses not registered in the prescribed manner are invalid. For example, in the 2009 National Research Development ... vs M/S Abs Plastics Limited the Delhi High Court held the issue to be clear-cut: "It is obvious that since this license agreement between the parties was not a registered agreement, this had no validity in the eyes of law."

## **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 began 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.

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. Eight 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. To fix this problem, the Chamber recommends that the Indian government appropriately limit the Copyright Board’s role to collective administration instead of the current system of granting and pricing of licenses. Furthermore, DPIIT should retract its memo expanding the scope of Section 31D and discourage legislative proposals in the same vein, instead looking to compliance with India’s international obligations.

### **Publishing & Periodicals Registration Bill**

The Chamber welcomes the Ministry of Broadcasting’s long overdue efforts to modernize the outdated Press and Registration of Books Act, 1867. However, we note that the draft Registration of Press and Periodicals Bill, 2019—rather than modernize the registration process for press and publications—appears to establish unclear, extra-territorial obligations on print and digital platforms. The Bill also does not explain how a registration will be granted or revoked. It also does not explicitly prevent national and international trademarks, trade names, and business names and signs from false registrations. Without such safeguards, spurious “name squatting” might hamstring access to information in India. The Chamber was encouraged to see that scientific and medical journals, a critical resource for Indian innovators, were not included in the Bill. All the same, we support redrafted language make it clear that Scientific, Technical, Medical, Specialty and all other academic journals and publications, as well as books, whether print, digital or online, are out of scope of the revised and final bill. Given these concerns, the Chamber strongly encourages the U.S. government to engage with the government of India to facilitate a robust redraft of this Bill.

## **Media Market Access Issues**

India's media and entertainment sector (M&E) is poised for tremendous growth, with clear opportunities to attract additional investment for Indian content creation, exports, and jobs. In 2020, the Chamber continued its positive engagement with the Ministry of Information & Broadcasting's (MIB). In 2021, we look forward to partnering with MIB to focus on the ease of doing business for the M&E sector for the benefit of greater innovation, investment, job creation, and local language content development. But while the GOI continues to liberalize the M&E sector incrementally, several unnecessary investment barriers remain. The Chamber also urges the government of India to remove restrictions on vertical integration and at least consider, if not fully adopt, TRAI's Recommendations on Issues related to New DTH Licenses and on Issues relating to Media Ownership.

- Broadcasting Content Services set 49%, covering uplinking of 'news and current affairs' TV channel; and FM Radio, via the government channel.
- Digital media, such as uploading/streaming of news, and current affairs through digital media, at 26% via the government route; note that previously these services provided by large broadcasting houses had no restrictions, so the Chamber recommends that the USG push for grandfathering existing investments.
- Print, exception for science and specialty journals, and some global magazines at 100% via the government route), is set at 26% via the government route.

## **Dilution of Broadcast IP**

It has been observed that MIB has been mulling changes to legislative framework governing sports broadcast in India. Though most 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"). 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 move 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.<sup>cxxxiii</sup>

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 combinations 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.

We strongly request 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.

## **Tax Incentives for the Creation of IP assets**

Indian tax law provides both a generous R&D tax credit and IP specific tax incentives in the form of a patent box. The R&D tax incentive ranges from a 100% super deduction up to 150% depending on the type of qualifying expenditure and industry sector. The patent box regime taxes licensing income and royalties at a 10% rate.

## **Enforcement**

### **Expediting Litigation**

Rightsholders continue to face real challenges enforcing their IP rights in India, including high rates of substandard and counterfeit medicines, online and physical piracy, and counterfeiting. To make matters worse, the courts' application of trademark law has led to years-long and expensive court cases, lack of deterrent-level penalties, and the transference of cases to non-specialized IP courts. The government of India has long recognized the challenge of pendency times, particularly its negative impact on business disputes and IP rights-holders.

In 2015/16 the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act, 2015 was signed into law including specific amendments to the Civil Procedure Code. Fundamentally, the purpose of the Act was to improve the overall commercial environment in India by making it easier and quicker to solve business related disputes. Specific reforms included an increased emphasis on solving disputes quickly and efficiently, streamlining commercial disputes and ensuring a relevant level of expertise at the presiding court level. Additional amendments were introduced in 2018 to improve the legislation and decrease pendency rates through the expansion of the types of cases that can be heard with the value threshold for commercial disputes being reduced, and the introduction of mediation proceedings.

An important feature of the original Act was the introduction of the option of summary proceedings. Order XIII A, subsection 2 allows for the application for a summary judgment. Indian case law is still evolving on this, however recent cases created some uncertainty on how summary judgements will be made. Subsection 2 of the Order states that "an applicant may apply for summary judgment at any time after summons has been served on the defendant", yet in the recent Skechers USA Inc. vs Pure Play Sports case the decision to move ahead with a summary judgment was taken by the judge. Expediting litigation and dispute resolution is a positive policy goal; the GOI, courts and legal community should be applauded for recognizing this long-standing issue and for moving ahead with relevant reforms. However,

it is also important that there is a clear and fair process in place that is followed uniformly, so that the format of summary judgments is not applied in cases where indeed a full trial is necessary.

### **Effective Border Measures and Remedies**

Furthermore, we 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.

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 rights holders 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.

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**

India continues to have the unfortunate status of being a major source of illicit camcords. The domestic industry is a principal victim of this form of copyright infringement, leading domestic constituents, such as the Andhra Pradesh Film Chamber of Commerce, to be outspoken on the issue. We hope that these issues would be resolved through enactment of the Draft Cinematographic Act (Amendment) Bill. At the time of this writing, the Bill sits with the Indian Parliament Standing Committee on IT, which has taken public comment on the issue, and listed it as an action item on its docket.

## **Systemic Efficiency**

### **Targeted Incentives for SMEs**

India, along with Brazil, are identified by The Index as the world's leading economies in targeted incentives to SMEs. 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.

## **INDONESIA**

### **Overview**

In 2016, the Indonesian Parliament (People's Representative Council) passed a wide-ranging patent law (Law 13 2016), with IP-restrictive provisions that sent a chilling message to the innovative and creative content sectors. To its credit, the government has since taken a deliberative approach to implementing regulations through a process marked by regular consultation with stakeholders. Key measures remain, pending implementation. The Chamber and its members are encouraged by signals that the Indonesian government appears willing to engage with industry to shape its patent law, consistent with international standards. The future direction of Indonesia's IP policies will become clearer as key implementation decisions are taken, especially in areas such as local working requirements, patent eligibility, trademark oppositions, patent linkage, and compulsory licensing that can serve to either enhance or undermine legal certainty for investors in the innovative and creative investment community.

## **Patents and related rights**

### **Patent Law**

In 2016, the Indonesian Parliament (People's Representative Council) passed a new wide-ranging patent law (Law 13 2016). While it aimed to strengthen Indonesia's innovation infrastructure and encourage more high-tech economic development through the creation and use of new technologies, overall the law did not improve what was already a challenging patenting environment. New restrictions on patentability for biopharmaceuticals were introduced together with provisions expanding the potential use of compulsory licensing and the parallel importation of medicines. Furthermore, Article 20 of the 2016 Patent Law seemed to make the granting of a patent conditional on localizing manufacturing and/or

R&D in Indonesia. Specifically, it mandated that all patent rights-holders “make” the patented product or process within Indonesia. Subsection (2) of this article stated that this production should support Indonesia’s industrial and development policies, specifically the “transfer of technology, investment absorption and / or employment”. No further details were provided as to the meaning or legal definition of “make” in this context. Indonesia has for many years had in place several mandatory localization requirements targeting certain industrial sectors (most notably the biopharmaceutical sector) but this new requirement broadened this to any patented technology.

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 (Undang-Undang (RUU) Omnibus Cipta Kerja) – simply delete article 20 of the 2016 Patent Act. Alternatively, patent holders can utilize importation or licensing to ensure patented products are available in the market. Although unexpected, the removal of this article would be a positive step and help alleviate some of the uncertainty with respect to Indonesia’s patenting environment. In October 2020, the Omnibus Job Creation Bill was passed into law, along with the revision of Article 20.

Additionally, Article 4 of the patent law denies patent protection to a wide range of biopharmaceutical inventions. Specifically, it prohibits, per se, the patenting of new uses and new forms of existing products. Such a narrow interpretation may have the unintended effect of diverting R&D activity in affected sectors away from Indonesia. This is an additional requirement that does not apply to any other types of inventions and is therefore discriminatory by nature. Article 27.1 of the TRIPS Agreement provides that “patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.” The Chamber recommends that the U.S. government work closely with the government of Indonesia to ensure that the implementing regulations provide greater clarity for domestic and international inventors.

Furthermore, Article 167 of the Patent Law allows the parallel importation of follow-on products under patent protection in Indonesia but approved for consumption in other markets. The law explains that this importation is to target the cost of medicines and, in particular, where prices in Indonesia are judged to be higher than the “international market.” No details are provided as to what constitutes a “higher price” or the “international market.” The Chamber encourages the U.S. government to seek clarity from the Indonesian government on the scope of the parallel importation policy proposed under Article 167 to ensure that the implementing regulations do not undermine innovative biopharmaceutical companies’ IP in Indonesia or increase the risk of counterfeits entering the market.

Finally, the Patent Law allows a limited form of patenting of computer-implemented inventions. The explanation to Article 4(3) seems to suggest that patents will be allowed when they fulfill a technical effect or problem-solving requirement. The Chamber encourages the U.S. government to work with the Indonesian government to expand the scope of Article 4(3) of software patentability to ensure that all forms of software are patentable in Indonesia.

### **Compulsory Licensing**

The 2016 amendments to the Patent Act (see above discussion under Indicator 2) included changes with respect to compulsory licensing, expanding a regime that was already outside international standards and highly permissive. In December 2018 new Implementing Regulations (Regulation 38/2018) were released by the Indonesian Government outlining the process and circumstances under which compulsory licensing could take place. These Regulations go far beyond the stated goals and circumstances for the issuing of compulsory licenses under the TRIPS Agreement. Specifically, the Regulations allow the relevant authorities broad sway to issue a compulsory license when a patent has not been manufactured in Indonesia within a period of three years of grant or if the patent has been used in a manner which is viewed as detrimental to the public interest. It appears these Regulations not only insert a local manufacturing requirement as a prerequisite for not issuing a compulsory license, but there is also no indication of what is meant by actions detrimental to the public interest.

In 2020, there were further developments on compulsory licensing with the issuing of a new Presidential Regulation, Number 77 2020, on July 7 (PERATURAN PRESIDEN REPUBLIK INDONESIA NOMOR 77 TAHUN 2020 TENTANG TATA CARA PELAKSANAAN PATEN OLEH PEMERINTAH). The new Regulation describes the circumstances and process under which government-use of patented technologies is allowed. Specifically, it relates to use of patented technologies and the overriding of 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. Article 13 and subsections (a), (b), (c) and (d), outline the non-national security/military emergencies that would allow the Government to use the powers granted under the law. These include medicines and biotechnology products to be used in the event of public health emergencies; veterinary and agricultural biomedical/biotechnology products; and a rather broad condition relating to any “processes/products to overcome natural disasters and / or environmental disasters.” The latter seems to encompass any and all patented products and processes that would be used in any type of natural or environmental disaster. With respect to the government use and overriding of patents for medicines and biopharmaceutical products sub-section (a) explicitly states that

this can be justified not only during a public health crisis, such as the current COVID-19 pandemic, but based on cost and specifically if a given “pharmaceutical products and / or biotechnology that are priced expensive”[sic]. The Presidential Regulations do not provide affected rights-holders the ability to appeal government-use decisions made. Unlike similar emergency measures that have been introduced around the world in response to the COVID-19 pandemic (including for example in Canada and Germany) the Regulation does not include any defined timeframe or suitable sunset clause as the pandemic subsides. Instead, the broad nature and scope of the Regulation suggest it will become a permanent feature of Indonesian law. The new Regulation also poses an immediate threat to current treatments and vaccines in development to address to COVID-19. This entails serious opportunity costs for future industry collaboration and investment. Before issuing government-use licenses, the Indonesian government should first engage with rights holders to discuss available access strategies, including voluntary licensing, already underway in the country. 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.

### **Annuity Payments**

The Indonesian Patent Office is currently issuing invoices for past annuity payments on previously abandoned patents which were not expressly withdrawn from the patent office. Annuity payments represent the renewal fees companies pay to maintain a granted patent. The invoices received from the Indonesian Patent Office represent up to three years of annuities as well as back taxes if due. The amounts are significant, and if companies do not pay, they have been threatened with property seizure. This practice is not in line with that of major patent offices worldwide.

### **Patent Prosecution Highways (PPHs)**

Although Indonesia is not a member of either the Global PPH or the IP5 PPH, the Directorate General of Intellectual Property Rights (DGIPR) and Japan Patent Office (JPO) have a PPH in place. The initiative began in 2016 for a three-year trial period. This is a positive feature of Indonesia’s national IP environment and is to be commended. The Chamber recommends that the U.S. government encourage the



Indonesian government to consider entering other PPH agreements in order to expedite the patent review process in Indonesia.

## **Copyrights and related rights**

### **Injunctive Relief**

The 2014 Copyright Act introduced a new ministerial notification system on online infringement, granting the Ministry of Communication and Informatics the power to disable access to infringing websites. While these powers had been in existence since the late 2000s, it was unclear the extent to which they applied to potential online acts of copyright infringement. 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—to considerable success: local news reports and industry sources suggest that access to between 250 to 300 infringing websites has been effectively disabled. In 2017, the government launched an “Infringing Website List” in a partnership between the Indonesian government and private-sector rights-holders—another welcome step.

Unfortunately, the scale of piracy in Indonesia remains a challenge, with sites like IndoXXI operating through a web of nearly 200 related URLs. Industry estimated in fall 2020 that the IndoXXI brands attracted 3.2 million visits from Indonesia alone. To address this problem, 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 ensure it continues to put initiatives in place that deter online copyright infringement.

### **National Digital Strategy & Cooperative Frameworks to Prevent Piracy**

In December 2020, the government of Indonesia issued a “National Digital Economy Strategy”, which will guide the country’s approach to not just the digital economy, but key IP and piracy issues. Intellectual property protections have been key to fueling the past two decades of digital transformation, and Indonesia has been no exception. The country is one of the most connected in the world, with an estimated 196 million Indonesians accessing the internet from a host of devices. As part of this process, the Chamber notes the importance of legal norms for copyright and market access to secure greater benefits for Indonesia’s digital economy.

Additionally, Indonesia maintains a number of protectionist policies—although some are admittedly not enforced in practice—which keep out legitimate content, including a proposed 60% local content screen quota, onerous pre-production content-review requirements, a prohibition on dubbing imported films, local replication requirement, foreign investment limitations, and other restrictions on the audiovisual industry. The Chamber recommends that the U.S. government collaborate with its Indonesian government counterparts to build on the positive momentum of the 2014 act, to work toward addressing the outstanding concerns of the creative community in Indonesia.

### **Pay-TV Piracy**

Pay-TV signal theft is a major problem in Indonesia and some channels are devoted almost entirely to distributing pirated content. The Chamber strongly urges the government to crack down on these pirate channels, as well as those engaged in the unauthorized trafficking, dissemination, decryption, or receipt of pay-TV, and instead to support the growth of legitimate pay-TV services.

### **Piracy Devices**

Piracy devices remain a prevalent problem in Indonesia. The Chamber recommends that the U.S. government help the Indonesian government increase enforcement efforts, including cracking down on piracy apps and on device manufacturers who preload the devices with apps that facilitate infringement. Moreover, the government should take action against key distribution points for devices that are being used illegally.

### **OTT Regulations**

In November 2020, the Ministry of Communication and Informatics promulgated regulations that require foreign OTT service providers to complete mandatory local registration, create a reverse onus for services interested in processing and storing data offshore, and create censorship mechanisms via mandatory takedown notices for OTT content without reasonable practical procedural consideration. Such requirements would stifle business development and add a burdensome barrier to market entry. Furthermore, in August 2019, KPI suggested that it would subject SVOD providers to its strict content monitoring, censorship, and classification requirements, which would raise another market access barrier for OTT content.

## **Trademarks and related rights**

### **Trademark Law**

In October 2016, a new Trademark and Geographic Indications law was passed. While primarily focusing on expanding the realm of protection for trademarks to non-traditional trademarks (including sound holograms and 3D marks) and improving the speed and administration of trademark applications, the law also strengthened existing enforcement mechanisms. Specifically, Article 100 strengthens existing criminal sanctions against trademark infringement. Fines have been increased to a maximum of 2 billion to 5 billion rupiah (roughly \$150,000-\$380,000) and prison sentences to between four and 10 years. The higher fines and sentences are applicable only in cases in which the infringing goods have led to public health issues, death, or environmental damage. Given the relatively high level of counterfeit medicines in Indonesia, this is a positive development. Unfortunately, there were also a number of negative developments increasing the already high level of uncertainty with regard to the protection of well-known marks.

Two decisions by the Supreme Court of Indonesia entrench the difficulties that rights-holders face to protect their registered and well-known marks from rival and potential bad-faith registrations and subsequent use. In September 2016, the Court rejected the claims of designer Pierre Cardin that a local company was infringing its trademark. The local company had filed a similar trademark in the late 1970s incorporating the Pierre Cardin name, whereas the French designer had only registered its trademark in Indonesia in 2009. In a different case, the Supreme Court held that Swedish furniture giant IKEA's locally registered trademarks were not valid, as they had not been used for a period of three years. The challenge of non-use came from a local furniture company wishing to file its own trademark acronym "IKEA," which is short for Intan Khatulistiwa Esa Abadi.

The Chamber encourages the U.S. government to cooperate with the Indonesian government to strengthen the legal protection for well-known markets in order to ensure that brand owners' goods are adequately protected in Indonesia. We also recommend a review of the procedures related to trademark opposition proceedings. TMO has an extremely narrow interpretation of trademark rights, and opposition proceedings in general only decide cases in instances where the parties' mark and goods are nearly identical. Given that Indonesia is a regional hub for manufacturing, machinery and know-how, improving these procedures is critical to keeping infringers/counterfeiters from obtaining "similar" but not quite identical trademark registrations. Also, TMO should allow for an invalidation/cancellation/appeal process. Today, once a decision is made in an opposition case (usually against the brand owner), the only further recourse is costly and time-consuming civil litigation.

## **Trade Secrets and related rights**

### **Regulatory Data Protection**

At present, Indonesia does not provide regulatory data protection for biologic or small-molecule medicines. The U.S. standard of data exclusivity is 12 years, and Indonesia's lack of data protection is a significant roadblock for innovative companies that are stimulating R&D in treatments for some of the riskiest and most complex issues facing human health. The Chamber recommends that Indonesia adopt a policy to provide regulatory data protection for biologic medicines.

## **Commercialization of IP assets and Market Access**

### **Barriers to Technology Transfer through Licensing**

While investment and technology transfer have become a clear priority for the government over the past several years, it has largely relied on restrictive measures that have made the investment climate increasingly complex and difficult. Protective measures included requirements to partner with Indonesian companies, local content and technology transfer requirements, restrictions on imports and exports, and equity ownership limitations in certain sectors. Over the years, the biopharmaceutical sector has been especially targeted with local manufacturing and/or local partnering requirements to receive market authorization. These general and sector-specific localization policies and mandates heavily influence the technology transfer and licensing environment.

Technology transfer and commercialization of publicly funded research remain relatively limited. Some state-funded universities (including the Institut Pertanian Bogor and Universitas Indonesia) have clear IP rights policies in place that encourage IP protection. While ownership of the invention remains with the government and university, researchers and inventors are provided with a guaranteed royalty rate of 40%.

Yet there are considerable barriers to the practical execution of licensing agreements and effective technology transfer for both foreigners and Indonesians. To begin with, to be valid and legally recognized, licensing agreements for all major IP rights must be registered with the Indonesian IP authorities. As part of this registration, rights-holders must submit the fully executed licensing contract. Unless registered with the relevant authorities, licensing agreements have no legal standing vis-à-vis third parties.

For example, Article 79(2) of the 2016 Patent Act states that “where a licensing agreement is not recorded at the Directorate General ... said licensing agreement will not have legal effects on a third party.” Even more onerously, all licensing agreements are subject to review by the Indonesian authorities. Article 78 of the Patent Act is quite clear that any licensing agreement should not adversely affect the Indonesian economy or national interest or “contain restrictions which obstruct the ability of the Indonesian people to master and develop technology in general and in connection with the Patented Invention in particular.”

If these criteria are not fulfilled, the authorities will refuse registration and thereby render the agreement legally void and unenforceable versus third parties. Finally, unlike most other jurisdictions, Indonesia requires the registration of licensing agreements with respect to trade secrets. Despite the confidential nature of this form of IP protection, the licensing and licensed transfer of trade secrets are subject to the same requirements as all other IP rights, including registration and official publication.

## **Enforcement**

In 2018, Indonesia’s customs authority implemented a trademark registry to better address counterfeit goods, but rightsholders note that it is costly and complex. Greater partnership between government and rightsholders is key to fighting trademark infringement, and the Chamber feels the following recommendations could help, including:

- Establishing joint inspections between the court, IP office, customs & brand owners for suspected shipments.
- Removing the local presence requirement for foreign companies to join customs’ trademark registry.
- Removing the \$7,000 (IRD 100,000,000) bank guarantee requirement to cover customs’ operation costs. (Note this money is remitted in full if suspected goods are proven as counterfeit).
- Removing measures that adjust the bank guarantee to the value of a shipment as well as additional fees for court proceedings.
- Removing the requirement that rightsholders obtain a commercial court order to detain shipments.
- Simplifying the process after a shipment is proven to be counterfeit. Currently, rightsholders must file a civil suit against an infringer.

## **MEXICO**

### **Overview**

A harmonized IP framework across North America will be critical to fostering greater economic and global competitiveness across the region. 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, which have been implemented over the course of 2020. Notwithstanding these positive developments, challenges remain to securing effective biopharmaceutical IP protection in Mexico. The U.S. Chamber encourages the U.S. government to work closely with its Mexican government counterparts to address the outstanding IP challenges outlined below in order to improve the environment for innovative and creative industries in the market.

### **Patents and related rights**

#### **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. For example, looking at patent statistics housed by WIPO between 1980 and 2018 there were a total of 9,373 published patent applications (patent publications by technology) under the categories "Computer technology" and "IT methods for management." This compares to 299,582 total applications published during this period, or 3.13% of the total. Statistics for the number of patents granted, not only applied for, show an even lower proportion of computer related applications granted patent protection. The WIPO statistics on the number of patents granted by technology during the same time-period shows a total of 1,456 patents granted under the categories "Computer technology" and "IT methods for management." This compares to a total number of 56,202 patents granted for all technologies, or 2.59% of the total number of patents granted. 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. 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.

### **Patent Linkage**

While a 2003 Presidential Decree introduced a basic system of patent linkage, the framework has several key deficiencies. First, process and use patents are excluded from the linkage 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 tend to be delayed and are often ineffective. Worse still, amendments to the Mexican Health Law from the country’s Senate would further reduce the linkage system’s scope—allowing only one patent listing per each new chemical entity and barring patents for biologics. If adopted, this reform would be a highly negative move by the Mexican authorities and further devalue the existing linkage regime and rights-holders ability to enforce their patents.

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. Transitional paragraph (5) of the law simply states that the IMPI shall “participate” with the Mexican drug regulatory authority COFEPRIS “in the establishment of the corresponding technical collaboration mechanism for inventions in the field of allopathic drugs.” At the time of research, no new regulations or laws had been passed. A proposal for a revised linkage regime has been put forth by the Chamber of Deputies in the Fall of 2020. Unfortunately, this proposal does not incorporate the requirements of the USMCA and would not address the deficiencies in the current system. The U.S. 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**

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 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.



## **Compulsory Licenses**

Senator Clemente Castañeda Hoeflich (Movimiento Ciudadano) has proposed an amendment to Art. 77 of Industrial Property Law that would require the Ministry of Health to initiate a process that could lead to compulsory licenses for three non-transmissible diseases of major incidence in the population. This would be a change from existing language that would mandate initiation of such a process only in cases of serious illnesses that are an emergency or a risk to national security. The Chamber understands the bill is awaiting discussion before the Senate Health Committee—which could begin as early as February 1st. The Chamber encourages the U.S. government to work closely with the Mexican government to ensure that any amendments to the Industrial Property Law do not alter the criteria for issuing compulsory licenses in order to ensure that life sciences IP is effectively protected in Mexico.

## **Patented Medicines Procurement**

Mexico outsourced the purchase of medicines for its public sector to the United Nations Office of Procurement Services (UNOPS). As a general rule, 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 rights holders 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). We understand that UNOPS then held negotiations with patent rights holders 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 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 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 has repeatedly attempted to engage UNOPS to better understand its mandate, operating model, and to discuss implementation. At all levels, UNOPS has rejected engagement with the private sector, providing limited, pro-forma answers to some questions and ignoring others. Likewise, the industry has engaged with the Mexican government to understand the new process, but no government official is the designated point of contact. This has left industry without sufficient information or a liaison to help navigate this opaque process. Lastly, UNOPS is continuously changing the dates, scope, terms, and product coverage. The lack of transparency and procedural due process is astonishing. Therefore, the Chamber requests that the U.S. government emphasize the importance of providing clear guidance regarding the purchasing process to reduce the high level of uncertainty currently plaguing this process.

Additionally, we would like to highlight the U.S. Chamber's 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. UNOPS also only accepts the owner of a product's regulatory registration as its legal representative, whereas Mexican law does not mandate this requirement. Innovative companies could therefore be ineligible to participate in ITB. Such requirements are inconsistent with USMCA and create an unjustifiable barrier to trade. The Chamber encourages the U.S. government to ensure that medicines packaging requirements are consistent with the provisions of USMCA.

## **Copyrights and related rights**

### **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. Specific changes include: i) a new notification system whereby ISPs are obliged to act expeditiously and remove suspected content upon receiving a notification (articles 114 and 232); ii) robust digital rights management (DRM) and technological protection measures (TPM) provisions outlawing the use, manufacture, sale, importation distribution or otherwise offering to the public circumvention devices and technologies (article 232); and iii) making illegal the use, manufacture, import or other form of distribution of satellite signal decoders (article 145). The Chamber welcomes these positive developments which will help better protect Mexican creators and IP-intensive industries operating in Mexico.

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. However, 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. The Chamber encourages the U.S. government to collaborate with the Mexican government to clarify the provisions on copyright-infringing content online.

## **Trade secrets and related rights**

### **The USMCA and Trade Secrets**

The USMCA agreement includes 21st century trade secrets protection which will better protect innovative and creative companies operating in Mexico. The agreement includes many positive elements, including: civil and criminal procedures remedies to protect against trade secret theft, judicial procedures to prevent the misappropriation of trade secrets during the litigation process, prohibitions impeding the voluntary licensing of trade secrets through discriminatory provisions, and penalties for government officials for the unauthorized disclosure of trade secrets. The Chamber encourages the U.S. government to work closely with the Mexican government to ensure that these provisions are effectively implemented in order to create a world-class trade secrets policy framework in Mexico.

### **Regulatory Data Protection**

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. On top of ongoing uncertainty in the legal framework, in 2015 Mexican authorities reportedly indicated that RDP would not be considered as applicable to biologics, although the extent to which this approach would remain in place in relation to Mexico's forthcoming obligations under the TPP Agreement (which includes an RDP term for biologics) is not clear. 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. The Chamber encourages the U.S. government to work with its Mexican government colleagues to press for more effective RDP in Mexico in order to support the growth of domestic innovation and create a stronger environment for biopharmaceutical foreign direct investment.

### **Registration Process**

Another key market access issue in Mexico concerns the excessive times taken for formulary inclusion and the 5-year registration renewal process. Both significantly exceed stated time frames. Mexico's Federal Commission for the Protection against Sanitary Risk (COFEPRIS) had made important improvements in the approval process despite limited resources and cost-containment pressures. Since the

beginning of the current administration, however, further progress by COFEPRIS in this area has been suspended. The agency has cut off communication with the pharmaceutical industry and put on hold the work and processes of its New Molecules Committee. The Chamber encourages the government of Mexico to restart this important work.

## **Commercialization of IP Assets and Market Access**

### **Licensing Requirements**

Historically, the registration of licenses with the IMPI was required for the license to have effect against third parties. Local legal analysis suggests that the registration process was not overly burdensome, and it was possible to submit a shorter version of the licensing contract with confidential information omitted. This was amended by Mexico's accession to the USMCA and the requirement to register licenses for patents and trademarks is now entirely voluntary as per the revised Industrial Property Law. The Chambers applauds this positive development and looks forward to working with the U.S. and Mexican governments to assure it is effectively implemented.

### **Failure to Follow Rule-of-Law on Procurement**

Ministry of Finance-led (SHCP) procurement of medicines are a source of concern due to the lack of transparency in decision-making and inconsistency 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. The NHC is supporting this centralized process by developing, with support of medical experts from public health institutions (IMSS, ISSSTE and national institutes), technical treatment guidelines in order to reduce the number of molecules that will be available in the currently-developing National Medicines Compendium, without clear criteria and without transparency around the decision-making process. To-date, the NHC's technical treatment guidelines are seemingly in line with procurement decisions made by the Ministry of Finance.

## **Enforcement**

### **Effective Border Measures and Remedies**

Long exemplified by the lawlessness of Mexico City's Tepito market for infringing goods, the country has struggled to stem the flood of illicit trade and counterfeit goods. Industry reported that the government's ability to respond worsened in 2019, as a wide-reaching austerity program slashed funding by 30% for critical enforcement agencies. In addition, existing provisions in Mexico's Customs Law only give authorities ex officio powers to initiate board measures--not make a determination 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
- Preventing banned offenders from re-registering on the platform

In the meantime, 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 last few years, Russia’s performance on IP protection has remained largely unchanged. And even though Russian policymakers define innovation-led growth as a strategic—even existential—goal, the resulting IP framework remains smothered by discriminatory treatment and mandatory localization policies. While there have been pockets of reform and sustained efforts—for example, in the enforcement of copyright online—problems persist. As outlined below, the Chamber supports the continued engagement of the U.S. government on this strategic market.

### **Patents and related rights**

#### **ROSPATENT Amendments**

In May 2016, the Federal Antimonopoly Service (FAS) published on its official website the draft “Roadmap for Development of Competition in the Healthcare Sector.” The Roadmap was approved by the Russian Government on January 12, 2018, via Decree No. 9-r. The Roadmap, inter alia, proposed amendments to patentability criteria for any new property or new application of a known active ingredient of a medicinal product (including new indications, new treatment methods, new combinations, and new pharmaceutical forms and manufacturing methods). Later in 2018, the Ministry of Economic Development issued Order 527 amended the way Russia’s patent office (ROSPATENT) receives and processes applications, creating new restrictions on second use patent claims for medicines. If implemented these restrictions are likely to reduce the number of eligible applications and scope of available patent protection for second use innovations.

Furthermore, some of the changes introduced in 2014 amendments to the Civil Code Part IV regarding patent term restoration came into effect in 2019. The Civil Code Part IV Article 1363 provides a mechanism for patent term restoration for biopharmaceuticals, agrochemicals, and pesticides with a maximum term of restoration available of five years. This restoration period is a positive feature of Russia’s IP environment as it relates to biopharmaceuticals. The 2014 amendments introduced several new layers and requirements for rights holders when applying for this restoration. The most significant of which was the requirement to apply for (and ROSPATENT to issue) an additionally distinct restoration-specific patent. Unlike the pre-2014 regulations, these new requirements are more restrictive with respect to both design claim and scope of the restoration-specific patent. Local Russian legal analysis suggests

that as a result of these new regulations coming into effect the number of patents eligible for term restoration has effectively been reduced.

## **Patent Enforcement**

The Chamber is concerned that the Russian regulatory system does not adequately 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. Because of this, any manufacturer can apply for and receive marketing authorization for a generic product and, in turn, participate in state tenders—even though a patent for the original 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 investigate the subject matter of biopharmaceutical patent infringement cases. One example of this would be the Russian courts’ refusal to grant 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 registration certificate. Because this mechanism amended the state-level registration process, the Ministry of Health published updated draft legislative proposals for changes to “Law No. 61-FZ. On the Circulation of Medicines”, including the introduction of a new administrative mechanism linking the approval of a follow-on medicine with the expiration of the exclusivity of a reference product. Specifically, the draft law requires that a follow-on applicant submit written documentation stating that the prospective registration does not violate any existing exclusivity. As of January 2021, the draft law was still being debated between the ROSPATENT, the Ministry of Economic Development and the Ministry of Health, but no final legislation has been passed or signed into law.

Looking ahead, the Chamber looks forward to continued follow-up from the 34th Foreign Investment Advisory Council meeting in October 2020, which introduced a planned register of Patented Pharmacologically Active Substances in Russia based on a consistently defended industrial position related to IPR protection. The biopharmaceutical industry anticipates that further work on patent linkage mechanisms can help resolve disputes prior to the launch of infringing product—a welcome change in



Russia's IP environment. As part of this process, further efforts are required to strengthen the enforcement system (e.g. implementation of preliminary injunctions in patent disputes in pharmaceutical sector and the others).

### **Compulsory Licensing**

Separately, decisions on dependent patents pose a new risk for the Russian patent enforcement environment. If a defendant is an owner of a dependent patent, this is likely to result in proceedings with a high risk of a compulsory license. However, if such patent is not recognized as dependent, this is likely to result in the refusal of a patent infringement action - the court is likely to rule that the defendant is using its own independent patent. There are several cases that demonstrate how the Russian courts have begun to issue compulsory licenses for biopharmaceutical products. In June 2018, the Moscow Arbitration Court (1st Instance) granted a compulsory license for an innovative cancer medicine developed in the U.S.—to a local generic drug company—that held a dependent patent protecting a small modification of the active ingredient in the original, innovative product. This decision was based on an extremely low evidence test and standard of proof. The Chamber notes that the dependent patent was later annulled by the Russian Federal Service for Intellectual Property (ROSPATENT) in November 2018 and the infringement/compulsory license case was settled on appeal. Another compulsory license was issued in July 2018 for local manufacturer Nativa to produce Celgene's Revlimid. Critically, the lower cost of the product by Nativa was considered by the court as being economically advantageous. Nativa also has several other pending lawsuits involving similar "pending patents" against originator products, and so the threat of further licenses has only grown.

In February 2019, the Moscow Arbitration Court (1st Instance) issued a second compulsory license against another U.S. innovative manufacturer based on a counterclaim by a local generic drug company that held a dependent patent on a minor modification of an ingredient in the original, innovative product. As before, this decision was also based on an extremely low evidence test and standard of proof but was nonetheless upheld by the appellate and Russian IP courts. The manufacturer holding the patent for the innovative product has been unsuccessful in challenging this dependent patent and intends to seek further judicial review by the Civil Chamber of the Supreme Court of the Russian Federation. The current lower court decisions constitute very dangerous precedent based on low or incorrect standards of proof and which misinterpret the situations in which compulsory licenses have been granted internationally.<sup>exxxiv</sup>

The Chamber is also deeply concerned about the Russian government's recently proposed compulsory licensing amendment and explanatory note on Article 1360 of the Civil Code of the Russian

Federation after years of ever-louder calls for compulsory licensing from the State Duma, Much of these efforts have been driven by the FAS. On November 22, 2019, the Russian Government submitted to the State Duma the draft Federal Law "On Amendments to Article 1360 of the Civil Code of the RF" (considering the use of an invention, utility model, or industrial design in the interests of national security). On December 15, 2020 the State Duma passed the draft in the 1st reading and sent it to other state authorities for providing any comments to the draft (up to January 13, 2021 comments were to be provided). The term for the 2nd reading has not been determined. That amendment would expand the government's discretion to issue a compulsory license "to ensure national security or protect human lives or health, in case of emergency" with a notice and compensation to the said patent holder as approved by the government. The U.S. Chamber and its members are also concerned about the Russian government's decision to grant a compulsory license for *remdesivir*. We note that repeated compulsory licensing and legal uncertainty will only erode the Russian IP environment and reduce incentives for future innovation, biopharmaceutical and otherwise.

## **Copyrights and related rights**

### **Online Piracy and Enforcement**

Since 2013, Russia has introduced and implemented (through the Civil Code Part IV) a range of new laws and regulations to help combat the country's high level of online infringement, including notice-and-takedown requirements, the granting of temporary injunctions by the Moscow City Court, and greater rightsholder cooperation with the Federal Service for Supervision in the Sphere of Telecom, Information Technologies, and Mass Communication (ROSKOMNADZOR). In 2017, legislative changes to the "Law on Information, Information Technologies and Information Protection" banned so-called "mirror sites" and obligated internet mediators (including search engines) to remove links to sites that have been found to host illegal content. Since 2018, ROSKOMNADZOR has reportedly been developing a database of infringing content where internet mediators (including internet service providers and search engines) can voluntarily link to this database and update their own access-disabling protocols. In 2018 a Memorandum of Understanding was also concluded between local audiovisual creative sector stakeholders and online intermediaries, including *Yandex* and *Mail.ru*, to address online piracy. But while this has delivered positive results we are still awaiting the Memorandum to be transposed into law as originally intended. The Chamber encourages the U.S. government to support the government of Russia's completion of that process without further delay.

Despite this progress, piracy challenges continue in Russia. Industry reports that the market's rate of illegal software use has remained unchanged (from 63% in 2011 to 62% in 2017) and hosts some of the world's most high-profile pirate sites, including: seasonvar.ru (a St. Petersburg-based streaming website of television programs with over 17,000 TV series on the site), 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). Finally, the notorious pirate site for copyright-protected journals and academic articles, Sci-Hub, was founded in Russia and continues to operate on Russian servers. The Chamber is hopeful that the positive momentum for online enforcement continues in Russia, given its reputation for copyright infringement.

### **Collective Management Organizations (CMOs)**

Currently, Russia's state-accredited collecting societies are replete with governance and transparency issues, which continue to concern the copyright community. Russia should, consistent with its WTO commitments, resolve the confusion surrounding the operation of collecting societies by confirming that rights-holders have the legal and practical ability to determine how to exercise their rights, including by allowing them to choose whether to entrust licensing to any collective, and if so, to which entity and for which rights.

### **Trade Secrets and related rights**

#### **Trade Secret Protection**

The Russian legal system offers poor protection of trade secrets. The law itself creates barriers—namely, overly prescriptive requirements that businesses must meet before commercial information is eligible for protection as a trade secret. As a result of the challenges in protecting trade secrets under Russian law, doing business in Russia is difficult for foreign companies in knowledge-rich industries. The Chamber recommends that the U.S. government work with its Russian counterparts to bring trade secrets law more into compliance with the TRIPS standards, even if it means doing so through multilateral trade groupings and make protection less onerous for rights-holders.

## **Trade Secret Enforcement**

Despite the seemingly favorable remedies landscape for trade secret holders provided by Russian law, enforcement is weak, unpredictable, and there is little deterrent for would-be infringers. Industry reports that Russian courts generally do not impose meaningful penalties for trade secrets breaches, even though Russian law provides for the full suite of civil and criminal remedies. Though preliminary remedies such as injunctions and seizures are theoretically available, both experience and some historical information indicate that injunctions are only rarely used, if at all. Criminal penalties also tend to be rarely used in IP cases, despite 2015 amendments to the criminal law. For example, in one case where there was a proven loss of \$2 million, the defendant was sentenced to undertake “corrective works” (similar to a community service penalty). The Chamber recommends that the Russian government adequately use all the tools at its disposal to administer effective and reasonable deterrent penalties for trade secrets misappropriation.

## **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, there remains a lack of progress in implementing this commitment and developing 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 time 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. Given the existing uncertainties in the Russian market with respect to the approval of follow-on products within a current term of exclusivity, there is a clear risk that these amendments will further undermine the practical availability of regulatory data protection in Russia. The Chamber will continue to advocate for the introduction and application of full coverage of protection for regulatory data in Russia.

## **Commercialization of IP Assets and Market Access**

### **Forced Localization Policies**

Russian industrial and economic policy has increasingly resorted to mandating local industrial production and R&D through the initiatives like the: Strategy for Innovative Development of the Russian

Federation 2020 (2020 Strategy), the State Coordination Program for the Development of Biotechnology (BIO 2020), the Strategy of Development of the Pharmaceutical and Medical Industries (Pharma 2020), the New Digital Society Strategy 2017—30 and the National Economic Security Strategy 2017. 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, in particular, are severe. Together, these localization policies create significant market-access barriers for rights-holders.

## **Enforcement**

### **Online Enforcement**

Russia continues to struggle with hard goods piracy and the sale of counterfeit goods online. Through the adoption of best practices and legislation, the Chamber believes that industry and government can proactively ensure that infringing items are not being sold on marketplaces. Suggested measures include 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. The Chamber also recommends that the Russian government work to coordinate with its enforcement agencies on a strategy for fighting counterfeiting on the internet.

### **Adjudication**

Industry reports that despite some mild improvements in the legal infrastructure with updated IP legislation and the creation of IP-specialized courts, court proceedings are very long and judges virtually never award preliminary injunctions in IP cases or permanent injunctions as a form of relief. Furthermore, industry reports that enforcement bodies (mainly police and customs) are not very active in fighting counterfeiting.

## **SAUDI ARABIA (KSA)**

### **Overview**

Despite some positive developments in the intellectual property regime in Saudi Arabia, the Chamber notes some instances in where there has been a lack of enforcement of IP protections. As part of efforts to improve its IP regime, 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 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. 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 – rather than improve – IP protections in the Kingdom. Finally, industry also reports that the Kingdom’s customs authorities are—by comparison to other markets in the region—actively engaged in addressing the sale of counterfeit goods. All the same, the growing availability of trademark infringing goods in the market speaks to the need for even-greater partnership between industry and the government on not just enforcement, but all IP issues. We encourage 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**

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.

In April 2020, SAIP issued damaging final regulations on the compulsory licensing of patents, which have the potential to frustrate Saudi Arabia’s efforts to promote innovation and economic growth. The final regulations largely disregard comments pharmaceutical innovators provided on draft regulations

SAIP published in July 2019. The Chamber’s view is that governments should grant compulsory licenses (CLs) in accordance with international rules and only in exceptional circumstances and as a last resort. Decisions should be made through fair and transparent processes that involve participation by all stakeholders and consider all relevant facts and options. By allowing SAIP to take patents away three years after they are lawfully granted for almost any reason and without prior notice to the patent holder, the regulations risk encouraging excessive use of CLs and denying patent holders the right to adequately defend their property interests.

### **Regulatory Data Protection**

In September 2020, SAIP published new draft regulations for the protection of confidential business information, including regulatory test data. Far from improving on a prior draft issued in December 2019, the new draft would further weaken RDP in Saudi Arabia. Among other things, the draft fails to grant RDP on a national basis, lacks clarity with respect to the scope of products covered, contains overly broad exceptions to RDP and continues to lack the necessary mechanisms for effective enforcement.

This 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.

### **Copyrights and related rights**

#### **Online Piracy and Piracy Devices**

In 2017, a pirate Pay-TV broadcaster called beoutQ rebranded some channels of Qatar-based beIN Sports and began broadcasting pirated live sports content—including soccer matches, football games, Formula One races and Olympic events—to more than 20 countries. In addition to live sports, beoutQ illegally streamed live television and on-demand movies from its 10 encrypted channels and apps embedded on set-top boxes. Further investigation found that Arabsat, a satellite operator based in Riyadh, Saudi Arabia, hosted the beoutQ signal.<sup>cxxxv</sup> Although the service went offline in 2019 and licensed content was reportedly available in January 2021, piracy in Saudi Arabia and the MENA region remain a threat.<sup>cxxxvi</sup> The Chamber notes that the beoutQ service did not cease operations on the behest of the government of Saudi Arabia, no rules have been established to prevent future infringement, and pirate services like *EVDTV*, *As-goal*, and *LiveHD7* continue to operate in the country. Farther afield, industry

reports that beoutQ-branded piracy devices are still widely available—making it easy to access a newer class of illicit streaming services based in Iraq, Egypt, and Morocco. Given these trends, the U.S. Chamber asks the U.S. government to maintain its engagement on piracy in the MENA region.

## **Enforcement**

The Chamber applauds certain enforcement measures in the Kingdom of Saudi Arabia, such as:

- A willingness on the part of Customs to share information and details of detained shipments. However, there are still inconsistencies between ports.
- The timely destruction of seizures by Customs (usually within a few weeks of the notified action). However, on some occasions, seizures are re-exported.
- No unnecessary fees for rightsholders during the complaint or enforcement process.

## **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. The Chamber notes that this proposal assumes that IP is a barrier to widespread access to vaccines, treatments, and diagnostics. But nothing could be further than the truth: IP protections were critical in underwriting the R&D capabilities needed to develop multiple vaccine candidates in under a year. And thanks to its manufacturing scale and logistical know-how, the private sector is a willing partner in affording widespread access when our world needs it most.

This development is unfortunate—especially since, over the past few years, the government of South Africa has worked hard to improve its engagement with stakeholders and technical experts on critical policy matters. The Chamber can point to numerous examples in where government proved open to not just listening to industry comments but addressing its concerns. The 2018 inclusion of a section entitled “Rule of law, legal certainty, and security of investments” in the country’s years-long, two-part IP Policy is but one example.



But despite this progress, the IP Policy also represents a missed opportunity. Much like its 2016 framework, the IP Policy Phase I lacked incentives to create, commercialize, and capitalize on IP as part of a broader industrial strategy. For any economy, what drives innovation and economic development is the creation of new forms of intangible assets and IP. Instead, the policy draws heavily on the expanded use of compulsory licensing, and unclear patentability criteria to achieve its policy goals—with the global pandemic spurring calls from lawmakers to depend even more heavily on these measures.

Chamber members believe in the potential of South Africa to become Africa’s innovation and creativity hub. We also 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. We encourage 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**

### **Patent Term Extension**

Section 7.1.7.1 addresses the Bolar exemption, which the Chamber believes provides a critical mechanism for generic companies to conduct pre-market testing prior to an innovative company’s patent expiration. The exemption allows for earlier development and approval of new generic medicines, stimulating competition in the marketplace. This, in turn, drives down the cost of medicines and helps to provide a variety of medical innovations in a given market. However, the Chamber believes that the Bolar exemption must be paired with other measures that promote patent rights, such as patent term extension, as in the U.S.

Patent term extension enables innovative companies to recover the patent life lost during the regulatory approval process. The balance struck between patent term extension and the Bolar exemption helps to ensure that the innovative company’s rights are adequately protected while promoting the growth of new generics. 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 in order to support the entry of generics into the marketplace while also creating a system which supports the innovator’s patent rights.

Fundamentally, we view 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.

## **Patentability**

As 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 a stakeholder consultation in this area before the IP Policy becomes a binding law.

## **Compulsory Licensing**

With respect to the issue of compulsory licensing, it is unclear what purpose the new 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 both “sustainability of supply” and “affordability” are related to such public health or national emergencies. Overall, it is difficult to see how this new IP Policy provides real-world incentives or will make it easier to invest, innovate, and create new products and technologies in South Africa.

### **Policies Encouraging the Use of “IP Flexibilities”**

Sections 7.1.7 and 7.1.9 of the IP Policy denote that compulsory licenses “are one of the most important tools to ensure that IP rights do not unduly restrict access to essential innovations.” By contrast, the Chamber believes that a stable, predictable IP system facilitates—rather than inhibits—the dissemination of new technology. Recent studies have shown that stronger IP protection results in faster access to new medicines in developing countries.<sup>cxvii</sup> In addition, robust IP protection results in the introduction of many medicines in developing countries that would not otherwise be available to patients in those markets. Finally, the global pandemic has shown that the global IP system is working. Given the importance of IP to increasing the availability of new technologies, including innovative medicines, the Chamber recommends that the South African government embrace a policy that ensures that compulsory licenses and other forms of IP expropriation are only used as a true tool of last resort, after all other options have been exhausted. An expansive use of compulsory licensing as a discretionary policy or fiscal tool runs the risk of diminishing the value of all IP in South Africa and, consequently, reducing all economic activity that relies upon IP, from basic research, to product development and testing, to access by the end user. Instituting greater flexibilities with respect to IP creates uncertainty for investors, which jeopardizes the potential for growth of the industry and deprives the local economy of the benefits which robust IP systems provide.

## **Regulatory Approval Delays**

The Chamber acknowledges South Africa's initiatives to improve regulatory systems and establish a streamlined regulatory framework for drug registrations and approvals. This includes the establishment of the South African Health Products Regulatory Authority (SAHPRA) as a separate entity, replacing the Medicines Control Council (MCC) in line with amendments to the Medicines and Related Substances Act, 1965. We understand that SAHPRA will now be responsible for monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, and clinical trials. However, the transition from MCC to SAHPRA has resulted in approval delays and increasing backlogs. This is further exacerbated by the lack of transparency around processes for considering new applications. The pharmaceutical industry welcomes the appointment of the new leader and board which have been more receptive to industry engagement and support; however, the South African government needs to invest more in terms of resources and capacity building to address the mounting delays and opaque decision making.

## **Substantive Search and Examination**

The Chamber welcomes the IP Policy's proposal to move toward a Substantive Search and Examination (SSE) system. We believe 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, we support 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 we broadly support the introduction of SSE, we re-emphasize 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. In fact, countries including India, Israel, Thailand, and Turkey are either in the process of reviewing, reforming, or eliminating their pre-grant opposition procedures. The Chamber looks forward to working with the South African government as it considers alternative patent opposition measures.

## **Copyrights and related rights**

### **Copyright Act Amendments**

In 2015, the South African Parliament drafted a bill to bring South Africa’s domestic law (the 1978 Copyright Act) in line with the WIPO Internet Treaties.<sup>cxviii</sup> Following a first draft, the Department of Trade and Industry assembled a panel to lead public consultations on the issue. In 2017 the Copyright Reform Act Bill and the Performers’ Protection Amendment Bill (PPAB) were released. That year, the Chamber submitted a letter to the government of South Africa noting that the bills as drafted would still not bring South Africa in line with its international obligations, such as the WIPO Internet Treaties, Berne Convention, and three-step test. At the time of this writing, those concerns have not yet been addressed.

The Copyright Reform Act Bill contemplates the introduction of a hybrid fair use/fair dealing exception for copyrighted works in South Africa. Such an exception not only contravenes international norms for copyright—it hasn’t been seen, let alone implemented, anywhere else in the world. The bill also establishes other vaguely-worded exceptions to copyright for educational and research institutions, accessible materials, and technological protection measures (TPMs). It also would allow the importation of parallel works into South Africa.

Under the proposed amendments, the South African government would also hold the copyright “on every work which is eligible for copyright and which is made by, funded by or under the direction or control of the state.” It is unclear how this proposed section would interact with, for example, publicly

funded academic research or state-commissioned cultural programming. Clarification is also needed regarding whether the academic researcher or creator of a work would retain any rights or whether all rights would automatically vest with the state funding entity.

Although South Africa's National Assembly approved a redrafted version of the Copyright Act Amendments (and PPAB) in 2018, key provisions remained unchanged. And in 2019, South Africa's Council of Provinces and Parliament approved the bill to be signed by President Ramaphosa. In summer 2020, President Ramaphosa returned the bills to Parliament, noting that several provisions did not comport with South Africa's Constitution. The Parliament has since held a number of hearings on the bills but have so far suggested only minor edits. The Chamber asks the U.S. government to continue its consultations with the government of South Africa to fully address the Chamber's aforementioned concerns.

### **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, it 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. South Africa's industrial policy has also placed a heavy emphasis on 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." In order 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. In the past twenty years, the creative industries have—by harnessing digital tools—leveraged their IP to make content more diverse, affordable, and accessible than ever. The Chamber looks forward to engaging with the government of South Africa on these critical issues. 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.

## **Barriers to Technology Transfer**

As a step in the right direction, South Africa introduced a national technology transfer framework in 2008. The Intellectual Property Rights from Publicly Financed Research and Development Act established the parameters by which publicly funded research can be commercialized and, crucially, where ownership over the generated IP resides. The act aims to stimulate research and the commercialization of publicly funded research. Broadly speaking, the act and its accompanying regulations establish the principle that the recipient will retain IP generated through publicly funded research. However, Section 11 of the act imposes restrictions on licensing transactions, including reserving the right for the South African government to directly intervene and cancel agreements. It also contains a number of localization components and geographical limitations on the use of the licensed technology. On a positive note, the Department of Science and Technology published the South African National Survey of Intellectual Property and Technology Transfer at Publicly Funded Research Institutions in April 2017, showing a notable uptick in patenting, licensing deals executed, company spinoffs, and commercialization activities in South Africa since the introduction of the legislation in 2008. The report also shows the scope of opportunity to make this growing dynamic more commercially attractive.

## **Tax Incentives for the Creation of IP Assets**

South African tax law offers a generous research and development (R&D) tax credit of up to 150% on qualifying R&D expenditure and accelerated asset relief. However, there are no IP-specific tax incentives available, such as a patent box.

\*\*\*

---

<sup>i</sup> World Health Organization. "Draft landscape of COVID-19 vaccines." (January 2021).  
<https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>

<sup>ii</sup> U.S Patent and Trademark Office. "Intellectual Property and the U.S. Economy." (2016).  
<https://www.uspto.gov/sites/default/files/documents/IPandtheUSEconomySept2016.pdf>

<sup>iii</sup> U.S. Chamber of Commerce. "Equality of Opportunity Agenda." (June 2020).  
[https://www.uschamber.com/sites/default/files/equality\\_opportunity\\_agenda\\_onepaggers.pdf](https://www.uschamber.com/sites/default/files/equality_opportunity_agenda_onepaggers.pdf)



- 
- <sup>iv</sup> Pew Research Center. “Diversity in the STEM Workforce.” (January 2018). <https://www.pewsocialtrends.org/2018/01/09/diversity-in-the-stem-workforce-varies-widely-across-jobs/>
- <sup>v</sup> Motion Picture Association. “The American Motion Picture & Television Industry: Creating Jobs, Trading Around the World.” (February 2020). [https://www.motionpictures.org/wp-content/uploads/2020/02/MPA\\_Economic\\_contribution\\_US\\_infographic\\_2019\\_Final.pdf](https://www.motionpictures.org/wp-content/uploads/2020/02/MPA_Economic_contribution_US_infographic_2019_Final.pdf)
- <sup>vi</sup> U.S. Chamber of Commerce. “Art of the Possible: 2020 International IP Index.” (February 2020). [https://www.uschamber.com/sites/default/files/023881\\_gipc\\_ip\\_index\\_2020\\_fullreport\\_final.pdf](https://www.uschamber.com/sites/default/files/023881_gipc_ip_index_2020_fullreport_final.pdf)
- <sup>vii</sup> U.S. Chamber of Commerce. “Statistical Annex to the International IP Index, 7<sup>th</sup> Edition.” (2019). [https://www.theglobalipcenter.com/wp-content/uploads/2019/02/023593\\_GIPC\\_IP\\_Index\\_2019\\_Annex.pdf](https://www.theglobalipcenter.com/wp-content/uploads/2019/02/023593_GIPC_IP_Index_2019_Annex.pdf)
- <sup>viii</sup> U.S. Chamber of Commerce. “Human Progress: Sustaining the Wave. The Innovation and Creativity Access Barometer.” (2019). [https://www.valueingenuity.com/wp-content/uploads/2019/11/023644\\_GIPC\\_Barometer\\_Report\\_2019\\_FINv2\\_WEB.pdf](https://www.valueingenuity.com/wp-content/uploads/2019/11/023644_GIPC_Barometer_Report_2019_FINv2_WEB.pdf)
- <sup>ix</sup> U.S. Bureau of Economic Analysis. “Intellectual Property.” (January 2021). <https://www.bea.gov/data/special-topics/intellectual-property>
- <sup>x</sup> U.S. Patent & Trademark Office. “Four USPTO intellectual property attachés elevated to rank of “Counselor” (December 2020). <https://www.uspto.gov/about-us/news-updates/four-uspto-intellectual-property-attaches-elevated-rank-counselor>
- <sup>xi</sup> Rupali Mukherjee. “Illegal cancer drugs from Bangladesh flood local market.” The Times of India. (November 18, 2019). <https://timesofindia.indiatimes.com/business/india-business/illegal-cancer-drugs-from-bdesh-flood-local-market/articleshow/72100024.cms>
- <sup>xii</sup> Shiv Sahay Singh. “Illegal narcotics trade on the rise along Bengal-Bangladesh border.” The Hindustan Times. (February 1, 2020). <https://www.thehindu.com/news/national/other-states/illegal-narcotics-trade-on-the-rise-along-bengal-bangladesh-border/article30708325.ece>
- <sup>xiii</sup> Hemanta Kumar Nath. “BSF seized contraband drugs worth over Rs 13 crore in Guwahati region in past one year.” India Today. (Nov. 30, 2019). <https://www.indiatoday.in/crime/story/bsf-seized-contraband-drugs-worth-over-rs-13-crore-in-guwahati-region-in-past-one-year-1624029-2019-11-30>
- <sup>xiv</sup> Indrani Bagchi. “Cattle in the way: India, Bangladesh trade smuggling charges.” The Times of India. (July 20, 2020). <https://timesofindia.indiatimes.com/india/cattle-in-the-way-india-bangladesh-trade-smuggling-charges/articleshow/77072720.cms>
- <sup>xv</sup> Sophia Yang. “Taiwan busts biggest piracy movie website 8maple.ru.” Taiwan News. (April 9, 2020). <https://www.taiwannews.com.tw/en/news/3913305>
- <sup>xvi</sup> International Intellectual Property Alliance. “2020 Notorious Markets filing.” (October 2020). [https://www.iipa.org/files/uploads/2021/01/IIPA\\_2020-Notorious-Markets.pdf](https://www.iipa.org/files/uploads/2021/01/IIPA_2020-Notorious-Markets.pdf)
- <sup>xvii</sup> Ibid.
- <sup>xviii</sup> Deloitte, Stowarzyszenie Kreatywna Polska. “Internet Piracy—Losses to Culture and the Economy.” (2017). [http://zpav.pl/pliki/aktualnosci/Deloitte/Broszura\\_piractwo\\_EN\\_Final.pdf](http://zpav.pl/pliki/aktualnosci/Deloitte/Broszura_piractwo_EN_Final.pdf)
- <sup>xix</sup> Casimir Jones SC. “Change in Data Exclusivity for Pharmaceutical Products in the United Arab Emirates.” Lexology. (October 2020). <https://www.lexology.com/library/detail.aspx?g=f3ddb9d9-f84d-44b0-bfdb-1cefa611df7c>
- <sup>xx</sup> World Trade Organization. “EU initiates WTO dispute complaint against Turkish measures affecting pharmaceuticals.” (April 2019). [https://www.wto.org/english/news\\_e/news19\\_e/ds583rfc\\_08apr19\\_e.htm](https://www.wto.org/english/news_e/news19_e/ds583rfc_08apr19_e.htm)
- <sup>xxi</sup> Office of the U.S. Trade Representative. “National Trade Estimate Report on Foreign Trade Barriers.” (2020). [https://ustr.gov/sites/default/files/2020\\_National\\_Trade\\_Estimate\\_Report.pdf](https://ustr.gov/sites/default/files/2020_National_Trade_Estimate_Report.pdf)
- <sup>xxii</sup> U.S. Chamber of Commerce. “U.S.-Brazil Trade Deal Takes Center Stage at U.S. Chamber’s U.S.-Brazil Connect Summit.” (October 2020). <https://www.uschamber.com/press-release/us-brazil-trade-deal-takes-center-stage-us-chamber-s-us-brazil-connect-summit>
- <sup>xxiii</sup> U.S. Chamber of Commerce. “U.S. Chamber Welcomes Signing of Trade Protocol between the U.S. and Ecuador.” (December 2020). <https://www.uschamber.com/press-release/us-chamber-welcomes-signing-of-trade-protocol-between-the-us-and-ecuador>
- <sup>xxiv</sup> U.S. Chamber of Commerce. “U.S.-UK Trade Negotiations: Private Sector Priorities.” (May 2020). <https://www.uschamber.com/comment/us-uk-trade-negotiations-private-sector-priorities>

- 
- <sup>xxv</sup> U.S. Chamber of Commerce. “U.S. Chamber Applauds Progress to Pursue U.S.-Kenya Trade Deal.” (July 2020). <https://www.uschamber.com/press-release/us-chamber-applauds-progress-pursue-us-kenya-trade-deal>
- <sup>xxvi</sup> U.S. Chamber of Commerce. “U.S. Chamber Statement on Intellectual Property in USMCA.” (December 2019). <https://www.uschamber.com/press-release/us-chamber-statement-intellectual-property-usmca-0>
- <sup>xxvii</sup> U.S. Chamber of Commerce. “U.S. Chamber Statement on the Regional Comprehensive Partnership Agreement (RCEP).” (November 2020). <https://www.uschamber.com/press-release/us-chamber-statement-the-regional-comprehensive-partnership-agreement-rcep>
- <sup>xxviii</sup> Brionne Dawson, Whitney Schneidman. “The U.S. and Kenya Launch Negotiations on a Free Trade Agreement: Will They Succeed?” U.S. Chamber of Commerce. (July 2020). <https://www.uschamber.com/series/above-the-fold/the-us-and-kenya-launch-negotiations-free-trade-agreement-will-they-succeed>
- <sup>xxix</sup> Ibid.
- <sup>xxx</sup> House of Commons of Canada. “BILL C-4.” (January 2020). <https://www.parl.ca/DocumentViewer/en/43-1/bill/C-4/first-reading>
- <sup>xxxi</sup> U.S. Chamber of Commerce. “U.S. Chamber Congratulates Daren Tang on Nomination to Lead World Intellectual Property Organization.” (March 2020). <https://www.uschamber.com/press-release/us-chamber-congratulates-daren-tang-nomination-lead-world-intellectual-property>
- <sup>xxxii</sup> Ibid.
- <sup>xxxiii</sup> World Intellectual Property Organization. “WIPO Match is an online tool to match seekers of specific intellectual property (IP)-related development needs with potential providers offering resources.” (Accessed 2021). <https://www.wipo.int/wipo-match/en/>
- <sup>xxxiv</sup> World Trade Organization. “Members to continue discussion on proposal for temporary IP waiver in response to COVID-19.” (December 2020). [https://www.wto.org/english/news\\_e/news20\\_e/trip\\_10dec20\\_e.htm](https://www.wto.org/english/news_e/news20_e/trip_10dec20_e.htm)
- <sup>xxxv</sup> World Intellectual Property Organization. “Hungary: Government Decree No. 212/2020 on Public Health Compulsory Licenses for Exploitation Within Hungary.” (May 2020). [https://www.wipo.int/news/en/wipolex/2020/article\\_0009.html](https://www.wipo.int/news/en/wipolex/2020/article_0009.html)
- <sup>xxxvi</sup> AmCham Indonesia. “Presidential Regulation Allows Government to Take Over Patents in Crisis.” (July 2020). <https://app.glueup.com/organization/1170/campaign/47986>
- <sup>xxxvii</sup> Ibid.
- <sup>xxxviii</sup> U.S. Chamber of Commerce. “OPEN LETTER TO HEADS OF STATE AND GOVERNMENT LEADERS”. (July 2020). <https://www.theglobalipcenter.com/wp-content/uploads/2020/07/Global-Business-Associations-Open-Letter-FINAL.pdf>
- <sup>xxxix</sup> UNDP. “Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries.” (2014). <http://apps.who.int/medicinedocs/documents/s21764en/s21764en.pdf>
- <sup>xl</sup> WIPO Advisory Committee on Enforcement. “The Interface of IP Enforcement and Competition Law: Contributions Prepared by Brazil and Peru” (13th Session, Sept. 3-5, 2018). [https://www.wipo.int/edocs/mdocs/enforcement/en/wipo\\_ace\\_13/wipo\\_ace\\_13\\_5.pdf](https://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_13/wipo_ace_13_5.pdf)
- <sup>xli</sup> World Trade Organization TRIPS Council. “Intellectual Property and the Public Interest: Promoting Public Health through Competition Law and Policy, Communication from China and South Africa” IP/C/W/634. (May 25, 2018)
- <sup>xlii</sup> World Trade Organization TRIPS Council. “Intellectual Property and the Public Interest: Promoting Public Health through Competition Law and Policy, Communication from South Africa.” IP/C/W/649. (Oct. 29, 2018).
- <sup>xliii</sup> Organization for Economic Cooperation and Development. “Trade in fake goods is now 3.3% of world trade and rising.” (March 2019). <https://www.oecd.org/newsroom/trade-in-fake-goods-is-now-33-of-world-trade-and-rising.htm>
- <sup>xliv</sup> David Blackburn et al. “Impacts of Digital Video Piracy on the U.S. Economy.” U.S. Chamber of Commerce. (2019). <https://www.theglobalipcenter.com/wp-content/uploads/2019/06/Digital-Video-Piracy.pdf>
- <sup>xlv</sup> U.S. Intellectual Property Enforcement Coordinator. “2013 Joint Strategic Plan on IP Enforcement.” (June 2013). <http://www.whitehouse.gov/sites/default/files/omb/IPEC/2013-us-ipec-joint-strategic-plan.pdf>
- <sup>xlvi</sup> World Customs Organization. “Illicit Trade Report.” (2017). [http://www.wcoomd.org/-/media/wco/public/global/pdf/topics/enforcement-and-compliance/activities-and-programmes/illicit-trade-report/itr\\_2017\\_en.pdf?db=web](http://www.wcoomd.org/-/media/wco/public/global/pdf/topics/enforcement-and-compliance/activities-and-programmes/illicit-trade-report/itr_2017_en.pdf?db=web)
- <sup>xlvii</sup> U.S. Customs and Border Protection. “Cargo Security and Examinations.” (2019). <https://www.cbp.gov/border-security/ports-entry/cargo-security>

- 
- <sup>xlviii</sup> U.S. Department of Homeland Security. “Combating Trafficking in Counterfeit and Pirated Goods.” (January 2020). [https://www.dhs.gov/sites/default/files/publications/20\\_0124\\_plcy\\_counterfeit-pirated-goods-report\\_01.pdf](https://www.dhs.gov/sites/default/files/publications/20_0124_plcy_counterfeit-pirated-goods-report_01.pdf)
- <sup>xliv</sup> U.S. Chamber of Commerce. “How Europe’s Privacy Law Is Undermining the Fight Against COVID-19 Internet Abuse”. (May 2020). <https://www.uschamber.com/series/above-the-fold/how-europe-s-privacy-law-undermining-the-fight-against-covid-19-internet-abuse>
- <sup>l</sup> U.S. Immigration and Customs Enforcement. “ICE HIS Launches Operation Stolen Promise.” (April 2020). <https://www.ice.gov/news/releases/ice-hsi-launches-operation-stolen-promise>
- <sup>ii</sup> U.S. Food and Drug Administration. “Canadian Drug Firm Admits Selling Counterfeit and Misbranded Prescription Drugs Throughout the United States.” (April 2018). <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/criminal-investigations/april-13-2018-canadian-drug-firm-admits-selling-counterfeit-and-misbranded-prescription-drugs>
- <sup>iii</sup> Fortune. “Movie piracy is on the rise as studios bypass theatrical releases.” October 2020. <https://fortune.com/2020/10/06/movie-piracy-digital-streaming-releases-2020-coronavirus-pandemic/>
- <sup>iiii</sup> U.S. Copyright Office. “Section 512 Study.” (May 2020). <https://www.copyright.gov/policy/section512/>
- <sup>liv</sup> U.S. Chamber of Commerce. “U.S. Chamber Commends Congress for Passing Bipartisan Measures to Protect Creators.” (December 2020). <https://www.uschamber.com/press-release/us-chamber-commends-congress-passing-bipartisan-measures-protect-creators>
- <sup>lv</sup> U.S. Chamber of Commerce. “Providing Certainty and Predictability: How Patent Linkage Mechanisms Help Innovators, Follow-On Manufacturers, and Patients.” (Sept. 2019). <https://www.theglobalipcenter.com/wp-content/uploads/2019/09/GIPC-Linkage-Zoom-In-Report.pdf>
- <sup>lvi</sup> . Parliament of Australia. “Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2019, Explanatory Memorandum. p.40.” (2019). [https://parlinfo.aph.gov.au/parlInfo/download/legislation/ems/s1216\\_ems\\_2d30b94a-4f04-46e8-bbe4-4be1e39bad05/upload\\_pdf/712877em.pdf;fileType=application%2Fpdf](https://parlinfo.aph.gov.au/parlInfo/download/legislation/ems/s1216_ems_2d30b94a-4f04-46e8-bbe4-4be1e39bad05/upload_pdf/712877em.pdf;fileType=application%2Fpdf)
- <sup>lvii</sup> Parliament of Australia. “Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2019, Explanatory Memorandum. p.17.” (2019). [https://parlinfo.aph.gov.au/parlInfo/download/legislation/ems/s1216\\_ems\\_2d30b94a-4f04-46e8-bbe4-4be1e39bad05/upload\\_pdf/712877em.pdf;fileType=application%2Fpdf](https://parlinfo.aph.gov.au/parlInfo/download/legislation/ems/s1216_ems_2d30b94a-4f04-46e8-bbe4-4be1e39bad05/upload_pdf/712877em.pdf;fileType=application%2Fpdf)
- <sup>lviii</sup> U.S. Chamber of Commerce. “Providing Certainty and Predictability: How Patent Linkage Mechanisms Help Innovators, Follow-On Manufacturers, and Patients.” (Sept. 2019). <https://www.theglobalipcenter.com/wp-content/uploads/2019/09/GIPC-Linkage-Zoom-In-Report.pdf>
- <sup>lix</sup> Ibid.
- <sup>lx</sup> PwC LLC. “Economic Impacts of the Canadian Educational Sector’s Fair Dealing Guidelines.” (June 2015). [https://www.accesscopyright.ca/media/1106/access\\_copyright\\_report.pdf](https://www.accesscopyright.ca/media/1106/access_copyright_report.pdf)
- <sup>lxi</sup> Standing Committee on Canadian Heritage, House of Commons of Canada. “Shifting Paradigms.” (May 2019). <https://www.ourcommons.ca/Content/Committee/421/CHPC/Reports/RP10481650/chpcrp19/chpcrp19-e.pdf>
- <sup>lxii</sup> Kristina M.L. Acri. “Implications of the Proposed Changes to Canada’s Pharmaceutical Pricing Regulations.” Fraser Institute. (July 2018). <https://www.fraserinstitute.org/sites/default/files/implications-of-changes-to-pharmaceutical-pricing-regulations-exsumm.pdf>
- <sup>lxiii</sup> UNDP. “Human Development Report.” (2020). <http://hdr.undp.org/en/content/latest-human-development-index-ranking>
- <sup>lxiv</sup> Ibid.
- <sup>lxv</sup> Chilean Chamber of Deputies. “RESOLUCIÓN N° 1351.” (October 2020). <https://www.camara.cl/verDoc.aspx?prmId=4161&prmDestinoId=3&prmTipo=RESOLUCIONENVIO>
- <sup>lxvi</sup> STAT News. “Chilean lawmakers support compulsory licensing for coronavirus medicines and vaccines.” (March 2020). <https://www.statnews.com/pharmalot/2020/03/18/chile-compulsory-licensing-coronavirus-covid19-vaccines/>
- <sup>lxvii</sup> Government of Chile. “Law 19,039 art. 89; Supreme Decree No. 107/08.” (Dec. 1, 2010).
- <sup>lxviii</sup> Government of Chile. “Law 19,039 art. 91; Supreme Decree No. 107/08.” (Dec. 1, 2010).
- <sup>lxix</sup> Government of Canada. “Chile joins the Global Patent Prosecution Highway.” (July 2020). <https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04528.html>

- 
- <sup>lxx</sup> Alliance Against Pay-TV Piracy. “Latin America Web Piracy Increases 9% Throughout 2018-2019, Alianza Reveals.” (January 2020). <http://www.alianza.tv/1.0/latin-america-web-piracy-increases-9-throughout-2018-2019-alianza-reveals/>
- <sup>lxxi</sup> Ben Miller. “Ten Ways Piracy is Everywhere in Latin America.” Americas Quarterly. (January 2019). <https://www.americasquarterly.org/content/10-kinds-piracy>
- <sup>lxxii</sup> Alliance Against Pay-TV Piracy. “Pay-TV Signal Piracy in Latin America and Caribbean.” (April 2018). <http://www.alianza.tv/1.0/alianza-report-pay-tv-signal-piracy-in-latin-america-and-caribbean/>
- <sup>lxxiii</sup> Chilean Chamber of Deputies. “Bill 8620-24.” (November 2020). <https://www.camara.cl/legislacion/ProyectosDeLey/tramitacion.aspx?prmID=12389&prmBL=11867-24>
- <sup>lxxiv</sup> European Commission. “Report on the protection and enforcement of intellectual property rights in third countries.” (December 2019). [https://trade.ec.europa.eu/doclib/docs/2020/january/tradoc\\_158561.pdf](https://trade.ec.europa.eu/doclib/docs/2020/january/tradoc_158561.pdf)
- <sup>lxxv</sup> European Commission. “Medicines for children & rare diseases – updated rules.” (Accessed January 2021). <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12767-Revision-of-the-EU-legislation-on-medicines-for-children-and-rare-diseases>.
- <sup>lxxvi</sup> TorrentFreak. “Former RapidShare Operators & Lawyer Acquitted of Copyright Infringement.” (January 2021). <https://torrentfreak.com/former-rapidshare-operators-lawyer-acquitted-of-copyright-infringement-210111/>
- <sup>lxxvii</sup> This assertion is expressly supported by the European Court of Justice holding in *ACI Adam BV and Others v Stichting de Thuiskopie and Stichting Onderhandeligen Thuiskopie vergoeding*, Case C 435/12, ECLI:EU:C:2014:254
- <sup>lxxviii</sup> Government of the People’s Republic of China. [http://www.sipo.gov.cn/zwgg/jl/201311/t20131106\\_876947.html](http://www.sipo.gov.cn/zwgg/jl/201311/t20131106_876947.html)
- <sup>lxxix</sup> Government of the People’s Republic of China. [http://www.gov.cn/zhengce/content/2015-01/04/content\\_9375.htm](http://www.gov.cn/zhengce/content/2015-01/04/content_9375.htm)
- <sup>lxxx</sup> U.S. Chamber of Commerce. “China’s Utility Model Patent System: Innovation Driver or Deterrent.” (November 2012). [http://www.uschamber.com/sites/default/files/reports/1211\\_china\\_patent\\_paper.pdf](http://www.uschamber.com/sites/default/files/reports/1211_china_patent_paper.pdf)
- <sup>lxxxi</sup> In March 2017, NCAC’s enforcement brigade investigated Beijing OrangeVR Co. Ltd. at the request of the Motion Picture Association of America (MPAA) for the unauthorized distribution of its products—including *Ant-Man*, *The Fast and Furious*, and *San Andreas*. NCAC imposed a fine of 30,000 RMB (\$4,500). It was the first case in China involving virtual reality (VR) technology subject to administrative penalty. <http://ent.sina.com.cn/m/c/2017-11-03/doc-ifynnnsc4222799.shtml>
- <sup>lxxxii</sup> U.S. Chamber of Commerce. “Competing Interests in China’s Competition Law Enforcement: China’s Anti-Monopoly Law Application and the Role of Industrial Policy.” (2014). [https://www.uschamber.com/sites/default/files/aml\\_final\\_090814\\_final\\_locked.pdf](https://www.uschamber.com/sites/default/files/aml_final_090814_final_locked.pdf)
- <sup>lxxxiii</sup> Government of the People’s Republic of China. “State Council Decision no. 709, Article 38.” <http://www.mofcom.gov.cn/article/b/g/201904/20190402855130.shtml>
- <sup>lxxxiv</sup> Government of the People’s Republic of China. “关于强化实施创新驱动发展战略进一步推进大众创业万众创新深入发展的意见 [Opinion on Strengthening the Implementation of the Innovation-Driven Development Strategy and Further Promoting the Developing of Mass Innovation].” (July 27, 2017). [http://www.gov.cn/zhengce/content/2017-07/27/content\\_5213735.htm](http://www.gov.cn/zhengce/content/2017-07/27/content_5213735.htm)
- <sup>lxxxv</sup> Government of the People’s Republic of China. “News Conference for the Fifth Session of the 12th National People’s Congress.” (2017). <http://www.xinhuanet.com/politics/2017lh/live/20170311a/index.htm#wzsl>
- <sup>lxxxvi</sup> See the published report on standard essential patents by Guangzhou Intellectual Property Court , <http://www.gipc.gov.cn/front/content.action?id=f25c23aaf89c482b9b78ede6ba1d78fa>
- <sup>lxxxvii</sup> The U.S. Chamber of Commerce, the American Chamber of Commerce in China, and the American Chamber of Commerce in Shanghai. “Joint Submission to the Ministry of Commerce on the Export Control Law of the People’s Republic of China (Draft for Comments).” (July 2017).
- <sup>lxxxviii</sup> Government of the People’s Republic of China. “National People’s Congress, Draft Revisions to the Standardization Law, Article 19.” (September 2017). [http://www.npc.gov.cn/npc/flcazqyj/2017-09/04/content\\_2028318.htm](http://www.npc.gov.cn/npc/flcazqyj/2017-09/04/content_2028318.htm)

---

<sup>lxxxix</sup> The “[two random selections, one public release](#)” principle denotes that both the inspection target and the inspecting official will be randomly selected in order to curtail opportunities for preferential treatment, and that the result of the inspection will be publicly released upon completion.

<sup>xc</sup> The American Chamber of Commerce in China, BSA | The Software Alliance, the US-China Business Council, the U.S. Chamber of Commerce and the U.S. Information Technology Office. “Joint Comments to the Ministry of Industry and Information Technology on the draft Notice on Regulating Business Behaviors in the Cloud Service Market.” (December 2016).

<sup>xc1</sup> U.S. Chamber of Commerce and the American Chamber of Commerce in China. “Comments on SIPO proposed Service Invention Regulations.” (2012).

<sup>xcii</sup> Government of the People’s Republic of China. “Administrative Provisions on the Internet Information Content Environment.” (2019).

[http://www.cac.gov.cn/2019-12/20/c\\_1578375159509309.htm](http://www.cac.gov.cn/2019-12/20/c_1578375159509309.htm).

<sup>xciii</sup> Government of the People’s Republic of China. “Implementation Opinions on Strengthening the Reform and Innovation of Intellectual Property Trials.” (2019).

[http://www.capitalip.org/news\\_detail\\_13722.html](http://www.capitalip.org/news_detail_13722.html)

<sup>xciv</sup> “IP legal cases on the rise in Beijing.” China Daily. (2019).

<https://www.chinadaily.com.cn/a/201911/06/WS5dc2604ca310cf3e35575c30.html>

<sup>xcv</sup> See the press release: <http://bjzcfy.chinacourt.gov.cn/article/detail/2020/06/id/5295100.shtml>

<sup>xcvi</sup> <http://www.court.gov.cn/zixun-xiangqing-225861.html>

<sup>xcvii</sup> “Shoddy, counterfeit goods in 40% China online deals: report.” Xinhua. (Nov. 3, 2017).

[http://www.xinhuanet.com/english/2015-11/03/c\\_134776510.htm](http://www.xinhuanet.com/english/2015-11/03/c_134776510.htm)

<sup>xcviii</sup> Government of the People’s Republic of China.

<http://www.cca.org.cn/jmxf/detail/28355.html>

<sup>xcix</sup> Government of the People’s Republic of China.

<http://www.ncac.gov.cn/chinacopyright/contents/11379/410138.html>

<sup>c</sup> Government of the People’s Republic of China.

<http://www.customs.gov.cn/customs/302249/mtj35/1803852/index.html>

<sup>ci</sup> Government of the People’s Republic of China.

<http://www.cnipa.gov.cn/docs/20190624164519009878.pdf>

<sup>cii</sup> Ibid. The official report of CNIPA states that in 2017, only 172 cases were transferred to criminal procedure out of nearly 30,130 cases that SAIC opened up for investigation in China. NCAC transferred 57 online infringement cases to criminal procedure out of 543 administrative investigation cases. The total cases transferred from administrative authorities to the procuratorate authority were 313 cases.

<http://www.sipo.gov.cn/docs/2018-04/20180425155906670179.pdf>

<sup>ciii</sup> Government of the People’s Republic of China.

[http://www.spb.gov.cn/xw/dtxx\\_15079/201710/t20171031\\_1404190.html](http://www.spb.gov.cn/xw/dtxx_15079/201710/t20171031_1404190.html)

<sup>civ</sup> See the white paper at <http://www.customs.gov.cn//customs/xwfb34/302425/3523464/index.html>

<sup>cv</sup> Ibid.

<sup>cvi</sup> Telam. “Los puestos de venta ilegal callejera aumentaron un 47,5% en enero.” (February 2020).

<https://www.telam.com.ar/notas/202002/430038-los-puestos-de-venta-ilegal-callejera-aumentaron-un-475-en-enero.html>

<sup>cvi</sup> Government of Brazil. “National IP Strategy.” (December 2020). <https://www.gov.br/inpi/pt-br/central-de-conteudo/noticias/cerimonia-marca-50-anos-do-inpi-e-lancamento-da-estrategia-nacional-de-propriedade-intelectual/EstrategiaNacionaldePropriedadeIntelectual.pdf>

<sup>cvi</sup> Government of Brazil. “National Innovation Strategy.” (November 2020). <https://www.gov.br/mcti/pt-br/acompanhe-o-mcti/noticias/2020/10/consulta-publica-a-estrategia-nacional-de-inovacao-ja-esta-disponivel-no-site-do-mcti>

<sup>cix</sup> Ibid.

<sup>cx</sup> Government of Brazil. “Lei de Propriedade Industrial. Artigo 229-C.” (Accessed January 2021).

[http://www.planalto.gov.br/ccivil\\_03/leis/l9279.htm](http://www.planalto.gov.br/ccivil_03/leis/l9279.htm)

<sup>cx1</sup> World Trade Organization. “TRIPS Agreement, Section 5, Article 27.1.” “..patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products

---

are imported or locally produced.” Until recently, ANVISA did not limit its role to the review of the potential sanitary risk aspects of the subject matter of the patent application, but also an application’s patentability requirements. (Accessed January 2021). [https://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_04c\\_e.htm](https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm)

<sup>cxii</sup> Licks Attorneys. “Ministry of Health creates IP advisory bodies and changes criteria for ANVISA’s prior consent process.” (October 2020). <https://www.lickslegal.com/news/ministry-of-health-creates-ip-advisory-bodies-and-changes-criteria-for-anvisas-prior-approval-process>

<sup>cxiii</sup> Government of Brazil. “Plano de Combate ao Backlog”. (Accessed January 2021). <https://www.gov.br/inpi/pt-br/servicos/patentes/plano-de-combate-ao-backlog-1>

<sup>cxiv</sup> Government of Brazil. “Lei No. 9279/1996.” (Accessed January 2021). [http://www.planalto.gov.br/ccivil\\_03/leis/l9279.htm](http://www.planalto.gov.br/ccivil_03/leis/l9279.htm)

<sup>cxv</sup> G1, Globo News. “Operação contra pirataria digital faz buscas em 12 estados”. (January 2019). <https://g1.globo.com/sp/sao-paulo/noticia/2019/11/01/policia-civil-deflagra-operacao-contrapirataria-digital-em-sp.ghtml>

<sup>cxvi</sup> Variety. “U.S. and Brazil Stage Unprecedented Joint Crackdown on Online Content Pirates.” (November 2020). <https://variety.com/2020/film/global/u-s-and-brazil-stage-unprecedented-joint-crackdown-on-online-content-pirates-1234824318/>

<sup>cxvii</sup> Government of Brazil. “PL 5204/2016.” (Accessed January 2021).

<sup>cxviii</sup> Government of Brazil, Ministry of Justice and Public Safety. “Boas práticas e orientações para a implementação de medidas de combate à pirataria nas plataformas de comércio online.” [Best Practices for the Implementation of Measures to Combat Piracy on E-commerce Platforms]. (December 2019). <https://www.mattosfilho.com.br/Documents/Guia%20pirataria%20come%CC%81rcio%20eletro%CC%82nico%20-%20v.%203.pdf>

<sup>cxix</sup> BSA\_The Software Alliance. “Unlicensed Software Survey.” (June 2018). <https://gss.bsa.org/>

<sup>cxx</sup> Government of Brazil. “Law 12.485/2011.” (September 2011). <https://www2.camara.leg.br/legin/fed/lei/2011/lei-12485-12-setembro-2011-611410-norma-pl.html>

<sup>cxxi</sup> Senate of Colombia. “Modifíquese el ARTÍCULO SEGUNDO al Proyecto de Ley número 333 de 2020 Senado, 284 de 2020 Cámara.” (November 2020). <http://www.secretariassenado.gov.co/index.php/legislatura-2020-2021/plenarias/noviembre/miercoles-18-de-noviembre-de-2020/proyectos-de-ley-17/pl-333-de-2020-senado-284-de-2020-camara/2109-p-063-modifiquese-art-2-pl-333-2020-sen-284-2020-ca-m-lozano-angelica/file>

<sup>cxixii</sup> Andean Community. “Decision 486: Common Intellectual Property Regime.” Accessed January 2021. <http://www.sice.oas.org/trade/junac/decisiones/DEC486ae.asp>

<sup>cxixiii</sup> World Trade Organization. “TRIPS Agreement, Article 31, L (i, ii, iii).” Accessed January 2021. [https://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_04c\\_e.htm](https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm)

<sup>cxixiv</sup> Senate of Colombia. “PL 372/20.” December 2020. <http://leyes.senado.gov.co/proyectos/index.php/proyectos-ley/cuatrenio-2018-2022/2020-2021/articulo/373-por-medio-de-la-cual-se-dictan-las-bases-de-la-br-politica-nacional-de-investigacion-cientifica-desarrollo-tecnologico-e-innovacion-i-d-i-para-la-seguridad-farmaceutica-y-se-dictan-otras-disposiciones>

<sup>cxixv</sup> Alliance Against Pay-TV Piracy. “Pay-TV Signal Piracy in Latin America and Caribbean.” (April 2018). <http://www.alianza.tv/1.0/alianza-report-pay-tv-signal-piracy-in-latin-america-and-caribbean/>

<sup>cxixvi</sup> Tito Yepes and Mauricio Ramirez. “Copyright Market in Colombia.” Fedesarrollo. (2019). [https://www.repository.fedesarrollo.org.co/bitstream/handle/11445/3806/LIB\\_Agosto\\_2019\\_Yepes\\_y\\_Ram%3%adrez\\_English.pdf?sequence=2&isAllowed=y](https://www.repository.fedesarrollo.org.co/bitstream/handle/11445/3806/LIB_Agosto_2019_Yepes_y_Ram%3%adrez_English.pdf?sequence=2&isAllowed=y)

<sup>cxixvii</sup> Government of India. “U.S., India sign MOU on IP Cooperation.” (December 2020). <https://pib.gov.in/Pressreleaseshare.aspx?PRID=1678004>

<sup>cxixviii</sup> Aditi Singh. “A computer program which makes ‘technical contribution’ patentable, not hit by Sec 3(k) of Patents Act. (Dec. 2019). <https://www.barandbench.com/news/a-computer-program-which-makes-technical-contribution-patentable-not-hit-by-sec-3k-of-patents-act>

<sup>cxixix</sup> Entertainment Times. “Piracy soars amidst pandemic.” (April 2020). <https://timesofindia.indiatimes.com/life-style/spotlight/piracy-soars-amidst-pandemic/articleshow/75193518.cms>

<sup>cxixxx</sup> Deloitte. “Economic impact of the recorded music industry in India.” (September 2019). [https://www2.deloitte.com/content/dam/Deloitte/in/Documents/technology-media-telecommunications/IMI%20report\\_singlePage.pdf](https://www2.deloitte.com/content/dam/Deloitte/in/Documents/technology-media-telecommunications/IMI%20report_singlePage.pdf)

- 
- <sup>cxxx</sup> Government of India. “Public Procurement Preference to Make in India.” (December 2019).  
[https://www.meity.gov.in/writereaddata/files/public\\_procurement-preference\\_to\\_make\\_in\\_india-order\\_2019\\_for\\_cyber\\_security\\_products.pdf](https://www.meity.gov.in/writereaddata/files/public_procurement-preference_to_make_in_india-order_2019_for_cyber_security_products.pdf)
- <sup>cxxxii</sup> Government of India. “National Electronics Policy.” (2019).  
[https://www.meity.gov.in/esdm/policies#:~:text=The%20National%20Policy%20on%20Electronics%202019%20\(NPE%202019\)%2C%20prepared,chipsets%2C%20and%20creating%20an%20enabling](https://www.meity.gov.in/esdm/policies#:~:text=The%20National%20Policy%20on%20Electronics%202019%20(NPE%202019)%2C%20prepared,chipsets%2C%20and%20creating%20an%20enabling)
- <sup>cxxxiii</sup> U.S. Chamber of Commerce. “Leveraging Intellectual Property in the Global Sports Economy.” (2018).  
[https://www.theglobalipcenter.com/wp-content/uploads/2018/06/023441\\_GIPC\\_Sports\\_Econ\\_Insides\\_03.pdf](https://www.theglobalipcenter.com/wp-content/uploads/2018/06/023441_GIPC_Sports_Econ_Insides_03.pdf)
- <sup>cxxxiv</sup> Court of the City of Moscow. “First Instance.” (2019).  
<http://kad.arbitr.ru/Card/322413fa-38a7-4085-9cc7-3c8ff9fd7d92>
- <sup>cxxxv</sup> Rebecca Hawkes. “beIN slams persistent piracy menace.” Digital TV Europe. November 8, 2019.  
<https://www.digitaltveurope.com/2019/11/08/bein-slams-persistent-beoutq-piracy-menace/>
- <sup>cxxxvi</sup> Aziz El Yaakoubi. “Saudi Arabia allows broadcast by Qatar-based beIN Sports TV channel.” (January 2021).  
<https://www.reuters.com/article/saudi-qatar-tv-int-idUSKBN29N1WY>
- <sup>cxxxvii</sup> Ibid.
- <sup>cxxxviii</sup> World Intellectual Property Organization. “WCT Notification No. 2.” (Accessed January 2021).  
[https://www.wipo.int/treaties/en/notifications/wct/treaty\\_wct\\_2.html](https://www.wipo.int/treaties/en/notifications/wct/treaty_wct_2.html)